



Inclusion in Research: Benefits and Strategies for Supporting Individuals with ID to Participate

AUCD

CORE/COCA Webinar – 10/24/16



We will discuss

- Historically, many abuses of people with disabilities in research, including lack of disclosing research problems to federal authorities (Sundram, 1998)
- Historically, devaluation in the conceptual images of people with disabilities and possible effects on research
- Now these images are transforming into a conceptual model of disability as a “natural part of human experience” (IDEA 2004)
- Inclusion has been incorporated into many aspects of society, but does not, however, appear to have reached research
- Organization of supports, strategies, and materials to support participation and consent
- Some recommendations and future resources

Examples of historical abuse

- Nazi atrocity “experiments”
- Willowbrook State School: intentional infection with live hepatitis virus to follow progression and test vaccine, parents told they were receiving vaccines, and the “experiment” was the only way of admission
- Fernald School, MA: ingestion of radiation by children with intellectual disability in exchange for milk, trips to baseball games, and dinners on the outside

Some protections against research abuse

- **Nuremburg Code** (1947/1949) – established standard of allowing human research only when direct voluntary consent is obtained
- **Declaration of Helsinki** of the World Medical Assembly (1964) – lessened the strict requirement for direct consent and allowed proxy consent in some cases if there was an expectation of direct benefit to the individual
- **Belmont Report** of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979) identified three fundamental ethical principles
 - Respect for persons – autonomy and protection – consent includes information, capacity, voluntariness
 - Beneficence – researcher’s duty to act with kindness and charity to enhance well-being
 - Justice – fairness in distribution of benefits and burdens of research, all people treated fairly, equality of all
- 1981 - **45 C.F.R. 46**, and 21 C.F.R. 50
- **Ethical and moral behavior** by researchers
- Knowledge, **research collaboration**, and self-advocacy by families, surrogates, and children with disabilities
- Excellent **guidelines** by professional organizations
- Excellent **conduct** by IRBs

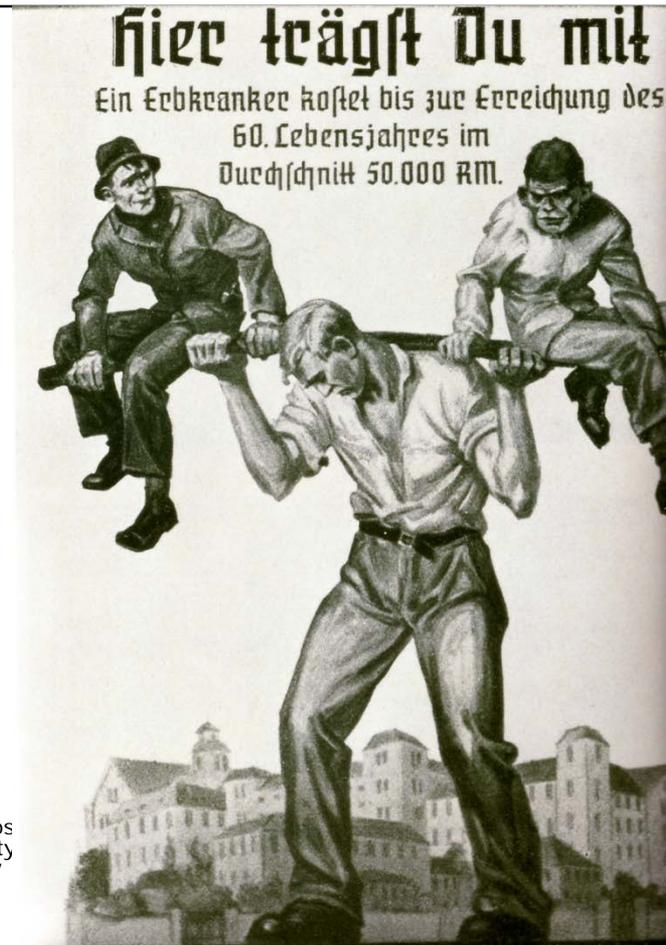
Balance the need for relevant new knowledge, inclusion, and risk



Historical images of disability

- “Totally incompetent”
- “Holy innocent”
- “Dangerous”
- “Pathetic”
- “Sick”
- “Alien”
- “Demonic”
- “Vegetable”
- “Living in an institution”

“You are sharing the load! A hereditarily ill person costs 50,000 Reichsmarks on average up to the age of sixty (From high school biology textbook.) Source: Deadly Medicine, 2004, p. 126



These devaluing historical images may underlie continuing unjustified exclusion from research and must be challenged

