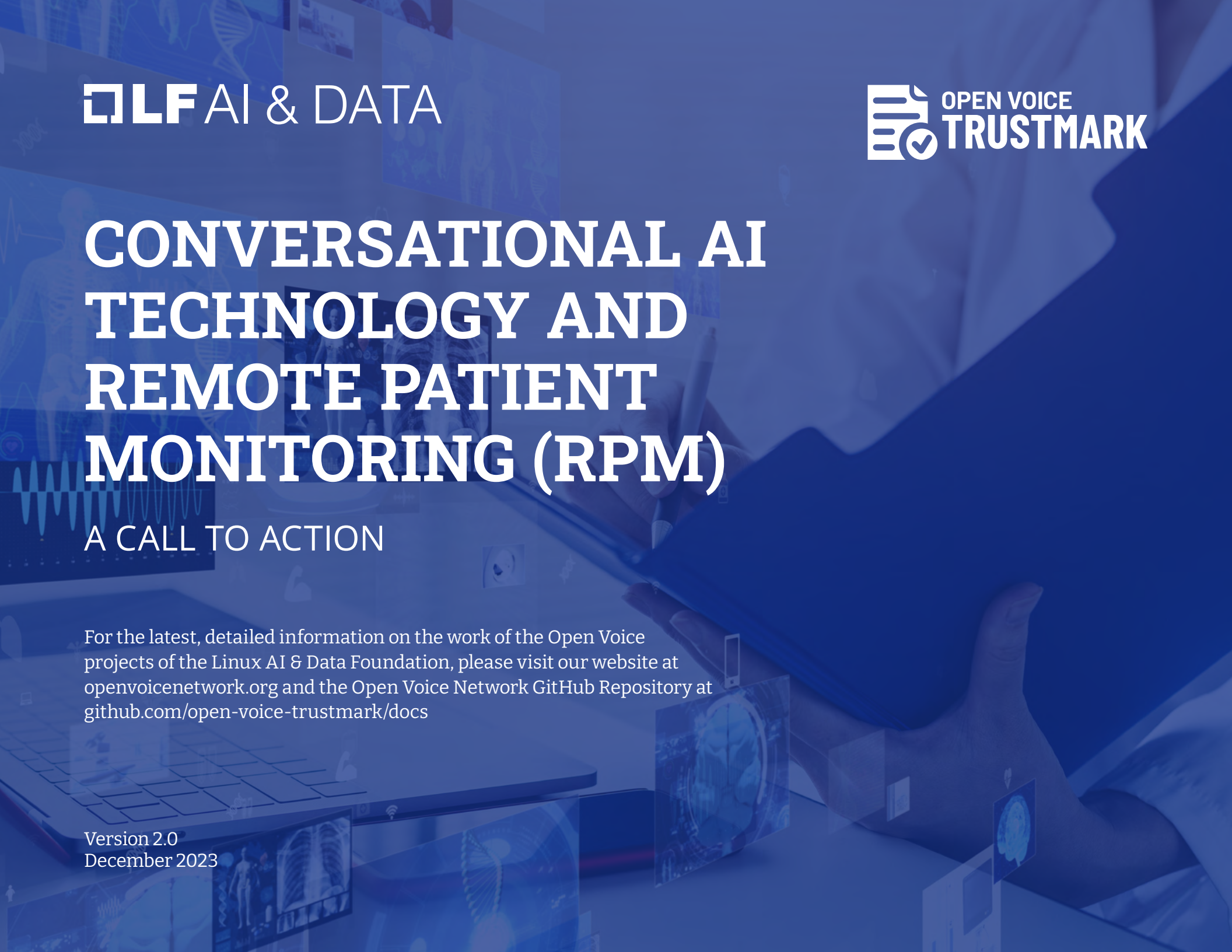

LF AI & DATA

OPEN VOICE TRUSTMARK

CONVERSATIONAL AI TECHNOLOGY AND REMOTE PATIENT MONITORING (RPM)

A CALL TO ACTION

For the latest, detailed information on the work of the Open Voice projects of the Linux AI & Data Foundation, please visit our website at openvoicenetwork.org and the Open Voice Network GitHub Repository at github.com/open-voice-trustmark/docs

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Executive Summary

This report by the Health, Wellness, and Life Sciences Community of the Open Voice TrustMark Initiative of the LF AI & Data Foundation was created for health care professionals, organizations, and enterprises considering, leveraging, or implementing conversational artificial intelligence technology (including voice assistance and generative AI applications) in **Remote Patient Monitoring (RPM)/telehealth** applications.

- As industry experts know all too well, there is a growing crisis in health and wellness delivery, driven by demographic, professional, and socio-economic market transitions. Technology-enabled **RPM** is an important response to this crisis. New research by Juniper Research (Remote Patient Monitoring 2023) forecasts an 8.8% CAGR in RPM adoption 2023-2027, to a global investment of $110 billion.
- RPM is a vital component of telehealth. This paper argues that **conversational AI technologies – most importantly, voice assistance – can and will be an important part of RPM**. In fact, early implementations suggest that across numerous clinical use cases, conditions, and symptoms conversational AI technologies and analysis drive **better patient outcomes** with significantly enhanced implementation and clinical efficiencies.
- There are many instances in which conversational AI technologies are now enabling effective RPM and better patient outcomes. Biomarker analysis – the identification of leading indicators of mental and physical conditions – may offer the greatest value in the provision of continuous care. **This paper notes several examples of RPM conversational AI use**.
- In the United States, **paths of reimbursement** for remote patient care grew with the first implementations of telehealth, and accelerated during the global 2020-2022 pandemic, as measured by advances in Current Procedural Terminology (CPT) coding and Center for Medicare/Medicaid Services (CMS) policies. However, as of publication, Federal reimbursement for RPM continues to expand, but state Medicaid reimbursement remains a patchwork quilt, and recognition or clearance of Software as a Medical Device (SaMD) – software being the core of conversational assistance – is still an outstanding issue.
- **Voice and conversational assistance AI technologies bring with them important legal, ethical, and technological issues** that begin – but do not end – with privacy. This paper and the TrustMark Initiative project of the Linux AI & Data Foundation provides guidance for risk mitigation.

Introduction

We are at the beginning of a new chapter in **Remote Patient Monitoring (RPM)** – one increasingly audible through **conversational assistance technology**, the combination of natural language processing, understanding, and generation (often termed "voice") and natural language generative artificial intelligence.

RPM is nothing new. Industry historians point to the 1948 transmission of radiology images over telephone lines, the early 1960's monitoring of blood pressure data from Mercury mission astronauts, and the 1970's RPM program at the Arizona (U.S.) Papago Indian Reservation as seminal moments. In the 21st century, technology and industry advancements – from wireless internet (Wi-Fi), the short-range communication technology known as Bluetooth, broadband, and changes to CPT codes – and the COVID-19 global pandemic – led to rapid growth in the use of RPM technology (and expansion of RPM coverage by government and private payers).

Despite its many implementations and successes, RPM is still in its early days. The industry issues that led to the current state of RPM are expanding and accelerating. Experts forecast a shortage of physicians and health care workers that may grow to 15 million worldwide by 2030. Across developed economies, the population is aging – and is increasingly saddled with life-shortening chronic conditions. In the United States, according to government sources, some 10,000 individuals of the Baby Boom generation now reach their 65th birthday each day (U.S. HHS.com). In impoverished and rural communities, clinical facilities are increasingly scarce.

And – despite growing recognition of and appreciation for RPM, a Medical Group Management Association poll revealed that just 25% of U.S. practices offer RPM services.

This paper – with respect to the technologies and processes that have blazed RPM's trail to date – points to the need for industry-wide recognition that conversational AI technology can and will play an important role in the future of RPM worldwide.

Our thesis: Conversational AI – the combination of artificial intelligence-enabled natural language processing, understanding, generation, and data analysis, along with new tools of generative AI – can provide patients, clinicians, and providers RPM at lower cost with increased adoption, broad utility, and expansive inclusivity – and ever-precise identification of leading indicators of a lengthening list of physical diseases and mental health disorders.

Given the challenge of aging and underserved populations, a shortage of clinicians, and a growing health equity gap, it behooves clinicians, providers, payers, and governments to explore, test, – and rapidly expand – the use of and reimbursement for RPM using the tools of conversational AI.

