Community Partnership in Precision Medicine: Themes from a Community Engagement Conference

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Background: Patient and community engagement in under-resourced communities is a key issue for precision medicine research. We report proceedings from a community-academic partnered conference in Los Angeles to promote community understanding of precision medicine and generate engagement recommendations.

Methods: Planning group review of planning, presentations, and audience discussions from facilitator notes and participant survey data from a one-day conference.

Findings: Community-academic planning broadened community participation and presentations. More than 80% of survey participants indicated they would participate in the national precision medicine initiative, and most were willing to share diverse sources of data. Discussions identified trust concerns related to historical research abuses, data privacy, potential effects of findings on health care, personal safety, research procedures, the time-frame for benefit, and confusion about different initiatives. Concerns were balanced by belief in science to improve health. Recommendations included a community partnered participatory approach with support for local community and academic teams to engage stakeholders with written/online resources and partnered workgroups addressing key concerns.

Conclusion: Conference participants expressed high willingness to participate in precision medicine studies, but discussions highlighted trust and transparency issues and suggested community partnered research with local capacity building. *Ethn Dis.* 2018:28(Suppl 2):503-510; doi:10.18865/ed.28.S2.503.

Keywords: Community Engagement; Precision Medicine; Partnered Research; Under-resourced Communities; Research Ethics

Background

Precision medicine refers to the use of genetic, other biological, behavioral, and environmental data on individuals to predict disease, health outcomes, and responses to treatment in order to develop interventions for genetic/behavioral determinants of health. Precision medicine is a growing and promising field that raises a range of community trust, engagement, and ethical concerns,[1-3] due to the long development period for discoveries and issues such as safety and control over data uses. The US Precision Medicine Initiative (PMI, also known as "All of Us"), launched by President Obama, initially allocated $215 million to the National Institute of Health (NIH), National Cancer Institute (NCI), US Food and Drug Administration, and Office of the National Coordinator to recruit one million volunteers beginning in 2017, the largest scientific cohort in US history. The PMI intends to obtain access to electronic health records and collect personal genetic, lifestyle, and environmental data (through biospecimens and mobile devices) to determine relationships to health and disease.[4] In addition, an Advisory Council to the NIH PMI developed recommendations for stakeholder engagement.[5] The report states: "Participant engagement and empowerment are core values for the Precision Medicine Initiative Cohort

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Program (PMI-CP). Whereas the majority of clinical research has been transactional in nature, with unidirectional data sharing from the individual to the study, the PMI-CP seeks true partnership between participants and researchers." PMI-CP refers to the main large cohort program of the US PMI. For under-resourced communities and persons of color, participation in such initiatives may raise concerns about historical research abuses, such as Tuskegee.[6] A national survey indicated that 79% of adults

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supported the Initiative, with LGBT and more educated participants more likely to say they would participate; and, compared with Whites, more Latinos also said they would participate.[7] A key concern is developing engagement models that promote transparency and address concerns of under-resourced communities.

To explore this issue, we report survey data and themes from a conference to inform local communities about precision medicine research. The conference, "Precision Medicine: What Is It and Where Could It Take You?" hosted on January 27, 2017, at the Torrance Cultural Arts Center in Los Angeles, California, resulted from a partnership development activity and two-way knowledge exchange.[8] Host organizations included community organizations: Healthy African American Families II (HAAFII); the Native Hawaiian and Pacific Islander Alliance; Hawai'i's Daughters Guild of California; and the Robert F. Kennedy Institute of Community and Family Medicine. Academic institutions were: the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center (LA BioMed); and the UCLA/Harbor/Charles R. Drew/ Cedars-Sinai Clinical and Translational Science Institute (CTSI).

The conference was designed to stimulate dialogue about the following questions: 1) What is precision medicine? 2) Unchecked, what are far-reaching implications of precision medicine for health care services? 3) What are community concerns around participating? 4) How can precision medicine affect individual and community health? 5) What are far-reaching impacts on families and communities of this type of research?

Conference planning involved precision medicine experts, community stakeholders and research and patient partners from CTSI-affiliated institutions. To inform academic and community groups about ways to engage communities in precision medicine research, we provide a description

of the planning process, conference content, and quantitative and qualitative data on stakeholder responses.