- *Totally incompetent*: “Cannot assent”
- *Holy innocent*: “Cannot care about everyday concerns like evidence-based practices”
- *Dangerous*: “Cannot safely associate with other subjects”
- *Pathetic*: “Cannot contribute”, “Cannot stand the stress of intervention”
- *Sick*: “Cannot meet study eligibility”, or “Nothing will help”
- *Alien*: “Will cause irrelevant results” “Will mess up my protocols”
- *Demonic*: “Must be locked away”
- *Vegetable*: “Cannot answer coherently”
- *Living in an institution*: “Not a part of society”

New conceptual model: “Natural part of the human experience”

- Disability is a natural part of the human experience, and exclusion denies an important part of humanity (See, e.g., IDEA 2004)
- Exclusion of individuals with ID may cause research results to be non-representative, non-generalizable
- The experiences of people with ID and their families are relevant and should be valued
- If the topic is “mainstream research”, they are part of the mainstream!
- “Nothing about me without me” (See e.g., Mactavish, Mahon, & Lutfiyya, 2000)



How is research used? Do these uses affect the lives of people with intellectual disability?

- Assessment
- Clinical care
- Legal and policy actions, e.g. education, living, employment
- Advocacy activities, and
- To further scientific inquiry

Why it is important to include people with ID in some research?

- Research results otherwise may not be representative of the general population
- Demonstrated human need of people with ID for research-based practices, i.e. identification is based on extent of difference from average, higher rate of co-occurring problems, recipients of many “developmentally and clinically-appropriate” interventions
- Extrapolation of general results may deny the unique needs of people with ID
- Differential effects: Efficacy and risks may be different
- Justice is enhanced when people with ID receive adequately evaluated practices
- May be unfairly excluded from beneficial practices
- Provides an opportunity to contribute to science and be respected for contribution to society
- Embodies their mutual “stake” in society
- May reduce the damaging perpetuation of unjustified societal exclusion (See also, Dresser, 1996; Yan & Munir, 2004)



The transition to include previously excluded groups

- Women
- Members of minority groups
- Older adults
- Children

Movement to include women and minorities

- In 1994 the NIH published its "Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research". These guidelines recommend that women be included in all biomedical and behavioral research:

“It is the policy of NIH that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.”

Movement to include older adults: The example of FDA and AHRC

- Agency for Healthcare Research and Quality, US DHHS. (2003). AHRQ policy on the inclusion of priority populations in research.
- US Government Accountability Office (2007). Prescription drugs: FDA guidance and regulations related to data on elderly persons in clinical drug trials (GAO-07-47R). Washington, DC.

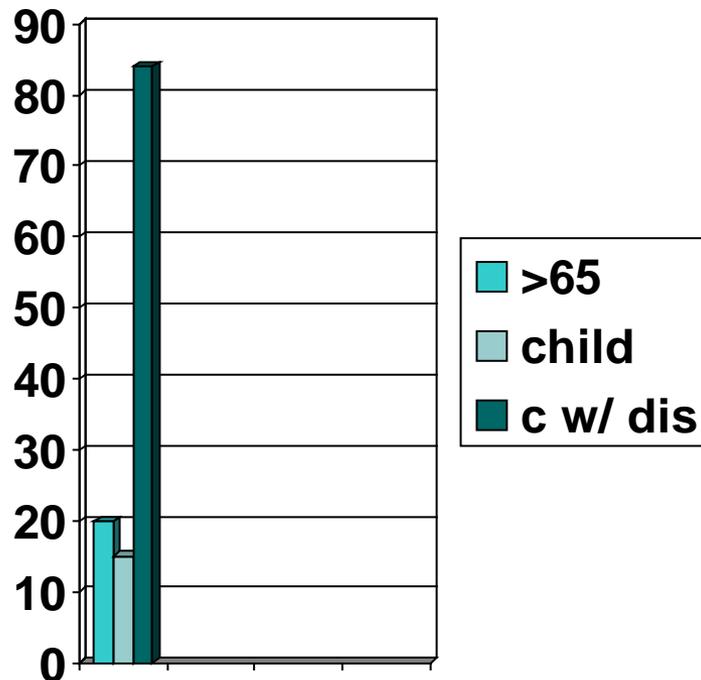
Movement to include older adults: Review by Zulman et al. (2011)

- However:
- Of 109 clinical trials published in 2007 (in JAMA, NEJM, Lancet, Circulation, BrMedJ) 20% excluded patients above a certain age, and almost ½ of the remaining used criteria that disproportionately exclude older adults.
- Conclusion: In our aging population, evidence could be improved by
 - eliminating upper age limits
 - reducing eligibility criteria that disproportionately exclude multimorbid older adults
 - Include outcomes that are more relevant to older adults such as functionality.

