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"I Don't Want to be Henrietta Lacks": Diverse Patient Perspectives on Donating Biospecimens for Precision Medicine Research

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Abstract

Purpose—To determine whether patients distinguish between biospecimens and electronic health records (EHRs) when considering research participation to inform research protections.

Methods—We conducted 20 focus groups with individuals who identified as African American, Hispanic, Chinese, South Asian and non-Hispanic White on the collection of biospecimens and EHR data for research.

Results—Our study found that many participants did not distinguish between biospecimens and EHR data. However, some participants identified specific concerns about biospecimens. These included the need for special care and respect for biospecimens due to enduring connections between the body and identity; the potential for unacceptable future research, specifically the prospect of human cloning; heightened privacy risks; and the potential for unjust corporate profiteering. Among those who distinguished biospecimens from EHR data, many supported separate consent processes and would limit their own participation to EHR data.

Conclusion—Considering that the potential misuse of EHR data is as great, if not greater than for biospecimens, more research is needed to understand how attitudes differ between biospecimens and EHR data across diverse populations. Such research should explore mechanisms beyond consent that can address diverse values, perspectives and misconceptions about sources of patient information to build trust in research relationships.

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Keywords

Research ethics; Informed consent; Biobanking; Diversity; Precision Medicine

Introduction

The collection of a wide range of patient information, including biospecimens and electronic health records (EHR), is the foundation of national efforts towards precision medicine.[1] The success of efforts to collect a broad spectrum of patient information, including genomic, environmental and lifestyle data, depends on broad public support and willingness to participate.[2] However, there are few empirical studies on whether and how patients distinguish between biospecimens and EHRs data when assessing the risks and benefits of research participation. Understanding the varying perspectives across diverse populations and the values that guide them on this issue will be useful for developing effective policies on human subjects protections and engaging groups that have been historically underrepresented in biomedical research.

In 2015 the Department of Health and Human Services (DHHS) proposed a new requirement that researchers obtain broad consent (i.e., consent for future, unspecified research studies) for biospecimens in its notice for proposed rulemaking (NPRM) to modernize and revise the 1991 Federal Policy for the Protection of Human Subjects known as the Common Rule.[3] Critics of the distinction between biospecimens and other sources of patient data referred to this as "biospecimen essentialism,"[4,5] asserting that requirements for broad consent are unwarranted and could negatively impact scientific progress. In January 2017, the DHHS issued the Revised Common Rule (RCR) without the proposed changes to informed consent for biospecimens.[6] However, recognizing the development of sophisticated bioinformatic tools and computational approaches,[7] the RCR stipulates that the distinction between identifiable and non-identifiable biospecimens be reviewed within the first year of the rule going into effect and at least once every four years thereafter. Accordingly, future iterations of the rule might treat all genomic information as identifiable, including biospecimens.

Missing from these policy debates are empirical data on the perspectives of patients, who are key stakeholders of the research enterprise. Studies have shown that the majority of patients prefer consent for use of their information for research[8]; however, few studies have examined whether and how diverse racial and ethnic patient populations distinguish between the use of biospecimens and other types of personal data in research. This gap is particularly important to address given the lack of diversity of samples and data in existing biorepositories, the majority derived from individuals of white European ancestry. While prior studies have examined barriers and facilitators to minority participation in medical research,[9,10] few studies have investigated how racial and ethnically diverse patients assess risks of donating their biospecimens as compared to other patient data, such as their EHRs, and how these differences might relate to levels of trust in the research enterprise.

To address this gap, we present qualitative data from focus group discussions conducted with racially and ethnically diverse patients from a community-based health system.

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Identifying specific distinctions patients make between biospecimens and EHR data when considering participation in precision medicine research may illuminate attitudes and expectations that bear directly on challenges for recruiting individuals and groups into research, and raise empirical questions in need of further investigation

Materials and Methods

This qualitative study was designed to identify attitudes of patients across diverse racial and ethnic populations about the collection of biospecimens and EHR data for prospective studies. Focus group methodology was chosen due to its suitability for exploring perspectives and attitudes when little empirical work is available on specific research questions.[11,12] IRB approval was obtained from Sutter Health and Stanford University.