METHODS

Data Sources

Data are from participant sign-in logs *(N*=101), a self-administered, precision medicine survey with items from a national study,[7] with study approval through the LA BioMed/ Harbor-UCLA CTSI. The survey was completed by 68 conference participants. Analyses were limited to descriptive frequencies of item responses. Qualitative data were obtained from notes taken by conference planners and facilitators on planning, conference proceedings and discussions, with study approval by the UCLA IRB for the PCORnet Community and Patient Partnered Research Network. Planning notes, conference proceedings, observations, interviews of conference planners, and facilitator notes were used to describe the process and content of the conference. Key themes on stakeholder concerns and recommendations were identified from notes by conference facilitators and confirmed with a conference planning group review.

RESULTS

Conference Planning

Partnership development and conference planning during a one-year period included community stakeholders and representatives from the sponsoring academic institutions. The partners reviewed histories of research

engagement in ethnically diverse, under-resourced communities, relationships with academic institutions (including areas of past and potential future conflict), institutions' interests in respectful engagement, and mutual goals for precision medicine research. This process was facilitated by a CTSI community engagement consultant. Key outcomes were: identification of goals and processes for collaboration; a draft memorandum of understanding; and a conference proposal to support community understanding of, and engagement in, precision medicine research. Conference evaluation plans included a feedback survey, pre-post questions using an audience response system, and a survey on engagement in precision medicine with items from a national survey.[7]

Conference Proceedings

In an opening overview and expert panel, precision medicine was defined as "an emerging approach for disease prevention and treatment that takes into account individual variation in genes, environment, and lifestyle." It was noted that precision medicine is not a new concept, because tailoring treatment to the individual and exposures is used for problems like hypertension and infections. However, advances in genomics and "big data," such as reduced costs of genome sequencing, have led to new, larger initiatives. Mendelian disorders (involving single genes), pharmacogenetic variation, complex conditions (like atherosclerosis, diabetes, and hypertension), and cancer were reviewed in terms of the promise of precision medicine. Clopidogrel (Plavix), an anti-platelet drug prescribed to reduce

risks for heart attacks and strokes, was used to illustrate tailoring drug prescribing to a person's genotype.

A community-academic panel provided information on informed consent, reviewed historical developments leading to the PMI, the role of civil-rights law and advocacy in protecting vulnerable populations, and implications of precision medicine research for diverse communities. A community panel raised stakeholder concerns, including the scope of data to be collected and analyzed, sensitivity of physical and biological samples, data privacy and ownership, historical research abuses and concerns about data uses, and participant safety. This led to an audience discussion of the ethics of research engagement in diverse populations, emphasizing genetics research.

A keynote address provided an overview of how precision medicine can facilitate medical progress. The address was followed by discussion of options to structure initiatives through community engagement (eg, using community advisory boards) and a testimonial by a mother and her child (now in his 20s) with a genetic disorder -- for whom participating in research led to solutions benefiting other patients. Between presentations, there were question and answer periods, report-backs, and summary comments by conference planners. Concurrent audience break-out sessions focused on two issues: 1) an open dialogue on the future of precision medicine research in the UCLA/LA BioMed/Cedars-Sinai/Charles R. Drew CTSI, to identify questions and concerns of stakeholders; and 2) strategies to develop community partnerships for precision medicine research.

The conference included community engagement exercises, including a "snowflake" activity to celebrate diversity and raffles of donated gifts.

Precision Medicine Survey Findings

The Table shows descriptive univariate results from 68 participants completing the precision medicine survey. Relative to respondents in the national survey,[7] the conference included a high percentage of participants having some college education or higher (79.4%), relatively few Whites (11.4%), and high percentages of racial/ethnic minorities or individuals of mixed race/ethnicity. After a brief description of the "All of Us" Research Program, most participants (93.9%) said the study should definitely or should probably be done, and a majority (77%) said that they would definitely or probably participate, with a similar response at the end of the survey. In response to a question about how long they would be willing to participate, nearly a third (31.3%) responded their whole lifetime. In addition, a majority would agree to provide urine, saliva, or hair, soil/water samples, a blood sample for DNA, a family medical history, or information from a Fibit/smartphone. Slightly more than half would permit data from social media or would participate in data submission by text at least once a day. A high percentage thought it was somewhat or very important to have incentives, including: learning information about their health and obtaining health care; free Internet use or a Fitbit/Jawbone/Misfit; being paid for their time; or getting a free smartphone/data plan.

