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March 31, 2020

Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW
Floor 7
Washington, DC 20201

To Whom it May Concern:

This letter represents comments submitted on behalf of the Digital Medicine Society (DiMe) for consideration by the Office of the National Coordinator for Health Information Technology (ONC) in response to the call for public comment on the draft 2020-2025 Federal Health IT Strategic Plan (plan).

Founded in 2019, DiMe is the first professional organization for experts from all disciplines comprising the diverse field of digital medicine. Together, we drive scientific progress and broad acceptance of digital medicine to enhance public health.

DiMe is a 501(c)(3) non-profit organization dedicated to advancing digital medicine to optimize human health. We do this by serving professionals at the intersection of the global healthcare and technology communities, supporting them in developing digital medicine through interdisciplinary collaboration, research, teaching, and the promotion of best practices.

We are grateful for the opportunity to provide our comments on the draft plan and strongly support the overarching goal for ONC, in collaboration with partners across the federal government, to "promote a health information technology (health IT) economy that increases transparency, competition, and consumer choice, while also seeking to protect the privacy and security of individuals' health information."

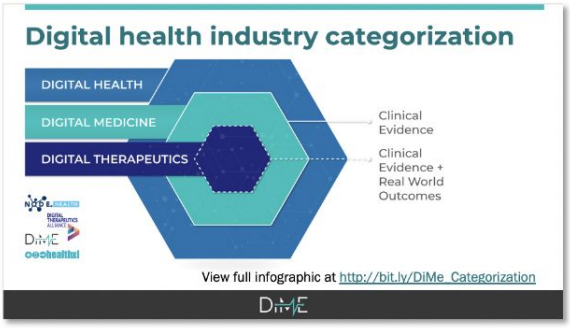
I. Overarching Comments

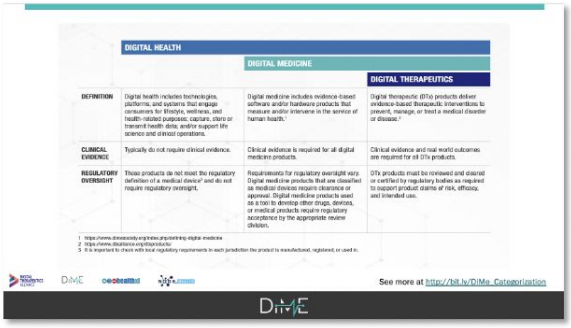
A. Language

- Suggestion: Replace “Health IT” with “digital health”

We suggest reconsidering the use of “Health IT.” The reference provided is from 2015 (outdated given the pace of innovation in digital health over the last five years) and references a World Health Organization (WHO) fact sheet that does not define Health IT, but rather describes the use of digital health tools.

Later in the plan, the term “digital health” is used (p10 & p18) and we suggest that this terminology is adopted uniformly throughout. Last November, DiMe proposed a definition of digital health developed by multiple stakeholders and experts across all relevant disciplines. This definition includes digital medicine products and digital therapeutics.





- Suggestion: Consider adopting “health promotion”

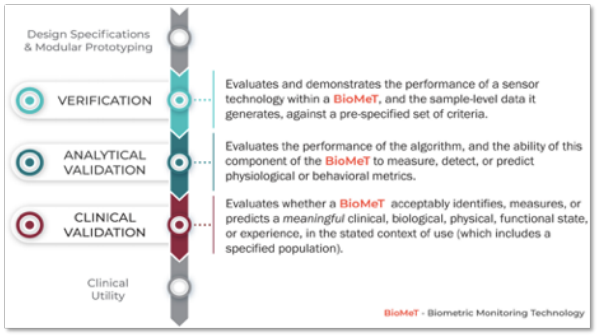
The first goal of the plan is to use digital health technologies to empower individuals to promote their own health and wellness. In 1998, the WHO coined the term, “health promotion” defined as the process of enabling people to increase control over, and improve, their health. This takes on powerful meaning with the new possibilities offered by digital health tools. We suggest that this language be adopted in the plan.