Focus Group Recruitment

We conducted 20 semi-structured, open-ended focus groups between January and July 2016 with patients at a large multispecialty group practice organization in northern California who self-identified with one of five racial and ethnic groups: African American, Chinese, Hispanic/Latino, non-Hispanic White, and South Asian. We conducted four focus group discussions with each of the five groups. Potential participants were identified by EHR review, using the inclusion criteria: age 18 or older; seen within the health system in the previous 24 months; English, Mandarin, or Spanish-speaking; and self-reported race or ethnicity of Non-Hispanic White, African American, South Asian, Chinese, or Hispanic/Latino. Patients were recruited with a goal of achieving age and gender balance within each group. In total, 3162 potential participants were identified and contacted, of whom 380 indicated interest. Of those, 248 patients met inclusion criteria and 122 ultimately enrolled in the study based on scheduling availability.

Focus Group Guide and Discussion

In each focus group, we showed six short (2–3 minute) animated videos describing the concept and process of precision medicine research, which we developed with health communications experts at Booster Shot Media.[13] The videos are available at http://thevaluesproject.stanford.edu/. We developed our focus group questions from themes identified through literature review and team discussion and tested and revised these for clarity.[14] We asked participants about their views on using their EHR data in precision medicine research (eg. *How would you feel about your EHR data being used for this type of research?*) followed by a question about their biospecimens. (eg. *How would you feel about your biological samples being used for this type of research*?)[15] A study team member moderated each focus group, and at least one additional team member was present for notetaking and observation. Native speakers on the research team moderated the Mandarin and Spanish focus groups.

Data Management and Analysis

We audio-recorded and transcribed all focus group discussions and used the qualitative software program Dedoose[16] to analyze the de-identified transcripts. Using a modified grounded theory approach, a subset of the research team developed a qualitative codebook

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based on *a priori* concepts from the focus group guide and *in-vivo* coding.[11] The coding team refined the codebook and all coders achieved an inter-rater reliability kappa ≥0.8.[12]

Results

The demographics of focus group participants are described in Table 1. Our study found that 1) many participants across our racial and ethnic focus groups did not distinguish between biospecimens and EHR data and did not identify unique risks associated with biospecimens. However, some participants raised specific concerns: 2) biospecimens are an extension of the "self" and require special care and respect; 3) biospecimens are a source of unjust profitability; 4) biospecimens contain DNA, which creates the possibility of identifiability and risks to privacy; 5) biospecimens create the potential for human cloning and 6) biospecimen use in research may warrant separate consent from EHRs. Table 2 indicates the number of and racial and ethnic makeup of the focus groups in which each of these themes emerged.

1. No difference in risks associated with biospecimens as compared to EHR data

When asked whether they distinguish between biospecimens and EHR data in considering the risks of participation in precision medicine research, at least one participant in 19 of our 20 our focus group discussions (Table 2) articulated that they did not see them differently. Some stated explicitly, "*I see them the same way*," or "*All same*" while others in the group nodded or gestured agreement.

In contrast, other participants in each of our focus groups raised specific questions and concerns about the collection of biospecimens. These, described in the findings below, reveal a spectrum of attitudes and beliefs about biospecimen use in research from racially and ethnically diverse patients.

2. Biospecimens are an extension of the "self" and require special care and respect

In our African American, Chinese, Hispanic and South Asian focus groups, some participants asserted that the physical nature of biospecimens retains an individual's essence even after samples are collected, stored and distributed for research. For several focus group participants, this durable connection created a heightened sense of vulnerability and required special care and consideration that do not extend to digital forms of patient data.

