Informing the recruitment of American Indians for the Precision Medicine Initiative

Results of deliberative discussions with American Indians about biospecimen donation and biobanking

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Funded by the Agency for Healthcare Research and Quality
Grant # R21HS023576

Partnerships for Native Health

Introduction

- American Indians and Alaska Natives (AI/ANs) encounter substantial health disparities in cancer, diabetes, and other chronic conditions
- AI/ANs have the worst 5-year survival from all cancers combined among all U.S. racial/ethnic minorities.
- AI/AN under-represented in clinical trials.
- Biospecimen research – legal, ethical, social, spiritual, and political issues.
- Biospecimen education to AI/ANs and solicit views on biobank and biospecimen research policies and procedures.

Precision Medicine

- Precision medicine - disease prevention and treatment that takes into account people's genes, environment, lifestyle
- $215 million investment in the President's 2016 Budget

Goals:

- Identify genetic differences between people that affect drug response - the right drug for the right patient at the right dose
- Knowledge to overcome drug resistance
- Tailor medical treatments to the individual
  - Increase effectiveness
  - Minimize adverse side effects
  - Use of combination therapies

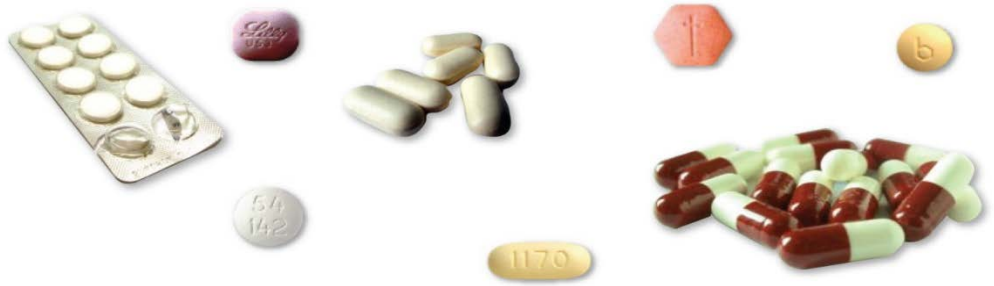


Image Source: National Human Genome Research Institute

Biobanks

- A biobank is a repository that processes, stores, and distributes biospecimens and data for use in research and clinical care.
- It may contain one or many tissue types, and it can be disease-specific, population-based, project-driven, genetic, commercial, academic, or even virtual, with centralized information on specimens stored at multiple off-site locations. http://specimencentral.com/biobank-directory/
- Most biobanks do not consider the unique legal, cultural, and ethical concerns associated with biobanking, including consent, confidentiality, secondary use of specimens, returning results to donors, and data sharing.
- History of unethical and unregulated research has led many AI/ANs to mistrust scientists, the federal government, and research in general.

Fred Hutchinson Cancer Research Center
Biobank, Seattle, WA



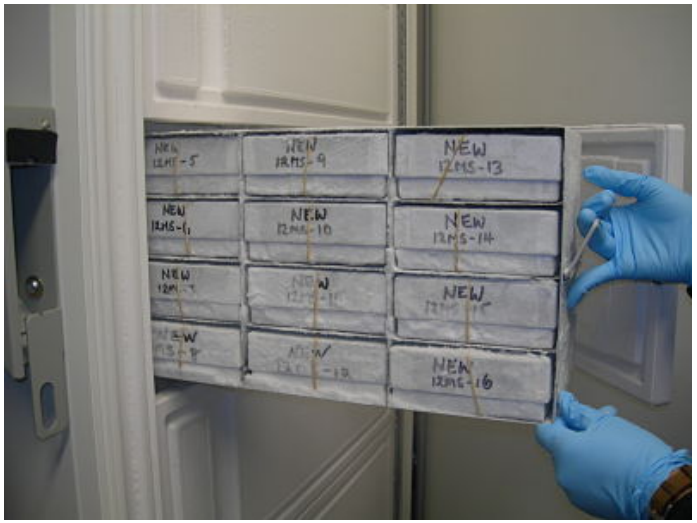






Photo credits: Katherine Briant | Source: Fred Hutchinson Cancer Research Center

Overall Goal

- To determine the effect of deliberative methods on views and concerns about biospecimen research and biobanking.

