

## California Precision Medicine Advisory Council Meeting Summary, September 25, 2023

1400 Tenth Street, Sacramento, CA 95814 (Hybrid)

#### **Council Seat Transitions**

- Outgoing: Corrin Buchanan, MPP, CalHHS Deputy Secretary for Policy and Strategic Planning
  - Deputy Secretary Corrin Buchanan concluded her time on the Council as an ex officio member
  - The Council thanked Deputy Secretary Corrin Buchanan for her dedication to the Council and support the last year.
- Incoming: Debra Cooper, PhD, CalHHS Assistant Secretary, Developmental, Rehabilitation & Community Services

#### **CIAPM Team Transitions**

- Incoming: Theresa Spezzano, MS; UC Merced (working on the RRC)
- Outgoing: Max Wayne, Intern
  - Concluded a 10-month internship with CIAPM
  - Max recently graduated from UC Davis with a Bachelor of Science degree in Managerial Economics, with a Minor in Accounting.
- Outgoing: Elyse Pennington, PhD, CCST Science & Technology Policy Fellow
  - Elyse was instrumental in elevating CIAPM's RFP development process to include proactive statewide community input, a fruitful partnership with the Mental Health Commission, and a series of informational interviews with out-of-state experts.

## Opening Remarks from the Chair and Vice Chair

Clara Lajonchere, PhD, Chair

• In the last six months, we've seen our modest CIAPM program elevated onto the national stage, assisting once-in-a-generation federal investments, particularly in biomedical research, pandemic preparedness, and biomanufacturing.

- It's a symbol of this moment we're living in, where health research is no longer automatically weighted down with 20- or 30-year time horizons. Rather, we're seeing AI, mRNA, and other skyrocketing technologies whittle down our expectations from decades to years or even months.
- Now's the time to strength our community partnerships to ensure research aims are anchored to patients' and families' needs.
- Industry, too, seems to be stepping up into this refreshed era of cross-sector collaborations, taking part in some cases with research at the earliest stages.
- At this time with CIAPM, we're seeing the baton being passed from one program
  to another, as the Cancer Disparities Projects wind down and the Depression
  Program ramps up. I was glad to briefly join the Cancer Disparities Research
  Symposium to witness the lively discussion around follow-on plans and data
  sharing.
- I remember the May 2019 All-Teams Meeting in the Governor's personal
  conference room, when the three cancer project teams first met. Even at that
  first gathering, they were brainstorming wildly about collaboration opportunities
  and datasets ripe for sharing. It's wonderful to see their projects come full circle,
  even through a historic time of dealing with a pandemic.
- With CIAPM demonstrating a new way of funding and advancing research that's collaborative, community-centric, and at the cutting edge of the growing field of precision medicine, I know California has a lot to offer the federal programs that are growing equally fast and at another order of magnitude.
- I want to thank all of you, as well, for the time you've invested to helping propel this small but mighty program forward. In between meetings, I know many of you feed our staff with connections, ideas, and constructive feedback that improves the quality of the entire program.

#### Keith Yamamoto, PhD, Vice Chair

- Building on what Clara shared about the momentum and volume we're
  experiencing in the precision medicine arena, there's a parallel drive to ensure
  that investments lead to equitable outcomes.
- For those unfamiliar with the recent National Academies' report, <u>Toward</u>
   <u>Equitable Innovation in Health and Medicine: A Framework</u>, I'd like to share some highlights as Co- Chair of the Academies' Committee on Emerging Science, Technology, and Innovation in Health and Medicine.
- As innovations in precision medicine, including gene editing, regenerative medicine, artificial intelligence, synthetic biology, and many other fields are advancing in labs and increasingly used in clinics, a new framework for how to fairly distribute the potential benefits of these technologies is necessary.