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Situation: An Ever-Widening Crisis

These are some of the reasons why RPM – specifically, RPM of greater adoption, greater use, greater inclusivity, and lower cost – is so important:

- **There is a shortage of physicians in the United States.**
  - A 2021 report published by the Association of American Medical Colleges projects the U.S. could see an estimated shortage of between 37,800 and 124,000 physicians by 2034, including shortfalls in both primary and specialty care (Association of American Medical Colleges, 2021).
- **There is a shortage of health care workers worldwide.**
  - The World Health Organization (WHO) estimates that there will be a shortage of 15 million health professionals in hospitals, nursing homes, and care centers worldwide by 2030 (Stroobants, J. et al., 2022).
- **There is a disparity in health equity – especially for underserved populations.**
  - "5 Vulnerable Populations in Healthcare" published in the American Journal of Managed Care (Joszt 2018) cites the following as underserved populations:
    - Chronically ill and disabled;
    - Low-income and/or houseless individuals;
    - Certain geographical communities, such as rural areas of the US and Native Americans living on reservations;
    - LGBTQ+ population
    - The very young and very old.
- **There are numerous medically underserved areas/ populations (MUA/P) in the US.**
  - MUA/P are designated by the Health Resources & Service Administration as having an insufficient number of primary care providers, high infant mortality, high poverty, or a high elderly population. A report published by the University of Medicine and Health Sciences cites four main communities in need of doctors (Harrah 2020):
    - Migrant and Hispanic populations
    - Rural communities
    - African American inner-city areas
    - Asia American and Pacific Islander inner-city areas.
- **The developed world population is aging.**
  - In October 2022, the World Health Organization reported that between 2015 and 2050 the proportion of the world's population over 60 years will nearly double from 12% to 22% (World Health Organization, 2022).
- **There is an increase in chronic conditions.**
  - In the U.S. alone, 86% of healthcare costs are going toward an epidemic of chronic health conditions (Holman 2020).
- **There is a digital divide within developed world populations: those with – and comfortable with – technology, and those without it.** In the United States as of 2021 (Learning.com),
  - only 77 percent of homes had broadband access – a number that dropped to 65 percent of Hispanic households, and to 57 percent in households with household income (HHI) of $30,000 or less. In comparison, broadband was present in 92 percent of US homes with household income of $75,000 or more.

Remote Patient Monitoring: An Evolving Solution to the Growing Problem

The American Telemedicine Association Remote Monitoring Special Interest Group (RM SIG), defines RPM this way:

> ***the collection of clinically relevant information about an individual which is reviewed by a care team and/or care processes. The clinician and the patient/client are not in the same room. Medical devices may or may not be utilized. Data can be self-reported or/or digitally uploaded by the patient or an on-site aide. (***https://www.americantelemed.org/community/remote-monitoring/*)***

The roots of Remote Patient Monitoring can be traced to a 1948 Philadelphia-area transmission of radiology images over a telephone line, and 1960 psychiatric consultations delivered through closed-circuit television. Other important early milestones in RPM development came in 1961, as the U.S. National Aeronautics and Space Administration (NASA) monitored the in-flight health of astronaut Alan Shepard with early EKG technology, a thermometer, and a respiration sensor in his microphone – a first use of voice in RPM; the development and deployment, in the 1970's, of an RPM program for the population of the Papago Reservation in Arizona; and in 1982, with the introduction of the first wearable biometric sports watch – one that used EKG technology to measure heart rate and activity. (Paul/Prevounce.com, February 2023).

In more recent years, the RPM opportunity has been enhanced by the turn-of-the-21st century introduction of the wireless internet (Wi-Fi), short-range communication technology (Bluetooth), and the spread and adoption of ever-faster broadband and cellular networks.

These technological innovations have enabled clinicians and providers to connect with more patient populations – and to do so with less cost, greater speed, and with more diagnostic precision. Overall, RPM promises to

- **Deliver Value-Based Care (VBC) and Fee-for-Service (FFS) cost management**, by reducing unscheduled acute-care costs, especially through the reduction of hospital admissions, readmissions, and emergency room visits
- **Help overcome clinician shortages, especially among rural and other underserved populations**
- **Expand medical care to populations underserved** for reasons of geography, economics, culture, and language
- **Improve accessibility to mental health services**
- **Reduce cancelled appointments and no-shows**
- **Help hourly-wage patients avoid loss of income**
- **Enable older and disabled individuals to live at home longer** and avoid or delay transition into more expensive skilled nursing facilities
- **Provide a level of continuous, value-based care**, which promises to reduce the number of hospitalizations, readmissions, and lengths of stay in hospital – all of which help improve quality of life and contain costs (Center for Connected Health Policy)
- **Effectively and efficiently screen populations in times of infectious disease/pandemics**
- **Extend access to care beyond normal hours**
- **Reduce patient and provider travel burden**

The use of RPM is growing rapidly. New research by Juniper Research (Remote Patient Monitoring 2023) forecasts the adoption of RPM within both developing markets and established markets to be $72 billion in 2023 and $110 billion in 2027, with 2023-2027 growth at 54%.

In fact, RPM's value to patients, clinicians, and providers is reflected in a push for new rules, such as the U.S. Centers for Medicare and Medicaid Services' (CMS) changes to handling Remote Therapeutic Monitoring reimbursement and the addition of Cognitive Behavioral Therapy in the Final Rule Physician Fee Schedule for 2024. Nixon Gwilt Law (NGL), which specializes in health care and innovation, notes they "have made recommendations to revisit the overall code structure to better align RTM with Remote Physiologic Monitoring and other care management services" (O'Connor, K. et al, 2022).

In 2023, Home Health Agencies began mandatory reporting of RPM, utilizing code G0322: the collection of physiologic data digitally stored and/or transmitted by the patient to the home health agency (for example, remote patient monitoring), and in 2024 Federally Qualified Health Centers (FQHCs) will be able to bill for RPM using code (G0511). (Paschall, 2023).

Working Definition of Conversational AI

Conversational AI implements voice technology in audible and/or textual automated interchanges between a human and digital device – often through virtual voice assistance software. Such interchanges can facilitates Interactive, automated patient engagement; inclusive engagement; accessible engagement; and biomarker precision medicine.

The Capabilities Added to RPM by Conversational AI/Voice Technologies

Conversational AI technologies – and specifically, voice technologies – are a new and game-changing addition to the RPM mix.

Remote Patient Monitoring requires biometric data transfer, and many RPM platforms include telehealth (real-time audio and/or video.) When paired, telehealth provides the episodic communication and care, and RPM provides continual biometric (objective) data to survey response (subjective) data to complete the remote care cycle. (Paschall, 2023)

That definition can now evolve, thanks to recent voice technology research and innovation. Broadly defined, voice technologies offer the following, through software that can reside on multiple types of devices:

- **natural language understanding and processing –** the ability of a computational device to "listen" to human utterances and translate spoken words into text, across dozens of languages and dialects
- **natural language generation –** the ability of a computational devices to turn text into human-like speech across dozens of languages and dialects
- **voice assistance –** through which a computer can proactively interact with a human (e.g., providing reminders, a clinical interview, or entertainment) or respond to human inquiries with trustworthy information on a 24/7 basis. This can enable interactive, automated patient engagement, including
  - brief verbal diary entries
  - conversational apps with patient/caregiver instructions and virtual coaches
  - data-gathering/reporting tools that use voice technology to gather and report new data and interact with wearable devices that track fitness and health conditions through blood pressure, glucose, heart rate, and digital ECG/EKG monitors
- **an automated means to**
  - obtain patient consent
  - confirm patient eligibility
  - on-board patients into care processes

- a means for continuous care and evaluation of chronic conditions, providing:
- Information on leading health indicators
- automated reminders
- instruction/education
- caregiver coordination and decision support
- companionship
- A trustworthy source of 24/7 information

- **inclusive and accessible patient engagement** across multiple languages, dialects, speech differences, and underserved populations (Pew Research Center, 2021)
- **AI-based speech/voice analysis**, which can provide assessments of leading indicators of the speaker's mental and physical health, as well as identify (with increasing accuracy) the speaker's gender, geographic region, ethnicity, educational-income level, body mass index, upper body strength, and personality type, and emotion. The human voice is:
  - a biometric identifier, similar to fingerprints in the ability to identify a unique individual
  - a biomarker (defined by Oxford a measurable substance in an organism whose presence is indicative of some phenomenon such as disease, infection, or environmental exposure), which, in voice, can provide increasingly precise indicators of mental and physical illness, ranging from schizophrenia to Parkinson's and respiratory conditions such as COVID-19.

