December 22, 2020

Dr. Leith States
Chief Medical Officer
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services

RE: Request for Information – Landscape Analysis to Leverage Novel Technologies for Chronic Disease Management for Aging Underserved Populations

Submitted via OASHcomments@hhs.gov

Dr. States:

The American Medical Informatics Association (AMIA) is pleased to provide input that will inform OASH's Landscape Analysis to Leverage Novel Technologies for Chronic Disease Management for Aging Underserved Populations.

AMIA is the professional home for more than 5,500 informatics professionals, representing front-line clinicians, researchers, educators and public health experts who bring meaning to data, manage information and generate new knowledge across the health and health care enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations, and public policy across settings and patient populations.

We are gratified that OASH recognizes the opportunities inherent in novel technologies to address chronic disease management in aging populations in underserved areas. While we agree that these technologies certainly offer much potential, we nevertheless caution that current available technology is not aligned with care delivery and payment models. In order to best leverage novel technologies for chronic disease management, there must first be a recognition that: **1) care delivery models must evolve in parallel with advancements in technology**, and **2) patients must be further empowered to take ownership over both their care and health data.**

This reality includes patient virtual access to qualified professionals (including nurses, physicians, pharmacists, social workers, therapists, dietitians) outside of normal care delivery times and our traditional notion of care delivery locations. Chronic care delivery and support

often occurs outside the four walls of the doctor's office or hospital. By necessity, it can occur in the community, at the supermarket, restaurants, and gyms. Technology will need to connect to these areas to deliver true medical behavioral support for chronic conditions. The explosion of sensor technologies, mHealth applications, and telehealth has led to an exciting era of "connected health" in which technology facilitates novel, patient-focused care delivery models. These technological advances and increase in patient engagement, however, have largely outpaced the development of novel ways of delivering patient-centered care. We ask that you keep these overall points in mind as you consider both our comments and potential policy solutions to some of the problems outlined below,

Below, we offer detailed responses gleaned from our membership to the RFI questions. Thank you for considering our comments. Should you have questions about these comments or require additional information, please contact Scott Weinberg, Public Policy Specialist at scott@amia.org or (240) 479-2134. We look forward to continued partnership and dialogue.

Sincerely,

Patricia C. Dykes, PhD, RN, FAAN, FACMI
Chair, AMIA Board of Directors
Program Director Research
Center for Patient Safety, Research, and Practice
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(Enclosed: AMIA Detailed Comments)

RFI Questions	AMIA Comments
Barriers and Opportunities for Technology-Driven Solutions	
What barriers (e.g., privacy concerns, other clinician and patient barriers) and opportunities are most relevant for bringing technology-driven solutions to aging populations in underserved areas?	Below are many, though certainly not all, barriers and opportunities identified by AMIA members. **Barriers** • Unclear data governance policies • Lack of best practice guidelines for the development and use of AI-based algorithms. • Monetary costs of developing solutions, which are passed onto the consumer. • Patients' lack of access to technology, internet, and/or broadband, a social determinant of health.[1] This includes an inability to afford such services, even if they may be prevalent where the patient is. • Lack of measurement of meaningful outcomes, such as long-term burden of chronic disease • Lack of connecting practical, everyday IT support of behavioral interventions to clinical data. • Patients' lack of understanding what technology they are using, where their data are going, and how private their data actually are. Privacy and ethical concerns only exacerbate as family members get involved with care and as proxies for decision-making (as if often the case with older populations). • Lack of proper provider and patient training on the complexity of certain technology solutions. • Lack of sustained use of solution over time by patient/consumer • Provider administrative and documentation burden, in addition to data burden, whereby through continuous body-worn sensors,

