

## **Community engagement in biobanking: Experiences from the eMERGE Network**

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### **Abstract**

Advances in genomic technologies and the promise of “personalised medicine” have spurred the interest of researchers, healthcare systems, and the general public. However, the success of population-based genetic studies depends on the willingness of large numbers of individuals and diverse communities to grant researchers access to detailed medical and genetic information. Certain features of this kind of research – such as the establishment of biobanks and prospective data collection from participants’ electronic medical records – make the potential risks and benefits to participants difficult to specify in advance. Therefore, community input into biobank processes is essential. In this report, we describe community engagement efforts undertaken by six United States biobanks, various outcomes from these engagements, and lessons learned. Our aim is to provide useful insights and potential strategies for the various disciplines that work with communities involved in biobank-based genomic research.

### **Introduction**

Since the completion of the Human Genome Project in 2003, advances in technology have allowed for rapid sequencing, storage, and analysis of human DNA. These developments have led to unprecedented interest and investment in genomic research, with the ultimate goal of improving public health.<sup>2</sup> This interest has been fuelled, in large part, by the vision of “personalised medicine,” in which prevention and treatment would be tailored to individuals’ unique genomic risks and predispositions.<sup>3,4,5</sup> Genome-wide association studies and similar epidemiological research approaches are laying the foundation for personalised medicine, and the success of these strategies depends on the willingness of large numbers of individuals and diverse communities to grant access to detailed medical and genetic information. To facilitate this kind of research, biobanks (defined as repositories of human DNA, RNA, tissue, blood, cells, and health data) are being established around the world, at both local and national levels.<sup>6,7</sup> Many of these biobanks are beginning to link data from study participants’ electronic medical records (EMRs) with their genetic data to accelerate the study of genotype-phenotype associations.

While EMR-linked biobanks promise to be a powerful research tool, they raise important social and ethical issues for individuals and communities. One issue is the security of an individual’s private, personal information. Recent studies have shown that de-identification of research data and tissue samples may fail to provide adequate participant security.<sup>8,9</sup> In addition to risks from possible re-identification, other key

issues for consideration include how to engage participants appropriately in the consent process with respect to undefined future research using their samples and data;<sup>10</sup> how or whether to return research results<sup>11</sup> and unanticipated findings to participants;<sup>12</sup> and how to protect the interests of the communities involved in the research.<sup>13</sup>

Recent, highly publicised controversies – including the settlement between Arizona State University and the Havasupai tribe over the use of stored blood samples<sup>14,15</sup> and the research use of blood spots from newborns in Texas without parental consent<sup>16</sup> – have highlighted the harms that research participants and investigators may encounter in the context of genetic research using banked samples and data. In both of these examples, researchers sought to make use of available biospecimens to further scientific aims, and in both cases, research participants or their family members objected when they learned how the samples were being used. From an ethical standpoint, community engagement offers an opportunity to show respect for the individuals and communities involved in research and it may also be instrumental in preventing barriers to future research.

### **Community engagement**

It is important to understand the concept of “community” in developing appropriate engagement strategies. “Community” can have many different meanings. For this paper, community refers to the variety of stakeholders affected by, or interested in, biobanking and genetic research issues. Similarly, the term “community engagement” has a number of connotations. Community engagement (CE) – “a process of inclusive participation that supports mutual respect of values, strategies, and actions for authentic partnership of people affiliated with or self-identified by geographic proximity, special interest, or similar situations to address issues affecting the well-being of the community of focus”<sup>17</sup> – has been proposed as an important step in ensuring that biobank research is carried out in an ethical, locally appropriate manner. CE can include a spectrum of community involvement and can be used to inform, consult, involve, collaborate with or empower communities.<sup>18,19</sup>

