Community Based Participatory Research: The Role of Training in Research Conduct

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Outline

- Importance of training in research, but especially in CBPR
- Training as an ethical issue
- Training and recruitment and retention
- Introduce Tooth Smart Health Start (TSHS)
- TSHS Training Model
- "Job Aids"
- Training examples:
  - Human subjects protection
  - Informed consent
  - BRFQ

Why invest in training?

- Scientific validity
  - Standardization, reproducibility, reliability
- Basic study conduct
- Reporting requirements, investigator support
- CBPR:
  - Limited to no field supervision
  - Labor intensive
  - Larger numbers of field staff with varied backgrounds
  - More reporting requirements and less straightforward
  - Study designs may require increased subject participation
  - Staff need to be equipped to function as an extension of the investigators—their eyes and ears

Why invest in training?

- Ethical issues:
  - Protection of human subjects:
    - CBPR: The practice of protection can be more demanding
      - Consent process
      - Mandatory reporting
      - Safety
      - Confidentiality
  - Benefits of study to society can be diminished if data has minimized validity, reduction in risk-to-benefit ratio
  - Success (and benefit) of any study hinges on recruitment and retention

Why invest in training?

- Recruitment and Retention:
  - Informed consent is a PROCESS
  - Retention is often an exercise in trust and respect
    - Compensation
    - Time commitments
    - Perceived incompetence
  - CBPR: Word gets out!

Tooth Smart Healthy Start

- NIDCR-funded, cluster-randomized clinical trial investigating the effect of motivational interviewing conducted by Dental Health Advocates (DHA) on reducing dental caries among children 0-5 living in Boston public housing
- 26 Housing Sites in Boston, Brookline and Cambridge
- 2 years of follow-up
- Control group activities:
  - Dental assessments & Fluoride Varnish (FV) applications: every 3 months
  - Behavioral Risk Factor Questionnaire (BRFQ): baseline, 1yr, 2yr
- Intervention group activities:
  - Control group activities + MI visits from DHA every 3 months
  - Satisfaction questionnaire @ baseline, 1 yr, 2yr

Tooth Smart Healthy Start

Study Team:

- Investigative Team (3)
- Project Manager
- Project Coordinators (2)
- Research Study Assistants (2)
- Data Clerk
- Compliance Officer

- Field Staff (17):
  - Research Dental Hygienists (2)
  - Research Project Assistants (10)
  - Dental Health Advocates (5)

Tooth Smart Healthy Start

- Research Project Assistants (RPAs):
  - Responsible for:
    - Subject recruitment
    - Administering the informed consent process
    - Enrolling subjects
    - Administering the 60-minute BRFQ using interview format (data entry)
    - Charting the clinical data during the dental health assessment
    - Follow-up FV adverse event calls
    - Administer the satisfaction questionnaire to intervention participants (data entry)

Tooth Smart Healthy Start

- Field Staff Demographics (RPAs & DHAs):
  - 40% are current residents of Boston public housing
  - Race/Ethnicity:
    - 60% White, Hispanic
    - 27% Black, Non-Hispanic
    - 13% Asian
  - Education:
    - 53% High school/GED/Some college/Certificate program
    - 46% College degree
      - 29% currently enrolled in grad program
      - 14% graduate degree

TSHS: Training Model

- Conducted primarily by the investigative team
- Standardized training protocols developed and used
- Training sessions use a variety of participatory methods, typically conducted in groups
- Where possible, "job aids" are designed and implemented
- Certification process requires demonstration and competence determination is standardized
- Quality assurance protocols are implemented and ongoing competency is reviewed and documented
- Required, annual refresher trainings

TSHS: Training Model

GOAL	METHOD	REINFORCEMENT
Theoretical Framework	Lecture/Discussion	Neighbor demonstrations
Task Content	Group Activity	Pop "quizzes"
Implementation	Shadowing, Modeling, Role-playing	Peer critiques, trainer feedback, job aids
Competency	Practice tapes	Tape reviews
Maintenance	Job Aids, Monitoring, QA	Re-training

"Job Aids"

- "Devices or tools (e.g. instruction cards, memory joggers, wall charts) that allow an individual to quickly access the information they need to perform a task." (www.businessdictionary.com)

Ask the task.		
How frequently performed?	Often <————> Rarely
How many steps?	Few <————> Many
Difficulty of steps?	Easy <————> Hard
Impact of error?	Trivial <————> Serious
Likelihood of task changing?	Low <————> High

- The more answers tend to be to the right, the more sense it makes to build a job aid.