Receiving information from the study was of interest, particularly lab and genetic results. A high percentage would be comfortable with data sharing with NIH (83.1%) and other US university researchers (79.7%). Most were comfortable with sharing data with other government researchers, drug companies, and researchers from other countries. A high percentage (90.3%) agreed that it would be important for community stakeholders to be full partners in all phases of research, with high agreement (>75%) for study design/implementation and analyzing data (65%). A majority would be personally interested in helping select study questions and interpreting data, and 30%-40% were interested in collecting and analyzing data or recruiting participants. Many indicated that stakeholder participation in PMI leadership would increase willingness to participate (42.6%) or not affect decisions (47.5%).

DISCUSSION THEMES

Themes from facilitator notes, confirmed by planning group review, are described below and focused on seven themes: trust, protection, health care decisions; benefits; procedures; specific initiatives; resilience.

Trust

The issue of trust in science, as well as researchers and the collection of biospecimens were the most commonly mentioned stakeholder concerns. Discussion included reflections on research abuses in minority communities (eg, Tuskegee). Examples of concerns included: profitability to others from research discoveries; uncertainty about how and by whom research data would be used; potential harm (eg, genetic profiling leading to exclusion from benefits; legal prosecution based on data released; aggregate genetic findings applied to individuals having certain profiles).

Protection

The issue of safety or adequate participant protection, while related to trust, was identified as its own issue of importance. Discussion topics included how best to communicate and implement safety procedures for participant privacy and clarifying the limits of those procedures, through transparent discussions and documentation.

Health Care Decisions

Important concerns involved: how precision medicine would affect individual health care; how research access to health care data might affect patients; and whether clinical data identified in research would have implications for clinical care. Academic participants clarified that most initiatives presented are descriptive studies, with intervention implications years later. Pharmacogenetic studies that assign treatments to identify predictors of response do have treatment implications, but such studies were not featured in this conference. Stakeholders felt this distinction could lead to potential confusion, particularly if studies recruited from the same doctors' offices. The need for clarity in consents was emphasized.

Benefit

Clarifying benefits of participation was highlighted as key to willingness of diverse communities to participate. Examples of benefits included: advances in treatment that might help participants or future generations; feedback on results, with sufficient information for participants to understand them; capacity building for communities to understand precision medicine; participant payments; and other benefits from partnering, such as receiving training to design studies or analyze data. Finding the "win-win" was noted as an important strategy.

Procedures

Community familiarity with research procedures was noted as a necessary precursor to discussing precision medicine, suggesting a staged approach to capacity building. NIH Certificates of Confidentiality were noted as a protection, but limits (eg, court orders) were known more to institutional review board experts than community participants. Research ethics, limits on confidentiality, and data uses were noted as key follow-up issues.

Specific Initiatives

Community stakeholders were unsure about differences among research initiatives and about precision medicine as a field, raising the importance of familiarizing communities with specifics of initiatives, such as "All of Us." Suggestions included a template summarizing study features, with visuals and narrative examples.

Resilience

Stakeholders expressed a belief in the promise of research to benefit communities, given true partnership and participation in design and oversight. Examples included input into