Movement to include children: The example of NIH

- US Congress urged more pediatric research by NIH (FY 1996)
- NICHD and AmAcadPeds, in a sample of NIH sponsored clinical research, found that 10-20% of studies inappropriately excluded children (1996).
- The NIH research policy of 1998 “The goal of this policy is to increase the participation of children in research so that adequate data will be developed to support the treatment modalities for disorders and conditions that affect adults and may also affect children.” (1998)
- “If children will be excluded... proposal must present an acceptable justification for the exclusion.” (1998)

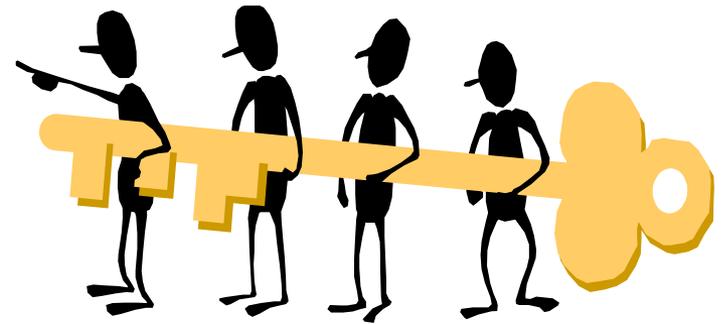
Exclusion of Children with Disabilities from Research



- >65, Zulman, 2011 (sample JAMA, NEJM, Lancet, Circulation, BrMedJ, 2007)
- Children, 1996 (NICHD and AmAcadPeds, sample of NIH sponsored clinical research, 10-20% of studies inappropriately excluded children)
- Feldman & Luckasson data, 2011 (84% unjustified exclusion of children with disabilities, sample CD, DP 1996-2010)

Accommodations in designing research

- Build relationships with families of children, including with disabilities
- Create a collaborative research team that includes families and individuals with disabilities
- Provide opportunities for shared selection and exploration of important questions



Practical ways to get truly informed consent

- Recruit through a self-advocacy organization if possible—provides support and credibility
- Less chance for coercion than recruiting through families or service providers



Go over elements of consent

- Discuss what “informed consent” means
- Why you are doing the research—what you hope to learn
- Why the research is important
- Who you are and why you want their participation
- How many people will be part of the research



Elements of consent (continued)

- What the benefits are of taking part in the research
- What will happen
- Risks or discomforts
- Other things they can do that would be less risky (alternative treatments or procedures)



Elements of consent (continued)

- How you will protect their privacy
- What will happen if they are injured
- Who they can call for questions and concerns
- Is the research completely voluntary?
Are they really making their own choice?
- Can you decide to drop them from the research? Why?



Elements of consent (continued)

- Will there be any costs to them for participating?
- What if something changes in the research?
- Who signs the consent? Does the participant have a guardian?
- Assent



Accommodations in consent/assent

- From the beginning, consider all research communication, e.g., clear, accessible, multimodal
- Support communication with pictures, videos of the process, explanations, etc.
- Periodically check for understanding
- Break the assent into pieces
- Teach the skills needed to provide genuine assent
- Document assent in ways that the individual can produce and understand, e.g. consent forms that include pictures, are printed in Braille, capture the child's agreement in a way that is comfortable for him/her





Conclusion

- People with disabilities can and should participate in research for human rights, societal, and scientific reasons
- Strategies and materials can be used effectively
- Engage all people – it may be a valued experience with benefits such as an opportunity to contribute, increased self esteem new social contacts, and supporting societal inclusion
- Consider a well thought-out balance regarding strategies, possible vulnerabilities, potential benefits, and reasonable accommodations
- Collaboration is required among individuals and families, researchers, advocates, government watchdogs, community agencies, and IRBs

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Thank you

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NOTHING ABOUT US WITHOUT US: Including People with Intellectual and Developmental Disabilities in Research

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October 24, 2016
AUCD Webinar



Institute on Disabilities



Institute on Disabilities

Pennsylvania's University Center for Excellence
in Developmental Disabilities

Education, Research and Service

VISION

A society where all people are valued and respected, and where all people have the knowledge, opportunity and power to improve their lives and the lives of others.



MISSION

The Institute on Disabilities at Temple University learns from and works with people with disabilities and their families in diverse communities across Pennsylvania to create and share knowledge, change systems, and promote self-determined lives so that disability is recognized as a natural part of the human experience.