Institutions and groups worldwide have recognised the value and benefits of community engagement in health prevention, research and policy initiatives. A report from the Bellagio Group, an international expert committee convened in 2005, named communication and stakeholder engagement as a core activity ultimately to improve population health through informing, and thus empowering, the public about uses of genomic information in disease prevention.<sup>20</sup> The National Institutes of Health (NIH) Office of Science Policy has likewise determined that CE can enhance research quality, improve protection of participants, and address local public health needs.<sup>21</sup> Recognising the importance of community input in clinical research, the 60 US medical research institutions receiving NIH-funded Clinical and Translational Science Awards are required to include a community engagement component.<sup>22</sup> Perhaps most relevant to biobank efforts, CE activities can help establish mutual understanding and

trust among stakeholders with disparate interests: research participants, the general public, investigators, research and healthcare institutions, and funders.<sup>23,24</sup>

Despite the widespread endorsement of CE efforts and a growing literature reporting the results of such projects involving large-scale genomic databases and biobanks in various countries,<sup>25,26,27,28,29</sup> there is a lack of information describing how engagement activities may be tailored to unique biobank contexts and communities; the role of empirical research studies versus more operationally oriented approaches (eg community advisory boards); and the impact these efforts can have on biobank policy and practice. In this report we describe community engagement efforts undertaken by six United States biobanks involved with the eMERGE Network, various outcomes from these engagements, and lessons learned. Our aim is to provide useful insights from these efforts and potential strategies for the multiple disciplines that work with communities involved in biobank-based genomic research.

### **Community engagement strategies within the eMERGE Network**

The eMERGE Network is a consortium of US research institutions funded by the National Human Genome Research Institute (NHGRI) to develop, disseminate, and apply approaches to combining genomic and EMR data for genetic research.<sup>30</sup> The consortium also includes a focus on ethical, legal and social issues (ELSI) in biobanking, utilising monthly teleconferences to discuss specific issues such as data sharing, return of research results, participant consent issues, and the role of community engagement.<sup>31</sup> Quarterly in-person meetings provide updates on genetic research progress and highlight group efforts to address ELSI and CE strategies. eMERGE I Network members include Group Health Cooperative/University of Washington (GHC/UW), Marshfield Clinic, Mayo Clinic, Northwestern University, and Vanderbilt University. Kaiser Permanente (KP) is affiliated with the eMERGE Network for the purposes of discussing ethical and regulatory issues. Table 1 presents an overview of the six biobanks' characteristics, and Table 2 provides a summary of community engagement efforts.

The community engagement efforts conducted by the sites involved with eMERGE were neither designed nor intended to be coordinated. Instead, each was a local response to the NHGRI funding requirement. The following section highlights *one* CE activity from each site to demonstrate the range of possible approaches and to illustrate how the biobanks tailored their CE activities to: (1) the specific stakeholders or community; (2) the context of the biobank (eg from an existing disease-specific study, or from a general biobank; opt-in vs. opt-out model); and (3) the stage of the biobank development. Outcomes presented are broad and include process and impact components. All CE empirical studies were approved by the individual site's Institutional Review Board (IRB).

## ***Group Health Cooperative/University of Washington***

### *Background*

Group Health Cooperative is a consumer-governed, nonprofit health organisation that provides medical care and health insurance to more than 580,000 members in the Pacific Northwest and Northern Idaho. Headquartered in Seattle, the Cooperative is part of a regional culture that values citizen participation in civic decision-making. Its members are primarily white, middle class, and relatively well-educated.

For the eMERGE project, the Group Health Research Institute has partnered with researchers at the University of Washington and the Fred Hutchinson Cancer Research Center to investigate genotype-phenotype links for dementia, carotid artery atherosclerotic disease, and statin-use complications. The project uses genetic and health data from the Adult Changes in Thought (ACT) Study,<sup>32</sup> a longitudinal study begun in 1994 that focuses on age-related dementia and cognitive decline. Participants are randomly selected Group Health members age 65 and older who were free of dementia at study entry. Although the original ACT consent covered genetic analysis, access to medical record data, and the possibility of data sharing with researchers outside Group Health, the Group Health IRB determined that the deposition of study data in the NIH database of Genotypes and Phenotypes (dbGaP) warranted re-consent. The re-consent process is described elsewhere.<sup>33</sup>