[1] https://www.amia.org/news-and-publications/press-release/amia-tells-fcc-broadband-access-among-social-determinants-health

	volumes of data are generated, making it unsustainable for clinicians to process and interpret at the point of decision-making. • Lack of provider and health system funding to implement solutions • Lack of mechanisms to consistently obtain timely feedback from providers • Lack of standards to incorporate patient-generated disease management data into a patient's EHR as part of disease history. • Perceived lack of provider interest in information from consumer wearable and mobile health technologies, including patient-reported outcomes and patient-generated health data • Lack of integration for multiple disparate data sources., including a lack of effective clinical summarization methods for Internet of Things (IoT) data. • Rapid technology change • Lack of support for "legacy" devices – even those only a few years old • Privacy concerns where for-profit companies develop devices that capture personal data from multiple aspects of a person's life. Those data are held in proprietary databases with little access and control by the individuals generating the data. **Opportunities** • Evaluating, creating, and implementing SDOH data related to technology. • Increased and increasing patient and provider access to data via FHIR-enabled solutions[2] • Examining hospital readmission rates and emergency department bounce-backs, which can result in data to guide earlier intervention. • Identification of data sources from community or non-clinical entities that could fill gaps (or enhance) information contained in the EHR

[2] https://www.hl7.org/fhir/overview.html

	• Automation of data capture, including self-reports / patient-reported outcomes for people with limited access to care • The commercial market is incentivized to develop more solutions, as aging population with chronic conditions increases. This includes opportunities to create scalable and affordable in-home monitoring solutions for early detection of complications from chronic disease. There are also opportunities to create a portfolio of solutions based on patient need and/or acuity levels. The solutions can be FHIR standard-enabled to make these fit for clinical use.
What federal policies currently limit the capacity to deploy and scale technology-driven solutions for aging populations?	Federal policies that limit capacity to deploy and scale technology solutions include: • Lack of consistent and clear Medicare reimbursement policies for telehealth. Though many of the previous restrictions have either been changed or waved over the course of the COVID-19 public health emergency, further clarity for providers is needed for beyond the PHE. • Medicare's bifurcation of remote patient monitoring and telehealth. Technology solutions are usually integrated, but current polices create treat them as separate when they naturally interoperate. • Medicare reimbursement policies that exclude nurses from payment models, recognizing key roles nurses perform in leading and managing care coordination and remote patient monitoring solutions and post-acute care services. • Health data flow from between HIPAA-covered entities and non-covered entities, with the patient often not knowing when his or her data is protection is covered by HIPAA, the FTC, or neither.[3] • FDA's current approach to regulating software-as-a-medical device (SaMD), which updates more often than hardware devices. However,

[3] See ONC report, "Examining Oversight of the Privacy & Security of Health Data Collected by Entities Not Regulated by HIPAA," https://www.healthit.gov/sites/default/files/non-covered_entities_report_june_17_2016.pdf

	FDA is currently seeking to address its review inflexibility with the Digital Health Software Precertification (Pre-Cert) Program.[4]
What new federal policies could facilitate the success of technology-driven solutions for aging populations?	• A major barrier to the practice of telehealth is the inability of providers to practice across state lines. Policies such as the PREP Act,[5] which is already being used to facilitate COVID-19-related services, could be further leveraged beyond the pandemic to further enable the use of telehealth across state lines. • Similar to Medicare CPT code 99453, "Initial set-up and patient education on the use of monitoring equipment," a similar patient education component could be included in a Medicare telehealth code. CMS can also use the MIPS program's Improvement Activities[6] to incentivize the use of technology-driven solutions. As the federal government has learned from many technology-focused policy developments in health care, including Meaningful Use and especially the Beacon Community Program[7] under the HITECH Act, providing financial incentives through value-based reimbursements that flexibly allow providers and care teams to utilize new technologies as they determine appropriateness drives broader and more effective adoption of new technologies and achieves better, more lasting quality improvements, than specifying new reimbursements for specific technologies. • The Office of the National Coordinator for Health IT (ONC) is currently working to develop a Health IT Workflow Automation Policy,[8] which seeks to, in part, "identify opportunities for automation in health care, in both clinical and administrative areas" and "explore what would need to be instrumented to enable such automation." We support continued development of this policy and