> "I feel more uncomfortable with giving a biological specimen because it feels like an attachment or extension of myself… a blood sample or a tissue sample feels connected to me and that makes me feel more vulnerable. 'Cause that was a direct piece of me versus a reaction to me. And then I think of the example of Henrietta Lacks, and I'm like, I don't want to be Henrietta Lacks." (South Asian Focus Group Participant)

Many participants across our five racial and ethnic groups cited the case of Henrietta Lacks as a cautionary tale when discussing potential risks associated with biospecimens. Lacks was an African American woman whose biospecimens were collected during a cervical cancer biopsy and later developed into the profitable HeLa cell line.[17] When participants alluded to

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her story, they raised concerns about the commercialization of her biospecimens that occurred without explicit consent. Several participants focused specifically on the question of individual identity and expressed concerns over the loss of control of the self.

For some participants who made these distinctions, religion and culture determined the acceptability of donating biospecimens to research, including reasons for altering the body; *how* biospecimens would be used; and whether these uses would fall within their moral parameters. One South Asian focus group participant explained her views in this way:

> "I was raised Muslim, and so there are very clear guidelines on how to conduct yourself medically. For example, you're allowed to give a kidney because that benefits someone else. But it has to benefit others, so at least one other person. And you can't have something done out of vanity…" (South Asian Focus Group Participant)

3. Biospecimens are a source of unjust profitability

A general concern over the commercialization of samples was raised by several participants across the groups; however, perspectives on why such activity would be objectionable differed. There was widespread concern over the potential for discrimination by insurance companies and the development of expensive, out-of-reach drugs by pharmaceutical companies.

> "The unfortunate aspect of the money motive is a major player in the whole health regime. I always have a little caution around insurance companies, and pharmaceutical companies… if big players who have money are investing in research, then I'm questioning their motive." (African American Focus Group Participant)

One Chinese focus group participant underscored this view, stating: *"Insurance companies and pharmaceutical companies are both really negative; they will accrue profit from this, so I will not want them to be involved in this [research]."*

Other participants raised different concerns over what they viewed as unfair monetization of patient biospecimens. Again, citing Henrietta Lacks and the injustice of corporate profit from the samples of unsuspecting patients, some participants asserted that if biospecimens contributed to corporate profit, those donating the samples should be remunerated.

> "If the industry is making billions of dollars, where does that leave the person who's partially responsible for that in the first place?" (Non-Hispanic White Focus Group Participant)

4. Biospecimens contain DNA, which creates the possibility of identifiability and risks to privacy

Participants in all of our focus groups raised specific concerns about privacy and the potential for breaches in confidentiality, and asserted that biospecimens left them more vulnerable than EHR data. As one non-Hispanic White focus group participant put it, "*That tissue can only come from one person.*"

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Several participants linked their concern to genetic material that they believed could only come from the biospecimens.

> "I have a serious objection to physical storage of tissue or blood sample because they are really DNA… To me, I would be very disconcerted about storing real traceable DNA…physical samples. Medical data does seem to be ok but not samples." (South Asian Focus Group Participant)

5. Biospecimens create the potential for human cloning

In highlighting the physical nature of samples, some participants focused on an inherent vulnerability of samples due to the unforeseen capabilities of technologies that could be applied to them in the future. Several participants made a distinction between "physical" vs. "digital" data. In expressing these reservations, participants in our African American, Hispanic and South Asian focus groups raised a specific fear of human cloning and for experiments not sanctioned by donors. Several participants referenced the case of Henrietta Lacks to underscore their fears and their limited ability to conceive of risks in the present given the potential for change in the future.

> "Because it's identifiable and that is, as far as I am concerned, highly identifiable information and reproducible. Are you going to clone? I do not know what the research and the context means for me - this physical data. But research data that is NOT physical - digital data - I think is a different notion of research for me on that." (South Asian Focus Group Participant)

Some participants' concerns about cloning were connected to identity and the risk that samples could be stolen or abused without the donor's knowledge. This participant describes a sense of personhood that endures in a sample that could result in an unknown "cloned self".

> "But just the idea of your 'DNA make-up' sitting somewhere, maybe long after you're gone…. Just having my 'who I am' sitting around somewhere waiting for someone to decide what to do with it or not do with it or to be stolen and then I have a clone of myself somewhere and then not know about it. It's just odd; it's just not good, that's all." (African American Focus Group Participant)

6. Biospecimen use in research should be conducted through separate consent from EHRs

When asked about their preferences for consent, participants expressed differing views. Some indicated that one consent for the collection and use of biospecimens and EHR data would be sufficient and others expressed a desire to have a separate consent process for biospecimens, citing the unknown capabilities of research in the future.