Table 1. Precision medicine conference participant survey, N=68

Survey Item	Total Respondents[a]	N	%
Completed college education or higher		54	79.4
Race/Ethnicity			
Asian		13	19.1
Black/African American		22	32.4
Native Hawaiian/ Pacific Islander		4	5.9
Multi-racial		11	16.2
White		13	19.1
Other		5	7.4
"All of Us" Study	65		
Definitely yes/probably yes should be done		61	93.8
Definitely no		4	6.2
Definitely or probably willing to participate in study	65	50	76.9
Willing to take part in study for:	62		
Lifetime		20	32.3
10 to 20 years		8	12.9
1 to 5 years		28	45.2
Not willing to participate		8	12.9
Participants are willing to provide:			
Urine	65	57	88
Saliva	54	46	85
Hair	53	45	84.9
Soil or water from home	66	57	86.4
DNA from blood sample	64	49	76.6
Family's medical history	65	54	83.1
Information from a Fitbit or smartphone	66	54	81.8
Information from social media accounts	62	32	51.6
Texting at least once a day	65	28	43.1
Important incentives for the study:			
Learning information about their health	65	60	92.3
Obtaining healthcare	65	54	83.1
Free internet	63	47	74.6
Free Fitbit, Jawbone, or Misfit	62	48	77.4
Getting paid for their time	64	43	67.2
Free smartphone and data plan	63	41	65.1
Comfortable sharing data with:			
National Institutes of Health (NIH)	65	56	86.2
Other government researchers	62	37	59.7
University researchers in the US	64	51	79.7
University researchers in other countries	64	36	56.3
Drug companies	61	36	59.0
Important for community stakeholders:			
To be equal partners in all phases of study	62	56	90.3
Select research questions	62	51	82.3
Design the study	62	51	82.3
Help recruit people	62	52	83.9
Help collect data	60	45	75.0
Analyze data	61	40	65.6
Help decide what to do with study results	60	46	76.7
Participants would like to be involved in:			
Selecting study questions	54	31	57.4
Interpreting data	54	31	57.4
Collecting data	54	18	33.3
Analyzing data	54	16	29.6
Having full community stakeholder participation would affect your participation decision:	61		
More willing to take part		26	42.6
Less willing to take part		6	9.8
Doesn't affect the decision		29	47.5
Willing to participate in study after competing survey	63	49	77.8

a. Totals do not all equal 68 as some respondents chose to skip the question.

design, participation of conference organizers as speakers at community meetings, and having resources in language appropriate for communities. Statements from individuals who benefited from research and from people who hoped for improved care also highlighted resilience as a theme.

COMMUNITY QUESTIONS IDENTIFIED

Break-out discussions focused on community questions about the future of precision medicine research locally and on partnership development for precision medicine research. Questions raised by community stakeholders about the PMI included:

1. How can the PMI reach vulnerable populations, such as homeless or low-income groups?
2. Will the PMI extend to under-resourced communities?
3. What environmental factors are relevant for the PMI, and for what populations?
4. Are there models of engagement of diverse populations from other countries that have universal health insurance coverage, which may inform PMI engagement strategies?
5. How will precision medicine advances affect health and health care disparities?
6. How worthwhile is it for community stakeholders to participate in precision medicine research?
7. What are the purposes of the PMI, and how can these purposes be explained to communities?
8. What are effective strategies for building community trust in PMI re-

searchers?
9. When PMI studies collect genetic samples, what happens to the data?
10. What PMI projects involve children, and what are implications for data use, eg, will children be reconsented as adolescents or adults for use of data?
11. How do PMI researchers select goals and designs? For example, how will communities know if studies are applicable to whole communities or subgroups?
12. How can data from PMI studies help the community, and how will the community be educated about this (ie, what is the feedback process)?
13. What is the duration of a PMI study and of uses of PMI data? How transparent is that information for the community?
14. What happens to unfavorable data from genetic research, as medicine gets more personalized? What protections exist to guard against inappropriate data use, such as possible harm to individuals based on genetic information?
15. How does commitment to helping one's children or future generations affect community interest in PMI?
16. How will PMI studies confidentially handle and protect unauthorized (undocumented) participants?
17. Who else needs to be at the table for communities to benefit from PMI studies (in terms of successful community engagement)? Examples of community responses to this question included: youth, seniors, faith-based organizations, community leaders, mothers, community members, and local doctors.
18. Who can best serve as a "bridge" between the community and PMI

researchers, as "honest brokers" for developing understanding, study engagement, and translation of findings?
19. What is the difference between precision medicine as a field and the "All of Us" Research Program?
20. Overall, what do we learn through the pain/uncertainty, data collection, and overall journey of PMI research?

The overall perspective of this group was that it is important for communities to raise such questions, and for community-academic partnerships to develop a process for questions and answers to be discussed openly, to support community decision making about the PMI. The group concluded by asking: how interested is this community in precision medicine research? Facilitators passed around a sign-up sheet for ongoing work groups on the questions raised.

