Becoming Involved in Research

Susan M. Fernandes, LPD, PA-C
Program Director
The Adult Congenital Heart Program at Stanford
Why should you engage in research?

• To contribute to moving science forward
• To receive the newest treatment
• To have the additional care and attention from the clinical trial staff
• To have an option for treatment when one doesn’t exist
• To help researchers find better treatments for others in the future
Participating in Clinical Research

• Why participate in ACHD clinical research?
  – The ACHD population can help us learn from the past and improve outcomes for a future generation of people with CHD.
  – Participation in ACHD research helps us better understand the cause of congenital heart disease which could lead to a cure or decrease in incidence.
Long –Term Complications

Arrhythmias
- Atrial
- Ventricular
- Sudden Death

Heart Failure
- Right and left
- Systolic
- Diastolic

Vascular lesions

Aortopathy

Valvular disease

PHT

Residual shunts

ACHD
Adult Co-Morbidities

- Atherosclerosis
- Systemic HTN
- Dyslipidemia
- Diabetes
- Obesity
- Sleep apnea
- Lung disease
- Hematologic disorders
- Renal dysfunction
- Liver disease
- Thyroid disease
- Psychiatric illness
- Cancer
- Maternal and fetal risk with pregnancy
Hospital Admission Rate
General Population vs ACHD

Age Groups (years)

Admission Rate (%)

- General population
- ACHD population

Verheugt CL et al. Heart 2010.96:872-78
Children and adults with congenital heart disease lost to follow-up

Only 40% still in CHD care

Overview

• Clinical research
  – Types of clinical research
  – Consent process
  – Participating in clinical research
  – Utilizing clinical research to drive clinical decisions
Types of Clinical Research

- **Observational**
  - Researcher is passive (observation)

- **Clinical Trial Design**
  - Researcher applies an intervention and examines the effect.

Hulley et al. Designing Clinical Research, 2013
Types of Clinical Research

• Cohort
• Cross sectional
• Case control design

Hulley et al. Designing Clinical Research, 2013
Types of Clinical Research

• Cohort
  – Observations are made in a group of subjects over time
  – Prospective: Studies that begin in the present and follow subjects into the future
  – Retrospective: studies that examine information collected over a period of time in the past

Hulley et al. Designing Clinical Research, 2013
Types of Clinical Research

Cohort Study Examples

Prospective cohort study
• The investigator measures fish intake in a group of subjects at baseline and periodically examines them at follow up visits to see if those who eat more fish have fewer coronary heart disease events

Retrospective cohort study
• The investigator retrospectively reviews the medical records of a group of subjects to see if the number of prior cardiac surgeries impacts the prevalence of cardiac arrhythmias

Hulley et al. Designing Clinical Research, 2013
Types of Clinical Research

• Cross sectional
  – Observations are made on a single occasion

• Example: The investigator interviews a group of subjects about current and past history of fish intake and correlates results with history of coronary heart disease.
Types of Clinical Research

- Case control design
  - Two groups selected based on the presence or absence of an outcome

- Example: Investigator examines a group of patients with coronary heart disease (cases) and compares them with a group who do not have coronary heart disease (controls), asking about past fish intake.
Types of Clinical Research

- Clinical Trial Design
  - Randomized versus non-randomized
  - Blinded versus unblinded
Types of Clinical Research

- Randomized and blinded: Two groups created by a random process, and a blinded intervention

Hulley et al. Designing Clinical Research, 2013
Types of Clinical Research

- Example: Investigator randomly assigns subjects to receive fish oil supplements or a placebo that is identical in appearance, then follows both treatment groups for several years to observe the incidence of coronary heart disease.

Hulley et al. Designing Clinical Research, 2013
Consent Process

• Investigators must obtain informed and voluntary consent from research participants
  – The nature of the research project
  – The procedures of the study
  – The medical, psychosocial and economic risks and potential benefits of the study
  – the alternatives to participating in the study
Exceptions to Written Consent

Waiver of Consent:
• When a study is difficult or impossible to carry out if informed consent were required from each participant.
• Very common with retrospective cohort study.

Implied Consent:
• Completing a survey
We can’t do clinical research without people who are willing to participate!!
Potential Breakthroughs
Participating in Clinical Research

• Read the consent form
• Risks and benefits
• Privacy protection
• Study withdrawal
• Study medications after trial
• Ask about compensation
Participating in Clinical Research

- Coercion
- Intimidation
- Emotional leverage
- Standard of care perception
Becoming Involved in Research

- ACHD team
- ACHA
- Visit Clinical Trials.gov
Clinical Research to Drive Clinical Decisions

• Where was it published?
  – Cardiology?
  – Peer reviewed?
• Who was the author?
• Original research versus review?
• What type of research design?
• What was the sample size?
• How homogenous was the study population?
Clinical Research to Drive Clinical Decisions

Don’t make care decisions based on something you have read until you discuss it with your ACHD specialist.
Thank You!