- What's needed is a reorientation of the culture of innovation, whereby we
  incentivize equity, expand participation of underrepresented communities in
  innovation, develop equity science, and create and promote equity playbooks
  targeted to specific areas of emerging science.
- In the report, we recommend the White House Office of Science and Technology Policy provide guidance to federal agencies and departments that oversee science and technology in adopting this new governance framework.
- We would also like to see OSTP convene a new Equity in Biomedical Innovation
  Task Force to galvanize action. As we've seen with CIAPM, California doesn't
  need to wait for the federal government to demonstrate what's possible.

## Updates from the Newsom Administration

Richard Figueroa, MBA, Deputy Cabinet Secretary

- This time of year is always busy for the Governor's Office, with over one thousand bills currently on Gov. Newsom's desk. He has until October 14 to sign or veto.
- Reforms to the Mental Health Services Act are likely to go to the voters in 2024
- A new program passed legislative review just this summer, which I think you'll be
  interested in: the CalHHS Innovation Accelerator Initiative was established with
  \$75 million to boost translation of research and development innovations that are
  scalable and that help to directly address disparities and inequities in California's
  safety-net programs. The CalHHS Team closed an RFP to identify a contractor to
  help shape the new program.
- I see a lot of potential for CIAPM to contribute its expertise and support, as Julianne has already started to do and, as I understand, will speak to later on.
- The initiative seems to want to build a more sustainable and shorter bridge between R&D and the agency's many programs that directly serve Californians, like Medi-Cal and SNAP.
- I see CIAPM's work earlier on in the research pipeline, with this new initiative providing an additional ramp for researchers to apply and implement their findings for faster and more effective outcomes.

## Major program updates

- Depression Research RFP went live 9/22
- Cancer Disparities Research Symposium & projects concluding
- Fall Internship (Due tonight: Applications for two student positions)
- BARDA Biomanufacturing Preparedness Consortium & Accelerators
- Update on ARPA-H

- Supporting the CalHHS Innovation Accelerator Initiative Network Expansion
- CA Dept. of Corrections & Rehabilitation
- Federation of State Medical Boards

## Depression Research Program

#### Overview

- \$9 million for research demonstration grants
- Competitive grant program to support precision medicine-base approaches to preventing, diagnosing, and treating depression.
- 3-5 projects, up to \$3 million per project, 36-month project period

#### <u>Timeline</u>

January 31, 2023, Released Notice of Funding Intent (NOFI)

July - August 2023, Hosted listening sessions

August 18, 2023, Request For Information (RFI) closed

September 22, 2023, Released Request For Proposals (RFP)

October 30, 2023, Letters of Intent deadline

December 1, 2023, Concept proposals deadline

January – February 2024, Announce finalists

February 15, 2023, Full proposals deadline

March - April 2024, Announce awardees

#### **Development Process**

- https://opr.ca.gov/ciapm/activity/research/depression/rfp.html
- To inform the development process of CIAPM's RFP on precision medicine approaches for depression prevention, diagnosis, and treatment and to ensure the RFP is responsive to community needs, CIAPM hosted an RFI and held five listening sessions throughout California. The information obtained from these opportunities was integrated into the RFP, released on September 22.

#### Request for Information (RFI)

- The RFI consisted of 13 questions covering five topics: demographics, community perspectives, impact of research, provider perspectives, and additional information. The questions asked about specific communities with high rates of depression, community needs and difficulties, ways in which research can respond to community needs, and guidance for partnerships between researchers and CBOs.
- Respondents (37 total):
  - 16 community organizations
  - 6 Universities

- 5 Providers
- o 3 Public agencies
- o 1 Private organization
- 3 Community members

#### Listening sessions

- CIAPM staff asked participants questions about the challenges that their communities face, resources their communities need, their vision for the best future for their community related to depression, and how academic institutions can best partner with CBOs.
- The listening sessions were hosted in partnership with the Mental Health Services Oversight and Accountability Commission and with support of the Office of the Surgeon General.
- CIAPM Staff hosted a virtual session about the RFI for any member of the public to contribute
- Locations for physical, hybrid, and virtual listening sessions:
  - Fresno County
  - Monterey County
  - Orange County
  - Riverside County
  - Humboldt County