- Suggestion: Replace “validated” with “fit for purpose”

One of the strategies under Objective 2b uses the language “validated health apps and other health IT tools.” There is no shared definition of what it means for a health app or digital tool to be “validated” and evaluation frameworks for different types of digital tools

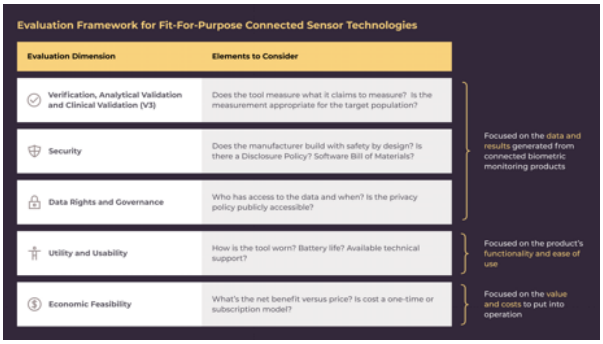
vary greatly based on the functional application of the tool, context of use, and associated risk. We recommend using the term “fit for purpose.”.

Of note, existing frameworks for evaluating whether digital health tools are fit-for-purpose should be referenced wherever possible. For example, the following frameworks have been proposed to evaluate biometric monitoring technologies (BioMeTs) and connected sensor technologies



This verification, analytical validation, and clinical validation (V3) framework has been proposed to evaluate whether a given BioMeT’s measurement performance is acceptable for a stated context of use.

Source: Goldsack J, Coravos A, Bakker J, Bent B, Dowling AV, Fitzer-Attas C, Godfrey A, Godino JG, Gujar N, Izmailova E, Manta C, Peterson B, Vandendriessche BV, Wood WA, Wang KW, Dunn J. Verification, Analytical Validation, and Clinical Validation (V3): The Foundation of Determining Fit-for-Purpose for Biometric Monitoring Technologies (BioMeTs). In press at NPJ Digital Medicine



This framework has been proposed to support a holistic evaluation of whether a connected sensor technology is fit-for purpose. It considers security, data rights and governance, usability and utility, and economic feasibility considerations in addition to measurement performance.

Source: Coravos, A., Doerr, M., Goldsack, J. et al. Modernizing and designing evaluation frameworks for connected sensor technologies in medicine. npj Digit. Med. 3, 37 (2020).

B. Workforce considerations

- The digitization of health requires a **bilingual workforce** well-versed in both the language of data science and the clinical implications of health technologies and advanced analytical solutions. Strategies to **better integrate technological and clinical expertise** are critical for the optimized deployment of digital health technologies and should be included in this plan.

- The preamble to the plan acknowledges that, “despite the risk of cybersecurity attacks, breaches, and other threats, healthcare organizations still have poor understandings of cybersecurity risks and best practices.” However, this risk is inadequately addressed in the subsequent plan. **Strategies are needed to align and collaborate with the security research community** to ensure the security of the digital health systems we are building and the safety of the communities we serve.

This movement is already underway. A number of security research organizations are already incredibly active in the healthcare industry and are working collaboratively with industry, patients, and government:

  - Biohacking Village
  - FDA-Led #WeHeartHackers Initiative
  - I Am The Cavalry
  - National Institute of Standards & Technology (NIST)
  - FDA Cybersecurity

- Clinical workforce challenges--current and future healthcare worker shortages and the mal-distribution of clinicians and the patients who need them--are not noted as underlying contributors to difficulties accessing care and poor health outcomes. Digital health technologies offer a variety of solutions that can help ameliorate these challenges and **specific strategies to address these workforce challenges** should be included in the plan.

C. Structural issues

- Any plan that relies on digital health technologies to improve health, healthcare, and health research should **include strategies to address the infrastructure and access issues that underlie the "digital divide,"** a term used to describe the gap between demographics and regions that have access to modern information and communications technology, and those that do not, or have only restricted access. Without such strategies, digital health tools will likely not realize their promise of reducing health disparities and may even cause them to increase.