> "And a sample has your DNA. Any tissue sample, your blood or a skin sample will have DNA. And nowadays, in research we do not know in five or ten years what they will be doing with DNA. Maybe cloning in another country or something. I don't know. So, I agree with him, actually, the more I think about it. I think it sounds better to be separate." (Hispanic Focus Group Participant)

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Other participants expressed a desire to choose among the types of research for which their samples would be used, based on their personal values.

> "Could you opt out of certain things, like I wouldn't want clones of me running around? …Being able to say: stem cell-yes or no? cloning-yes or no? Like you get to decide what research your tissues are being used for because for some people there is a very strong value or ethical statement they want to make." (African American Focus Group Participant)

Others expressed discomfort with the storage of biospecimens, but did not object to collecting data derived from the sample. One participant expressed the view that little is lost with using only data:

> "I'd like it if it could be separate because then they can retrieve the information that you've given without having your actual tissue. You know, they get your blood readings and your type and all that without having the actual tissue." (Hispanic Focus Group Participant)

Discussion

Biospecimen exceptionalism refers to the idea that the use of tissues, blood and other sources of bodily information in research presents more significant risk to study participants than patient data found in EHRs. Many argue that this is a dangerous misconception and that digital data may present even greater privacy risk.[18] Our study suggests that some patients do differ in their views about biospecimens and EHR data and would want additional information about biospecimens through a separate consent process. However, their reasons extend beyond issues of identifiability and privacy, and suggest that it is imperative to investigate not only *whether* research participants distinguish between biospecimens and EHR data, but *how and why*.

Bioidentities and biospecimens

Our study findings reveal heterogeneity in views on the relationship of biospecimens to the human body and personal identity. As opposed to framings of the body as merely the integration of physiological components, some may conceive biospecimens as extensions of their identity that continued even after fragmentation. Social scientists have described perceptions of durable links and dynamic fluidity between the body and identity as "bioidentity."[19] Recognizing biospecimens as a source of unique personhood suggests that samples have "social lives"[20] that continue with their donation to research.[19] This framing not only raises questions concerning storage, use and the potential value derived from the samples, but whether researchers and institutions might have special responsibilities to address specific group beliefs. In 2004, the Native American Havasupai tribe in Arizona provided 4000 samples for diabetes research. The tribe asserted that subsequent research, including studies of population origins, violated their religious beliefs and left them vulnerable to stigmatization, which resulted in a law suit and the eventual return of biospecimens to the tribe.[21,22] The case of the Havasupai tribe illustrates the diversity of views on the body and group identity, and reveals the high stakes for acknowledging and taking seriously these differences.

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In our study, discussion about specific concerns related to biospecimens primarily emerged in our African American, Hispanic and South Asian focus groups. Those who view biospecimens as retaining individual identity may desire specific information about policies on storage and details about the parameters of future research uses and commercialization. We encourage further exploration of the extent to which religious and cultural differences influence attitudes on biospecimens as compared to other patient data and how these beliefs impact support of and participation in precision medicine research. The lack of established norms for addressing privacy concerns over the use EHR data and biospecimens in research has resulted in legal challenges and lapses in public trust.[23–25] The heterogeneity in individual and group experiences with biomedical research and inequities in healthcare may contribute to public expectations for precision medicine research. Previously, we discussed how the "spillover effect," which suggests patients who trust their individual healthcare provider tend to have higher levels of trust in their healthcare system,[26] may contribute to levels of trust in research and impact willingness to participate.[15] Our research suggests that for some patients, historical and ongoing injustice and health disparities may contribute to disparities in research participation.