Inclusion and Empowerment of Youth and Families in Participatory Action Research

- Transition Discoveries
 - PA DD Council Project
 - Fourth year



Overarching Goals

- Engage transition stakeholders resulting in the identification of key components and strategies leading to successful transition
- Develop tool as a measurable means by which to monitor transition progress to inform systems change: *Quality Indicator Assessment Instrument*



What do *we* mean by inclusive research?

- More equally shared and more democratic
- More inclusive of people with intellectual disabilities across different stages of the research
- Often called ‘participatory’ or ‘emancipatory’
- Research that matters to people, involves them, and respects them.

(Nind, 2014; Nind & Vinha, 2014; Walmsley & Johson, 2003)

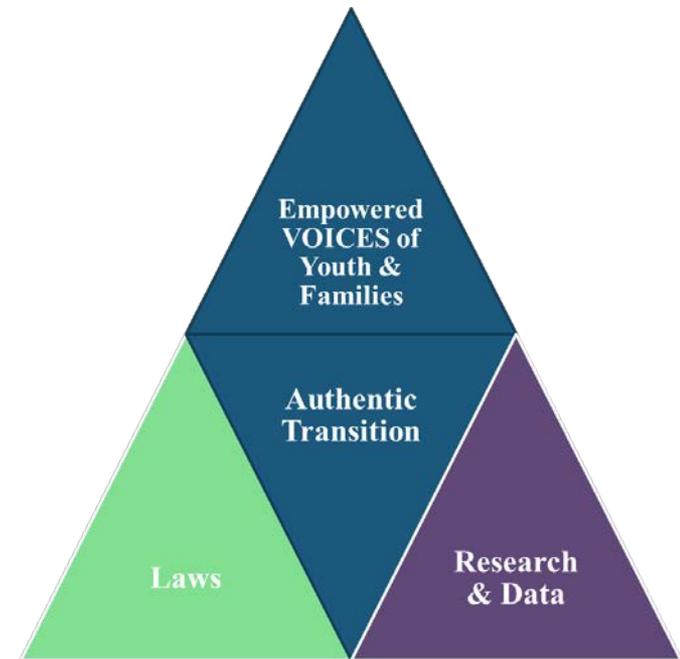
PAR Methods

- Give “Genuine Voice” both within the project (PAR) and throughout the project
- There is growing attention to the use of participatory action research (PAR) methodologies, with involvement of constituents at all levels (Burstein, Bryan, & Chao, 2005; Power, 2002; L. E. Powers, 2006; Small, 1995).
- ***Traditionally, research informs practice. However, this research project engages youth, families, and transition stakeholders as informants.***
- ***What are the potential challenges to engaging youth, families, and transition stakeholders in the research?***
- ***What are the potential benefits?***



Benefits of PAR Methodology

- Identification of “what’s working” from a broader community perspective based upon the authentic voices of youth, families, and transition stakeholders.
- Evidence that PAR empowerment research with persons with disabilities, may result in increased skill development, self-reliance, empowerment, and social and policy change (Burstein et al., 2005; Stewart & Bhagwanjee, 1999; Suarez de Balcazar, Fawcett, & Balcazar, 1998).



PAR Principle #1

Builds on strengths and resources within the community

- Advisory Board members include youth with disabilities, parents and family members, community members, transition professionals
- Focus groups with key stakeholders
- Sessions at PA Transition conference in 2014, 2015, and 2016 to get feedback from stakeholders before new phase
- Working together with PaTTAN, Lehigh Valley CIL on “transition regional sessions”



Focus Group – Authentic Dreams and Goals

Youth	40
Family	48
Total Participants	88
Total captured audio	Over 15 hours

Focus Group – Successful Transition Practices

Youth	79
Family	44
Professionals	292
Total Participants	238
Total captured audio	Over 26 hours

PAR Principle #2

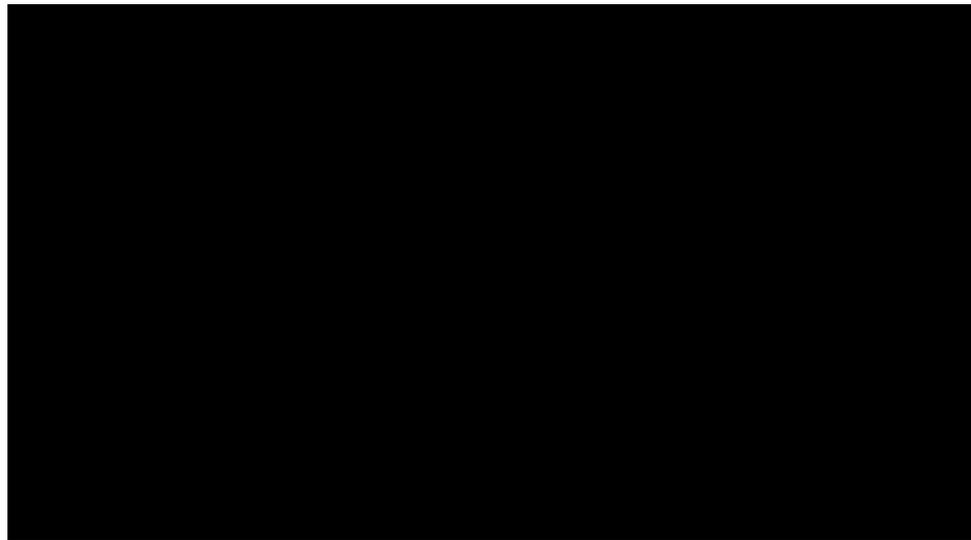
Facilitates collaborative partnerships in all phases of the research