- In addition to the digital divide, variation in individuals' numeracy and health literacy will give rise to health disparities if not addressed. These skills determine how well people can use health data and information to improve their health and inform their care decisions. The plan should include specific **strategies to address differences in individuals' numeracy and health literacy**.

D. Data governance

Data governance is the rules and procedures in place to ensure the availability, usability, integrity, and security of data. Absent robust data governance, it is impossible to confidently use data to optimize health while protecting the confidentiality and privacy of individuals with certainty.

- Privacy and security considerations are mentioned throughout the plan. However, rather than referencing strategies for "promoting" a culture of privacy and security, this plan must prioritize **immediate multi-stakeholder action to develop, implement, and enforce a framework for U.S. health data governance**.
    - Data cannot safely be the currency of our healthcare system without thoughtful data governance strategies that mitigate the risks of 1) confidentiality and privacy violations, and 2) discrimination (in particular against vulnerable populations) through the misuse of health data or mal-distribution of the benefits.
    - Increasingly, health data is being created and held by organizations not covered by the Health Insurance Portability and Accountability Act (HIPAA). This will only increase given the recent passage of HHS' interoperability final rule as HIPAA privacy protections do not apply when patients transfer data to consumer apps. In recognition of the enormous, lucrative, and largely unregulated health data economy that grows larger every day, data governance must be prioritized in this plan. In addition to protecting individuals, this will also help speed the benefits of digital health to population health, healthcare, and health research.

- Digital health data are growing 40% year on year. In addition to traditional lab and diagnostic tests, clinicians, researchers, and patients now have access to social, environmental, and sensor data collected continuously outside of the clinic. Electronic health records (EHRs), designed for tracking procedures and billing, are not optimized to receive flows of data generated by the second or milisecond. Nor do they place patients at the center of their own health and healthcare. This plan should include specific strategies for determining the **optimal data architecture in this era of data abundance**.

E. Learning health system approaches and the integration of care and research

- Healthcare systems in which knowledge generation processes are embedded in daily practice to produce continual improvements in care are called learning health systems. The plan should include specific strategies for **creating a data-driven ecosystem to address both acute and chronic health needs, constantly incorporating and learning from any and all information that is relevant to a particular person**, while simultaneously optimally promoting the maintenance of health.

- It is encouraging to see movement toward a value-based care system identified as a significant opportunity in a digital health system. However, rather than stating that "this movement is likely to continue" the plan should include specific strategies for

driving the continued shift toward value based care. In addition to creating new incentives for healthcare providers to improve quality and patient outcomes, **this shift will create a strong incentive to generate and use high-quality data and analytics** to make decisions and limit risk. All incentives to generate the highest quality data possible should be identified and implemented in this plan in order to build a data-driven ecosystem.

- The plan states that putting research into action by strengthening feedback loops between scientific and healthcare communities to efficiently translate evidence into clinical practice and improvement is a federal health principle. To **ensure that every patient has access to the right care, in the right place, at the right time, and at a price both the individual and society can afford**, the plan should include specific strategies to **collapse the distinctions between the data and evidence used to inform decisions about approving new therapies, their reimbursement, and their use with each unique individual during routine clinical care**.

F. The role of government

The plan states that being "a responsible steward" is a core federal health principle and that, where possible, the federal government should rely on the private sector. We fully support this multi-stakeholder, cooperative approach to advancing digital health. We also want to stress that this must not diminish the role of government. Rather, this plan should **clarify the specific role of the government in incentivizing and overseeing industry as they drive innovation**. This should include:

- **New legislation to advance a policy similar to the Genetic Information Nondiscrimination Act (GINA)** that protects Americans from discrimination based on their genetic information in both health insurance (Title I) and employment (Title II). To address risks such as discrimination against patients and individuals in this new era of digital health, and in particular against vulnerable populations, we need as a minimum the same protections for individuals based on their digital specimens, plus additional protections against such additional discrimination such as credit scores and life insurance.