### *CE Method Highlighted*

Negotiations with the Group Health IRB about re-consent for eMERGE participation highlighted the need for internal policy to govern the conduct of large-scale genomic research, as well as the need for empirical data about members' preferences, goals, and concerns. The GHC/UW community engagement project began with a focus group study<sup>34</sup> to gather member perspectives about participation in genome-wide association studies linking genetic data and EMR data and continued with a consensus development panel of stakeholders. The consensus development panel (CDP) is presented here. The CDP had three goals: (1) to discuss genome-wide association studies (GWAS) and related whole-genome research and the ethical, legal, and social implications of such studies; (2) to develop recommendations for Group Health leadership for policy on GWAS and similar work; and (3) to serve as a demonstration project for similar efforts across the United States. The group consisted of 13 members representing GH members, researchers, healthcare providers, and legal and administrative representatives. The panel met in person seven times to deliberate on issues it identified as key priorities, including informed consent, return of research findings to participants, and sharing study data with researchers outside GH.

### *Outcomes*

The consensus panel arrived at 11 key recommendations, outlining the ways in which research risks should be described to prospective participants; the advisability of re-consent; the need to offer aggregate – and where appropriate, individual – research

findings to participants; and the clear description of datasharing plans as part of the informed consent process. The panel also urged GH to ensure that genetic studies are reviewed and managed in the same fashion as other kinds of research, while acknowledging public perceptions that genetic research can be more risky than other forms of health research. These recommendations formed the basis of a final report presented to the Group Health Cooperative Board of Trustees in December 2009. A manuscript is in preparation.

### ***Kaiser Permanente***

#### ***Background***

The Kaiser Permanente (KP) Research Program on Genes, Environment, and Health (RPGEH) is building a population-based biobank that integrates clinical data from electronic medical records, biospecimens, and information on behavioral and environmental factors.<sup>35</sup> The programme seeks participation from 500,000 adult KP health plan members in Northern California. When completed it will represent one of the largest and most diverse biobanks in the US. KP members 18 years and older are eligible to participate and are recruited via a mailed invitation letter in English, Spanish or Chinese. Participants give broad consent for their data and biospecimens to be used for research. Some 430,000 members have contributed survey data, 160,000 of whom have also contributed a biospecimen.

#### ***CE Method Highlighted***

The objectives of the RPGEH's community engagement efforts are both content- and process-oriented: to obtain community consultation and to build a relationship that values the community's role in biobank research. The community engagement process has used surveys, focus groups, interviews and a Community Advisory Panel (CAP) in order to gain the perspectives of various stakeholders. The CAP (highlighted here) provides an opportunity to develop and strengthen an ongoing relationship between multiple community representatives and the RPGEH. There have been two cohorts of CAP members since 2006, each lasting two years and including about 25 members. A third CAP is currently being recruited. Engagement involves participation in quarterly meetings, ongoing dialogue and consultation about various RPGEH related activities, and participation in other advisory and working groups. CAP members receive an honorarium of \$100 for each meeting attended.

CAP membership reflects a diversity of sociocultural communities, including: KP members, local residents, patient advocates, genetics experts, representatives of historically under-represented communities, safety net and public health providers, local government, faith-based organisations, and corporate health plan purchasers. CAP members are leaders or individuals who represent a certain constituency or provide important expertise.

The process of building a relationship of mutual learning and trust between the RPGEH and CAP members, in which community members and researchers feel

comfortable asking each other questions, uses a variety of community organizing and capacity building methods and a mix of small-and large-group activities. RPGEH and community members plan meetings together to encourage more equitable power dynamics. Similarly, meeting agendas attempt to reflect the joint priorities of CAP and RPGEH leaders.

#### *Outcome(s)*

The CAP has assisted in reviewing research processes, protocols, and instruments, and provided feedback on reasons for, and barriers to, participation in the RPGEH. It has also provided input on the range of community concerns about genetics research. The CAP has proven to be a successful mechanism to help create a stronger relationship between researchers and community members and has been instrumental in providing guidance on a number of issues. One noteworthy example is their input on the importance of obtaining participants' re-consent before depositing their data in dbGaP. Their recommendation that the RPGEH use an opt-in mechanism for re-consent was influential in the programme's decision to adopt this approach.

