A Goodness-of-Fit Ethic for Evidence Based Developmental Interventions

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Evidenced Based Practice & Developmental Science

- "The integration of the best available research with clinical expertise in the context of patient characteristics, culture, and preferences" *APA, 2005*
- "The systematic synthesis of research and applications to promote optimal developmental outcomes in the context of stakeholder characteristics, culture, & preferences"

EBP Mission

- "Prepare, maintain & make accessible systematic reviews of the effects of interventions so as to inform precedent and inauguration (Boruch)

Beneficence & NonMaleficence

As the potential for developmental science to promote the welfare of children and families increases so does the potential to unintentionally inflict harm:

- Ill-informed social policies
- Group stigmatization
- Direct harm to individual participants

Beneficence & Scientific Validity

- To be of benefit, an "experiment should be such as to yield fruitful results for the good of society"

Nuremberg Code, 1946

Scientific Validity & Developmental Science

- Scientific principles
  - Systematic collection of reliable and objective information

Campbell Collaboration Evidence Grading Scheme (EGS);

- Multidisciplinary & Multi-Contextual Knowledge & Methods
  - Knowledge of biological, physical, interpersonal, cultural, & historical factors relevant to desired outcomes
  - Multidisciplinary & multi-contextual methods of assessment (Boruch)
  - Co-morbidity (Weisz)

Dynamic Nature of Development

- Temporality of change

  - Change produced by interventions at one point in the life cycle may be only temporary; Weisz "Do treatment effects last?"
  - Research most useful for practice & policy -- will consider short-term and long-term outcomes--including the need for developmental boosters.
  - "Treatments are designed to be linear but problems are not" Weisz recommends a modular approach

Internal, External, & Ecological Validity

- Efficacy-Effectiveness Studies
- Standardized Vs. Clinical/Educational/Services Practice
- Evidence Based Assessment (needs & outcomes)

(Weisz)

Goodness of Fit Ethics

- Research benefits can be maximized and harms minimized by analysis of characteristics of participants and experimental methods that may conjointly reduce or exacerbate research vulnerability.
- Fitting research procedures to participant characteristics will maximize scientific advancement and the protection of participant and social welfare.

Weisz Specificity of Treatment Effects

Goodness of Fit Intervention Design & Evaluation

Bidirectionality

- Research and theory guide intervention strategies
- Evaluation of interventions & policies inform theory & future research

Intervention Goods Who decides?

"Public health is what we, as a society, do collectively to assure the conditions in which people live can be healthy." IOM 1988

"Public health is primarily concerned with the health of the entire population, rather than the health of individuals"

Childress et al (2002) *J Law, Medicine & Ethics*

Gatekeepers & Stakeholders

- Policy Makers
- Funders
- Investigators
- Communities
- Service Providers
- Family Members
- Participants

Role of Gatekeepers & Stakeholders

- Identify problems in need of investigation
- Ecological validity of:
  - *Hypotheses*
  - *Data interpretation*
  - *One "size fits all" risk prevention & development promoting programs*
- Feasibility & Sustainability of:
  - *Manualized treatment*
  - *Standardized teaching*
- Individual and group harms

Why have practitioners not adopted EDPs? (weisz)

We need to fit intervention research to:

- The need for treatment options recognizing stakeholder disagreements (parent-child-therapist)
- Co-morbidity
- Standardized vs. Clinical Methods
- With practitioner competence & possibilities for training
- Need for easily accessed information (Campbell Corporation)

Stakeholder Knowledge and Goals

INVESTIGATOR

- Apply & Generate Knowledge
- Scientific method
- Testable hypotheses,
- Range of ethical procedures available to protect participant rights and welfare
- Continued research support

SPONSORS & POLICY MAKERS

- Fiscal Priorities
- Political priorities
- Timing priorities
- Obligations to constituents outside the participant community

PARTICIPANT COMMUNITY

- Health priorities
- Cultural values
- Fears and hopes about the general or specific scientific enterprise
- The real world context in which hypotheses will be studied

PRACTIONE RS

- Employment concerns
- Intervention skills & preferences
- Training needs
- Fears & hopes about the consequences of evaluation
- Understanding of the real world context in which hypotheses will be studied

Goodness of Fit & Stakeholder Perspectives

- Mutual investment in scientifically valid and ethically conducted studies
- Different perspectives on the value, validity, risks and potential benefits of research.
- The responsible conduct of research is informed by and implemented through a fitting of these mutual goals and different perspectives.
- Goodness of fit is achieved through a process of *co-learning* among stakeholders

Which stakeholder represents the primary ethical relationship?

- Participants: Protection of autonomy & privacy, welfare
- Science: Threats to scientific validity
- Practitioners: Privacy protections, respect for professionalism, training
- Community: Social value, community stigma, &sustainability
- Sponsors & Policy Makers: Feasibility & accountability

Goodness of Fit Ethics

- Ethical Commitment to do the right thing
  "Minimizing bias" (Campbell Collaboration)
- Ethical awareness to identify ethical challenges among stakeholder needs
- Ethical competence to generate alternative solutions to balance ethical priorities

Goodness of Fit & Nonmaleficence

- Resist pressure to conduct studies that serve the wishes of the majority society at the expense of participant population needs
- Resist societal or policy pressures to draw conclusions about cause-effect relationships that go beyond the data
- Avoid confusing economic, multilevel or process limitations of an intervention strategy with limitations of populations served
- Evidence that an intervention is ineffective serves society as well as evidence of intervention effectiveness (both new interventions & treatment as usual)