PARTNERSHIP MODELS

The group reviewed concepts of engagement, feedback, and meaningful participation in planning and conducting research to give the community more immediate "wins." The group reviewed the community partnered participatory research (CPPR) approach,[8,9] a documented form of community-based participatory research and examined the Community Partners in Care, or CPIC, a group-level randomized trial in Los Angeles on the added value of community coalitions over expert assistance to improve depression services,[10,11] with a similar model used for post-disaster recovery in New Orleans.[12] Together, these initiatives received the 2014

Team Science Award of the Association of Clinical and Translational Science. Key features that were discussed included the equitable co-leadership of community and academic stakeholders in design, implementation, analysis, and dissemination. The approach is based on principles of trust, respect, power sharing, and transparency through two-way knowledge exchange and finding the "win-win" to maintain engagement. This model was noted as having promise for local precision medicine initiatives.

Feedback from both workgroups led to a motion from all conference participants for "a full community partnered research approach for precision medicine initiatives that focus on under- resourced communities." This recommendation passed unanimously, focusing mainly on LABioMed/Charles R. Drew, given their roles in serving under-resourced communities. Issues raised in discussion and comments to conference planners included: 1) the limited availability of funds to support full engagement; and 2) whether this model for design and study process are understood in precision medicine research, as opposed to disparities research -- where participatory research is common. The discussion led to a suggestion for a development phase to apply a full partnership model to precision medicine research locally.

Community Debriefing

Community partners in a post-conference debriefing provided suggestions for future workshops, including: 1) fewer presentations and more discussion time; 2) more community speakers; 3) fewer topics; 4) information on the scientific development of precision medicine (from basic to clinical), in order to "normalize" precision medicine as a new stage of medical practice -- with additional tools, challenges, and strategies; 5) providing consent forms / human subjects information in community-friendly language; and 6) focusing on trust as the primary issue, with participant safety and data uses as examples. A main suggestion was for teams of community and academic leaders to take information on precision medicine back to local communities, supported by written or online materials with visuals and stories.

Discussion

We report descriptive survey results and qualitative themes from an engagement conference for academic and community stakeholders concerning precision medicine and the "All of Us" Research Program. Conference participants included investigators from academic institutions, some with experience in partnered research, as well as community members and academic leaders with an interest in precision medicine. Therefore, participants would be expected to be more interested in and supportive of the PMI, compared with a general population sample. To gauge comparability, the conference included a replication of the national PMI survey, completed by 68 attendees, primarily non-White, whereas the national sample was about half White, and our conference participants had a relatively high level of education. The majority of participants thought that the "All of Us" initiative should be conducted. They indicated a high level of willingness and intensity (lifetime participation) to participate and favored full community partnership in such research. The conference and national samples were similar in terms of percentages willing to share diverse personal data with NIH or other US researchers. Many of the discussion themes were similar to those addressed in the

The conference participants indicated a high level of willingness and intensity (lifetime participation) to participate and favored full community partnership in such research.

NIH's Community Engagement Recommendations for the NIH Precision Medicine Initiative,[4,5] including using research participants and advocates as partners in all phases of research. Similarly, conference participants echoed the report's emphasis on the importance of building trust through scientific integrity, sharing individual and aggregate findings with participants, and transparency in safety and data security issues and procedures.

Discussions indicated that knowledge exchange addressing community concerns about precision medicine, in

a local context, was key to engaging diverse populations, especially for collecting biospecimens, medical records, environmental samples, and mobile technology data. Engagement models from health disparities research, such as the CPPR, may be important resources for precision medicine studies. Further, as noted in the NIH report, stakeholders reinforced the importance of tangible benefits to communities and participants, asking about and responding to preferences, and addressing safety, data use, protection/privacy and ownership issues in a straightforward manner. Conference workgroup discussions highlighted the need for an intentional, iterative process of sharing concerns and providing transparent explanations and documentation to communities, through locally engaged academic and community leaders. Training "champions" to explain manageable pieces of information supported by up-to-date, transparent information in clear language may help establish a legacy of trust in this field in diverse communities.

Conclusion

Through a community-academic planning process, the group hosted a conference on community engagement in precision medicine research. The conference focused on academic and community presentations and dialogues on trust, research ethics, and engagement strategies. Quantitative data reflected a high level of overall interest and willingness to participate in precision medicine research, and specifically the "All of Us" Research Program. Conference discussions suggested that

there is a need to convey fully to community stakeholders what precision medicine is, the process of research development, and how specific community concerns will be handled. Concerns most noted were related to trust, safety, uses of data, benefits to participants and communities, and inclusion of diverse populations. Addressing such concerns, while building on community resilience and faith in the promise of science to improve health, may help achieve true engagement.

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