

Ethical issues in Epidemiological Research

Dr.Sriyakanthi Beneragama

MBBS,MD, Masters in Research Bio-ethics (Australia)

Consultant Epidemiologist, National STD/AIDS Control Programme,

Member, Ethical Review Committee, Faculty of Medicine, Colombo.

Types of Epidemiological Studies

- **Experimental Studies –Clinical trials, Field trials, Community Interventions and Cluster randomised trials**
- **Non-Experimental Studies- Cohort Studies (follow up studies/Incidence studies)**
 - Case –Control Studies
 - Cross – Sectional Studies (prevalence studies)
 - Ecologic Studies (unit of observation is a group of people vs. individual)

Hierarchy of Evidence

- Systematic Reviews and Meta Analysis
- Randomised controlled trials with definitive results
- Randomised controlled trials with non-definitive results
- Cohort Studies
- Case – Control Studies
- Cross – Sectional Surveys
- Case Reports

Some Important Epidemiological Studies in the Past

- Fluoride Supplementation in water – Community Intervention trial in 1940s, led to primary prevention of dental caries
- Framingham Heart study - Long term follow up studies in 1949, led to understand the Epidemiology of cardio -vascular mortality
- Salk vaccine field trial - in 1954 the largest formal human experiment ever conducted paved the way to prevent paralytic polio myelitis

Appropriate Study Designs for the Research Question

- Double blind- randomised controlled trials }
To address questions to do with drug treatment or other medical interventions
- Longitudinal cohort studies – questions about prognosis
- Cohort/ / case – control studies – questions about causation
- Case reports alerting – though methodologically weak, have a place in doctors to adverse drug reactions

“Concern for the interests of the subject must always prevail over the interests of science and society.”

Physicians’ Oath of the World Medical Association

Bradford Hill Criteria for Assessing Causality

- Strength of an association
- Consistency
- Specificity
- Temporal relationship
- Dose-response relationship (biological gradient)
- Biological plausibility
- **Coherence**
- **Reversability (experimental evidence)**
- **Analogy**

Possible Harms to the Individuals in a Study

- Loss of reputation or exposure to discrimination
- Emotional distress
- Fear
- Discomfort, embarrassment or shame
- Cause offence

Possible Harms to the Study Population/Community

- Disempowerment, make them feel inferior
- Add to harmful stereotypes
- Disappointment, feeling let down or misled
- Drained, overburdened or misled
- Loss of resources

Participatory Research

Involve communities themselves in the research questions and to link the research to their own development

- ✓ community consultation in protocol development
- ✓ appropriate information disclosure
- ✓ informed consent
- ✓ protection of confidentiality and right of dissent
- ✓ community involvement in the conduct of research

Participatory Research ctd.

- Community is transformed
 - by losing fear, gaining confidence, self esteem and direction
- Health promoting
 - by enhancing resiliencies that exists in the communities
- Assists self empowerment
 - by removing barriers

Minimisation of the Harm to the Study Participants

- **Consultation**
- **Justification**
- **Ownership of data and publication issues**
- **Community advisory group**
- **Budget**
- **Confidentiality**
- **Informed consent**
- **Prepare for the possibility of causing distress**

Tuskegee Syphilis Study



Blood work to
test for syphilis

Tuskegee Syphilis Study



Tuskegee, AL
Macon County

Tuskegee Syphilis Study



Spinal taps

Tuskegee Syphilis Study



Ends, Means, Subjects and Objects

There is a **danger** of reducing
research **subjects**
to research **objects**

- Be aware of the humanity in each person
- Treat persons as **ends in themselves** and never solely as **means to ends**
- Includes honesty, consent

Utility

- Make best use of scarce resources
- Research participants are a valuable resource not to be exploited
- Ensure value of the research question
- Ensure quality of method

Evaluation

Family study of resistance:

Background:

There are several small Aboriginal communities in Western Australia which have high exposure to Asbestos and yet very low levels of asbestos related diseases.

Purpose:

To find out if there is a genetic basis to resistance to asbestos – related disease

Method:

Blood samples from all members of exposed but unaffected families, investigations for genetic variation they have in common

Funding source:

Asbestos products Aust.Pty.Ltd.

Thank you