[4] https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-software-precertification-pre-cert-program
[5] https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx
[6] https://qpp.cms.gov/mips/improvement-activities
[7] https://www.healthit.gov/topic/onc-hitech-programs/beacon-community-program
[8] https://www.healthit.gov/topic/scientific-initiatives/health-information-technology-workflow-automation-policy-development

	believe it will aid in further facilitating the success of technology-driven solutions. • A future update to the ONC Information Blocking rule could include key use-cases related to aging in place and the use of technology. This can aid in facilitating the flow of information in these settings. • Policy initiatives to support older adults to receive care "where they are," with regard to the technologies they already have or have easy access to. For example, do not require a change in technology someone has and already uses, but support ways to leverage what already exists. • Further development of care delivery and payment models to support advanced hospital level care in the home. • Data control policies need to support the control of personal data sourced from sensor-based and other devices in the hands of the person who generates them, including the right to see their data in real time and delete sets permanently. These should be backed by fines severe enough that private entities will not violate them.
What are the ways in which technology-driven solutions are manifested (e.g., software platforms, wearables, robotics, etc.) and how is the integrity of data collected ensured (e.g., fidelity, and accuracy of data)?	Broadly, technology-driven solutions manifest themselves as small-scale studies in academic environments that often fail to translate to everyday living because the commercial environment does not support a path to sustainability. They also manifest themselves as products from start-up companies that either do not serve the needs of the population, or fail because they do not achieve market viability. Often, the race is to grab "user share" and then sell these novel solutions to another company, a success metric that does not serve the needs of a given population. In the clinical environment, however, these are manifested by patient portals and their associated mobile applications; body-worn sensors combined with patient-reported outcome data and/or social determinants of health data (which feed into an algorithm); and home sensors that track movement, monitor heart failure, monitor patient adherence to medication regimens, detect arrhythmias, and detect toxic reaction to chemotherapy

	As for data integrity, it requires someone to take ownership or stewardship of the data. Patient-collected data requires patients being aware that this information will be utilized to drive their healthcare. They need to be able to modify and change it in a controlled, date-time stamped, annotated manner. Thus, metadata become very important in these third-party technologies. Patients can provide some level of validation through active submission of the data. Patient-collected data, however, need clinical summarization to be useful outside of an acutely managed program. Device creators, third parties, and health care organizations that learn to develop clinically useful summaries of this data for providers will need to establish some minimum acceptance criteria and validity testing. The criteria for usage in clinical care should be transparent and provided to the end users. Device creators should additionally provide solid plans to collect large scale anonymous user data to set up the baseline (almost similar to post market surveillance). Data integrity can then be monitored with the solid baselines.
How will training data sets be established and implemented to drive effective technology solutions that improve chronic disease outcomes for aging populations in rural areas?	When discussing establishing ad implementing training data, we must be careful that the algorithms cannot advance faster than clinicians' ability to integrate it into decision making. For example, a machine learning algorithm can correlate continuous vital signs (heart rate, activity, Sp02) in conjunction with patient reported outcomes (PROs), to generate a risk score against the patient's individualized baseline. Clinicians need to understand how to interpret the risk score, which requires knowledge of the data elements that went into the score calculation. Further, synthetic data sets – probably created by resampling real data – are crucial to start building better models, with diverse, representative data needed. Along with this, collecting data from multiple points of care, in both rural and urban areas, is vital. However, in rural areas, individual facilities may be too small to produce large datasets on their own, so drawing from multiple data sets will increase both data volume and data diversity (and representativeness).