- Deliberative approaches include:
  - Citizen's Panels or Councils
  - Citizen's Juries
  - Deliberative focus groups
  - Deliberative polls
  - Issues forums, community forums, deliberative forums
  - Town Hall meetings
  - Deliberative democracy

Deliberation

- Deliberative methods are a distinct approach to obtaining public input.
- Participants informed.
- Participants encouraged to discuss, learn from others, and examine and refine their own views.
- Many people have pieces of an answer to a solution.
- Deliberation has been used in ethical debates on biobanking.
- Biobanking incorporated into the national health research agenda.
- Deliberation is essential to ensure that Native Americans make informed decisions about biobank participation.

Specific Aims

- Assess attitudes and concerns related to biobanking among American Indians and healthcare providers with a survey and discussion.
- At each of our 7 sites, deliver culturally adapted biobanking education, but without collective discussion, to a group of 30 community members and healthcare providers.
- After the educational sessions, randomize participants at each site into DI and NDI groups. NDI will engage in non-educational, non-deliberative activities while DI discusses cultural and regulatory issues relevant to biobanking.
- Compare attitudes and concerns related to biobanking between the DI and NDI groups after the deliberative discussion session.

METHODS

Methods: Study Sites

1. Billings Clinic Cancer Center (Billings, MT)
2. Vucurevich Cancer Care Institute (Rapid City, SD)
3. University of Oklahoma (Oklahoma City, OK)
4. Northern Plains field center of the Strong Heart Study (SD)
5. Arizona field center of the Strong Heart Study (Phoenix, AZ)
6. Sacramento Native American Health Center (Sacramento, CA)
7. Northeastern State University (Muskogee, OK)

Methods: Eligibility Criteria

Participants were 21 years of age or older and either:

- Self-reported American Indian or Alaska Native

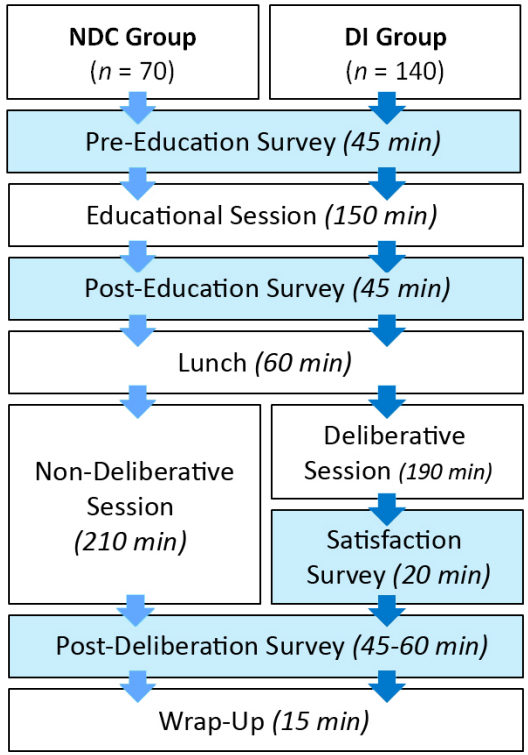
OR

- Healthcare provider (Native or non-Native)

Methods: Study Design

- 30 participants per site
- All receive education
- After education, 2/3 to Deliberative Intervention and 1/3 to Non-deliberative control group (BINGO)
- All participants receive $125 compensation for their time and effort for the full day workshop (9AM-3PM).

Figure 1. Study design & timing



NDC = non-deliberative controls
DI = deliberative intervention

Methods: Framework

- Health - interconnected and interdependent with family, tribe, and nature.
- Emotional, mental, and spiritual aspects of well-being.
- Our survey and deliberations sought to include these cultural values, which position biospecimen research within the context of the family, community, environment, and spiritual world.

Methods: Education

- Framework
- Experience
- Prior education on biospecimens
- Literature
- National Congress of American Indians genetic research materials
- One hour powerpoint presentation to all participants.

Education Topics

- ✓ What a biospecimen is and how they are collected.
- ✓ What a biobank is.
- ✓ In what ways biospecimens are important in research.
- ✓ How biospecimens can be used to advance prevention and treatment of cancer and other diseases.
- ✓ The Precision Medicine Initiative.
- ✓ Ethical, legal and social considerations related to biospecimen donation for research.
- ✓ The informed consent process.
- ✓ Pros and cons of donating biospecimen(s).

Methods: Survey

1. 53 item survey; ~20 minutes to complete
2. Baseline (before education)
3. After education
4. After deliberation or BINGO
   - Deliberation group – Satisfaction questionnaire

   ✓ Demographics
   ✓ Health History
   ✓ Willingness to donate biospecimens for medical research
   ✓ Views about medical research(ers)
   ✓ Circumstances under which they would feel comfortable donating biospecimens
   ✓ Biobank views and preference

Methods: Post Education

- Survey, lunch, randomization
- Deliberative Discussion Topics:
  - What are your views and concerns about biospecimen research and biobanking?
  - What are the pros and cons of donating biospecimens and biobanking?
  - What are your recommendations to make the process of biobanking more acceptable?