#### Listening Sessions & RFI Themes

- 1) Access to care is difficult due to language, cultural, geographic, and stigma-related barriers
  - Participants at all listening sessions and RFI respondents noted that there are
    not enough providers who look like them, share their identity, and are culturally
    competent. Participants noted that finding a therapist requires time and multiple
    iterations to find the right match.
  - Participants at three listening sessions noted that they would like to see more
    promotion of virtual/remote options to increase access for youth, rural areas, or
    people with mobility or accessibility issues. Participants also noted that 988
    needs additional language options.
  - Participants noted a need for more drop-in centers for those who want to seek care or comfort in- person, and more centers and services for people experiencing homelessness.
  - Participants and respondents noted that language barriers hinder access, communication, and privacy, and CBOs often face the burden of addressing these barriers.

- Participants and respondents noted that there is a lack of resources, interpretation availability, and culturally informed treatments for many communities. Respondents noted that the lack of culturally informed treatments, diagnostic tools, and preventative measures hinders healing in many communities who have not traditionally been represented in clinical trials.
- 2) Mental health education is lacking, and workforce development needs to be supported
  - Participants at three listening sessions noted that many communities do not understand the meaning of depression or wellness and suggested that CBOs and/or researchers distribute resources that describe mental health in culturally informed ways.
  - Participants at all listening sessions and RFI respondents noted that depression rates are high among youth, mental health education should begin at an early age and be comprehensive across the curriculum, and teachers and counselors should be trained for mental health crises.
  - Participants and RFI respondents noted that there should be a focus on mental health literacy, easier access to mental health services, and assistance navigating the mental healthcare system.
  - Participants noted a need for a more bilingual and bicultural mental health workforce, and therefore more training programs to encourage diverse sets of people to enter the mental healthcare field.
- 3) Society, family structure, and culture have an important and complex impact on mental health
  - Participants and RFI respondents noted that, in general, people do not know the early signs of depression, and depression treatment is not viewed equally to treatments for physical ailments.
  - Participants noted the role that intergenerational trauma plays in mental health.
  - Participants at two listening sessions noted that peer and family support groups would help address isolation and the lack of a sense of belonging that contribute to depression.
  - Participants at all listening sessions and RFI respondents also noted cultural aspects of stigma in Black, Latino, LGBTQ, and Native or tribal communities that lead to challenges in accessing care.
  - Youth participants at two listening sessions noted that parents tend not to be the
    best role models of mental wellness, but also noted that nurturing parents who
    reflect a healthy attitude towards mental wellness can have a strong positive
    impact on children.
  - Participants noted that appreciating and maintaining Native cultures builds a strong sense of community and belonging through using Native languages,

holding indigenous ceremonies, working with sweat leaders, water-based activities, and learning indigenous and tribal history.

- 4) Provided tips for partnerships between academic research institutions and community-based organizations
  - Participants at two listening sessions and RFI respondents noted that there needs to be improved communication between providers, researchers, community organizations, and patients.
  - Participants at three listening sessions noted that CBOs or tribal organizations should either act as community advisory boards or co-PIs, with the goals of equal partnership, community involvement in study design and data collection, and meaningful data sharing.
- 5) Provided depression-related success stories
  - Participants noted that programs that focus on skill development and culturally adapted programs are effective, minimize stigma, and increase access.
  - Participants shared success stories of effective partnerships between CBOs and researchers that allowed for collaboration and treated everyone as equals.
  - Youth participants at two listening sessions noted several community organizations that provide no- judgement spaces and leadership opportunities, which could serve as a model for future projects.
  - RFI respondents listed community organizations that may be interested in research collaborations.