The Economic and Operational Value Added to RPM by Conversational AI/Voice Technologies

Conversational AI technologies add the following to the core value proposition of RPM noted above:

- **Lower implementation and operating costs:** many conversational AI-RPM services can be provided using existing and widely adopted consumer technologies – smartphones, cellular communication
  - **Of note: the widespread adoption of smartphones** across all ages and income levels offers significant potential for conversational/voice-enabled RPM. In 2023, 91 percent of Americans owned and operated smartphones (Edison Research, 2023); in 2021, smartphones were owned by 76 percent of American adults with household incomes of less than $30,000 – a percentage significantly higher than households of similar income with broadband (see above).
  - **Smartphone owners increasingly use their phones to monitor health.** Deloitte's 2022 Connectivity and Mobile Trends Survey (Deloitte Center for Technology, Media & Telecommunications, 2022) reported:
    - At least a third of smartphone users are monitoring their health and fitness with their phones, and 1 in 5 use meditation or mental wellness apps.
    - Nine in 10 consumers who own these devices use them to track fitness and monitor health metrics.
  - **Voice is delivered through software,** which can be installed on multiple devices – especially smartphones. The 2021 U.S. installed base of voice assistance software on smartphones (140.1 million) exceeded by 54 percent that of smart speakers (90.7 million) (voicebot.ai, 2022).
  - **RPM voice services can be delivered accurately through cellular technology.** Home broadband and/or Wi-Fi may not be required.
  - **Voice technology is also a regular element within smart homes,** and is increasingly a part of remote controls and smart appliances.
- **Lower barriers to adoption:** as noted above, a high percentage of prospective patients may already own and use daily the digital tools required for conversational AI-based RPM services

- **Inclusivity:** the ability of conversational AI technologies to listen and speak in the language of fluency for both patient and provider (and to translate one language to the other, when necessary)
- **Biomarker analysis:** the ability to detect in a patient's voice leading indicators of anxiety, stress, and mental and physical illness
- **Increased automation of clinician/provider daily work:** the ability, through natural language speech-to-text understanding, to provide transcripts (in multiple languages and dialects) for record keeping, the submission of claims, and communication with patients.
- **For clinicians/providers,** conversational AI provides the ability to capture patient-clinician interaction in both direct and automated connection with remote patients. This enables:
  - Acoustic analysis and sentiment analysis of voice biomarkers to monitor key health indicators for awareness/diagnosis and continuously evaluate chronic conditions
  - Hands-free clinical care

Today's RPM Voice Technology Toolkit

Today's RPM voice technology toolkit includes

- Voicebots that can:
  - automatically and accurately transcribe clinical conversations
  - provide information 24/7 that accurately reflects scientific and clinician consensus regarding symptoms and conditions
  - listen, translate, and speak in dozens of languages
  - engage solitary patients with reminders, alerts, communication, and entertainment
  - schedule and manage appointments
  - be accessed through commonly used personal technology, such as the smartphone
  - be used for direct, real-time interaction with clinicians
- textual and acoustic analysis of what is said, which can:
  - gauge patient sentiment, including anxiety and stress
  - provide ever-precise biomarker analysis of mental and physical illnesses ranging from schizophrenia to Parkinson's and COVID-19

These capabilities can provide patient, clinician, and provider value by themselves, or as a complement to other RPM approaches with wearable, at-home, or telehealth technologies.

For Developers: a 0.1 List of Conversational AI RPM Requirements

The following is suggested as a starting point for Conversational AI RPM developers. This list will be extended and revised over time.

A Conversational AI RPM implementation – by itself, or as part of a larger RPM system – **MUST** provide:

- Acceptance within Current Procedural Terminology (CPT) codes and Center for Medicare/Medicaid Services (CMS) billing (see below)
- Processes that allow patients to schedule appointments
- Processes for clear communication and acquisition of patient consent
- Unidirectional or bidirectional integrations with electronic medical records
- Accurate time tracking of interaction and use for the purpose of reimbursement
- Care pathways that are customizable by symptomology and patient

- A range of modalities for engaging patients according to patient condition and environment, and according to the technology availability, e.g., broadband, WI-FI, cellular within the environment
- Single, secure sign-on
- Continuous care services, which could include daily or periodic biometric assessment, survey questions, educational content, and videoconferencing, as well as the provision of intervention alerts to practitioners
- Natural language inclusivity services, which enable patients to be accurately heard and spoken to in their language or dialect of fluency
- IT support for patient and provider
- Documented policies as to the privacy and clinical use of patient voice data (whether acoustic or translated to text)
- Data security that provides patient and provider safety.

("Telehealth for Providers: What You Need to Know," U.S. Department of Health and Human Services, 2023, May; Bill Paschall, Clear Arch Health, presentation to the Open Voice Network Health, Wellness, and Life Sciences Community, 2023, June).

Three Significant Challenges to Conversational AI in RPM

The development of RPM solutions using conversational AI technologies must include careful consideration of **three** significant issues: 1. reimbursement, 2. the use of large language models, and 3. the legal/ethical use of voice data.

Reimbursement

Billing and reimbursement for RPM is an evolving, often patchwork issue. Billing and reimbursement requirements for RPM services – for physical and mental health -- vary among different payers/insurers and for different geographic locations (U.S. HHS, May 2023).

Today's policies, regulations, and requirements have evolved with technological change over the past decade. The COVID-19 global pandemic led to time-bound acceptance of selected RPM practices; in some cases, acceptance has been extended or made permanent – in some cases, not. For instance, as of Q4 2023, Medicare reimbursement for audio-only telehealth services (a COVID-19 innovation) is currently only covered through December 31, 2024.

This paper, in accord with U.S. Department of Health and Human Services guidance published earlier this year, will not attempt to guide readers on billing and reimbursement details and practices. Providers are strongly encouraged to connect with billing and reimbursement experts to clearly understand definitions, requirements, and processes.

The technology community – especially those envisioning or pursuing RPM solutions with and through conversational AI – must open and drive conversations with the Center for Medicare/Medicaid Services as to what conversational AI can do, what it is appropriate for, and how it can replace/supplement human-to-human communication across the telehealth/RPM reimbursement codes.

Dr. Emre Sezgin, who has served as Principal Investigator, Information Technology Research and Innovation at Nationwide Children's Hospital, Columbus, OH observed: "To push forward RPM and related voice-enabled solutions, the health care systems must be ready to adopt different types of voice technology implementations as an alternative health care delivery modality." Among the practical considerations for the future of evolving RPM technology with conversational AI are answers to questions such as: If an app collects data remotely using only conversational AI, should it be billed as a separate class of telehealth (Sezgin, E. et al., 2020)?

The push for new rules has already begun. Early in 2022 the U.S. Centers for Medicare and Medicaid Services (CMS) suggested 2023 Medicare Physician Fee Schedule changes to Remote Therapeutic Monitoring (RTM) reimbursement. Nixon Gwilt Law (NGL), which specializes in healthcare and innovation, notes they "have made recommendations to revisit the overall code structure to better align RTM with Remote Physiologic Monitoring and other care management services" (O'Connor, K. et al, 2022).

General guidance for technology developers regarding billing and reimbursement:

In general, a technology solution for RPM is a non-starter if it does not provide:

- a clear (and integrated) path to one or more Current Procedural Terminology (CPT) codes and Center for Medicare/Medicaid Services (CMS) billing
- tested/proven data necessary for billing, such as time on remote care management, number of biometric readings and alert capability, condition-based surveys, education and care plans
- the opportunity for direct, real-time interaction between patient and a designated clinician
- for Chronic Care Management, billing that occurs from a certified electronic medical record (though this requirement currently does not exist for Remote Physiologic Monitoring or Remote Therapeutic Monitoring.) (Paschall, 2023).

Generative AI, Large Language Models, and HealthCare

As noted above, Conversational AI is a combination of natural language processing, understanding, and generation, and the AI technologies that enable computers to understand the intent of a human inquiry, and to formulate relevant and accurate responses to that inquiry. Increasingly, the list of Conversational AI technologies includes **generative AI and large language models.**

One well-known model is OpenAI's ChatGPT; there are dozens, perhaps hundreds of others. It is a category of artificial intelligence that, since OpenAI's 2022 introduction of ChatGPT, has been the subject of countless articles and commentaries.

Generative AI refers to a subset of AI technologies that learn to predict the next word, or sequence of words, given the preceding context (Yu, Xu, Hu, Deng, Healthcare 2023). Generative AI models use advanced algorithms and machine learning techniques to learn patterns and relationships from existing data, and generate new content that is similar in style, tone, or structure. They have the unique ability – distinct from traditional AI models – to create new content, and more importantly, to amplify human management of information. They also can provide nonsensical or inaccurate information (so-called hallucinations), and in some cases, cross lines of intellectual property protection (IBM, 2023).

For RPM, generative AI suggests a future of deeper, better, and (for efficiency's sake) more automated information sharing with patients, and across more languages – if multiple issues are addressed.

We are in the early days of the transformation promised by generative AI. Allow us to offer the following guidance, as well as cite the October 2023 paper "Leveraging Generative AI and Large Language Models: A Comprehensive Roadmap for Healthcare Integration," published in Healthcare, the peer-reviewed, open access journal on health care systems, industry, technology, policy, and regulation.

Five important observations for clinicians and providers beginning a generative AI journey:

1. In clinical settings, **the first requirement** is that generative AI systems must consistently generate responses that accurately represent clinical and scientific consensus. So-called "hallucinations" and expositions of non-consensus internet commentary are unacceptable.

a. Such systems should also enable easy reading comprehension and information retrieval for patients and clinicians, reduce demographic bias to the greatest possible level, and be integrated into EHR systems.

2. **Not all large language models (LLMs) are the same.** Based upon the training data set, LLMs are classified as either foundation (or base) LLMs, or instruction fine-tuned LLMs. (The latter may also be referred to as domain-specific LLMs.)
   a. Instruction fine-tuned LLMs better understand the context, input, and output from a specific application domain – and are, in general, safer, more accurate, less biased, and harmful. Such instruction fine-tuned LLMs are also generally more respectful of intellectual property, and provide necessary citation and sourcing.