#### ***Marshfield Clinic***

##### *Background*

The Personalized Medicine Research Project (PMRP) is a large population-based biobank enrolling people from Central Wisconsin who receive their medical care at Marshfield Clinic.<sup>36,37</sup> Currently there are approximately 20,000 enrolled and recruitment is ongoing. The database includes DNA, plasma, serum samples, and questionnaire data. Medical records can be accessed for additional information relevant to outcomes being studied. The biobank was developed to help facilitate genomics research and community engagement is ongoing.

The community engagement process for PMRP has involved three main activities: focus groups, the organisation of a Community Advisory Group (CAG), and public education/community communication. Efforts to engage the community started prior to the beginning of enrolment into PMRP and continue throughout the recruitment and enrolment process. Details of the complete PMRP community engagement process are published elsewhere.<sup>38</sup>

##### *CE Method Highlighted*

In this paper, the focus will be on methods used for public education and community communication that were targeted at adults (18 years of age and older) in Central Wisconsin. The goal was to increase knowledge and understanding about PMRP *prior* to beginning biobank participant enrolment. Community groups such as Rotary, Lions, and Kiwanis were provided with names of speakers to talk about PMRP at their meetings. The CAG helped to identify additional groups and organisations to be contacted. Talks to community organisations were heard by approximately 1,000 potentially eligible participants, timed with recruitment in that area. There was a video that could be used at these talks, and a brochure, a flyer, a poster and a 'frequently

asked questions' (FAQ) pamphlet were developed and used in letters of invitation, as handouts at community talks, and for placement throughout the Marshfield Clinic. Local and national media releases were sent out to coincide with the launch of enrolment. Local media releases announced the 1,000<sup>th</sup>, 5000<sup>th</sup>, 10,000<sup>th</sup> and 15,000<sup>th</sup> participant enrolments, and media releases announced the start of the first two studies utilising PMRP data. Newsletters are sent out periodically to inform PMRP participants of current studies, findings, and developing issues related to PMRP and are available for recruiting, community interest, and education. A website was developed that includes information about PMRP, detailed programmatic materials, links to related internet sites, updates about project progress, emerging discoveries, and publications.

### *Outcome(s)*

A number of lessons were learned from this engagement process. The initial education materials were far too dense. With input from focus groups and the CAG, the longer documents were shortened and simplified, leading to more meaningful and usable education tools. Adding a tear-off packet that listed the project name and contact information to the poster was effective and convenient. The video was not worth the expense because it became out of date quickly and it was often challenging to use it in local venues when speaking to a community group. Being aware of unique subgroups within the community, i.e. medical, service and civic organisations, allowed for development of appropriate means of disseminating information. Strategies and contacts were developed for the various subgroups.

### *Mayo Clinic*

#### *Background*

The Mayo Clinic Biobank is a multi-purpose population-based biobank of Mayo Clinic patients.<sup>39</sup> The Mayo Clinic has locations in Minnesota, Florida, and Arizona. The population is not geographically constrained – there are patients who travel to the Mayo Clinic from all over the world who may participate in the biobank. The biobank is located in Rochester, Minnesota. All Mayo Clinic patients aged 18 and older, who are legal residents of the US, are eligible for participation. Participants are recruited during routine medical appointments. Unsolicited volunteers are also accepted. As of December 2010 more than 14,000 individuals had consented to participate, with recruitment ongoing. In addition to providing blood samples, participants complete a health questionnaire and authorise access to clinical data and other tissue collected in the course of treatment.

Mayo Clinic has conducted a number of community engagement efforts. The first engagement was a deliberative democracy event held to facilitate community influence in the development and governance of the biobank. Other engagements have included an interview study of Mayo patients and a survey of Olmsted County, Minnesota, USA, residents to learn more about the community's opinions on the biobank.

### *CE Method Highlighted*

In September 2007, the Mayo Clinic held a deliberative democracy event to engage community members. The goal of the event was not only to allow the expression of different points of view, but to also encourage real compromises and the formulation of new policy recommendations for the Mayo Biobank. Additional aims were to learn the opinions of community members about biobanks generally, and to evaluate new methods for community engagement in biobanking.