Justice

- Children and families should have equal opportunities to share the benefits and burdens of intervention research

Scientific Validity through a Cultural Lens

- Race, Ethnicity & Culture
  - Definition
  - Fluidity
  - Identity
- Panethnic categories
- Population Generalizability
- Within group differences

Goodness of Fit

- ✓ **Describe theory & evidence for definitions of race, ethnicity, or culture**
- ✓ **Avoid panethnic terminology**
- ✓ **Consider within group differences**
- ✓ **Justify the use of comparative designs**
- ✓ **Select/construct measures with psychometric evidence of cultural validity/equivalence**
- ✓ **Consider the effect of racial discrimination**
- ✓ **Study coping & resilience**

EXPERIMENTAL & CONTROL GROUPS

- Equipoise

"There is a state of honest disagreement in the community of experts as to the preferred intervention"

- Control Groups
  - *Local vs. Best Practices*
  - *Ethnic & class disparities in access to services*
- Longitudinal Studies
  - *Cannot provide effective intervention at end of study*
  - *Discourage individuals from seeking services*
  - *Sustainability*

Informed Consent

How can investigators:

- Respect the dignity and autonomy of vulnerable participants to consent to intervention research *and*
- Insure that ill-informed or incompetent choices do not jeopardize their welfare or leave them open to exploitation?

Goodness-of-Fit

- Identifying Vulnerability

  Which characteristics of the individual and research context render participants more or less susceptible to consent misunderstandings or coercion.

Individual Consent Vulnerabilities

- Cognitive Vulnerabilities
  - Mental Health Disorders
  - Medical Disorders
  - Immaturity & lack of experience
- Legal Naiveté
  - Consent is a waiver of rights
  - Unfamiliar with state reporting laws

Research Context Consent Vulnerabilities

- Dual Roles
  - Investigator & Service Provider
  - Research & Service Program
- Consequences
  - Fears about continuation of services
  - Therapeutic misconception

Waiving Parental Permission

- Permission should not be waived for investigator convenience
- Mature minors
- Confidentiality concerns
- Best interests of the child
- Familiarity with research & research rights
- Cultural conceptions of adult authority
- History of Family Decision Making
- Avoid Institutional biases and cultural stereotypes
- Consent Advocate

Goodness-of-Fit

- Minimizing Consent Vulnerability

  How can research and ethical procedures be fitted to participant characteristics to minimize vulnerability?

Enhancing Consent Capacity

- Simplified presentation
  - Terms
  - Reading level (5th grade)
  - Video presentation
  - Sequential single-unit disclosure
  - Question-answer format
- Supported decision-making
- Participant advocates

Research Participant's Bill of Rights

Bruzzese & Fisher (2003) *Applied Developmental Science*

- ✓ To be fully informed
- ✓ To have all questions answered
- ✓ To freely choose to participate or to refuse participation
- ✓ To withdraw or not answer questions
- ✓ To privacy and confidentiality
- ✓ To be protected from harm
- ✓ To know the results of the study
- ✓ To understand these rights

Confidentiality

- Protects
  - Participant privacy
  - Social, economic, and criminal harms
- Encourages
  - Future participation
  - Participant responsibility
- Avoids
  - Feelings of betrayal
  - Actions based on false or inaccurate data
  - Undue investigator decisional authority **(Fisher, 2002, 2003)**

Confidentiality Procedures

- Anonymity
- De-identification
- Subject Coding
- Certificate of Confidentiality

Confidentiality Uncommon Challenges

- Recruitment Risks
  - Identified treatment sites
  - Interviews in the community
  - Interviews with informants
- Disclosure Risks
  - Identification of members of unique populations

Confidentiality Uncommon Challenges

- Unexpected Information About Harmful Behaviors
  - Toxic drug dose to self or others
  - Child abuse or neglect
  - Statement of violent or suicidal intent

The Scientist-Citizen Dilemma

- Do scientists have a citizen's obligation to help those they know are in jeopardy?
- Does the investigator role supercede such citizen obligations?
- Do scientists with expertise in problems of suicidality, child abuse, or violence have a special obligation to help those they know are in jeopardy?

Reasons to Disclose

- Mandatory Reporting Laws
- Participants who are suicidal may not know they need help
- Others may be in harms way
- Iatrogenic effects of failure to disclose

Goodness of Fit Confidentiality & Disclosure Practices

1. Identify behaviors or other information that might require disclosure for the specific population within the specific research context
2. Evaluate whether risk can be validly assessed and if so a criteria for disclosure
3. Identify relevant laws for researchers & practitioners
4. Identify referral & reporting resources--if necessary and feasible help institutions develop services

Goodness of Fit Disclosure Practices

5. Consider disclosure/reporting risks (scientific validity; over-reporting; lack of services)
6. Determine a policy that fits the needs of the population, legal requirements, and research and community resources Train the research & intervention team
7. Clearly explain disclosure procedures in parent permission & child assent.

Training for Evidence Based Intervention Research

- Developmental research methods & theory

Interpreting Effect Size & use of meta-analysis (Weisz)

- Normative & atypical developmental processes
- Contextual influences & multidisciplinary collaboration
- Policy analysis
- Stakeholder needs analysis, program design, & evaluation
- Evidence based assessment & interventions

  Weisz graph on evidence based training; Campbell Corporation database

- Co-learning approaches to investigator-participant partnerships (identify problems, train practitioners, feasibility)
- Principles for the responsible conduct of research