3. **There are many instruction fine-tuned LLMs developed specifically for healthcare use.** Three examples: Kahun Medical, which runs a tailored literature search for each patient based on an immense knowledge graph of over 30 million evidence-based medical insights; Microsoft's Azure AI Health Bot, which provides out-the-box healthcare intelligence that can be customized and connected into existing workflows, using answers from a healthcare organization's own content sources, as well as leveraging generative AI to provide answers from credible sources like the National Institutes of Health and the U.S. Food and Drug Administration; and Google's Med PaLM a large language model (LLM) that aligns Google's large language models to the medical domain using medical exams, medical research, and consumer queries.

4. **The use of generative AI in health care is an open issue –** one of considerable debate and study. As the Leveraging Generative AI and Large Language Models paper reports:

   "Generative AI and LLMs (large language models) have also sparked intense debates and discussions regarding their potential benefits, future perspectives, and critical limitations for healthcare and medicine." In a seminal review of 60 initial papers that assessed the utility of ChatGPT in health care education, research, and practice, 51 of the papers (85 percent) cited benefits, while 58 (97 percent) raised concerns and possible risks.

5. Overall: **in time, and with careful development, generative AI will be a "plus benefit" to the health industry, and may provide great value to RPM solutions.** As the paper expressed it: "With proper handling of ethical concerns, transparency, and legal matters, (generative AI) technologies could not only expedite research and innovation but foster equity in healthcare."

Law and Ethics: Earning Trust, Promoting Dignity

The use of conversational artificial intelligence to deliver RPM demands careful consideration of a host of legal and ethical issues.

These should not be seen as barriers to development nor implementation; instead, developers, clinicians, and providers are encouraged to begin solution design with these considerations in mind.

Core Ethical Principles for Conversational AI

In March 2023, the Open Voice TrustMark Initiative, a project of the Linux AI & Data Foundation, published an important overview of the ethical principles essential to the use and practice of conversational AI.

Six principles were highlighted, with definitions and suggested actions distilled from the extensive body of AI ethics research and commentary:

- **Privacy –** A fundamental human right. Collect voice data only for a specific purpose and duration. Users [e.g., patients] must understand how voice data is used, collected, and shared; must give explicit consent to how it is used, collected, and shared; and, must be able to easily access, rectify, suppress, limit, oppose, and transport voice data.

There are numerous government and industry-specific regulations that govern the protection and use of information that can identify or be ascribed to an individual. Existing regulations that protect patient and user privacy include the Health Insurance Portability and Accountability Act (HIPAA), the (GDPR) of the European Union, and many national or state-based data privacy laws.

- **Transparency –** Disclose decisions regarding the acquisition and use of personal voice data and present them in an easily accessible, understandable, and explainable format.
- **Accountability –** Ensure that a one or more humans are identified as responsible for every decision regarding data acquisition, analysis, use, and storage, and that senior management is fully aware of the potential harms caused by illegal or unethical practice.
- **Inclusivity –** Enable all individuals to communicate and be understood, regardless of gender, age, ethnicity, fluency-dialect, or physical ability.
- **Sustainability –** Understand the environmental impact of the large computational resources demanded by voice and natural language training models
- **Compliance –** Conduct proactive governance of corporate practices in accord with existing laws, regulations, and best ethical guidelines.

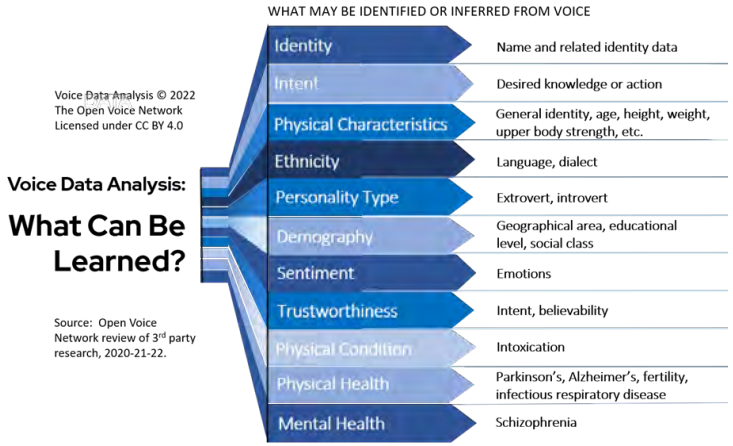
With a focus on RPM, we share additional thoughts on four topics: the unique value and risks of voice data (acoustic and transcribed); inclusivity; accessibility; and the new risks of generative artificial intelligence

The Unique Value and Risks of Voice Data

As noted above, conversational artificial intelligence is the product of the of AI-enabled natural language processing, understanding, and generation, and, increasingly, generative AI.

Though textual input is common, the human voice is increasingly the source of the natural language communication. A human voice is both a biometric (providing unique identification of the individual) and a biomarker (which, through AI-based analysis of acoustic data, can detect leading indicators of physical or mental illness, or infer one or more conditions of the speaker.) The human voice – and its tone, cadence, pronunciation, and word choice -- can also be used to infer a long list of conditions, including gender, ethnicity, educational level, sentiment, and body mass index.

This chart from the Open Voice TrustMark Initiative, a project of the Linux AI & Data Foundation, points to the current state of voice and textual analysis as of Q4 2022:



For RPM, the Open Voice TrustMark Initiative encourages (subject to proper legal and ethical considerations) use and continued development of

- **Voice-based patient identification** to enable rapid sign-on for registered, consent-providing populations
- **Patient intent analysis and understanding,** a proven, increasingly accurate capability across all current voice assistant systems that enables a smart speaker to select a song or set a timer and a smartphone to search or change a page. In RPM solutions, this can enable automated communication with patients – reminders, condition interviews, patient requests, even entertainment
- **Acoustic biomarker analysis of leading indicators of physical and mental conditions.** This is a rapidly growing area of clinical and academic research that promises significant value in service delivery and efficiency. There are numerous (see below) professionally reviewed implementations.

In all cases, clinicians and providers must review carefully

- what data is collected
- why the data is collected – the purpose and expected outcome
- which specific data is analyzed and for what purpose
- who is collecting the data
- how the data is collected and stored – how private? How secure? Who has access?
- how long data will be stored
- inherent biases within the data that may shape results
- how the analysis will be interpreted

This is not only an issue for clinicians and providers. Health-related data is currently being harvested by commercial enterprises.

"Apple knows more about my blood pressure than my doctor does," said Dr. Yared Alemu, Ph.D., founder of TQ Intelligence, a firm that analyzes voice biomarker data to measure the severity of emotional distress in children and adolescents. "I need to know how they and other commercial apps are using the data they're collecting. Personalized medicine vs. personalized commerce respects rights and helps build trust for legitimate conversational AI healthcare apps.

"To do otherwise hurts our ability to be able to use life-saving apps important for patient healthcare. We have an opportunity to improve quality of life and lower healthcare costs."

Inclusive Engagement to Reach More Patient Populations

In nations and regions of diverse cultures and languages, the enabling RPM for multiple languages, dialects, and accents can dramatically expand a clinician's ability to engage with more patients, and with traditionally underserved populations.

A best-case scenario is for patients to be heard and spoken to in their language of greatest fluency. Case studies from global health information firm Wolters Kluwer indicate greater levels of patient trust – and corresponding positive patient action – when target populations communicate in language considered to be "theirs."

Development of language, accent, dialect, and difference support – and real-time translation -- has come a long way, but given the scope it is still a work in progress.

As of November 2023, the voice assistant Amazon Alexa supported 14 languages and dialects, including English, French, German, Hindi, Italian, Japanese, Portuguese (Brazilian) and Spanish. According to Google Support, the Google Assistant device as of October 2021 supported Danish, Dutch, English, French, German Hindi, Italian, Japanese, Korean, Norwegian, Spanish, and Swedish. As of October 2023, Apple's Siri supported more than 20 languages, including Arabic, Cantonese, Danish, Dutch, Finnish,

English, French, German, Hebrew, Italian, Japanese, Korean, Malay, Mandarin, Norwegian, Portuguese (Brazil), Russian, Spanish, Swedish, Thai, and Turkish.

The well-regarded, open-source NLP engine Rasa – one of the many independent conversational AI platforms designed for enterprise use – has been used to train models in Hindi, Thai, Portuguese, Spanish, Chinese, French, Arabic, and several other languages and dialects.

As noted, Wolters Kluwer Health has been a health industry leader in extending its voice services to non-English speaking populations. About 40% of Wolters Kluwer Health's journey series are offered in both English & Spanish, with the remainder of those journeys being released in Spanish during this coming year.

According to Wolters Kluwer Health's Freddie Feldman: "Since 2020 we've been also offering programs voiced by a Black voice actor, in an effort to better connect with patients of the Black community. My team is preparing to begin a study quantifying the efficacy of voice interfaces where the racial background of the VUI matches that of the patient."

Also: it must be noted that the ensuring of diversity within an RPM development team is a good first step toward expanding patient inclusivity. Are the languages, perspectives, and cultural/user experiences of prospective patients incorporated into the initial design (Li, 2020)? Well-rounded teams can also minimize potential bias because of the range of experiences and perspectives that can be drawn from throughout the entire design process (Orduña, 2019).