	Another way to obtain training data is a combination of both purchasing data from participants and donation by participants during the development, pilot stage, and preliminary launch stage.
How will AI solutions be validated? What metrics will be used to evaluate the effectiveness of AI/machine learning algorithms?	The field of informatics plays a crucial role here – from problem definition, to solution design, to validation of data sufficiency and computational methods, and to effectiveness studies. There are multiple levels of metrics that can be used to evaluate effectiveness: (1) how does the AI solution perform on its specific task (accuracy, sensitivity/specificity, F-1, etc.); (2) how does integrating the AI solution into clinical care affect process efficiency; (3) how does integrating the AI solution affect care outcomes for the health system (mortality, readmission, cost), provider (burden), and for the individual (morbidity, disability/disease burden, quality of life measures, as appropriate). Further, EHR and patient-reported outcomes data should be validated against the algorithms to see how well they responded to expected or unexpected health effects. This systematic monitoring is known is "algorithmovigilance," which is one important way to maintain quality, minimize harm, and promote trust in healthcare AI.[9] Finally, we point you to a forthcoming AMIA position paper that lays out an informatics-led policy framework for adaptive (AI/ML) clinical decision support (CDS) tools. The paper calls for identification of two policy concepts: transparency metrics and communications standards. Transparency metrics would describe how Adaptive CDS algorithms are trained, including the data acquisition processes (e.g, patient cohort selection criteria) and preprocessing or "data wrangling" steps that must be clearly documented. Communications standards articulate the components of the Adaptive CDS and describe the intended use(s) and expected user(s), similar to US Food and Drug Administration's (FDA's) prescription drug-labeling

[9] https://www.regenstrief.org/article/algorithmovigilance-monitoring-healthcare-ai/

	requirements.[10] We believe that this should not only apply to CDS, but to any AI-related algorithms, whose development should be transparent and should be monitored publicly or to the extent possible (for proprietary options).
How will healthcare team and patient trust in technology solutions be addressed? How will legal and ethical issues be addressed for technology solutions designed for improving chronic disease outcomes?	Trust is built through a combination of marketing and experience, and well defined through consumer privacy notices like the Model Privacy Notice developed by the ONC.[11] We thus need to support pilots and evaluations that make it easy to try and show the benefit. One suggestion is implementing a mechanism that engages the patient in collecting/reporting to the clinical team ethical and legal questions related the technology solutions in chronic condition management. The patient should also be made fully aware of policies and procedures for deleting data from devices. Extensive education about the purpose of the technology should be provided, as well. For example, the patient should know that remote monitoring technology is not the same as an emergency response system. Patients should also be maximally engaged with the care itself. They can do this by, for example, reporting back outcomes data, including reports on their lifestyle goals, which may not be captured by other solutions. Further, patients should be encouraged to engage their support network in their care.
How will bias and variance be addressed in machine learning algorithms for this application? How will supervised versus unsupervised learning be used to develop inferences and patterns from data sources? What will be the challenges and proposed solutions for data cleansing and transformation?	Data should be compliant to existing standards as much as possible during the generation and collection stages, which should minimize the efforts of data cleansing and transformation. The emphasis should be in the upper stream of generating portable, reusable and sharable data, not in the downstream to clean and transform the data. Data collection should also aim to be as representative as possible (multiple specialties, multiple institutions, multiple patient populations). Data that reflect the broader population of interest, including social determinants of health, is key to reducing bias in models/algorithms. One way to address the

[10] Jeffery Smith, Setting the agenda: an informatics-led policy framework for adaptive CDS, Journal of the American Medical Informatics Association, Volume 27, Issue 12, December 2020, Pages 1831–1833, https://doi.org/10.1093/jamia/ocaa239

[11] https://www.healthit.gov/topic/privacy-security-and-hipaa/model-privacy-notice-mpn

	issue practically is to introduce IRB to the algorithm development process, especially during features/parameter selection/discard processes. Finally, we point OASH to our 2019 comments on FDA's "Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback."[12] In it, we proposed that FDA modify and supplement its proposed framework with 1) a stronger emphasis and acknowledgement of how starkly different continuously learning algorithms must be treated from "locked" algorithms; 2) a discussion of how new data inputs will impact the algorithm's outputs; 4) a discussion of how cybersecurity risks, such as hacking or data manipulation, may influence the algorithm's output; 4) a discussion of how manufacturers should use evolving knowledge about algorithm-driven bias to ensure that algorithms used in affected products do not facilitate or promote such bias.
Will AI deep learning and neural networks approaches and solutions be appropriate and used for chronic disease improvement for aging populations?	These methods certainly can play a role, perhaps a critical role to make the solution smarter. However, the products should be effect-oriented, not approach-oriented. Regardless of the approach, AI technologies need to start with a clear framework of transparency, periodic evaluations, and ongoing evaluation of bias. This is an area that more AI researchers should be encouraged to explore further because this field will generate a large amount of data over time due to the nature of chronic conditions. These data can be used by AI researchers to improve the performances of the interventions/devices/software, to improve patient outcomes eventually.
What are the per-person-costs of technology-driven solutions in the context of this RFI?	Per-person costs to consider are: smartphone costs, monthly data access plans, internet costs, other devices depending on how the solution is packaged, and whether billing codes cover the services for the patient. We also note the costs associated with the burden of the disease. This extends to