Survey Analyses

- Frequencies and means for survey responses
- t-tests for differences between discussion group and non-discussion group

RESULTS

Results: Baseline Demographic Characteristics

	Respondents (N = 197) n	%
Age *mean (sd)*	45.0	(15.2)
Female	139	(70.5)
Ethnicity*		
AI/AN	153	(78.1)
NHW	29	(14.8)
NHB	1	(0.5)
Hispanic	12	(6.1)
Asian	4	(2.0)
NHPI	1	(0.5)
Other	3	(1.5)
Education		
Less than high school	10	(5.2)
High school	35	(18.0)
Some college	68	(35.1)
College graduate	81	(41.8)

Participants were asked to endorse 1 but data were entered with more than 1 main race/ethnicity.

	Respondents (N = 197) n	%
Marital status		
Currently married	74	(38.5)
Never married	65	(33.9)
Divorced	53	(27.6)
Income		
under 20k	50	(26.0)
20-under40k	49	(25.5)
40-under60k	34	(17.7)
60-under80k	22	(11.5)
more than 80k	37	(19.3)
Employment		
Full time	115	(59.6)
Part time	26	(13.5)
Unemployed	39	(20.2)
Retired	13	(6.7)

Results: Baseline and Post Education Survey

Frequencies and means for responses to biobanking baseline and post education survey.

	Baseline (N = 197) n %	**1st followup** (N = 193) n %
Willingness to donate biospecimen*; *mean (sd)*	3.5 (1.2)	3.7 (1.2)
Which types of biospecimens willing to donate?		
Blood	155 (86.6)	156 (84.8)
Urine	148 (86.0)	152 (84.9)
Hair	128 (76.6)	129 (73.7)
Nail	109 (67.3)	116 (66.7)
Skin	81 (52.6)	100 (57.8)
Saliva	144 (83.2)	144 (79.6)
Tumor	95 (60.5)	118 (67.8)
Stool	91 (56.9)	96 (55.5)

*How willing are you to donate biological specimens? 1= Not willing; 2=Somewhat Unwilling; 3=Undecided; 4=Somewhat Willing; 5=Very Willing.

Results: Baseline and Post Education

How likely would you be to donate a biospecimen if:

Means for responses to biobanking baseline and post education survey.

	Baseline (N = 197) mean (sd)	**1st followup** (N = 193) mean (sd)
…you knew about the researchers?	2.2 (0.9)	2.2 (0.8)
…approved by community leaders?	2.1 (0.9)	2.2 (0.8)
…used in cancer rsch and family with cancer?	2.5 (0.7)	2.5 (0.7)
…biobank run by Native organization?	2.3 (0.8)	2.1 (0.8)
…biobank run by local organization?	2.0 (0.9)	2.0 (0.9)
…your specimen sent to research center you never heard of?	1.2 (1.0)	1.1 (0.9)
…biobank run by a university?	1.8 (0.9)	1.8 (0.9)
…biobank run by IHS?	1.8 (1.0)	1.7 (1.0)
…biobank run by federal government?	1.4 (1.0)	1.5 (1.0)
…to a biobank that let you choose which kind of research your specimen would be used for?	2.3 (0.9)	2.2 (0.8)
…to a biobank that let you withdraw you specimen at any time?	2.2 (0.9)	2.2 (0.9)

(0=Very Unlikely; 1=Somewhat Unlikely; 2=Somewhat Likely; 3=Very Likely)

Results: Baseline and Post Education

I would donate a biospecimen:

Means for responses to biobanking baseline and post education survey.

	Baseline (N = 197) mean (sd)	**1st followup** (N = 193) mean (sd)
…if researchers told me the study results when the study was finished.	3.2 (1.0)	3.1 (1.0)
…for the good of future generations even if it would not help my own generation.	3.4 (0.9)	3.5 (0.9)

0=Strongly disagree; 1=Somewhat disagree; 2=Neither agree nor disagree; 3=Somewhat Agree; 4=Strongly Agree

Results: Post Discussion and BINGO

Means for responses to biobanking attitudes baseline questionnaire using reduced sum scores among participants in all 3 waves and by randomization

	Baseline (N=186)	**1st followup** (N=186)	**2nd follow up with deliberative discussion** (N=136)	**2nd follow up with BINGO** (N=50)
How willing are you to donate?	3.8 (1.1)	3.9 (1.1)	3.9 (1.2)	3.9 (1.0)

