California Initiative to Advance
Precision Medicine

California Precision Medicine Advisory Council Draft Meeting Summary, November 2021

Update from the Newsom Administration

Sam Assefa, Director of Governor's Office of Planning and Research

- He has an appreciation that zip code contributes to health in addition to genetic code, and that health is affected by land use planning and physical spaces.
- The role of government and of OPR is to focus on listening to communities instead of instituting top-down policies.
- He stressed that policy should be driven by science and data.

Richard Figueroa, Deputy Cabinet Secretary

- The 2021-2022 budget year was good, and 2022-2023 looks to be the same with an estimated $30 billion surplus. However, for the first time in ~30 years, we are running up against the Gann Limit, which is a constitutionally established spending limit established by proposition 4 in 1976.
- For 2022-2023, California may be as much as $20B over the Gann Limit, because of a combination of high earners and federal funds flowing to the state.
- There are some caveats, such as spending on "capital outlay and infrastructure"; it's unclear if research falls into that category. But we don't want to stretch the spirit of the limit too much, because a lawsuit could hold up the entire budget.
- For anything over the Gann Limit, the state either must spend it on schools, or give it back to taxpayers.
- More about the state appropriations limit (SAL) can be found in a report by the Legislative analyst's office: https://lao.ca.gov/reports/2021/4416/SAL-042121.pdf

Accepted August 2021 meeting summary

- Discussion about utilizing *promotores* though DHCS
- Budget presentation: $4.8 to last through program sunset date January 1, 2026, about $0.88 per year for administration

- In-person meetings are important, at least two per year in Sacramento
- Update on ACEs projects
- Annual report
- Reports back from working group

Guideline Amendments

At the May 2021 meeting, guidelines were suspended so that if there were three or more nominations for one position, we would institute ranked choice voting.

During this meeting, the guidelines were amended to:

- Adopt ranked-choice voting
- If there is only one nominee, require that that nominee still receives 2/3 of the vote
- Clarify that if there are exactly two candidates and they tie, members will vote again until one nominee achieved a simple majority

ARTICLE 3. COUNCIL ORGANIZATION

> 2. The Council will elect a Chair and a Vice Chair for a one-year term. The Vice Chair will be responsible for fulfilling the Chair's duties when the Chair is unavailable.
>
> > c. Elections
> >
> > i. Elections will be conducted via secret ballot.
> > ii. Election ballots may not be submitted via email.
> > iii. ~~In the event of a tie, the Council will have a new round of voting that includes all candidates. The new round will not be a runoff.~~
> >
> > *If there is only one nominee, a 2/3 majority vote is required for the nominee to be elected.*
> >
> > *iv. In the event of a tie:*
> >
> > > *A. If there are exactly two candidates, all eligible council members will vote again. The process will repeat until one candidate received a simple majority.*
> > >
> > > *B. If there are more than two candidates, a winner will be chosen via ranked choice voting.*

All council members present voted in the affirmative; the following council members voted in favor via email:

- Oliver
- Bonnie
- Fatima

Discussion about CPMAC meeting format

Members are supportive of in-person meeting in February.

Pfizer has mission-critical travel only through March; UC is also recommending critical travel only.

Members also decided to meet in Santa Clara the day before PMWC, with a hybrid model so that people can attend virtually.

Asset Inventory

The statutorily required California Precision Medicine Asset Inventory has received a second make-over, this time to change from being hosted on Tableau, to ArcGIS.

It is an online mapping tool to foster cross-sector and community collaboration to ensure that research results are aligned with California's priorities.

CIAPM staff also created a video to orient and explain the asset inventory.

Users are now able to add and update their entries with an online form.

Working Group report-back: Data Integration

Complete: High-level landscape analysis of ongoing efforts to integrate SDOH data, within and external to California state government

Primary Sources
- CA Health Homes program and Whole Person Care pilot projects
- California Advancing and Innovating Medi-Cal (CalAIM)
- CHHS Center for Data Insights and Innovation
- Gravity Project: process and accomplishments
- US Office of the National Coordinator for Health Information Technology SDOH Workshop
- National Interoperability Collaborative (new membership)
- Community Information Exchange
- NASEM Changing the Culture of Data Management and Sharing
- National Alliance to Impact SDOH: 2020 Report
- CA Breaking Barriers Masterclass Webinar series

Complete: Identify areas of opportunity to advance the integration of SDOH data into healthcare decision-making

Current Efforts in California State Government

- Department of Health Care Access and Information All Payer Claims Database
- Health and Human Services Center for Data Insights and Innovation
- Coleridge Initiative Administrative Data Research Facility
- Department of Health Care Services Advancing and Innovating Medi-Cal (CalAIM)
- California Institute for Regenerative Medicine

Current State-Level Health Information Exchange (HIE) Efforts

Other States

- Nebraska's CyncHealth
- New York's Bureau of SDOH
- North Carolina's NCCARE360
- DC/Maryland
- Ohio's CliniSync
- Michigan's Health Information Network
- State Health Information Exchange Program
- Utah's Alliance for the Determinants of Health

California State Government

- California Health and Human Services Agency
  - Advisory Committee to deliver recommendations by Summer 2022 for standing up a Data Exchange Framework by 2024
- CalAIM: California Advancing and Innovating Medi-Cal
  - "....provide for non-clinical interventions focused on a whole-person care approach via Medi-Cal that targets social determinants of health and reduces health disparities and inequities."
  - May 2021 Report: *CalAIM and Health Data Sharing: A Road Map for Effective Implementation of Enhanced Care Management and in Lieu of Services*
- California Department of Health Care Access and Information (HCAI)
  - Office mandate: to make California's health care data available to policymakers, researchers, and innovators in order to help make the California's healthcare system more sustainable.

