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Brief Communication

BRIEF COMMUNICATION

Biospecimen Sharing Among Hispanic Women in a Safety-Net Clinic: Implications for the Precision Medicine Initiative

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Abstract

Biospecimen donation is key to the Precision Medicine Initiative, which pioneers a model for accelerating biomedical research through individualized care. Personalized medicine should be made available to medically underserved populations, including the large and growing US Hispanic population. We present results of a study of 140 Hispanic women who underwent a breast biopsy at a safety-net hospital and were randomly assigned to receive information and request for consent for biospecimen and data sharing by the patient's physician or a research assistant. Consent rates were high (97.1% and 92.9% in the physician and research assistant arms, respectively) and not different between groups (relative risk [RR] = 1.05, 95% confidence interval [CI] = 0.96 to 1.10). Consistent with a small but growing literature, we show that perceptions of Hispanics' unwillingness to participate in biospecimen sharing for research are not supported by data. Safety-net clinics and hospitals offer untapped possibilities for enhancing participation of underserved populations in the exciting Precision Medicine Initiative.

On January 20, 2015, President Obama announced the Precision Medicine Initiative (PMI), a bold new research effort that has the potential to revolutionize how we treat disease, including cancer. Although this initiative promises to result in great scientific advances, questions remain as to how members from diverse communities in the United States will become involved and benefit from discoveries resulting from the PMI. Without adequate racial/ethnic representation, the PMI has the potential to exacerbate cancer disparities, as higher-resource individuals benefit more from adoption of technological advances than those from low-income groups (1).

The participation of racial/ethnic and low-income populations in biospecimen sharing is vital to the success of the PMI. Published reports show that there is under-representation of racial/ethnic groups, including Hispanics, in biobanks (2,3). Hispanics comprise a growing population in the United States that is largely absent from public data sets, such as The Cancer Genome Atlas (TCGA; <3%). Furthermore, Hispanics make up 4% of participants included in the National Cancer Institute's Cancer Epidemiology Cohort infrastructure program (4). Although some data exist on Hispanics' willingness to donate biospecimens for research (3,5,6), less is known about actual provision of these specimens, and no data exist on methods of consent. Here we report results of a study among Hispanic women who were randomly assigned to receive information and request for consent for biospecimen donation by either: 1) patient's physician or 2) a research assistant who was not part of the health care team. We hypothesized that consent rates

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Table 1. Patient characteristics by random assignment arm

Characteristic	Physician (n = 70)	Research assistant (n = 70)
Age, mean ± SD, y	47.0 ± 13.1	46.4 ± 10.0
Hispanic subgroup, No. (%)		
Mexican	66 (94.3)	67 (95.7)
Other	4 (5.7)	3 (4.3)
Education, y, mean ± SD	8.9 ± 4.2	8.6 ± 4.1
Income, $/mo, mean ± SD	1034.7 ± 718.4	1046.3 ± 682.8
Health insurance, No. (%)		
None	54 (77.1)	59 (84.3)
Medicaid	14 (20.0)	8 (11.4)
Medicare/private	2 (2.9)	3 (4.3)
Spanish-speaking, No. (%)	56 (80)	63 (90)
Limited health literacy, No. (%)	59 (84.3)	54 (77.1)
Cancer diagnosis, No. (%)	21 (30.0)	13 (18.6)

would be higher in the physician arm than the research assistant arm.

Eligible women were age 18 years or older, of Hispanic ethnicity, English- or Spanish-speaking, and had undergone a breast biopsy at Maricopa Medical Center, a safety-net hospital in Phoenix, Arizona. Consent for biospecimens included provision of formalin-fixed paraffin-embedded tissue from the prior biopsy and a saliva sample (for DNA) collected at the time of consent. Study recruitment involved a two-step process. First, the provider asked the patient about her interest in participating in the trial. If she agreed, she was randomly assigned to be consented by the provider or the research assistant. Using an electronic tablet, the consent was shown to the patient and was also explained verbally by the consenter. All patients were given additional time to read and review the information on the tablet and provided the opportunity to ask questions prior to signing. Eighty-five percent (119/140) of women were consented in Spanish. The consent covered future research (including genetic studies) and noted that biospecimens could be kept indefinitely, utilized to develop commercial products, or shared with research collaborators without reconsent. Data collection included sociodemographic variables, risk factor information, and health literacy (7). We recruited 140 patients (70 to each arm) (see Supplementary Figure 1, available online), which was estimated to give 85% power to detect a difference of 20% or more between the two groups. The relative risk (RR) and 95% confidence interval (CI) were estimated comparing the proportion of individuals consenting to biospecimen collection between the two arms. The study was approved by the Institutional Review Board at Maricopa Medical Center. All statistical tests were two-sided, and a *P* value of less than .05 was considered statistically significant.