[12] https://www.amia.org/sites/default/files/AMIA-Response-to-FDA-AIML-SaMD-Modifications-Draft-Framework_1.pdf

	affected individuals having to learn how to use new technologies/solutions, spending time entering data, and following the protocols laid out for them
Key Indicators & Data Sources of Technology-Driven Chronic Disease Management	
What key indicators or data sets will be used to perform measure outcomes (e.g., racial, ethnic, gender, and socioeconomic disparities)?	This question will depend on the specific chronic condition(s). Regardless, the outcome should focus on individual level, community level, and society/national level in both short term (5-10 years) and long term (10 to 30 years). Key indicators like social determinants of health (SDOH) data can begin to be captured through ICD-10 codes. The Uniformed Data System (UDS)[13] is also a decades old data set that has measured and tracked quality at federally-qualified health centers across the US, currently including data on over 30 million people. The UDS offers direct measures on people and populations most at risk of racial, ethnic, gender and socioeconomic disparities and should be included in any analysis of technology's impact on these populations. An additional indicator is life expectancy and quality of life, which has its own measurement tools.[14,15] Finally, cost is measurable indicator that should be considered, as well.
What existing methods, data sources, and analytic approaches are being used to assess and monitor technology-driven solutions (e.g., AI) in healthcare systems?	Data sources include electronic health records, personal health portals and mHealth tools, Census data, and claims data. Analytic approaches include machine learning (classification, clustering, etc.) and statistical modeling of data (time series, logistic regression, etc.) A peer-review process is also a way to provide some sense of assessment and monitoring.
What selected health conditions should be addressed as priority conditions to assess	Chronic conditions, namely heart disease and diabetes, should be prioritized, as these are both highly prevalent and costly. Further, disability is a common

[13] https://bphc.hrsa.gov/datareporting/reporting/index.html

[14] Institute of Medicine (US) Council on Health Care Technology; Mosteller F, Falotico-Taylor J, editors. Quality of Life and Technology Assessment: Monograph of the Council on Health Care Technology. Washington (DC): National Academies Press (US); 1989. 6, Assessing Quality of Life: Measures and Utility. Available from: https://www.ncbi.nlm.nih.gov/books/NBK235120/

[15] Higginson IJ, Carr AJ. Measuring quality of life: Using quality of life measures in the clinical setting. *BMJ*. 2001;322(7297):1297-1300. doi:10.1136/bmj.322.7297.1297

