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

IMPROVING CHILDREN’S HEALTH THROUGH DENTAL HEALTH
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

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<th>GOAL</th>
<th>METHOD</th>
<th>REINFORCEMENT</th>
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<td>Theoretical Framework</td>
<td>Lecture/Discussion</td>
<td>Neighbor demonstrations</td>
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<td>Task Content</td>
<td>Group Activity</td>
<td>Pop “quizzes”</td>
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<td>Implementation</td>
<td>Shadowing, Modeling, Role-playing</td>
<td>Peer critiques, trainer feedback, job aids</td>
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<td>Competency</td>
<td>Practice tapes</td>
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<td>Job Aids, Monitoring, QA</td>
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“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)

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

“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
Informed Consent Process

- Job Aids
  - Tracking Card
  - ICF Placards

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<th>Study Activities</th>
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<th>6 Month</th>
<th>9 Month</th>
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<td>Dental Screening/Fluoride Varnish</td>
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<td>Dental Health Advocate</td>
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<td>$40 Gift Card &amp; Satisfaction Survey</td>
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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