- Inclusion in all phases of research
 - Grant proposal/development of project goals
 - Research protocol development
 - Focus group procedures and questions
 - Target audiences and comfortable locations
 - Ideas about incentives
 - Marketing and dissemination
 - Data gathering
 - Data analysis
 - Project reports



PAR Principle #3

**Integrates knowledge and
action for mutual benefit of
all partners**

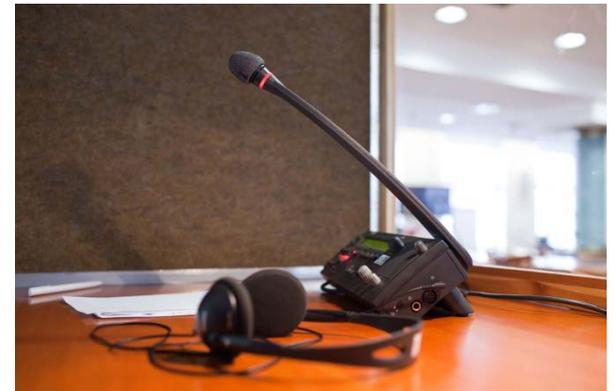


[PYLN leader reviews phases of TD project](#)

PAR Principle #4

Promotes a co-learning and empowering process that attends to social inequalities

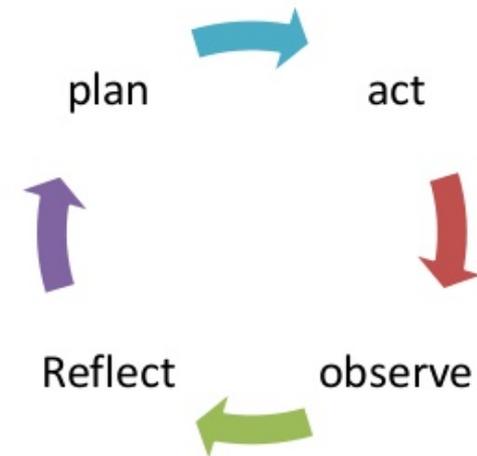
- We as researchers learn from the knowledge and theories of the community members involved
- Community members acquire further skills in how to conduct research
- Finding accessible locations, limitations to those
- We are all learning about how social inequality gets upheld through research
- Simultaneous translation of focus group to promote linguistic competency of project and highlight how other projects/institutions may not be addressing same need



PAR Principle #5

Involves a cyclical and iterative process

- Projects support growth and development of PYLN
- Maintaining grounded theory approach
- Utilizing advisory committee and PYLN to analyze thematic data in order to then (re)create next round of themes to explore
- Translational = working with/disseminating info to state systems in real time



PAR Principle #6

Disseminates findings and knowledge gained to all partners

- Project reports at various types of outlets/by various stakeholders
 - DD council reports
 - State meetings
 - AUCD
 - AAIDD
 - PA Transition Conference
 - State legislative expo
 - GW Transition program coursework
 - PYLN youth leadership events



Guideline One: Who or what are we trying to *understand*?

- Question: Are our inclusive research efforts focused on fixing marginalized people or on fixing the **inequitable conditions and structures that marginalize people?**

Guideline Two: Does our work mitigate or transform?

- Question: Are our inclusive research efforts a threat to the existence of injustice or do they merely mitigate the symptoms of injustice?

Guideline Three: Are we dancing around or digging in?

- Are our inclusive research efforts contributing to the *permanent* redistribution of access and opportunity or leaving the current distribution in place and helping marginalized people be more comfortable as *marginalized* people?

Guideline Four: Who are the experts?

- Are our inclusive research efforts based in collaborations with marginalized people deferring to their expertise? Are we working “on” marginalized people or “with” marginalized people?

(adapted from Gorski, et.al, GMU)

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