All participants in the deliberative democracy event were residents of the county in which the Mayo Clinic is situated, and were sampled to represent the county's demographic composition. Members of minority groups in the community were over-sampled to ensure representation in the deliberations. The number of participants was small and the racial/ethnic profile of the county is relatively homogenous, so specifically selecting for minorities was necessary. The Rochester Epidemiology Project (REP) provided both local demographic information and lists of potential participants.<sup>40</sup> Thirty potential participants were recruited, and 21 participated in the event. Participants were paid \$400 for their time and effort.

Prior to the event, each participant was sent a booklet describing DNA biobanking that included an explanation of the science involved, the aims of biobank-based research, and an introduction to common ethical concerns. On day one, professional stakeholders gave presentations outlining the promises and challenges of biobanking from various viewpoints, including those of researchers, patient advocates, legal professionals, and privacy specialists. On days two and three, participants were divided into three small groups to facilitate open discussion. Professional facilitators led the small-group discussions. On day two, the groups explored individual values, hopes, and concerns. On day three, they developed specific recommendations. During the afternoon of day four, everyone reconvened in the large group and discussed the various recommendations. The entire engagement was recorded, and the recordings were transcribed and analysed.

### *Outcome(s)*

Specific policy recommendations produced by the community engagement event that have been implemented in the design and operation of the Mayo Biobank include: 1) development and use of a simplified informed consent process; 2) an option for participants to withdraw from the biobank; 3) ongoing community oversight, including the creation of a Community Advisory Board; and 4) publication of a community newsletter and website to inform participants and community members about the biobank.



## *Northwestern University*

### *Background*

The Northwestern University biobank, NUgene, is a biospecimen repository with longitudinal medical information from an ethnically diverse urban population of patients at Northwestern University-affiliated hospitals and outpatient clinics.<sup>41</sup> Since 2001, more than 10,000 Chicago area patients have enrolled in NUgene. Participants' biospecimens are combined with data from a questionnaire and updates from EMRs. Patients are recruited through a variety of clinical settings, and consent to the distribution and use of de-identified samples and data for genetic research.

The eMERGE community engagement process involved a mixed-methods approach utilising focus groups, a national survey of Institutional Review Board (IRB) professionals,<sup>42</sup> and a consensus meeting to obtain input from various community stakeholders regarding the consent process for high-throughput genomic research and sharing of genetic research data. The first phase of this process will be presented here.

### *CE Method Highlighted*

The goal of the first CE phase was to gather information about biorepository participants and the public's views toward genetic research and data sharing. Focus groups were chosen as a less structured method of eliciting data, one which allowed for open discussion, varying viewpoints, discovery of unanticipated findings, and clarification of information. Eligible biorepository study participants were NUgene participants, 18 years or older, not previously contacted for other research studies, and English speaking. Eligible public participants were 18 years or older and English speaking. They were recruited from three diverse Chicago neighborhoods representing the geographic areas from which the NUgene Project recruits participants.

To help facilitate discussion, participants received a one-page fact sheet that the investigators developed and pretested, summarising the NIH Data Sharing Policy<sup>43</sup>. A brief information form, completed by each focus group participant, included standard demographic measures and two questions about medical information and research. Three NUgene participant focus groups (n=21) were conducted at Northwestern University's Chicago campus, and three public focus groups (n=28) were conducted at three Chicago neighborhood facilities in May, 2008. Participants received a \$70 gift certificate and their travel was reimbursed.

Experienced moderators used a pretested focus group discussion guide consisting of eight open-ended questions directly relating to the study's objectives. Focus group discussions were audiotaped and transcribed and independent checks by two investigators confirmed accurate and verbatim transcription. Data reduction and analysis were conducted through standard qualitative methods of coding, notation, and theme identification. Detailed findings are reported elsewhere.<sup>44</sup>

### *Outcome(s)*

Data from the focus group and survey studies were presented at a consensus meeting of diverse stakeholders such as clinicians, investigators, ethicists, regulatory professionals and patient advocates, held in December 2009 at Northwestern University. These engagement efforts identified participant views about data sharing, influenced biobank patient communication, and informed written consent materials and mechanisms used to educate biobank participants. In particular, focus group participants expressed an interest in receiving further information about genetic research in general, and data sharing more specifically.