Accessible Engagement

Conversational AI solutions can also open and extend care to individuals, who are often excluded or struggle with traditional screen-based digital solutions, such as older individuals, or persons with visual impairment. Solution design that takes accessibility into consideration has consistently shown to be of heightened value across all populations.

As Anil Lewis, Executive Director, Jernigan Institute at National Federation of the Blind, said on the Open Voice Network's Future of Voice podcast in February 2023, accessibility "begins at the design and development stage. Good intentions are simply not good enough."

This is just one of many organizations aiming to make people's lives better. Their feedback on products designed for their specific constituency is invaluable.

Voice and Conversational AI in RPM: Current Implementations and Trials

The Vanderbilt "Hospital at Home" Program: RPM for Short-Term Treatment

The option to use technology with natural language offers timely assistance to underserved populations as well as others facing the growing waiting lists to see a specialist.

Vanderbilt's "Hospital at home" program provides RPM as an affordable option to those undergoing short-term treatment that would otherwise be in a dedicated medical facility, such as those requiring administration of IV antibiotics.

"When a voice experience is built well, it can be a democratizing tool," said Dr. Yaa Kumah-Crystal, MD, MPH, MS, Assistant Professor of Biomedical Informatics and Pediatric Endocrinology at Vanderbilt University Medical Center whose research focuses on communication and documentation in health care and developing strategies to improve workflow and patient care delivery.

From Dr. Kumah-Crystal's perspective, voice technology can promote effective patient communication and the best possible

patient outcomes by facilitating

1. Interactive, automated patient engagement
2. Inclusive engagement
3. Accessible engagement, and
4. Biomarker precision medicine support with vital physiological data points previously unavailable from wearable technologies.

Voice applications can easily gather and share data from wearable and other devices that track fitness and health conditions through blood pressure, glucose, heart rate, and digital ECG/EKG monitors. This makes them particularly useful for the health and well-being of those benefiting from proactive care and support, particularly for larger communities, such as actively aging and elderly, and chronic diseases.

Because it is flexible and portable, voice technology can be used in the health care facility or the patient's home, nursing home, or assisted living facility.

Wolters Kluwer Health: Voice for Education, Behavior Change, and Reducing Readmission

Voice technology can be used to implement more accessible applications that support patients and caregivers with instructions, data, and the ability to better manage their own health.

Through natural language exchange or brief verbal diary entries, patient data can be collected and analyzed with artificial intelligence for content, e.g., sentiment and biomarkers, for health and well-being implications. These data points inform a more effective patient mental/physical health management program.

Wolters Kluwer Health provides a series of over 20 different Interactive Voice Response (IVR)-based interface programs into which care teams can enroll patients. One program, EmmiJourneys, "features mostly post-discharge topics, with the main goal of preventing hospital readmissions, but also educating patients and changing behaviors," explains Freddie Feldman, Director, Voice & Conversational Interfaces at Wolters Kluwer Health, noting "We're adding chronic care journeys in the future."

Emids: A Holistic Conversational Coach to Cut the Specialist's Waitlist

A digital Diabetes coach designed to draw on more physical data, focuses on behaviors that promote healthier outcomes over time started out by being more engaging than using a logbook to track blood glucose levels. Particularly when the patient is a child, it can also reinforce attitudes and actions that are life-changing.

In 2017, as Amazon Alexa supported more voice technology skills/apps, Canadian software engineering firm, Macadamian (acquired by Emids in early 2021), created My Diabetes Coach to help develop and reward necessary lifelong compliance habits that could mitigate the health complications that might otherwise happen to a child with Diabetes. Back in 2018, it was powered by HealthWise.

Timon LeDain, VP, Customer Solutions, Emids, said "we are currently working with clinicians to streamline the waitlist for patients suffering from BPPV [benign paroxysmal positional vertigo, the most common form of dizziness.] The persona is on a 10-month waiting list to see a specialist. If a chatbot can direct a typical BPPV sufferer to be diagnosed and treated quickly by a physiotherapist knowledgeable in the practice, that would remove them from that waiting list and allow those specialty cases (like dizziness caused by a tumor) to be seen sooner."

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EU-Japan Project Uses Conversational AI for Virtual Senior Engagement and Companionship

Conversation-driven technology is at the heart of remote communication, engagement, and companionship with many seniors (McTear, M. et al 2022).

In their recent conference paper, "Empowering Well-Being Through Conversational Coaching for Active and Healthy Ageing," Michael McTear and his colleagues present a scalable approach involving a virtual coach for seniors being developed in a 3-year joint European and Japanese funded research project called e-VITA.

The virtual coach, built on the open-source Rasa framework, aims to enable older adults to better manage their own health proactively by providing individualized profiling and personalized recommendations on daily activities that support healthy aging in critical areas:

- cognition
- physical activity
- mobility
- mood
- social interaction
- leisure, and
- spirituality.

The virtual coach captures and monitors data using unobtrusive sensors and emotion analysis used within dialogues to assess the user's situation, such as location, activity, and vital state, from heart rate and mood to surrounding temperature. The virtual coach remotely provides support through natural interactions with 3D-holograms, emotional objects, or robotic technologies using multimodal and spoken dialogue technology, advanced knowledge graph representations, and data fusion (McTear, p 258).

Orlov: Voice Assistance to Mitigate Social Isolation, Enable Secure Access to Health Information

Laurie M. Orlov, Principal Analyst, Aging and Health Technology Watch, has long tracked the evolution of voice technology and its promise for assisting older adults as they age. In her report, "The state of voice-AI and older adults 2022," she noted that in addition to substantial improvements in voice technology software required to enable the older adult population to fully accept and benefit from the more complex capabilities of voice assistance "...

users will expect clearer privacy protections to support greater personalization and smarter, more conversational interactions with voice assistance. Conversational AI and voice assistants will help mitigate social isolation among older adults and enable them to securely access health and other personal information easily in the privacy of their home (Orlov, L., 2022)."

Voice Technology as a Complement to Wearables and Other RPM Technologies

Deloitte's "Connectivity & Mobile Trends 2021" survey," noted that the use of devices, such as Apple Watch or Fitbit (acquired by Google), were expanding beyond step-and-calorie counting to serve as a hub for gathering, explaining, and sharing medical information on conditions, such as heart health, sleep quality and duration, stress levels, possible COVID-19 symptoms, and some chronic health condition indicators (Deloitte, 2021).

The Apple Watch System 7 was released in October 2021 with a larger face that made it easier to read the results of its blood-oxygen sensor, built-in ECG app, and heart rate notifications. It came with fall detection and could use conversational AI to phone for assistance. It is part of a class of smart digital devices, such as Fitus, designed to appeal to seniors, that can detect and display some health and fitness irregularities, announce results, transmit reports, and use conversational AI to engage patients in better health care practices.

Also in 2021, disease-specific wearable monitoring products with conversational AI features were created in partnership with stakeholder users. For example, with the support of the National Blind Association and certified diabetes educators, Prodigy® specialty device maker incorporated conversational AI as a main feature of its Prodigy VOICE Blood Glucose Monitoring System, to offer verbal instructions for use and reporting in four languages, which provided greater accessibility for home healthcare and RPM. For those requiring continuous glucose monitoring, wearable sensors such as the Dexcom G6 CGM System of a patient's glucose numbers on compatible smart devices.

Coincidentally, major developers of blood pressure monitors began to expand their capabilities and facilitate accessible use through the addition of conversational AI, to provide verbal alerts when pressure is not within range. Offering full verbal instruction in several languages facilitated use outside the clinical setting and served a wider range of patients.

Startups such as Redfox.ai have released new tools to provide conversational AI accessibility through any smartphone or the web, to guide patients through at-home health tests and medical device use to assist patients at the point of care — more efficiently and cost effectively.

Biomarker Analysis: Finding Indicators of Physical, Mental Health in Voice

TQ Intelligence: Voice for Child and Adolescent Mental Health

TQIntelligence was awarded a National Science Foundation (NSF) Small Business Innovation Research Phase II grant for $1 million in November 2021. As part of the NIH's Bridge2AI, Voice as a Biomarker of Health project TQIntelligence uses voice + AI technology to collect information from voice samples to help therapists treating children and adolescents with mental health issues that may be unable, or afraid, to articulate negative emotions, such as anger, fear, and sadness.

The goal is to identify kids in crisis for timely decision making about appropriate treatment, monitor treatment effectiveness, and not only support decision making by therapists, but also guide family decisions about getting the right help at the right time.

Founder and CEO of voice technology implementation company, TQIntelligence, Dr. Yared Alemu, PhD, a behavioral health psychologist, is particularly enthusiastic about advancing ethical voice technology applications aimed at supporting mental health and brain development of youth growing up in low-income, BIPOC communities — a population most often affected by trauma, which is associated with anxiety and depression and can negatively affect brain development and life choices.

According to Dr. Alemu, "The promise of leveraging conversational AI for remote monitoring is providing decision support for families as well as giving access to important information to clinicians. Remote monitoring changes episodic care to continuous care, for example by enabling a kid suffering from anxiety to record and analyze daily diary entries with as little as a 15 second voice sample."