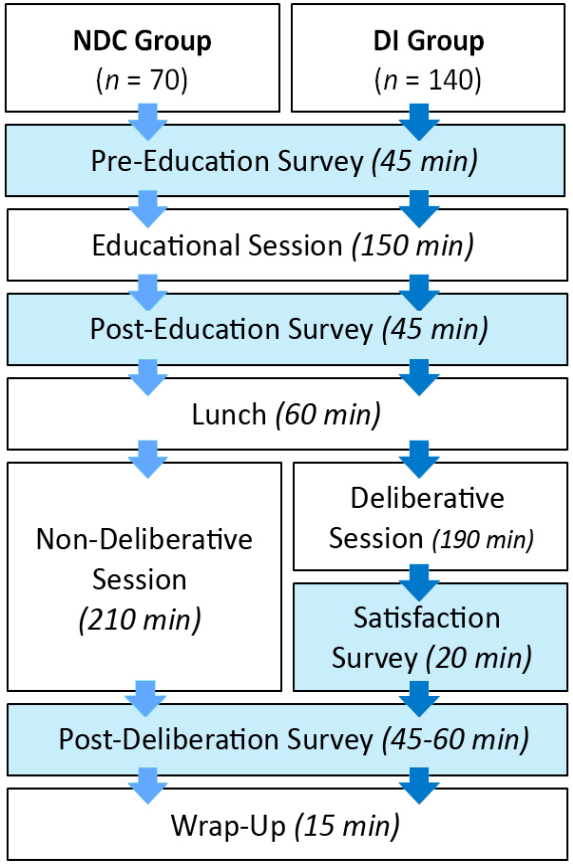
No statistically significant differences between deliberative discussion and BINGO groups based on t-test findings.

Deliberative Discussion

Non-Deliberative Discussion

- BINGO
- ~1.5 hours
- Final survey
- Gift card

Figure 1. Study design & timing



NDC = non-deliberative controls
DI = deliberative intervention

Deliberative Discussion

- 20 participants
- 1.5 hours
- 3 Approaches with pros and cons
  - Yes, would donate unconditionally
  - No, would not donate
  - Yes, would donate but with conditions
- Audio recorded
- Final Survey and Satisfaction survey (33 questions)
- Gift card

Approach Two – Choosing to Donate Unconditionally

Supporters of Approach Two generally favor donating biospecimen(s) unconditionally to biobanks and/or researchers for research purposes.

Pros

- Individual donation may help future generations in preventing disease and staying healthy
- You can take satisfaction in contributing to your community
- You will be agreeing to a request from people you respect
- You will be supporting scientific advances

Cons

- You may not know the details of what will happen to your biological specimen or how it will be used, now or in the future
- You may not be able to decide what kind(s) of research your biological specimen is used in
- You may not be able to withdraw your specimen at anytime
- Personal information (i.e., name, address, health information, etc) would be kept with your biospecimen
- You may not know the direct benefit of the research to you or your community

Qualitative Analyses

- Transcription of audio recordings
- Dedoose qualitative software
- Thematic analysis of transcripts from the 7 deliberative groups
- Codes developed by 3 research staff
  - Pros
  - Cons
  - Influences on participation in biospecimen research
  - Recommendations – biobank, researcher(s), process

Results: Deliberative Discussions

Historical and Current Relationships

- Mistrust of federal government, pharmaceutical companies, research(ers), Indian Health Service, tribal government.

- Loss of culture; acculturation/assimilation policies:

"You take our land, you take our children, you take our grandmothers, and now you want our DNA."

- Indian Health Service underfunded; meds cost too much:

"Somebody's going to find a benefit or cure, but somebody's also going to find a way to make money off of it, and it's not going to be us. It's not going to be the person donating."

- Allocation of money and resources by government:

"The government needs to spend money on programs that will help with some of the problems we have now, like accidents, infant mortality, and suicide."

Results: Deliberative Discussions

Native Worldview vs. Scientific View

- Biospecimens much more than *just* biospecimens:

  "Blood represents our ancestors and our future generations"; tied to the land (Relational view) [*traditional NH belief that one's mana (spirit or power) resides in all body parts*].

  "To us, any part of ourselves is sacred. Scientists say it's just DNA. For an Indian, it is not just DNA, it's part of a person, it is sacred, with deep religious significance. It is part of the essence of a person (Dr. Frank Dukepoo, a geneticist of Hopi and Laguna ancestry, 1998 interview in San Francisco Chronicle).

  "Science tries to explain things away to the point where there's no meaning left. Without meaning, we're not a people. We have to be careful of those that would peddle nothingness by explaining everything away."