- **Government-led evaluation and enforcement of existing policies and regulations** such as HIPAA and the new Cures Act Final Rule, to ensure that policy meaningfully impacts health. Change through policy making requires evaluation of impact and enforcement where there is non-compliance and/or where the risks of non-compliance are high. For government legislation promoting the safe, effective, and equitable adoption of digital initiatives to meaningfully impact health, evaluation and enforcement is necessary.

- **Monitoring the market and rapidly reacting to unintended consequences.** Unintended consequences of industry-driven digitization of health include concerns about safety, efficacy, and equity:
    - Inadequate anonymization practices risk individuals' privacy and security. One recent study found that individuals could be reidentified from an "anonymized" U.S. dataset with only three data points in hand: date of birth, zip code, and gender.
    - The challenges accessing high quality real-world data (RWD)--despite 10 years of government investment in EHRs--highlight the importance of monitoring the efficacy of digital initiatives.
    - There is major geographic variation in the adoption of alternative payment models, as well as racial disparities in both the performance of digital health tools and the use of algorithms for identifying at-risk patients. Health disparities are projected to worsen along the digital divide and with tech literacy.

II. Feedback on Goal I: Promote Health and Wellness

- Per comment in Section I.A of this comment, we suggest including the concept of health promotion.

- The first three strategies under Objective 1a and the first two strategies under Objective 1b rely on increased use of consumer health apps and increased data liquidity. These strategies are critically important. However, they put patients and individuals at risk without additional strategies in place to:
    - Develop, implement, and enforce a robust framework for health data governance.
    - Draft privacy legislation to protect health data outside of HIPAA covered entities.
    - Fund initiatives to support consumer choice of high quality, safe, effective, ethical, and secure digital health technologies (e.g. apps and other connected sensor technologies).

- We suggest that the second strategy for pursuing Objective 1c, "foster greater understanding of how to use Health IT," be strengthened and made more specific. Digital health technologies offer great possibilities for overcoming disparities in health and access to information in care. They also pose huge risk for exacerbating these same disparities if strategies for overcoming the digital divide and variance in numeracy and health literacy are not fully addressed.

In addition to educational activities and strategies to overcome infrastructure challenges for the broad deployment of digital health, this plan should include incentives for developers to create digital health tools that require only the most simple technologies and government monitoring for and addressing unintended consequences arising from the digitization of healthcare.

- The third strategy under Objective 1c focuses on the "capture and integration of social determinants of health data into EHR." We suggest that the plan not stipulate that all digital health data be integrated into traditional EHRs. Rather, the plan should challenge the notion that all data should be forced into EHRs held by healthcare systems that are largely built in such a way that clinicians find it difficult to navigate the data they already contain. The plan should include strategies to first explore which data architecture (e.g. modified EHRs, the patient centered record, etc.) is optimized for storing and optimizing access and usability of health data.

III. Feedback on Goal II: Enhancing the Delivery and Experience of Care

- We fully support Objective 2a, to "ensure safe and high-quality care through the use of health IT." We emphasize the need to apply a broad definition of patient safety in the digital era, including privacy, security, and equity considerations as risks of potential harm to patients that must be recognized and mitigated.

- We recommend that this broad definition of patient safety drive the tactics used to implement the strategies outlined to support Objective 2a. Specifically, there should be support for implementing technologies that are broadly accessible, private, secure, and equitable. There should also be monitoring and enforcement to ensure optimal and equitable outcomes.

- The data governance strategy is fundamental to realizing all of the data-driven objectives of this plan--it ensures that individuals' confidentiality and privacy is protected, and risks of discrimination through the misuse of health data or mal-distribution of the benefits are mitigated. The placement of this strategy makes sense based on the organization of the document, but we hope this strategy will be the cornerstone of the plan.

- The first strategy under Objective 2b mentions "validated health apps and other health IT tools." In this context, "validated" is a meaningless term and we recommend replacing it with "fit for purpose."

