



Advancing Ethical Research Conference

Baltimore, MD | December 5-7 | Pre-Conference Programs: December 4

The Uncomfortable Conversation: Talking about Diversity Luncheon Session on December 7, 2014

Note: Different colored text refers to the notes from different working groups.

1. **David Tillmanⁱ writes, “the most striking feature of earth is life, and the most striking feature of life is its diversity” The American population is diverse; and there are effects of race/ethnicity/poverty on health, security and most other issues. What happens when we don’t have diverse populations in research studies?**

- a. **Will we be able to answer our research question?**

- a. Can we answer research?

- Doing oncology- need to know our diversity
- Not able to
- Diversity of population with disease
- Infectious disease. Collect data on
- Norplant-great example – Thailand
- Older patients and gender- can the same medications be applied
- Behavioral- social- economic differences can affect ability to receive the medication

- a. - Depends on the research/research questions, clinical vs. behavioral

- don't want a diverse population when using focus groups/studying

- PTSD in soldiers- you want a representative group, don't want to mix higher level commanders with young soldiers.

- b. **Will we be preventing equal access to a good thing or will we be abusing one population by using them to advance another?**

- Depends on the research question and budget for analysis.

- Asthma study included children through adults but didn't include enough children to have usable data.

What happens when we don't use diverse populations in research studies?

- Depends on the research: social behavior vs. clinical
- Nongeneralizable results
- Bias
- Science loses out
- Goes against the concept of justice

2. **Cultural competence is defined as a set of congruent behaviors, attitudes, and policies that come together in a system, agency, or among professionals and enables that system, agency, or those professionals to work effectively in cross-cultural situations. Many view cultural competence as the ‘ability to address differences’.**

- a. **How do you or your office address cultural competency?**

- b. **How do you design and development education programs around cultural competence?**
- c. **Consider the statement, “cultural competence – not a matter of minimizing differences and pretending they don’t exist, but is more about acceptance and adaptation to differences ...” If this statement is true, then what are some actions or responses we can take to ensure we have a culturally competent organization.**

Cultural Competence

- Translations
- If there is therapeutic benefit that-
- Training diversity
- Asking to enroll non English speeches
- Diversity on IRB
- Institutional Resources of what to think about
- Community members ask in the application how they are addressing cultural competence
- Life experience
- Insure Institution is more diverse.
- What could we develop
- Cultural inclusion
- Suggestion box
- Restorative justice groups

Cultural Competence

- Could have many dimensions (skin color, religion, ethnic background, upbringing)
- Could be more subtle (political, value system)
- Developing a program
- Identify problems and resources, prioritize- can't do everything
- Responsibility for diverse recruitment talk more about it
- Would be best to have cultural sensitivity resources that are university wide for all clinical/medical issues, not just research
- Can't know it all, be more open about acknowledging lack of familiarity with potential subjects

3. **45 CFR 46 (102 i) refers to minimal risk, “...the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests is concerned with not only physical harm but other harms that could potentially damage participants.” Exempt Category 2 further illuminates our understanding of risk by excluding research where “any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation”.**

- a. **What is the relationship between ‘diversity’, ‘inclusion’ and ‘risks’? Take into consideration the non-physical risks in research that are listed in Exempt Category 2.**
 - Risk of or criminal/civil liability/financial standing/employability/repetition

- Substance abuse- population may not accurately reflect the population, AA, Latino, White
- Selective community
- Selection of “outside communities” that have different ethnic groups that are outside of the institutions community; equal distribution
- Group harms- stigmatization
- Damaging to subjects financial standing, employability or reputation
 - o Assure confidentiality
 - o De-identify data
 - o Waiver of documentation; if exempt may not require consent

- 1.) Employability, respect for autonomy
- You want to exclude the less amount of people as possible
- Too much diversity could bias the study- may not apply, may need homogeneous
- Broad based study and not enough diversity would not be applicable to the entire population
- Minority or diverse pop. Are not necessarily vulnerable (doesn’t mean they shouldn’t be participants)
- Prisoners or military may think they have to participate
- 2.) Researcher empathy for potential participants
- Make sure the participants are truly informed
- Be mindful of the possible researcher/participant relationship (doctor/patient, employer/employee)
- Guarding confidentiality
- Relationship is relative, depends on type of study
- One factor can affect others

b. How can researchers guard against non-physical risks to participants?

- Do not designate at exempt category
- Script of consent
- Think outside of the box

4. Katherine Millerⁱⁱ from Columbia University writes, “Research has shown that social diversity in a group can cause discomfort, rougher interactions, a lack of trust, greater perceived interpersonal conflict, lower communication, less cohesion, more concern about disrespect, and other problems.” Other research has also shown that “greater diversity leads to increased productivity”. Still others believe that greater diversity in research, leads to better science. How do diversity and inclusion (D&I) affect our organizations and our research?

a. Does diversity and inclusion really make us smarter? Why or why not?

- Havasupai, group hours
- Yes makes us smarter, allows us to hear other point of life.
- Also introduces discrimination
- Group think is the problem
- Improves

Yes. Absolutely. Rich diversity of gender. Why is gender so important? If you have homogenous group of people, can’t go beyond in different groups.

- Diversity- “travel the world by interacting with them.”
- Invisible vs. visible-> culture vs. ways of thinking
- Appearance vs. Non- appearance

b. How might we weave D&I into research?