Promethean nightmare of cloning

Our finding that participants who are concerned about donating biospecimens fear the possibility of identifiability, loss of privacy, and misuse by insurers and other third parties is similar to previous studies of public attitudes towards genetic research.[27–30] Cloning as a specific risk of donating biospecimens is also consistent with the few empirical studies that have examined patient perspectives across diverse groups.[31] Hopkins suggests that the primary characterization of cloning as an ethical issue in genetic research centers on concerns over the loss of human uniqueness and individuality, and the fear of out-of-control scientists.[32] For some participants, the gap in scientific expertise and lack of trust create what Rose and Rose describe as a Promethean nightmare in which unpredictable motivations of a cloner go unchecked.[33]

To understand these fears, it is important to consider how these social anxieties emerge from historical and social circumstances that position genetics research as part of a much larger political narrative for specific groups. Previously, we described how personal and group history of negative experiences with the healthcare system informed some participants' concerns about the potential for abuse by researchers and third parties such as pharmaceutical and insurance companies.[15] Participants who described a greater sense of vulnerability over donating biospecimens for research may experience a heightened sense of social vulnerability overall and are more likely to be from groups that are historically under-represented in research. The narrow focus of human subjects regulations on identifiability and individual privacy may fail to address fears over violations of bioidentity and prospects for cloning that extend beyond risks of "breaches," and stem from failures in research relationships and resulting skepticism of stewardship.

Building Trust in the Research Enterprise

Our findings underscore the importance of trust for patients contemplating participation in precision medicine research and the need for public discussion about the collection of

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biospecimens as compared to other patient information. Specifically, our findings suggest that there is a range of attitudes that require further exploration to develop effective approaches towards building trust and institutional trustworthiness in precision medicine research.[15] For example, identifying how institutional policies on storage and distribution of biospecimens affect trust and perceptions of protection of bioidentity will be essential to productively engaging with diverse populations. While education may be needed to address potential misconceptions that greater privacy risk resides with biospecimens as compared to EHR data,[18] technical assurances by themselves may not adequately address the concerns of patients who understand the self as inextricable from the physical body.

While public fear and lack of trust are important to acknowledge and address, public attitudes alone do not warrant regulatory changes to human subject protections. Redefining de-identified biospecimens as human subjects research and requiring consent may negatively impact research and could render many existing samples unusable and thus violate expectations of donors who offered them for research use in good faith. Furthermore, creating additional labor-intensive consent processes for patients whose samples are routinely taken in clinical care and tracked for use in future studies could pose substantial logistical and technological challenges for research generally believed to be low-risk and would unlikely eliminate Promethean nightmares or ultimately repair trust.

Instead, we encourage community engagement to probe public fears over the collection of biospecimens that go beyond the potential for identifiability and privacy breach. Although the relative risk of identifiability from EHR data may be greater than for biospecimens,[18] a narrow sense of privacy risk may fail to address concerns of patients who view their biospecimens in terms of bio-identity or fears of cloning, and to provide opportunities for individuals and groups to share their experiences and fears about bad actors. This is particularly important for groups who have and continue to experience an acute sense of uncertainty and vulnerability towards institutions such as the government, particularly in the current political climate. Creating communication mechanisms that explore diverse public views and address fears and misconceptions should be a long-term investment in creating trusting research relationships.

Study limitations

Recruitment of study participants was limited to one community-based health system in Northern California and was not designed to reflect the general U.S. population. Our participants—particularly those in the Chinese, non-Hispanic White, and South Asian groups—had higher educational levels and incomes than the national average. However, participants did represent a wide range of racial, ethnic, linguistic, and immigration backgrounds. In addition, our study was designed to identify through open-ended discussions the range of attitudes and perspectives that may bear on research participation. Focus group discussion, while well-suited to illuminating perspectives and experiences, does not provide precise quantifiable data as compared to other methods such as individual interviews or surveys.

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Conclusion

Our study findings suggest that while many patients may not differentiate between biospecimens and EHR data when assessing research risks, a subset may have specific concerns about samples. These may extend beyond risks to individual privacy and potential for breaches, and include issues related to how individuals view their bodies in terms of individual and group identity and the perception among some that biospecimens require special respect and care. The interconnected themes we identified suggest the need for further research to investigate the factors that influence these views. For example, certain beliefs may be held more strongly in certain religious and sociocultural groups. Understanding the extent to which these differences exist for populations historically under-represented in biomedical research will be particularly important for achieving the goals of diversity and inclusion in precision medicine research.