California State Legislature

Active legislation would impact state health information exchange plans:

- AB 1131: Health Information Networks
- AB 1231: Health Information Exchange: Demonstration Projects
- SB 371: Health Information Technology

Potential Project Idea

Partner with the CA Surgeon General and the CA Institute for Regenerative Medicine
CIAPM is undergoing an exploration of a potential knowledge network project in close partnership with the Office of the California Surgeon General (OSG) and the California Institute for Regenerative Medicine (CIRM). The ideal end product would grant researchers access to de-identified and secure state administrative data to:

- Advance outcomes research relative to SDOH and other data to serve as a knowledge base to inform clinical and social service decision-making
- Accelerate the discovery-to-clinical application pipeline

Consider existing models of support such as the California Cancer Registry and the California Policy Lab.

Project Discussion

Members discussed and agreed that the opportunity to continue scoping a partnership with OSG and CIRM was aligned with the working group's goals. Members encouraged CIAPM staff to continue exploring a potential partnership.

Working Group report-back: Equitable Consent

Website: Equitable Engagement and Consent in Clinical Research

- Definition, including cultural competency and proportional representation
- Introduction
  - Delineate between different types of consent (consent to be treated, research consent, etc.)
  - Overview of research engagement, and where the consent process fits in the life cycle
  - Current statistics in URM participation
- History, including case studies
- Existing laws and policies
- Best practices and toolkits for funders, researchers, research staff, and potential and existing research participants
- Inclusion of stories and quotes from community members
- Link to CIAPM's existing community engagement guidance

Meeting: California Institute for Regenerative Medicine

- Maria Bonneville, VP of Public Outreach and Board Governance
  - Introductions to patient advocacy groups and nonprofits
    - ALS
    - Parkinson's
    - Type 1 Diabetes

- Alzheimer's
- Invited to workshop about Community Care Centers of Excellence
  - Transportation
  - Consent

Meeting: Takeda Executives
- LaShell Robinson, Director, Diversity & Inclusion in Clinical Trials
- Sherika Blevins, Senior Manager, US Medical Affairs
- Jennifer Graf, Advisory Lead, Ethics & Compliance R&D
  - Include content for clinicians who refer for research trials
  - Polls and surveys
  - Leverage UC and others for dissemination
  - Stories, quotes, and videos from other stakeholder groups
  - https://www.researchincludesme.com/

CDPH Office of Health Equity Advisory Council
- Attend council meeting December 1st
- Meetings with leadership and other members

Report: Achieving Diversity, Inclusion, and Equity in Clinical Research
- Multi-Regional Clinical Trials Center at Brigham and Women's Hospital and Harvard
- Includes a toolkit, with guidelines including (but not limited to):
  - Participant and Community Engagement
  - Diverse Participant Engagement Strategies
  - Recruitment Strategy
  - Participant time Commitment Models
- The report also includes several case studies including (but not limited to):
  - Omapatrilat
  - Bucindolol
  - Plavix
- Report webpage: https://mrctcenter.org/diversity-in-clinical-research/

Link to report from webpage; incorporate principles, toolkits, case studies

TASK	STATUS (as of February 2022)
Reach out to people and organizations that are doing similar work.	Ongoing
Create high-level outline for website content	Done
Collect and organize resources related to consent and data sharing	Ongoing
Create one-pager to describe the project	Done
Update and build out presentation to introduce the project, to elicit feedback	Done
Set up 1:1 meetings with thought leaders	Ongoing
Get on agendas at meetings with relevant groups and organizations	Ongoing

Public comment

Dear CIAPM team,

My name is James Stewart and I am a district activist leader with the National Multiple Sclerosis Society and a patient advocate with Americans for Cures representing the MS community. Thank you for allowing the public to join the meeting and for valuing input from the public. It's also very helpful to have your meetings accessible by Zoom even if meetings are held in person. You are all doing incredibly important work and I wonder how we can get more public engagement to increase awareness of the value of science and how precision medicine and stem cell research could help them. It occurs to me that it may be possible for CIAPM to reach out to each of the patient advocacy groups, such as the National Multiple Sclerosis Society, or the ALS Association or the Alzheimer's association to inform them of the progress that's being made. Each of these patient advocacy organizations know the people who will benefit from the work that you are doing. They each have ability to reach out to their social networks to help disseminate not only what you are doing, but also how it will benefit them. I think establishing communication with them will help to educate the public.

Thank you, James