### ***Vanderbilt University***

#### *Background*

Vanderbilt's biobank, BioVU, is composed of a synthetic derivative (SD) of Vanderbilt University Medical Center's (VUMC) electronic medical record and DNA extracted from residual blood samples collected in the course of clinical care in the outpatient setting and scheduled to be discarded.<sup>45,46</sup> The SD contains all clinical information in the EMR and its associated entry-order relational database but stripped of personal identifiers and modified in other ways. The name 'synthetic derivative' comes from both alterations (eg date shifting to mask actual dates, which protects against re-identification) and extractions (eg of textual and structured information that is identifiable). Although BioVU data is considered by the Vanderbilt IRB to be of non-human origin, patients are given the opportunity to opt out of having DNA included in this repository.<sup>47</sup> DNA has been collected from samples from adults since 2007, and from children since 2009. Access to the SD and BioVU is subject to oversight primarily by the IRB and an internal, multi-disciplinary Operations Oversight Board.

Because of the unique nature of this approach, a variety of efforts have been made since the conceptualisation stage of BioVU to engage and respond to the various communities who may be involved in BioVU. Patients were originally surveyed about their attitudes and preferences,<sup>48</sup> and are routinely surveyed about their understanding about the opt-out process;<sup>49</sup> faculty and staff participated in a web-based survey; and two focus groups and a large survey were conducted with community members. BioVU has a community advisory board composed of a diverse group of individuals who make recommendations about emerging issues. The community engagement effort involving patient exit interviews (PEI) will be presented in this paper.

#### *CE Method Highlighted*

Since BioVU is based on a non-human subjects model, with biological samples collected from residual clinical samples, individuals do formally give consent for inclusion in the biobank. Patients are notified of BioVu in their standard Consent to Treatment/Agreement to Pay forms and processes at the time of registration. For this reason, exit interviews conducted at the time patients are interacting with the

registration process are an integral component of the development and ongoing operation of the BioVU resource. This approach has been employed routinely since 2006 to assess: the effectiveness of posters and informational bulletins in communicating the existence of the programme to patients; the awareness of the BioVU programme among adult patients in outpatient clinics; and the acceptability of the BioVU model among parents in preparation for a paediatric expansion. Adult patients were interviewed at the time of their exit from the phlebotomy area, and the parents of paediatric patients were interviewed at the time of their child's subspecialty or primary care clinic visit. Interviews included brief surveys with both structured and open-ended questions. In all cases, interviews were kept brief. Participation rates have been high (70 per cent or greater of parents/patients approached in any given study have agreed to be interviewed). The times, days, and locations varied in each effort to ensure a random sample of patients was obtained.

#### *Outcome(s)*

The information gathered through these efforts has informed biobank programme development and implementation, altered the set of communication materials, and guided the paediatric expansion. Because of the helpfulness of these approaches, information from exit interviews has become a critical continuing component of programme evolution and evaluation.

#### **Discussion**

An increasing number of biobanks are being developed to collect and store DNA and other health data from large numbers of individuals. Demonstrating respect for persons who volunteer to participate in research is an ethical good in itself. Moreover, by taking the initiative to engage their respective communities, researchers lay the groundwork to foster mutual understanding and trust,<sup>50</sup> encourage public interest and participation in research, and potentially enhance the impact of their studies. Ongoing communication and relationships with research participants are also important. When questions or concerns do arise about participant data, such relationships may help to avoid outcomes such as a ban on research, as in the Havasupai case,<sup>51,52</sup> or destruction of samples, as in the Texas blood spot settlement.<sup>53</sup> Furthermore, engaging with communities can provide empirical data to aid policy-makers, genomic researchers, public health scientists, and community leaders in developing locally appropriate policies and procedures for biobank-based research.

