California Precision Medicine Advisory Council Meeting Summary, February 2021

Update from the Newsom Administration

- Kate Gordon, Senior Advisor on Climate, Director of Governor's Office of Planning and Research
- Richard Figueroa, Deputy Cabinet Secretary

Accept November 2020 meeting summary

Overview: CA efforts in Alzheimer's

- Dept. Public Health Alzheimer's Disease Program (1984)
- CA Alzheimer's Disease Centers (university medical centers; 1984)
- California Healthy Brain Initiative (2019-22)
- CHHS Alzheimer's Disease and Related Disorders Advisory Committee (1988)
- Governor's Task Force on Alzheimer's Disease Prevention and Preparedness (2019-20)
- Master Plan for Aging (Nov. 2020)
- California's State Plan for Alzheimer's Disease: An Action Plan for 2011-2021

The existing programs don't seem to focus on data integration, which could be a nexus for CIAPM to add value.

Update: CIAPM-sponsored projects in cancer disparities

- Improving Precision Medicine for Breast Cancer in Latinas: A Multi-Tiered Approach
  - Elad Ziv, MD, UCSF
- Reducing Cancer Disparities through Innovative Community-Academic Partnerships
  - Manali Patel, MD MPH, Stanford
- Integrated Machine-Learning Platform to Inform Precision Therapy in Underrepresented Triple Negative Breast Cancer Patients
  - William Kim, PhD, and Pablo Tamayo, PhD, UC San Diego

The Stanford and UCSF teams had to make significant changes to their projects and timeline because of COVID-19. Both these teams have requested no-cost extensions which will take their projects into 2023. The UCSD team, led by non-clinical researchers, have had fewer COVID-related setbacks and are on track to finish on time.

Working Group report back: Data Integration

Consensus: The Working Group needs to identify how their strengths and assets would be best used to further data integration in California. We need to do more background research to asses current efforts so that we don't duplicate work.

The Gravity Project

Mission
To create and maintain a consensus-building community to expand available SDoH core data for interoperability and accelerate standards-based information exchange by using HL7® FHIR®.

Background
Initiated in November 2018 by SIREN (Social Interventions Research and Evaluation Network, UCSF) with funding from the Robert Wood Johnson Foundation to convene broad stakeholder groups in identifying and harmonizing social risk factor data for interoperable electronic health information exchange.

Goals (paraphrased)
- Develop recommendations on how best to capture and group SDoH data elements for interoperable electronic exchange and aggregation.
- Collaborate with coding and terminology suppliers to address coding gaps.
- Develop and test an HL7 FHIR SDoH Implementation Guide.

Deliverables/Products
Toolkits, integration guides

The Gravity Project is doing work that was recommended in _Precision Medicine: An Action Plan for California_.

Action Item:
CIAPM staff will meet with Gravity Project Leaders to

- Assess Gravity Project's scope, goals, roadmap, products, and funding sources
- Identify unmet needs, and ways in which CIAPM and the Gravity Project can work together to expand the impact and increase implementation of the Gravity Project's work at scale, specifically as it relates to precision medicine

Action Item:
CIAPM staff will reach out to the member of Gravity Project from the California Office of Statewide Health Planning and Development (OSHPD) to determine his involvement, interests, and goals.

CIAPM's role in the SDoH data integration space should be to

- Leverage the strength of the group.
- Make recommendations to OPR and the Governor's Office.

- Extend beyond Gravity's current remit, perhaps by driving a national dataset around SDoH.
- Amplify, translate, pull the levers of policy within the state government to amplify the best practices.
- Enhance value, implementation, and adoption.
- Facilitate, convene.

Action Item:

CIAPM staff will send out example definitions of SDoH to be reviewed prior to the next working group meeting.

TASK	STATUS
Meet with Gravity Project leadership to understand how we can work together and if it would be worth it for CIAPM staff to join as members	Done
Consider drafting guidelines for the "Minimum viable product," or minimum common metrics for SDOH.	Not yet started
Connect with newly-launched CHHS Center for Data Insights and Innovation (and other state entities)	Not yet started
Consider reaching out to other groups (NASEM)	Not yet started
Look into what other states and nations (UK, Denmark, Canada) have accomplished	Started
Define SDOH for working group	Example definitions gathered for consideration at next meeting

Working Group report back: Equitable Consent

Existing laws and regulations related to informed consent

- Federal Law: Revised common rule ("common" because the same guidance appears in several different places in federal law). A recent update includes new language for broad consent for unspecified future use of biospecimens.
- California Protection of Human Subjects in Medical Experimentation Act, including the experimental subject's bill of rights

- California has an existing consent checklist that covers everything in state and federal law, but doesn't have an equity lens: https://oag.ca.gov/sites/all/files/agweb/pdfs/research/consent-checklist.pdf
- All of Us research program
- NIH Genomic Data Sharing policy: requires some features to be included in the consent form regardless if the samples are identified, deidentified, or protected health information

Project options

- Project suggestions fall into one or more major domains:
  - Community Engagement
  - Content Development
  - Implementation Science
  - Policy
- Create recommendations, a policy document, and/or a template for a California-centric universal consent.
- Write consenting guidelines for staff at FQHCs (Federally Qualified Health Centers) and community clinics.
- Work with community-based organizations to help underrepresented minorities (URM) understand their role in research.
- Create or invite grantees to create video content to expand on the work of UCLA, or scale work that has already been done.

VIDEO: Universal Consent to use leftover biological samples from medical visits for research

TASK	STATUS
Clarify the problem(s) that we are trying to solve.	Drafting list to send out prior to next working group meeting
Reach out to people and organizations that are doing similar work.	Creating org list and collecting potential contacts
Look into providing stipends to community members who participate in the project	Ongoing