Source: http://www.daveswhiteboard.com/wp-content/uploads/2012/02/job-aid-part-2-ask-the-task.jpg

"Job Aids"

- A way to insert investigator oversight or "investigator voice" into the field
- Extends the training environment into the field
- Eases anxiety related to job performance
- Faster transition times from training to field
- Relieve burden on employee who has multiple responsibilities
- Increase standardization in job performance
- Helps to keep large teams organized
- Manages drift
- Facilitates quality assurance

Quality Assurance

- Annual refreshers on everything
- 6-month quality assurance monitoring
  - QA tape in the field, randomly selected
  - Competency checklist
- Triggers for retraining
  - Changes to the instrument or protocol
  - Problems identified through monitoring of forms and data
  - QA tape doesn't reach competency requirements

Training Examples

- RPA Trainings:
  - Human Subjects Protection
  - Informed Consent Process
  - Behavioral Risk Factor Questionnaire (BRFQ)

Human Subjects Protection

- NIH/CITI training not easily translatable
- Format: Lecture/Discussion
- Content: What constitutes research, when and why it involves human subjects, and why and how participants need to be protected
  - All content is catered to provide understanding of TSHS in the context of the Belmont principles
- Evaluation: Completion of a post-test
- Benefits:
  - Most foundational training that is referenced throughout all other trainings
  - Assists in understanding of how study design and conduct (future tasks) is with human subjects protection in mind
  - Allows for additional focus on issues of importance in CBPR (e.g. confidentiality)

Informed Consent Process

- Session 1:
  - Format: Group discussion/Activity
  - Content:
    - Review the ethical requirement for informed consent
    - Develop strong knowledge and understanding of the study purpose, design, procedures and documentation
    - Develop familiarity with task content (ICF, job aids)
    - Discuss and model appropriate behavior and interaction during consent process including word choice, tone of voice, facial expressions and body language
    - Model of consent process provided
  - Homework:
    - Practice consent materials out loud
    - Get comfortable with content

Informed Consent Process

- Session 2:
  - Format: Role-playing
  - Content:
    - Group role-playing exercises and peer critiquing
    - Implementation of job aids
    - Practice makes perfect
  - Homework:
    - Practice

Informed Consent Process

- Certification:
  - Complete a practice tape
  - Achieve competency on certification checklist
- Quality assurance:
  - Complete QA tape in the field every six months
  - Maintain competency

CERTIFICATION CHECKLIST

1. Introduction
☐ Goal: To prevent dental cavities.
☐ What is dental decay?
☐ Dental decay can be prevented.

2. Background
☐ Explanation of Fluoride Varnish
☐ Explanation of Dental Screening (including use of a plastic mirror and small light)
☐ Description of Dental Health Advocates (DHAs)

3. Purpose
☐ Goal of study: To see if counseling parents, along with FV and dental screenings will pr

4. What happens in this research study?
☐ Explanation of two groups
☐ Mention of random assignment
☐ Discussion of timeline for FV and dental screenings
☐ Discussion of timeline for DHA visits
☐ Mention of study duration of 2 years

5. General Study Activities: Preventive Dental Visits
☐ Mention that dental hygienist will record dental information (including use of a plastic small light if not mention previously).
☐ Description of audio-taping for dental screening
☐ Description of FV allergy

Informed Consent Process

- Job Aids
  - Tracking Card
  - ICF Placards

Tooth Smart HEALTHY♥START IMPROVING CHILDREN'S HEALTH THROUGH DENTAL HEALTH	Study Activities				
	Baseline	3 Month	6 Month	9 Month	12 Month
Questionnaire					
Dental Screening/ Fluoride Varnish					
Dental Health Advocate					
$40 Gift Card & Satisfaction Survey					
If you have any questions, would like to schedule your next appointment, or have a new phone number to share with us, please call us at (617) 414 - 1177					

Behavioral Risk Factor Questionnaire

- Session 1:
  - Format: Group discussion/Activity
  - Content:
    - Review the study context for the BRFQ
    - Interviewing techniques
    - Importance of standardization
  - Homework:
    - Critical review of instrument:
      - What do questions mean? Purpose?
      - Words that might be confusing?
      - Ways to reword without changing meaning?

Behavioral Risk Factor Questionnaire

- Session 2:
  - Format: Role-plays/Pop "quizzes"
  - Content:
    - Review of Homework #1
    - Begin reinforcement of content through selected role-plays
    - Introduce job aid
  - Homework:
    - "Stalk your neighbor"

Behavioral Risk Factor Questionnaire

- Session 3:
  - Format: Role-play, peer critiques, modeling
  - Content:
    - Review of Homework #2
    - Implement job aid
    - Practice makes perfect!

Behavioral Risk Factor Questionnaire

Behavioral Risk Factor Questionnaire

- Certification:
  - Complete a practice tape
  - Achieve competency on certification checklist
- Quality assurance:
  - Complete QA tape in the field every six months
  - Maintain competency

CERTIFICATION CHECKLIST {BRFQ}

MODULE 1: Child Sociodemographics
- ☐ Directions provided verbatim.
- ☐ #2: Correct skip pattern applied.
- ☐ Directions related to race/ethnicity provided verbatim.
- ☐ #3: Assessment of whether all applicable races for the child have been select

MODULE 2: Health and Access
- ☐ Directions provided verbatim.
- ☐ Correct application of skip pattern for child's age.
- ☐ If applicable, #2-7:
  - ☐ Directions provided verbatim.
  - ☐ Time frame, "often" and "bothered" emphasized.
  - ☐ Skip patterns correctly applied.

MODULE 3: Insurance
- ☐ Directions provided verbatim.
- ☐ #1: Correctly apply skip pattern.
  - ☐ If applicable, #1a: Assess whether all that apply have been selected.
- ☐ #2: Correct skip pattern applied.
  - ☐ If yes, skipped to #5.
  - ☐ If no, continued with #3.
    - ☐ Clarifies time frames in responses IF necessary.
- ☐ #5: Provided FV prompt prior to question.

Questions?