Results: Deliberative Discussions

Generational Differences

"If you ever sat down with the old folks, they're hard-headed and they're set in their ways. "Who are you? Don't even come at me with that. You might not be able to convince them, and others will do what they say."

"I think it's important to be involved so that we can work to make this kind of research acceptable and beneficial to our people."

Results: Deliberative Discussions

Individual/Autonomous vs. Collective Decision

- Personal decision
- Collective Decision
- Elders/traditional beliefs decide if donation culturally congruent
- Tribal policy dictates donation

"You may think you're helping, but maybe your tribe doesn't see it that way. Then it comes down to, do you do what you think is right, or do you do what your tribe thinks is right?"

"I don't know how my tribe feels about biobanking and things like that."

Results: Deliberative Discussions

Ethical Challenges of Biospecimen Research

- Cloning, bioweapon development
- Deception about use of biospecimens
- Ancestry studies to challenge origins of Native people.

  "There are tribes that are doing blood testing to see who is relate to who and kicking people out of the tribes saying, "You're not related to this person so you're not one of us."

- Resulting treatments/medications will be too expensive

  (Biocolonialism – commercially driven genetic research that secures ownership for profit or academic advancement, e.g. 1/5 of human genes in U.S. patented; LorrieAnn Santos w/Imi Hale 2008 article)

Results: Deliberative Discussions

Recommendations

- Federal Government – build trust, work w/tribes.
- Pharmaceutical Companies – offer compensation; equal access to discoveries, particularly for groups who participate in research.
- Education – for communities and researchers in bioethics.
- Researcher – Native, culturally grounded, CBPR.
- Process – Transparency, updates about use of biospecimens and discoveries, enlist tribal members to recruit and enroll Native participants, demonstrate research is meaningful.
- Informed Consent – honor as a contract; severe penalties for breaking contract.

Research should be GREAT!

- **G**overnance – shared governance or input into ownership of specimens and policies of biobank.
- **R**e-consent – for each specimen use.
- **E**ducation – on-going and informative.
- **A**ccountability – researchers come from population of focus; policies/laws enforced to ensure protection of participants.
- **T**ransparency – use of biospecimens is open to participants.
- **Research** – reflects the priorities of the people.

Tauali`i M, Davis EL, Braun KL, Tsark JU, Brown N, Hudson M, Burke, W. Native Hawaiian Views on Biobanking. J Cancer Educ. 2014;29(3):570-576

Deliberative Quality and Experience Survey frequencies and percent. N=113

	Disagree Strongly N (%)	Disagree N (%)	Agree N (%)	Agree Strongly N (%)
The information presented was clear and easy to understand.	0 (0)	3 (3)	49 (43)	58 (51)
The materials presented all sides of the issues.	2 (2)	9 (8)	58 (51)	38 (34)
By the end of the discussion, I understood why people held certain beliefs that were different from mine.	3 (3)	4 (4)	65 (58)	40 (35)
The discussion led me to change some of my opinions.	11 (10)	34 (30)	48 (43)	19 (17)
More events like this should be held as a way of getting the views of people throughout the country.	0 (0)	2 (2)	50 (44)	60 (53)
I think the recommendations made by the group will influence how research findings are used.	2 (2)	15 (13)	65 (58)	29 (26)
I could tell that the facilitator favored some positions over others.	45 (40)	45 (40)	16 (14)	4 (4)
The facilitator made sure that all opinions were considered.	0 (0)	3 (3)	49 (43)	58 (51)

Conclusions

- Similar findings in other qualitative studies with American Indians, Alaska Natives, Native Hawaiians, Pacific Islanders, Aboriginal People of Australia, Hispanics, African Americans, Asian populations.
- **Consensus** on value of biospecimen research, education, CBPR, need for oversight, shared governance, reconsent.
- Greater public and researcher education needed.

Dissemination

- Report to participating sites.
- Work with National Congress of American Indians to create “toolkit” for working with American Indian communities on biospecimen research.
- Advise Precision Medicine Initiative recruitment centers.

Native Hawaiian and Pacific Islander Qualitative Studies

- Santos, LA. Genetic Research in Native Communities. Prog Community Health Partnersh. 2008;2(4):321-327.
- Tauali`i, M, et al. Native Hawaiian Views on Biobanking. J Cancer Educ. 2014;29(3):570-576.
- Kwan, PP, et al. Use of a community-based participatory research approach to assess knowledge, attitudes, and beliefs on biospecimen research among Pacific Islanders. Health Promot Practice. 2014;15(3):422-430.


Mahalo