Community engagement represents an important means of balancing pragmatic concerns (such as resource limitations and regulatory requirements) with ethical norms. In many cases, funding agencies now mandate an ethics component in large-scale genomic research applications. Furthermore, investigators' plans should take into account not only the research goals but also the unique characteristics of the local community. These interests and motivations should shape the goals, as well as the method of community engagement adopted by the biobank. As a result, community engagement will require diverse approaches.

## **Meeting challenges**

Although community input did lead to improvements in biobanking procedures and protocols, a number of challenges were also encountered. For example, eliciting participant views about biobanking and research was sometimes difficult as not all participants were familiar with genomics and informatics. To address this issue, some of the sites offered pre-reading materials, educational presentations with time for questions and answers, and supplementary website information. Some sites also had challenges in recruiting diverse participants and eliciting multiple perspectives. To be more inclusive, plans included oversampling of minorities for engagement efforts and actively recruiting participants who were supportive, as well as cautious, to participate in biobank efforts.

Likewise, a number of sites had some difficulties in identifying diverse and active participants for their community advisory groups. To ensure diversity of their community advisory members, sites worked closely with community leaders and consulted with community academic partners to identify a broad representation for their advisory boards. To encourage participation over time, sites offered compensation and involved the community advisory members in the agenda-setting and meeting facilitation process. Some of the advisory groups had trouble coming to consensus on issues discussed, which presented the challenge of incorporating differing views into recommendations. To facilitate consensus, one site allowed for as many meetings as were necessary for discussion, brought in external speakers, and held joint meetings of their expert and community advisory groups.

Lastly, an overarching constraint, similar to that of other community engagements, is the level of resource commitment needed. CE can require a considerable time commitment, increased costs, and specialised expertise.<sup>54,55,56</sup> One strategy to increase available resources was to include the costs of newsletters and meetings of community advisors as necessary expenses in grant applications. eMERGE ELSI investigators also shared their experiences and expertise with one another and helped review tools and CE protocols in development stages, providing valuable insight. The experience of the eMERGE partners demonstrates that one size of community engagement does not fit all, and that an up-front investment of time and resources is important for engagement efforts to succeed.

## **Future directions and research**

The eMERGE Network biobank sites plan to explore the impact and evaluation of CE, and to continue community engagements via newsletters, community advisory boards, and empirical data gathering. Additional discussions are planned for investigators throughout the eMERGE Network to share and receive feedback on their biobanking and CE experiences, challenges, and future opportunities.

To further our understanding about how best to conduct and utilise CE efforts in the context of biobanking and large-scale genomic research, future research is needed to

provide systematic evaluation of the effectiveness of various methods of community engagement and to assess the impact these research institution–community partnerships have on research processes, outcomes, practice, and policy. Although a number of organisations have set out general principles, frameworks, and best practice for successful community engagements<sup>57,58,59</sup>, currently no standardised measures exist for evaluating CE goals and outcomes in biobank-based research.

In addition, further efforts are needed to identify ways to translate the findings of biobank-based community engagement efforts into institutional and broader health policy developments. How should empirical data from community engagements be incorporated into policy? How can the informational needs of policymakers be incorporated into the design of community engagement activities? How should policymakers weigh community views when there are important differences among stakeholders' perspectives?

### **Conclusion**

As population-based biobank research activities continue to increase, so does the need for input from stakeholders and community members in the development of appropriate institutional practices and broader public policy. Increasingly, funding agencies require that proposed research include a community engagement component, in recognition that such efforts can improve the quality and impact of biobank-based research. Biobank CE efforts need to have clearly defined goals; they should tailor approaches to the local context, and create processes to support continued interaction between research institutions and the community. The varied eMERGE Network community engagement experiences reported here are presented with the hope that they will provide useful insight and information for other communities and investigators planning, or already conducting, biobank-based research efforts.