#### Informational interviews with Subject matter experts

- 1. Nii Addy, Yale University (Community Engagement and Holistic Perspective)
- 2. Valerie Earnshaw, University of Delaware (Stigma Reduction and Community Partnerships)
- 3. Joseph Himle, University of Michigan (Mental Health and (some) Industry Partnership Experience)
- 4. Darrell Hudson, Washington University (Depression, Social Equity, and Community Engagement)
- 5. Sahnah Lim, New York University (Mental Health in Asian Communities)
- 6. Samantha Meltzer- Brody, University of North Carolina Chapel Hill (Women's Mental Health and Community Engagement)
- 7. Susan Shortreed, Kaiser + University of Washington (Mental Health Statistics)
- 8. Shiv Darius Tandon, Northwestern University (Women's Mental Health and Community Engagement)

#### Informational interviews summary

Gaps in depression research

- Individualized treatments
- Cultural competency
- Co-morbidities
- Sustainable outcomes
- Big datasets
- Racial representation
- Community partnerships require time for trust to build, and community partners must be engaged with the project from conception through follow-up
- Industry partners mut have a value-add and there must be protections in place for community partners

#### Out-of-state selection committee recruitment: respondents' areas of expertise

- 5 Community engagement
- 4 Mental health
- 2 Women's mental health
- 1 Depression
- 1 Stigma
- 1 Industry
- 1 Statistics
- 1 Asian American community
- 1 African American community

#### Discussion

Selection Committee members discussed the following topics:

- 1. Additional suggestions for out-of-state experts
- 2) Guidance for applicants regarding industry/private-sector partnerships

#### Break

Lunch was generously provided by the California Biotechnology Foundation, a 501(c)3 organization with a long history of working with the State of California, opinion leaders, and other stakeholders, connecting them with the latest research and data from industry experts and research institutions. Special thanks to Executive Director Patty Cooper and her staff for making this possible.

## Call for Council Member Nominations

#### Sought expertise

- Familiarity with the Central Valley
- Extensive Industry / Biomanufacturing Experience

- Awareness of Health Equity Priorities and Practices
- Network Orchestrator

## Representative Research Collaborative

Approx. \$5 million will eventually be made available for competitive grants, once the program structure is confirmed and established.

# Aim 1: Establish a formal partnership with NIH to expand All of Us activities throughout the Central Valley and Far Northern California

#### 1) Status updates

- Staff will present at the October 6 Regional Collaboration Call of CBOs and LHDs via California State University Fresno consortium of Human Services Agency and Public Health Directors, Deputy and Assistant Directors, and Health Officers (the Central California Public Health Consortium), and distributing outreach pieces via quarterly newsletter and regional communications subcommittee
- Surveying potential state agencies who could perform enrollment outreach to state employees

#### 2) Next steps

- Meet with All of Us tribal engagement/enrollment team
- Draft MOU
- Re-engage state agency partners from original 2020 proposal
- 3) Continue gathering information
- 4) Grant Program Development: Preliminary Approaches
  - Request for Information

#### Aim 2: Broadly Advance Representation in Research

- 1) General outreach about the importance of representation in research
  - Multi-lingual press releases
  - Conferences, meetings, and workshops
    - Health care providers
    - Patient advocacy groups
    - Researchers

#### 2) Outreach strategy

- Adapt existing All of Us promotional materials for new populations
- Consider host to leverage State's existing expertise in provide services to ~18 million recipients
- Consider outreach to the ~250,000 employees of the State:

#### **Discussion Topic**

1) Health care providers, patient advocacy groups, researchers, and affinity groups would be appropriate community partners.

## 2024 Priorities Preliminary Brainstorm

- 1) Expanding CIAPM's scope
  - More targeted leveraging of federal investments
  - Partnering directly with federal agencies
  - Elevating/accelerating equity-centric solutions
- 2) Updating the 2018 Action Plan
  - Supporting our Precision Medicine network more broadly versus funding research projects
  - Up-and-coming topics for future demonstration projects

### **Public Comment**

Alice Beecher Popejoy, PhD provided comments in writing