Biomarker Analysis for Precision Medicine Support

Ongoing work to expand disease-specific vocal biomarker databases through public and private research partnerships promises more accurate diagnosis and classification of psychiatric, cognitive, and physical changes through digital devices.

"If we can get this right, RPM might allow for patients to provide more data on how patients are doing," said Dr. Kumah-Crystal of the Vanderbilt University Medical Center.

Conversation-based applications and digital voice-enabled biometric measurement tools can be used to detect changes in respiratory conditions, depression, Schizophrenia, anxiety, bipolar disorder, cancer, diabetes, Rheumatoid Arthritis; dementia/ Alzheimer's, multiple sclerosis and other neurodegenerative disorders; as well as unhealthy activity in the cardiovascular system, such as heart attack or stroke (Tracy et al., 2020; Fagherazzi et al., 2021; Mei et al, 2021; Kwon et al., 2022).

When paired with digital devices such as EKGs, ultrasounds, stethoscopes, data, audio and video, applications using conversational AI to track key health parameters remotely can help fill the gap between patient visits and help turn talk into recommendations for targeted therapeutic action outside of the clinical setting.

Especially for rural and underserved populations, accessing advanced RPM capabilities can facilitate more equitable patient and caregiver support and decision making leading to better outcomes and fewer unnecessary in-person visits to clinicians and costly emergency rooms.

Voice for Early Detection of Respiratory Disease

By early 2021, COVID-19 screening tools facilitated by conversational applications emerged. The Vocalis hyper-rapid COVID-19 screening tool, VocalisCheck, had achieved an accuracy of 81.2 percent in identifying COVID-19 infection based on patients' voice samples. Collaborating on clinical trials with the Municipal Corporation of Greater Mumbai, Israeli startup, Vocalis received the CE mark, which indicates that it has been manufactured to the European Economic Area (EEA) health, safety, and environmental protection standards, for its hyper-rapid COVID-19 screening tool (Ganguly S., 2021).

Chris Landon, M.D., CEO of Technology Development Center Labs and Studio in Ventura, California observes:

"In the companies that seek our expertise, voice is being explored as a biomarker for exertion and exercise capacity. We're also in the early stages of trying to understand if changes in voice can be used to predict early exacerbations or even help identify motivation/readiness to begin programs.
"To avoid the dangers of using artificial intelligence to expand the physician and health care practitioner's Clinical Decision Support beyond their experience in the last ten cases of history and

symptoms still requires vigilance and continued informing of the algorithm and quality improvement."

In a joint study with Beth Israel Medical Center to facilitate identification of vocal biomarkers for Huntington's disease, Canary Speech, Inc. used its patented technology with biomarker data to enable analysis that identified more than 1,000 features of speech differentiating healthy patients from Huntington's Disease patients (O'Connell, 2022).

Co-founders Henry O'Connell and Jeff Adams got a jumpstart in the market a decade ago by combining their expertise in neurology research at the National Institutes of Health and on the founding Amazon Alexa speech AI team, respectively. Canary Speech holds three US Patents and two European patents.

Support for Voice Biomarker Research Expands the Medical Possibilities for RPM

Expanding the available databases of novel vocal biomarkers is an important step toward monitoring patients, diagnosing specific conditions, or grading the severity or the stages of a disease or for drug development. Like traditional biomarkers, they must be validated analytically and qualified using an evidentiary assessment (Robin et al., 2020 & Fagherazzi, et al., 2021).

The value of transmitting information obtained from voice biomarkers to healthcare providers using devices most already own, such as a smartphone, is inspiring investment by private and public entities.
Until about 2020, most vocal biomarker research focused on common neurodegenerative diseases, such as Parkinson's, where voice disorders are frequent — 86% of the time (Tracy et al 2020). Subsequent work on vocal biomarker data supported by private and public/private research is uncovering opportunities to identify and monitor additional medical conditions with greater accuracy (Fagherazzi et al, 2021).

Public/Private Partnerships Designed to Accelerate Vocal Biomarker Database Growth

Public-private partnerships are investing in the tremendous potential for using vocal biomarkers in health care.
In September, 2022, the National Institutes of Health (NIH) announced The NIH Common Fund's Bridge to Artificial Intelligence (Bridge2AI) program, which plans to invest $130 million over four years to accelerate the widespread use of artificial intelligence (AI) and best practices by the biomedical and behavioral research communities.

To support ethical use and avoid pitfalls such as unintentional bias, the program assembled team members from diverse disciplines and backgrounds to generate tools, resources, and detailed data that are responsive to AI approaches.

"Generating high-quality ethically sourced data sets is crucial for enabling the use of next-generation AI technologies that transform how we do research," said Lawrence A. Tabak, D.D.S., Ph.D., Performing the Duties of the Director of NIH. "The solutions to long-standing challenges in human health are at our fingertips, and now is the time to connect researchers and AI technologies to tackle our most difficult research questions and ultimately help improve human health (National Institutes of Health. 2022)."

As one of four inaugural data generation projects funded by NIH's Bridge2AI, Voice as a Biomarker of Health is being led by the University of South Florida and Weill Cornell Medicine to create a large, national databank of de-identified voices linked to selected biomarkers of health. Twelve institutions will collaborate.

The project received $3.8 million with subsequent funding over three years of up to $14 million, contingent upon NIH appropriations by Congress.

The goal is the equitable use of the human voice as a tool when diagnosing and treating diseases, from cancer to depression, based on the sound of a patient's voice with an eye toward establishing voice as a biomarker used in clinical care (Gillis, 2022; Long, 2022; National Institute of Allergy and Infectious Diseases, 2020).

The ethically sourced voice samples will go through AI analysis to identify signs of disease, such as slow speech. The research seeks biometric data that can be used to help diagnose and inform earlier treatment in five categories — voice, neurological, respiratory, psychiatric, and children's speech disorders.

Past and Recent Investments in Voice Biomarker Research

Research by US medical institutions and public-private partnerships have explored for nearly 25 years the human voice as a biomarker to supplement remote patient care.

Originally funded by a 1999-2004 grant from the National Science Foundation (NSF), work by Carnegie Mellon University and the University of Pennsylvania created AphasiaBank, a shared multimedia database of interactions by 180 aphasic individuals and 140 non-aphasic controls performing a uniform set of discourse tasks for the study of communication in aphasia -- the partial or total loss of the ability to articulate ideas or understand language. And, the work continues as AsphasiaBank support by NIH-NIDCD grant R01-DC008524 for 2022-27 (Forbes, M., et al 2012).

A major international research project, Remote Assessment of Disease and Relapse in Central Nervous System Disorders (RADAR-CNS), from 2020 to April 2022 was a collaboration of clinicians, researchers, engineers, computer scientists and bioinformaticians from 22 organizations from across Europe and the United States. The project aimed to improve people's quality of life and change how depression, epilepsy, and multiple sclerosis are managed and treated. It used voice data collected on mobile devices to detect changes in behavior, sleep, or mood based on conversational AI before it is perceived by the patient to help predict, or avoid, a relapse (Fagherazzi et al., 2021 and Innovative Health Initiative, 2021).

Among its successes, the RADNAR-CNS team was awarded the Harald Frey prize by the Michael Foundation in October 2021, for their work on the use of wearables to gauge the likelihood of sudden unexpected death in epilepsy (Innovative Medicines Initiative, 2021).

RADAR-CNS was co-led by Janssen Pharmaceutica and King's College London funded by the Innovative Medicines Initiative 2 (IMI2) Joint Undertaking with support from the European Union's Horizon 2020 research and innovation program and EFPIA (Fagherazzi et al., 2021).

In November 2021, the Council of the European Union approved a proposal to build upon the work of the Innovative Medicines Initiative as the Innovative Health Initiative. The new public-private partnership expands the focus to a broader range of cross-sectoral discoveries, such as medical device/drug combinations or diagnostics based on AI (Innovative Health Initiative, 2021).

Conclusion

Conversational AI — the combination of artificial intelligence-enabled natural language processing, understanding, generation, and data analysis, along with new tools of generative AI — can provide patients, clinicians, and providers RPM at lower cost, increased adoption, broad utility, and expansive inclusivity – and ever-precise identification of leading indicators of a lengthening list of physical and mental diseases/disorders.

Given the challenge of aging and underserved populations, a shortage of clinicians, and a growing health equity gap, it behooves clinicians, providers, payers, and governments to explore, test, and rapidly expand the use of and reimbursement for RPM using the tools of conversational AI.

The use of conversational AI technologies – and most importantly, voice technologies – poses an important and highly beneficial opportunity for developers, clinicians, and providers of RPM.