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**Table 1. Overview of Biobank Characteristics**

|                                      | <b>GHC/UW</b>  | <b>Kaiser Permanente</b>                       | <b>Marshfield Clinic</b>                                  | <b>Mayo Clinic</b>  | <b>Northwestern University</b>  | <b>Vanderbilt University</b>                          |
|--------------------------------------|--|--|---|---|---|---|
| <b>Institutional description</b>     | Consumer-governed nonprofit HMO  | Integrated health care delivery system         | Medical centre  | Medical centre  | University medical centre   | University medical centre                             |
| <b>Geographic area served</b>        | Seattle area, Washington   | Northern California                            | Central Wisconsin   | Southeast Minnesota   | Chicago area, Illinois  | Central Tennessee                                     |
| <b>Year established</b>              | 1994   | 2005   | 2002  | 2009  | 2001  | 2007  |
| <b>Disease focus</b>                 | Alzheimer's disease and dementia   | All diseases represented in patient population | All diseases represented in patient population            | All diseases represented in patient population                      | All diseases represented in patient population  | All diseases represented in patient population        |
| <b>Current enrolment<sup>a</sup></b> | 1,200 living participants <sup>b</sup> ; 1,700 deceased                    | 160,000  | 20,000  | 14,000  | 10,000  | 105,000   |
| <b>Eligibility criteria</b>          | GHC members 65 or older not diagnosed with dementia at time of study entry | KP members 18 or older                         | Patients 18 and older receiving care at Marshfield Clinic | Mayo Clinic patients 18 and older who are legal residents of the US | Patients 18 and older receiving inpatient or outpatient care in NU-affiliated hospitals and clinics | Patients receiving outpatient care in VUMC facilities |

<sup>a</sup> Approximate numbers at time of publication

<sup>b</sup> ACT participants who re-consented for eMERGE

**Table 2. Overview of Community Engagement Efforts**

|                      | <b>GHC/UW</b>  | <b>Kaiser Permanente (KP)</b>  | <b>Marshfield Clinic</b>   | <b>Mayo Clinic</b>   | <b>Northwestern University</b>  | <b>Vanderbilt University</b>  |
|----------------------|--|--|--|--|---|---|
| <b>Stakeholders</b>  | Existing Alzheimer's cohort from the ACT study, their surrogates and Group Health (GH) members from the Seattle, WA metro area, consumer representatives, GH leadership, researchers     | KP members in northern California, community members, participants, refusers, investigators, IRB members, community panel members, funders, KP leadership  | Adults from central Wisconsin, Marshfield Clinic employees, refusers, community representatives  | Residents of Olmsted County Minnesota, Biobank participants, Researchers, Clinicians, Mayo leadership, Ethicists and IRB professionals   | General public in Chicago area, biorepository participants, IRB professionals, research ethicists, clinicians, investigators, patient advocates                                       | Vanderbilt Clinic, diverse adult outpatient clinic in Nashville, TN, community members, medical center and university faculty and staff   |
| <b>Specific Aims</b> | Learn about beliefs, attitudes, opinions and experiences with informed consent, data sharing, return of results; Develop policy recommendations; Disseminate results and recommendations | Understand concerns and attitudes about participation in genetic research and in the biobank; Explore ethical and social issues; Develop recommendations and best practices; disseminate results and recommendations | Obtain feedback and reactions on informational materials; Learn how to improve enrolment process; Obtain information to guide operations; Facilitate knowledge and understanding | Develop recommendations for bio-bank procedures and policies; Assess understanding and concerns of participants and community residents; Obtain ongoing input and guidance on biobank operations | Assess attitudes toward genetic research /biobank participation and data sharing; Educate stakeholders about data sharing; Recommend guidelines for informed consent and data sharing | Assess ethical, scientific and societal advantages and disadvantages of the non-human subjects model; Determine best practices for oversight, community involvement and communication |
| <b>Methods</b>       | Focus groups<br>Consensus development panel  | Focus groups<br>Mail surveys<br>Telephone interviews<br>Community Advisory Panel (CAP)   | Focus groups<br>Public education/<br>community communication<br>Community Advisory Group (CAG)   | Deliberative democracy<br>Mail surveys<br>In-person interviews and observation of consent process<br>Community Advisory Board  | Focus groups<br>Web-based survey<br>Consensus meeting<br>Community Advisory Board (CAB)   | Focus groups<br>Mail survey<br>In-person interviews<br>Patient notification<br>Community Advisory Board   |

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