- Depends on study/research population. How are you recruiting? Language, picture, son flier in community.
- "Pay attention details"
- Behavioral-survey/interview/interaction.
- Biomedical
- Fill algorithm for languages
- Enlist the population
- If you don't make information available to them- then you are excluding them.
- The way research is started
- Needs/desires of the community
- "what is going on in your community?"
- Network
- Feedback loop
- More information of the "diversity"
- Think beyond the "high level" categories
- Advertise for a study? Know about your population. Over sample.
- Capture the "trust" of the population
- Reaching out to the community stay involved/don't disappear.

c. What examples can you provide that utilize differences to strengthen the foundation of an organization?

- Oregon-white-Hispanic/black/native American
- Study circles- different communities
- Exchange of info. On both ends.
- Sponsor regular community meetings
- Unconscious bias- acknowledges doing the work, go out to the community.
- Be involved in the community.
- Are researchers and study staff equipped to deal in cultural differences- e.g. young women staff in and Muslim community study- culturally sensitive.
- Might miss those with criminal record if study questions could implicate them
- Stigma
- Full disclosure of sensitive content upfront
- What would happen if there were a focus group
- Group settings
 - o Dynamics can get out of hand
 - o Hard to give everyone equal voice
- Consent is important- need to know ahead about risks of disclosure/ non-physical risks
- Ability to leave at any time
- Groups of "sex offenders" in a study support group
- Not used to thinking of selves as objects- can be uncomfortable if already fear objectification/ being categorized
- Researcher is on a "higher" level than participant, subject-> object
- Exacerbating discomfort of daily life
- Input from community in research question
- Guarding against non-physical risks?
- Training> cultural sensitivity
- Be mindful of intersection of what's being studied and employment
- Structure of study doesn't put person at social risk
- Are numbers of study participants sufficient to protect participant from exposure
- Data security, locked files, de-identified data
- Mobile device for recording info- put them at risk- theft
- Know your demographics-> risks->consult and engage

- Make participant aware of the risks
- Diverse populations and regions may have different risks- social
- Remind of reputation, employability, criminal liability
- Do different communities
- Study subjects
- Are you excluding people because of inclusion culture- e.g., criminal/civil liability

5. Think about how you might write a policy about diversity and inclusion in research studies. Is diversity equally important for all research?

- Diversity: how do we define it? Lots of different options: gender, racial, mental competency, socio-economic, age, education, documented/not, language, sexual orientation
- Inclusivity or exclusivity?
- Who has a stake in the outcome/will be affected? Are they represented at the table? If not, how will you involve them?
- Health disparity research is already focusing on a population for a reason. Homeless, racial, illegal immigrants

a. Is diversity equally important for clinical and non-clinical research studies? What about studies with or without the expectation of direct benefit?

Before you can determine importance you must define diversity as it applies to the research you evaluate. Diversity policy is extremely important
Particularly defining who has a stake in the outcome/will be affected? Are they being represented? If not how will you involve them? Why or why not and provide a rationale in your study addressing diversity. This practice would be equally important for studies with/without direct benefit.

- Depends on population you're studying and where the study is located
- Multi-center or local?
- Yes- equally important. Research feeds in to clinical care.
- When is it unimportant? National studies clusters of populations in certain area but broad base should even it out.
- Depends on effort level to be more inclusive
- Direct benefit? Important with or without
- Important distinction- direct benefit/harm
- Yes. Focused on inclusive policies to encourage participation.
- Important to include diverse group when expectations of a benefit in a clinical study. Important that a diverse population potentially benefits from findings
- If didn't are diverse group cannot generalize. Relevant even if our clinical setting
- \- yes because results may not be generalizable if only one group is included if studies have direct benefit, then diversity if especially important for share benefit across groups.

b. Could "diversity" be "bad" for a study? (Think social science research. Perhaps the researchers are legitimately interested in a very particular population.) How would you want to address this in policy/guidance?

It could provide stigma to the pop. Being studied so mitigation of stigma or clear aims/research questions should be created by investigators. Also consider if only focus on one population. How would you compare your results?

- Possibly. When looking at desired population- why review/include other populations

- But if only focus on one population. How do you compare your results?
- Study focusing on one population could be used in positive or negative way- immigrant/migrant research
- Depends on amount of stigma that could be derived
- **Need to talk at purpose of study.**
- **If have very diverse group might be able to say anything about specific group**
- **Can make a potential significance or draw an inference to be able to say anything.**
- **Especially of a characteristic of that group might affect that outcome**
- **Policies cannot be on specific that make it inflexible/**
- **Researcher needs to identify that exclusion criteria**
- **Diversity could be bad depending on what your research question is and how small your planned sample size is.**
- **If you don't have enough people in each sample then you might not be able to say anything**
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c. Is diversity equally important for very small studies?

- Yes. You want representation of everyone. Who could benefit from the research?
- Small studies can have limited funds- so perhaps a pilot study of one group and expand later. But is that ethical? Instead you could look for more funding.
- Rules of different IRBs may affect funding and related qualifications
- In writing policy- define what is reasonable to exclude
- Generalization of knowledge is directly related to selection criteria of study
- Methods- Male/female is not inclusive enough so set standards- suggested formats for questions
- Need to know they did their due diligence in population study and give reasons why population was selected. Should be somewhere in protocol study
- In templates include policy number for reference-> diversity worksheet- could be part of application
- Be explicit on what information should be provided
- Have a mandate of a diverse committee will help to ensure diversity in protocol/study/etc. (avoids unintended bias)
- Secondary review of diversity portion of study. Reviewers should have different perspectives
- Have to notice/address power differential- pressure can be problematic
- Able-bodyism-> ways for visually impaired/limited mobility to participate-> if asking about care-giver, care-giver can't be there
- Insured/not insured- even being insured can be very different.

ⁱ *Nature* 405, 208-211 (11 May 2000) | doi:10.1038/35012217

ⁱⁱ *Scientific American Magazine*, September 2014 Issue