- **Technology-enabled RPM** is an important response to the growing crisis in health and wellness delivery, one driven by demographic, professional, and socio-economic market transitions.
- **Conversational AI technologies – most importantly, voice assistance – can and will be an important part of Remote Patient Monitoring.** Conversational AI technologies promise not only improved patient outcomes through the provision of continuous care to underserved populations, but significant operational efficiencies. The widespread adoption of consumer-based voice devices – especially smartphones – gives clinicians and providers a significant installed base of potential users, one that spreads well across age, gender, and household income strata.
- **Conversational AI is being used and developed now for RPM.** There are many instances in which conversational AI technologies are now enabling effective remote patient monitoring and better patient outcomes. Biomarker analysis – the identification of leading indicators of mental and physical conditions – may offer the greatest value in the provision of continuous care.
- In the United States, **paths of reimbursement** for remote patient care grew with the first implementations of telehealth, and accelerated during the global 2020-2022 pandemic, as measured by advances in Current Procedural Terminology (CPT) coding and Center for Medicare/Medicaid Services (CMS) policies. However, as of publication, reimbursement remains a patchwork quilt, and recognition and approval of software – the core part of conversational assistance – is still an outstanding issue.
- **Voice and conversational assistance AI technologies bring with them important legal, ethical and technological issues** that begin – but do not end – with privacy. This paper and the TrustMark Initiative project of the Linux AI & Data Foundation provides guidance for risk mitigation.

This paper is but a start to a detailed explication of the use and value of conversational AI technologies in RPM.

We look forward to continued exploration of this important topic.

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About the Open Voice TrustMark Initiative of the LF AI & Data Foundation

The Open Voice TrustMark Initiative is an incubation project of the LF AI & Data Foundation, dedicated to making conversational AI worthy of user trust, and formed in March 2023. The TrustMark Initiative

- Translates an ethical code that respects the individual's privacy rights, regulations, and legislation for conversational applications into implementable actions that mitigate risk for developers, clients, and the public and promotes values of transparency, accountability, inclusivity, and sustainability
- Provides public/industry education on critical ethical issues and best practices through training courses, published policies/guidelines and a self-assessment and maturity model for organizations, and
- Enables public identification of individuals/organizations (through badges/certifications) who strive to implement best practices outlined by the TrustMark initiative.

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About LF AI & Data Foundation

The LF AI & Data Foundation supports and sustains open-source projects within artificial intelligence (AI) and the data space. It is a greenhouse growing and sustaining open-source AI and data projects from seed to fruition. We provide support to projects for open development among a diverse and thriving community, in addition to a number of enabling services that include membership and funding management, ecosystem development, legal support, PR/marketing/communication, events support, trademark management, export control filings, and compliance scans.

For more information, please visit lfaidata.foundation

About the Linux Foundation

Founded in 2000, The Linux Foundation is supported by more than 1,000 members and is the world's leading home for collaboration on open-source software, open standards, open data, and open hardware. Linux Foundation's projects are critical to the world's infrastructure including Linux, Kubernetes, Node.js, and more. The Linux Foundation's methodology focuses on leveraging best practices and addressing the needs of contributors, users, and solution providers to create sustainable models for open collaboration. For more information, please visit linuxfoundation.org.

Appendix A. Vocabulary Terms

Conversational AI

The implementation of voice technology in audible and/or textual automated interchanges between a human and digital device that facilitates interactive, automated patient engagement; inclusive engagement; accessible engagement; and biomarker precision medicine.

Remote Patient Monitoring and Management (RPM)

Personal Health and medical data collection from an individual in one location, which is transmitted via electronic communication technologies to a provider in a different location for use in care and related support (CCHP.org, 2010-2023).

Voice Technology

Auditory or textual communication between digital-to-human interaction that mimics human speech.

Reference List

Association of American Medical Colleges (AAMC), (2021, June 11) AAMC Report Reinforces Mounting Physician Shortage, [Press release]. https://www.aamc.org/news-insights/press-releases/aamc-report-reinforces-mounting-physician-shortage

Center for Connected Health Policy (CCHP.org), (2010-2023) What is telehealth? https://www.cchpca.org/what-is-telehealth/?category=remote-patient-monitoring

Chen, A. (2019, March 14). Why companies want to mine the secrets in your voice. The Verge. https://www.theverge.com/2019/3/14/18264458/voice-technology-speech-analysis-mental-health-risk-privacy

Deloitte. (2021, June). How the pandemic has stress-tested the digital home. CMO Today. The Wall Street Journal. https://deloitte.wsj.com/articles/how-the-pandemic-has-stress-tested-the-digital-home-01628880858

Deloitte Center for Technology, Media & Telecommunications. (2022). Connectivity and mobile trends, 3rd edition. Deloitte Insights. https://www2.deloitte.com/us/en/insights/industry/telecommunications/connectivity-mobile-trends-survey.html

Fagherazzi G., Fischer A., Ismael M., Despotovic V. (2021, April 16). Voice for health: The use of vocal biomarkers from research to clinical practice. Digital Biomarkers, 5(1), 78-88. https://doi.org/10.1159/000515346

Forbes, M., Fromm, D., MacWhinney, B. (2012, August 01). AphasiaBank:A resource for clinicians. Seminars in speech and language. 33(03): 217-222 https://doi.org/10.1055/s-0032-1320041

Ganguly, S. (2021, May 19). Healthtech startup Vocalis' COVID screening tool 81 pc accurate, gets CE mark. Yourstory. https://yourstory.com/2021/03/healthtech-startup-vocalis-health-covid-screening-tool

Google, Introduction to Med-PaLM, (2023, November) https://sites.google/med-palm/

Gillis, E. (2022, November 16). Your voice could help diagnose disease, other issues through AI [Video]. Yahoo!Finance. https://finance-yahoo-com.cdn.ampproject.org/c/s/finance.yahoo.com/amphtml/news/voice-could-help-diagnose-disease-011853082.html

Harrah, S. (2020, November 05). Medically underserved areas in the US. University of Medicine and Health Sciences. https://www.umhs-sk.org/blog/medically-underserved-areas-regions-where-u-s-needs-doctors

Holman, H.R. (2020). The Relation of the Chronic Disease Epidemic to the Health Care Crisis. ACR open rheumatology, 2(3), 167-173. https://doi.org/10.1002/acr2.11114

IBM. (2022). What are AI hallucinations?, https://www.ibm.com/topics/ai-hallucinations

Innovative Health Initiative (IMI), (2022). From IMI to IHI. https://www.ihi.europa.eu/about-ihi/imi-ihi

Innovative Medicines Initiative (2021, October 9). Wearable can predict risk of fatal epilepsy complication. [Press release]. https://www.imi.europa.eu/news-events/newsroom/wearable-can-predict-risk-fatal-epilepsy-complication

Institute of Medicine (US) Committee on Quality of Health Care in America. (2001). Crossing the quality chasm: A new health system for the 21st century. Washington, DC. National Academies Press. https://doi.org/10.17226/10027

Joszt, L. (2018, July 20), 5 vulnerable populations in healthcare. American Journal of Managed Care. https://www.ajmc.com/view/5-vulnerable-populations-in-healthcare

Juniper Research. (2023) Remote Patient Monitoring. https://www.juniperresearch.com/researchstore/healthcare-government/remote-patient-monitoring-research-report

Kwon, N, Kim, S., Predeck, K, Adams, Adams, J, O'Connell, H. (2022, August). Depression severity detection using read speech with a divide-and-conquer approach. Canary Speech. https://canaryspeech.com/wp-content/uploads/2022/08/Canary-Speech-Depression-Severity-Detection-Using-Read-Speech-With-A-Divide-And-Conquer-Approach.pdf.

Learning.com, 25+ Digital Divide Statistics You Need to Know, (2022, September), https://www.learning.com/blog/the-digital-divide-statisics-you-need-to-know

Li, M. (2020, October 26). To build less-biased AI, hire a more diverse team. Harvard Business Review. https://hbr.org/2020/10/to-build-less-biased-ai-hire-a-more-diverse-team

Long, A. (2022, September 13). USF Health, Weill Cornell Medicine earn inaugural funding in NIH's newly launched Bridge2AI initiative, will create artificial intelligence platform for using voice to diagnose disease. Hot News, Morsani College of Medicine, Research, USF Health Lead Story. https://hscweb3.hsc.usf.edu/blog/2022/09/13/usf-health-cornell-earns-inaugural-nih-funding-to-create-artificial-intelligence-platform-for-using-voice-to-diagnose-disease/

McTear, M., Jokinen, K, Dubey, M., Chollet, G, Boudy, J, Lohr, C., Roelen, S. D., Mossing, W, Wieching, R. (2022, June 17). Empowering Well-Being Through Conversational Coaching for Active and Healthy Ageing. ICOST 2022. Lecture Notes in Computer Science, vol 13287. Springer, Cham. https://doi.org/10.1007/978-3-031-09593-1_21

Mei, J., Desrosiers, C., Frasnelli, J. (2021, May 06). Machine learning for the diagnosis of Parkinson's disease: A Review of Literature. Frontiers in Aging Neuroscience. 13. https://doi.org/10.3389/fnagi.2021.633752

Microsoft, "Microsoft introduces new data and AI solutions to help healthcare organizations unlock insights and improve patient and clinician experiences (2023, October), https://blogs.microsoft.com/blog/2023/10/10/microsoft-introduces-new-data-and-ai-solutions-to-help-healthcare-organizations-unlock-insights-and-improve-patient-and-clinician-experiences/

