Recruitment & Consent of Women with Intellectual Disabilities in a Randomized Control Trial/Health Promotion Study

Susan L. Parish, PhD, MSW
Nancy Lurie Marks Professor of Disability Policy
Director, Lurie Institute for Disability Policy

October 2011
Background

- Women with developmental disabilities have among the worst rates of cervical and breast cancer screening in the United States
- Our focus: Empowering women to be informed, assertive patients
**Women Be Healthy intervention**

- Intervention designed to improve women’s knowledge and empowerment related to cervical and breast cancer screening
- Eight classes include hands-on experiential learning, field trip to GYN office, focus on empowerment AND knowledge
  - How to assert needs and ask questions with health care provider
  - How to describe symptoms
  - How to relax for stressful procedures (particularly pelvic exam)
- Schedule of recommended procedures

*Women Be Healthy* used with ~500 women with intellectual disabilities

Satisfaction reported in initial pilot testing
Study Design

- Randomized control trial (wait-list controls)
- 21 sites across North Carolina
  - Community rehab programs
  - Community colleges
  - Other disability service provider organizations
- Pre-test, post-test interview design
- Computer-assisted interviews
- Randomized sample at each site
- Curriculum taught by on-site instructors who were not members of the research team (5 hrs of training provided)
- Interviewers did not know the status of the participants
- Post-test interviews mean of 13 days after intervention
Challenges

- How do we ethically enroll women with developmental disabilities in health promotion research?
  - Erroneous assumptions that they cannot consent
  - Erroneous assumptions that their consent is not necessary
  - Research literature is replete with examples of proxy consent
Approach to Recruitment

- Open information sessions at community partner sites for potential participants, guardians, staff
  - In practice, few guardians attended
- Research team:
  - Played video that depicted *Women Be Healthy* activities & included interview with former participant
  - Explained study purpose & research studies in general
  - Explained consent forms
  - Used numerous pictures; designed for people with limited literacy
  - Assisted with signing the consent forms
  - Did not permit on-site staff to “help” women to sign consent forms
- AFTER a consented, her guardian was contacted for consent as well (if necessary)
Description of the Sample (n=203)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Percent of Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race is Black(^1)</td>
<td>47%</td>
</tr>
<tr>
<td>Lives alone or with partner</td>
<td>8%</td>
</tr>
<tr>
<td>Lives in formal residential setting</td>
<td>42%</td>
</tr>
<tr>
<td>Lives with family caregiver</td>
<td>50%</td>
</tr>
<tr>
<td>Age (mean)</td>
<td>40 years</td>
</tr>
</tbody>
</table>

\(^1\) <2% of the sample were Latina, Asian or Native American
Consent & Enrollment by Guardianship Status

<table>
<thead>
<tr>
<th>Guardianship Status</th>
<th>Consented</th>
<th>Did not Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Independent</td>
<td>86%</td>
<td>14%</td>
</tr>
<tr>
<td>Has Guardian</td>
<td>83%</td>
<td>17%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Guardianship Status</th>
<th>Enrolled</th>
<th>Did not Enroll</th>
</tr>
</thead>
<tbody>
<tr>
<td>Independent</td>
<td>86%</td>
<td>14%</td>
</tr>
<tr>
<td>Has Guardian</td>
<td>61%</td>
<td>39%</td>
</tr>
</tbody>
</table>

No statistically significant group differences at consent; Significant differences in enrollment (Chi-square = 21.13; p<.001)
Discussion

- This process (required by IRB and the community partners) disempowered women who wanted to participate but were not their own guardians.
- We felt that seeking consent or assent *first* from the women with disabilities was critical to empower them to choose to participate or not.
- We felt that consent rates <100% (achieved at all sites) was a success and indicative that we were not coercive.
- Obtaining consent from guardians was challenging.
- We do not know the reasons guardians did not consent; anecdotally, we heard that the content was objectionable.
Thank you!

Co-authors: Jamie Swaine, Karen Luken, Lindsay Atkins at UNC-Chapel Hill
Funders: US Department of Education, NIDRR, Grant # H133G090124; North Carolina Office on Disability & Health; Lurie Institute for Disability Policy at Brandeis University; NC Department of MH/DD/SAS