technology-driven capacity to influence access, timeliness, and quality of healthcare treatment and preventive services to aging populations living in rural areas?	outcome of chronic conditions. Chronic pain (especially back pain), migraines, diabetes, obesity, and depression are all major contributors to disability (as well as long-term costs to the health system). In addition to prevalence rate, additional criteria that can be used to prioritize other conditions are mortality rate and negative effects on one's quality of life, including depression and other consequences of social isolation.
Examples of Health Promotion using Technology-Driven Solutions	
Describe novel technology-driven approaches (e.g., AI) that may prevent the onset, progression, or escalation of chronic disease states in patients who have decreased frequency of health system interaction during the COVID-19 pandemic, such as aging Americans living in rural areas.	We note that technology sophistication varies depending on the patient's acuity level. Health conditions with lower acuity may include a phone app where the individual enters symptoms, and through the use of a digital thermometer and pulse oximeter, the individual enters data values, which go to a remote nurse who monitors trends. An algorithm could identify changes upon entry of symptoms and vital signs, then trigger questions to the patient for additional information. For patients with higher acuity conditions, such as those with heart failure or undergoing chemotherapy, the use of body worn sensors for physiological data (heart rate, heart rate variability, Sp02, respiratory rate, activity levels), combined with temperature and patient reported outcomes, can feed a dashboard where qualified staff in virtual care/command centers provide monitoring and just in time interventions. SDOH can also be addressed through technology-driven approaches. For example, technology can be tied to healthcare that allows local delivery of fresh, healthy food for those high-risk patients who are unable or unwilling to leave the home during the pandemic.
What is the established evidence or evaluation supporting proposed benefits, and the evaluation of potential harms of AI-driven solutions such as increased racial bias?	We refer OASH to Park *et al.*, who conclude that "[…] the performance of AI tools in medicine depends on the understanding, trust, and subsequent behaviors of users. AI evaluation also requires integration into the existing clinical environment and a platform to collect, store, and process data, and to deliver the outputs to users in a timely manner."[16] Choudhury *et al.*'s meta-analysis, which focused on studies that used machine learning algorithms in

[16] Yoonyoung Park, Gretchen Purcell Jackson, Morgan A Foreman, Daniel Gruen, Jianying Hu, Amar K Das, Evaluating artificial intelligence in medicine: phases of clinical research, *JAMIA Open*, Volume 3, Issue 3, October 2020, Pages 326–331, https://doi.org/10.1093/jamiaopen/ooaa033

	the care of geriatrics patients with chronic conditions similarly concluded that "[t]o improve geriatric care, models must not only be developed but also integrated into clinical workflow."[17] In fact, their review did not identify any studies that integrated their model into clinical workflow. Finally, we would be remiss if we did not mention the landmark study by Obermeyer *et al.*, which found evidence of racial bias in a widely used algorithm, such that Black patients assigned the same level of risk by the algorithm are sicker than White patients.[18] This study is vital research that must inform how policy is made with regard to algorithms.
Public-Private Partnerships	
Provide ideas of the form and function of a public-private partnership model to leverage the adoption of technology-driven solutions to improve outcomes for at-risk populations such as aging Americans living in rural areas.	We note that there currently exist business models that support the collaboration between vendors, the pharmaceutical industry, private laboratories, emergency response companies, and providers/universities on IRB projects to develop new ideas and measure impact. However, these business models are challenged with lack of communication and broadband infrastructure in rural areas. We recommend continued engagement with Congress and the FCC, with continued investment in programs such as the Lifeline Support for Affordable Communications.[19] Further, HHS can partner with corporations and non-profit organizations like supermarkets, gyms, and homeless shelters to help address SDOH.
What organizations, groups, and/or, associations should HHS engage as part of such a collaborative effort?	On an intergovernmental level, OASH should coordinate with the NIH's All of Us Research Program, which is building an impressively diverse research dataset.[20] The dataset can help HHS glean how environment, lifestyle, and genes impact the health of at-risk populations and better inform which

[17] Avishek Choudhury, Emily Renjilian, Onur Asan, Use of machine learning in geriatric clinical care for chronic diseases: a systematic literature review, *JAMIA Open*, Volume 3, Issue 3, October 2020, Pages 459–471, https://doi.org/10.1093/jamiaopen/ooaa034
[18] Obermeyer, Ziad & Powers, Brian & Vogeli, Christine & Mullainathan, Sendhil. (2019). Dissecting racial bias in an algorithm used to manage the health of populations. Science. 366. 447-453. 10.1126/science.aax2342.
[19] https://www.fcc.gov/lifeline-consumers
[20] https://allofus.nih.gov/about/diversity-and-inclusion

	technology-driven solutions to assist in leveraging. OASH should additionally engage HRSA, specifically the Bureau of Primary Care. We also recommend engaging with community-level organizations, such as local religious organizations and universities (who often serve as their local communities' health support) to aid in implementation aspect of any collaborative effort. Finally, the National Association of Community Health Centers (NACHC), and larger state-based community health center organizations should be part of this collaboration.