Next Move Strategy Consulting. (2022). Patient monitoring market by product, by type and by end user Global opportunity analysis and industry forecast 2022-30). In ResearchandMarkets (ID: 5601842). https://www.researchandmarkets.com/reports/5601842/patient-monitoring-market-by-product-by-type?utm_code=fz89hg&utm_exec=jamu273prd

National Institutes of Health. (2022, September 13). NIH launches Bridge2AI program to expand the use of artificial intelligence in biomedical and behavioral research [Press Release]. https://www.nih.gov/news-events/news-releases/nih-launches-bridge2ai-program-expand-use-artificial-intelligence-biomedical-behavioral-research

National Institute of Allergy and Infectious Diseases. (2020, December 16). NIH Joins NSF for Initiative Supporting Smart Health Research. NIH: National Institute of Allergy and Infectious Diseases. [Press Release]. https://www.niaid.nih.gov/grants-contracts/nsf-initiative-smart-health-research

O'Connell, H. (2022, December 7). Finding Biomarkers in Huntington's Disease. Canary Speech. https://canaryspeech.com/blog/finding-biomarkers-in-huntingtons-disease

O'Connor, K., Nixon, C., Papp, C. (2022, July 11). Proposed changes to remote therapeutic monitoring reimbursement in the proposed 2023 Medicare physician fee schedule. Nixon Gwilt Law. https://nixongwiltlaw.com/nlg-blog/2022/2022/7/11/proposed-changes-to-remote-therapeutic-monitoring-reimbursement-in-the-proposed-2023-medicare-physician-fee-schedule

Open Voice Network. (2023). Ethical guidelines for voice experiences: A case for inclusivity and trustworthiness. https://openvoicenetwork.org/resources

Orlov, L. (2022, June). The state of voice-AI and older adults 2022. Aging and Health Technology Watch. https://www.ageinplacetech.com/files/aip/The%20State%20of%20Voice-AI%202.0%20and%20Older%20Adults%20-%20Final_0.pdf

Orduña, N. (2019, July 16). AI-driven companies need to be more diverse. Here's why. World Economic Forum. https://www.weforum.org/agenda/2019/07/ai-driven-companies-need-to-be-more-diverse-here-s-why/

Paschall, Bill, "Remote Patient Monitoring Billing and Reimbursement," presentation to the Open Voice Network Health, Wellness, and Life Sciences Meeting (2023, June 8)

Paul, Adam, History of Remote Patient Monitoring: How It Began & Where It's Going, Prevounce.com, February 1, 2023. https://blog.prevounce.com/history-of-remote-patient-monitoring-how-it-began-and-where-its-going.

Pew Research Center. (2021, April 7). [Mobile Fact Sheet]. Mobile phone ownership over time. https://www.pewresearch.org/internet/fact-sheet/mobile/#mobile-phone-ownership-over-time

Robin, J., Harrison, J., Kaufman, L., Rudzicz, F, Simpson, W. Yancheva, M. (2020). Evaluation of speech-based digital biomarkers: Review and Recommendations. Digital Biomarkers, 4(3): 99-108. https://doi.org/10.1159/000510820

Sezgin, E., Huang, Y., Ramtekkar, U. & Lin. S. (2020). Readiness for voice assistants to support healthcare delivery during a health crisis and pandemic. Npj Digital Medicine, 3(1). https://doi.org/10.1038/s41746-020-00332-0

Stroobants, J. et al., (2022, July 28). Severe shortage of caregivers at heart of European healthcare crisis. Le Monde. https://www.lemonde.fr/en/international/article/2022/07/28/severe-shortage-of-caregivers-at-heart-of-european-healthcare-crisis_5991700_4.html

Tachus Blogs, "Internet Speeds: USA vs. The Rest of the World, Tachus Community, July 14, 2023, https://www.tachus.com/post/internet-speeds-usa-vs-the-rest-of-the-world#.

Tracy, J.M., Ozkanca, Yl, Atkins, D.C., & Hosseini Ghomi, R. (2020). Investigating voice as a biomarker: Deep phenotyping methods for early detection of Parkinson's disease. Journal of biomedical informatics, 104, 103362. https://doi.org/10.1016/j.jbi.2019.103362.

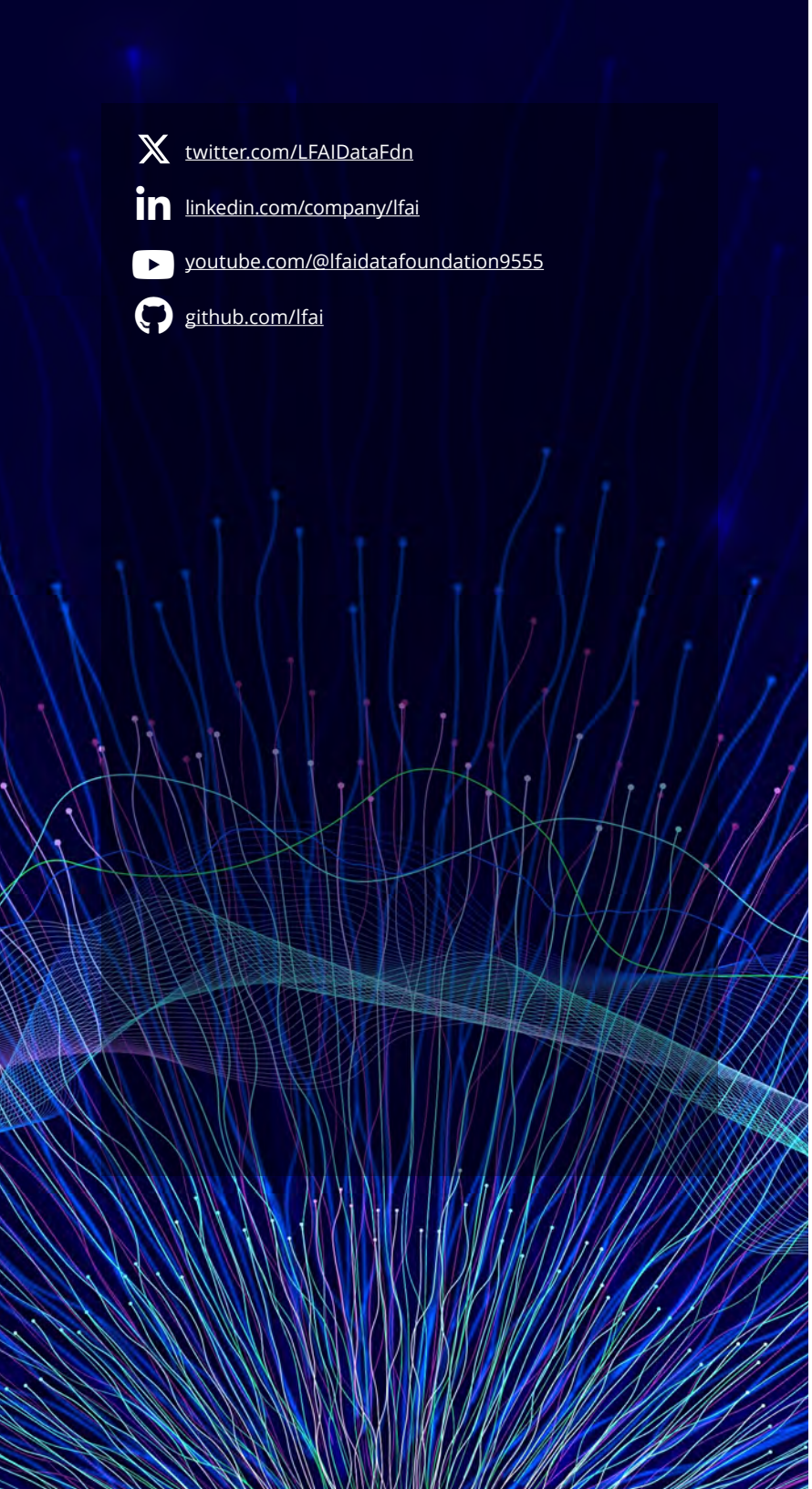
United States Department of Health and Human Services (2023, May) Coverage to Care, Telehealth for Providers: What You Need to Know. https://www.go.cms.gov/c2c

Vixen Labs. (2022). Voice Consumer Index 2022. https://vixenlabs.co/wp-content/uploads/2022/06/VixenLabs_VoiceConsumerIndex2022.pdf

World Health Organization. (2022, October 1). Ageing and Health. [Fact Sheet]. https://www.who.int/news-room/fact-sheets/detail/ageing-and-health

Yang S., Lee J., Sezgin E., Bridge J. and Lin S (2021). Clinical advice by voice assistants on postpartum depression: Cross-sectional investigation using Apple Siri, Amazon Alexa, Google Assistant, and Microsoft Cortana. JMIR mhealth and uhealth https://doi.org/10.2196/24045

Yu P., Xu H., Hu X., and Deng C. (October 2023). Leveraging Generative AI and Large Language Models: A Comprehensive Roadmap for Healthcare Integration," Healthcare 2023, 11, 2776, https://doi.org/10.3390/healthcare11202776



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