- Objective 2c and the associated strategies highlight the critical importance of developing the current healthcare workforce to be technically confident and competent. We applaud the strategies outlined to support, develop and invest in the

technical capabilities of the healthcare workforce, both in practice and within government.

- Recognizing the challenges healthcare providers have faced over the last decade implementing some forms of digital health technologies, we are delighted to see the potential of these tools to automate processes and reduce burden recognized under Objective 2d. We agree that there is significant potential for these approaches to allow clinicians to spend more time in patient care.

IV. Feedback on Goal III: Build a Secure, Data-Drive Ecosystem to Accelerate Research and Innovation

- We are delighted to see the need for harmonized data elements and standards noted under Objective 3a. We encourage an even more aggressive strategy aiming not just to improve harmonization, but achieve it.

- Again, data governance is mentioned, and we continue to advocate for developing a robust, nationwide health data governance strategy as the cornerstone to this plan.

- Collectively, the strategies under Objective 3a, to "advance individual- and population-level of health data" may be insufficient to protect individuals from this broad use of their health data. Given the ease with which we can reidentify individuals in de-identified data sets using their digital data specimens, extra protections are needed. GINA was passed in 2008 and protects Americans from discrimination based on their genetic information in both health insurance (Title I) and employment (Title II). We recommend a similar law to protect individuals from discrimination based on their digital specimens, with additional provisions to ensure protections including life, disability, and long-term care insurance.

- Objective 3b, to "support research and analysis using health IT and data at the individual and population levels" recognizes the potential for today's abundance of digital health data to power research and, in turn, better health. We would build on the strategies identified under this objective, adding strategies to:
    - Promote learning health system approaches where internal data and experience are systematically integrated with external evidence and put into practice, patients get safer and higher quality care, and healthcare delivery organizations become better places to work.
    - Use digitized, person generated health data to collapse the silos between healthcare and health research, including for new medical products.

V. Goal IV: Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure

- Objective 4a, to "advance the development and use of health IT capabilities" focuses on the need for all stakeholders to have confidence and trust in digital health technologies, which we agree is absolutely critical to the success of this plan. The strategies that support this objective could be strengthened by:
    - Providing funding for consumer reviews and reports on digital health products. Our organization has been seeking funding to develop exactly these reviews and reports for nearly a year and have been unsuccessful to date with no grantmaking institution interested in supporting the work.
    - Strengthening the strategy to "build an evidence base on the utility and impact of health IT," commiting to funding the evaluation of utility and impact and monitoring the impact of digital health implementation for unintended consequences.
    - Committing to enforcing principles of digital health technology safety and user-centered design principles.

- The goal of transparent expectations for data sharing articulated in Objective 4b is critically important to the success of this plan. We recommend strengthening this objective, committing to not just establishing expectations, but enforcing them.

- We are thrilled to see a commitment to enhancing technology and communications infrastructure in this plan. We commend ONC for recognizing the importance of this infrastructure to ensure equitable distribution of the benefits of deploying digital health technologies.

- Objective 4d, to "promote secure health information that protects patient privacy" is fundamental to the success of this plan. We encourage ONC to consider strengthening federal commitment to this goal by revising it to "ensure secure health information that protects patient privacy."

- The strategy to "increase patient understanding and control of their data" is essential. We recommend replacing the word "patient" with "individuals'" to recognize that individuals who do not currently self-identify as a patient should also understand and have control over their health data. This strategy would also benefit from more clarity with regards to how it will be implemented, evaluated, and modified if disparities in health literacy persist.

Thank you for the opportunity to provide feedback on the draft 2020-2025 Federal Health IT Strategic Plan. We appreciate ONC's bold vision and leadership on this multifaceted

topic. We are thrilled to see the breadth of issues tackled in this broad, ambitious plan and we are confident that the final plan will have an enormous impact on health, healthcare, health research, and the lives of the patients we all serve.

Respectfully submitted,

Jennifer Goldsack

Executive Director

The Digital Medicine Society (DiMe)