

*Challenges and Solutions
from a Tribal IRB
Perspective;
Case Example of
Oversampling*



Objectives

- ▶ Ethical Principles and Guidelines for Research Involving Human Subjects
- ▶ Challenges of measurement from an IRB perspective
- ▶ Solutions of measurement from an IRB perspective
- ▶ A case example, the South Dakota Tribal Pregnancy Risk Assessment Monitoring System (PRAMS)



Ethical Principles and Guidelines for Research Involving Human Subjects¹

- ▶ A. Boundaries Between Practice and Research
- ▶ B. Basic Ethical Principles
 - 1. Respect for Persons
 - 2. Beneficence
 - 3. Justice
- ▶ C. Applications
 - 1. Informed Consent
 - 2. Assessment of Risk and Benefits
 - 3. Selection of Subjects



¹ The Belmont Report, <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>

Challenges

- Research vs. Practice
 - Harm has been done
 - Relevance questionable, focus of research oftentimes determined by others
 - Moratoriums may mean loss of benefits from research
 - Apprehension about publications contributing to limits of sharing AI/AN work, progress, efforts, ideas



Solutions

- Research vs. Practice
 - Participate in revisions to federal regulations to include tribal needs
 - Promote (require) community based participatory research
 - Enforce tribal rights and responsibilities



Solutions

- ▶ Requests for Applications – AI/AN inclusion
- ▶ AI/AN as researchers, peer-reviewers
- ▶ Oversampling
- ▶ Inclusion of AI/AN race
- ▶ Race classification verification



Solutions

- ▶ Variables
- ▶ Recruitment (mechanism)
- ▶ AI/AN as authors, analysts
- ▶ AI/AN benefits optimized



Respect for Persons

- ▶ Two ethical convictions:
 - that individuals should be treated as autonomous agents, and
 - that persons with diminished autonomy are entitled to protection



Challenges

- Respect for Persons
 - Individual vs. Family and Community decision-making
- Beneficence
 - Assessment of risk, benefits and harms not always from tribal perspective
- Justice
 - AI/AN inclusion (limited) in federally funded projects



Solutions

- Respect for Persons
 - Individual vs. Family and Community decision-making
 - Tribal oversight
- Beneficence
 - Assessment of risk, benefits and harms from the tribal perspective
- Justice
 - AI/AN inclusion in federally funded projects



Beneficence

- ▶ Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being
- ▶ Two general rules:
 - (1) do not harm and
 - (2) maximize possible benefits and minimize possible harms.



Measurement Background

- ▶ Small sample sizes (numerator)
- ▶ Denominator issues
- ▶ Inclusion of race
- ▶ Race categorization (AI only vs. AI + other(s))
- ▶ Racial misclassification
- ▶ Variables
- ▶ Recruitment (mechanism)
- ▶ Tribal variation
- ▶ Collapsing of AI/AN into “Other”



South Dakota Tribal Pregnancy Risk Assessment Monitoring System (SDT PRAMS)

»» *Hecel Oyate Kin Nipi Kte*
So That The People May Live



Table 1. Infant (<1 year), neonatal (<28 days), and postneonatal (28–364 days) deaths and average annual death rates by IHS Region for American Indians/Alaska Natives^{a,b}, compared to whites^a, Contract Health Service Delivery Area counties, United States, 1999–2009

Region	Age	AI/AN		White		AI/AN:White	
		Count	Rate ^c	Count	Rate ^c	Rate Ratio ^d	95% CI
Northern Plains	Infant	795	1,163.4	5,858	596.5	1.95 ^e	1.81–2.10
	Neonatal	377	551.7	3,903	397.4	1.39 ^e	1.25–1.54
	Postneonatal	418	611.7	1,955	199.1	3.07 ^e	2.76–3.42
Alaska	Infant	303	1,295.1	323	503.7	2.57 ^e	2.19–3.02
	Neonatal	111	474.4	177	276.0	1.72 ^e	1.34–2.19
	Postneonatal	192	820.7	146	227.7	3.60 ^e	2.89–4.50
Southern Plains	Infant	540	824.5	2,869	767.8	1.07	0.98–1.18
	Neonatal	268	409.2	1,721	460.6	0.89	0.78–1.01
	Postneonatal	272	415.3	1,148	307.2	1.35 ^e	1.18–1.54
Southwest	Infant	773	766.5	4,716	559.1	1.37 ^e	1.27–1.48
	Neonatal	391	387.7	3,131	371.2	1.04	0.94–1.16
	Postneonatal	382	378.8	1,585	187.9	2.02 ^e	1.80–2.26
Pacific Coast	Infant	404	888.4	8,381	522.6	1.70 ^e	1.53–1.88
	Neonatal	195	428.8	5,447	339.6	1.26 ^e	1.09–1.46
	Postneonatal	209	459.6	2,934	182.9	2.51 ^e	2.17–2.89
East	Infant	143	716.3	8,948	554.6	1.29 ^e	1.09–1.52
	Neonatal	62	310.5	6,139	380.5	0.82	0.63–1.05
	Postneonatal	81	405.7	2,809	174.1	2.33 ^e	1.85–2.91
Total	Infant	2,958	914.3	31,095	567.3	1.61 ^e	1.55–1.67
	Neonatal	1,404	434.0	20,518	374.4	1.16 ^e	1.10–1.22
	Postneonatal	1,554	480.4	10,577	193.0	2.49 ^e	2.36–2.63

SDT PRAMS

- ▶ A survey for mothers of young infants
- ▶ Questions about the mothers experiences, behaviors, health during pregnancy
- ▶ Goal: AI statewide and tribe-specific population-based surveillance data on pregnancy and early infancy

- ▶ 39 PRAMS funded across the US
- ▶ SDT PRAMS the first tribal-based PRAMS



SDT PRAMS Objectives

- ▶ To improve understanding of maternal behaviors and experiences and their relationship to pregnancy outcomes
- ▶ To develop new maternal and child health programs and to modify existing programs
- ▶ To influence public health policy at the tribal, state, and federal levels



SDT PRAMS Objectives

- ▶ To help health professional incorporate the latest research findings into their standards of practice
- ▶ To monitor progress toward tribal, state, and national health objectives and goals



SDT PRAMS Topics

- ▶ Nutrition, food security, and exercise
- ▶ Breastfeeding initiation and duration
- ▶ Attitudes and feelings about the pregnancy
- ▶ Barriers to and content of prenatal care
- ▶ Pregnancy–related violence
- ▶ Psychosocial support and stress
- ▶ Use of alcohol and tobacco before and during pregnancy
- ▶ Infant’s early development, health care, sleep position, and exposure to passive smoke



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