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Table 1

Participant characteristics

	Overall (n=122)	African American (n=23)	Chinese (n=28)	Hispanic / Latino (n=20)	Non-Hispanic White (n=26)	South Asian (n=25)
Sex						
Female	65 (54%)	11 (48%)	14 (50%)	11 (55%)	15 (58%)	14 (56%)
Male	55 (46%)	12 (52%)	14 (50%)	7 (35%)	11 (42%)	11 (44%)
No response	2 (2%)	0 (0%)	0 (0%)	2 (10%)	0 (0%)	0 (0%)
Age (years)						
Mean (SD)	56	57 (15)	57 (19)	55 (14)	60 (17)	50 (17)
Range	20–95	23–82	20–87	31–80	24–95	22–81
No response	4 (3%)	1 (4%)	0 (0%)	0 (0%)	1 (4%)	2 (8%)
Education						
High school degree or less	15 (12%)	5 (22%)	0 (0%)	10 (50%)	0 (0%)	0 (0%)
Some college or technical school	14 (11%)	5 (22%)	2 (7%)	4 (20%)	1 (4%)	2 (8%)
College degree	41 (34%)	7 (30%)	11 (39%)	2 (10%)	11 (42%)	10 (40%)
Graduate degree	52 (43%)	6 (26%)	15 (54%)	4 (20%)	14 (54%)	13 (52%)
Gross annual income						
$50,000 or less	29 (24%)	6 (26%)	6 (21%)	11 (55%)	1 (4%)	5 (20%)
$50,001 to $100,000	24 (20%)	8 (35%)	3 (11%)	5 (25%)	5 (19%)	3 (12%)
$100,001 to $200,000	41 (34%)	3 (13%)	13 (46%)	4 (20%)	11 (42%)	10 (40%)
$200,001 or greater	25 (18%)	4 (17%)	6 (21%)	0 (0%)	9 (35%)	6 (24%)
No response	3 (2%)	2 (9%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

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Table 2

Focus Group Themes

Theme		Representative Quote	# Focus Groups (N=20 total)
1.	No difference in risks between biospecimens and EHR data	*I have no problem with the tissue samples or the blood…To me it's the same as the data. (Hispanic Focus Group Participant)*	19 African-American 3 Chinese 4 Hispanic 4 Non-Hispanic White 4 South Asian 4
2	Biospecimens are an extension of the "self" and require special care and respect	*I do think there's so much about our medical information, particularly samples, tissues samples and blood samples, that is uniquely identifying to us that it's almost as if your name was in there… It's not technically you that's in there, it's anonymized, and yet for all intents and purposes it is. (Hispanic Focus Group Participant)*	9 African-American 2 Chinese 1 Hispanic 2 South Asian 4
3	Biospecimens are sources of unjust profitability	*If they're going to pick fifty samples and yours happens to be one of them and they discover some world-saving drug and they make a trillion dollars, where's your share of that? Because you helped do that. (Non-Hispanic White Focus Group Participant)*	8 African American 1 Chinese 2 Hispanic 1 Non-Hispanic White 4
4	Biospecimens contain DNA, which creates the possibility of identifiability and risks to privacy	*I don't tend to be really concerned about privacy, but when it's your biological samples, I think my kind of privacy alert went up - just as far as DNA analysis and Big Brother. That seems a little scarier for some reason. (South Asian Focus Group Participant)*	20 All groups
5	Biospecimens create the potential for human cloning	*Can you make another "me" out of that, right? I don't want that to happen…A clone, right? I don't want that to happen. (African American Focus Group Participant)*	8 African-American 3 Chinese 1 Hispanic 2 South Asian 2
6	Biospecimen use in research may warrant separate consent from EHRs	*I would say yes. I'd like to separate [the consent processes]. If I couldn't separate bio from just electronic health record, I don't think I would [participate]. (Hispanic Focus Group Participant)*	12 African-American 1 Chinese 3 Hispanic 3 Non-Hispanic White 2 South Asian 3