Participant characteristics reflect those of a safety-net hospital serving primarily a Southwest Hispanic population: a high percentage of Mexican-descent and Spanish-speaking women, low education and income levels, and a high proportion with limited health literacy (Table 1). Consent rates for biospecimen and data sharing were high in both arms: 97.1% in the physician-delivery arm and 92.9% in the research assistant–delivery arm, with no statistically significant difference (RR = 1.05, 95% CI = 0.96 to 1.10, *P* = .25, calculated using Pearson's chi-squared test) (Table 2).

Results of our study show high rates of consent for biospecimen and data sharing among low-income, un/underinsured

Table 2. Informed consent for biospecimen and data sharing among participants randomly assigned to consent delivered by their physician vs a research assistant

Random assignment arm	Positive consent No. (%)	RR (95% CI)	P*
Research assistant	65/70 (92.9)	1.00 (Ref)	
Physician	68/70 (97.1)	1.05 (0.96 to 1.10)	.25

*Two-sided Pearson's chi-squared test was used to calculate the *P* value. CI = confidence interval; RR = relative risk.

Hispanic women, regardless of whether the request for consent was delivered by their physician or a nonmember of the health care team. Having a nonphysician obtain consent addresses the possible concerns that conflation of research participation and clinical evaluation may drive biospecimen donation (5).

Reported reasons for lower participation of Hispanics in biospecimen sharing include limited English proficiency, limited health literacy, or cultural norms (6,8), as well as immigration status among foreign-born individuals (9). Our results suggest that health literacy is not a factor given the high rates of participation in spite of limited health literacy (~85%). While an argument can be made that racial/ethnic minorities constitute "hard-to-reach populations," emerging data on Hispanics suggest that this ethnic community is willing to and does share biospecimens for research purposes (3,6–8). Further, Loffredo et al. showed that trust was not an issue in willingness to donate biospecimens among foreign-born Hispanics (6).

Our findings have direct implications to the efforts of the PMI, where biological samples will be queried for genetic variations and could contribute to diminishing racial/ethnic disparities in cancer outcomes. However, without access to biological samples that are representative of the diversity in the United States, this will not be possible, as is the case in TCGA. Our high rates of consent for biospecimen sharing are consistent with published data on Hispanics, which include provision of biospecimens among residents in rural areas (10), willingness to donate biospecimens among foreign-born inner-city individuals (6), and data on Mexican Americans from the National Health and Nutrition Examination Survey (11).

Limitations of our study include the select patient population of Hispanic women, primarily of Mexican descent from a single institution, limiting generalizability. Although consent rates were high when not obtained by the patient's physician, suggesting that conflation of research participation and clinical evaluation did not influence the high rates, we cannot fully exclude this possibility.

The continued racial/ethnic shift in the US population is projected to result in a majority-minority distribution by 2043 (12). However, to date, there is marked under-representation of racial/ethnic minority groups in clinical trials (13,14) and biospecimen banks (2,3). To address this inequity, an understanding of how to best include and engage individuals from under-represented groups, including Hispanics, will be required. We propose that this ethnic group's unwillingness to donate biospecimens is a myth not supported by data. Unlike other racial/ethnic groups, most Hispanics do not have a marked history of mistrust of the medical community. Partnerships among academic institutions, safety-net clinics, and hospitals offer potential for enhancing participation of diverse racial/ethnic groups and underserved individuals, which will be important for PMI efforts. These partnerships will ensure that medically underserved populations benefit from the exciting discoveries that are yet to come from precision

medicine and help prevent false discoveries that result from sampling from a homogeneous population (15).

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Notes

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