

Discussion on Evidence Based Practice Introductory Remarks

Ernest D. Márquez, Ph.D.

Associate Director for Special Populations
Director, Offices for Special Populations and
Rural Mental Health Research
National Institute of Mental Health



Acknowledgements

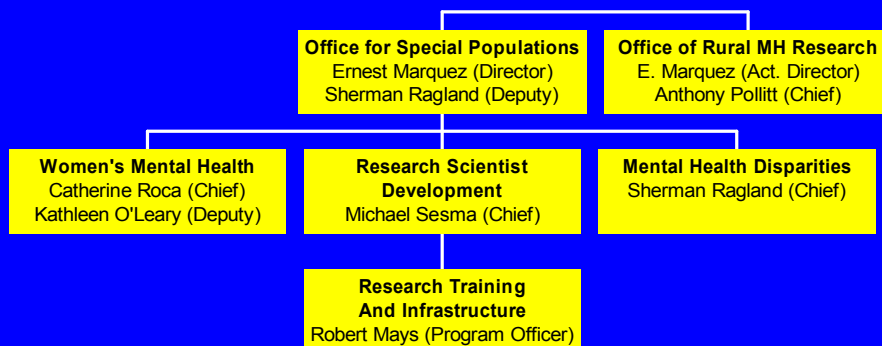
- For providing slides in this presentation:
 - Sergio Aguilar Gaxiola, University of California, Davis
 - Gino Aisenberg, University of Washington
 - Jane Yamaguchi, California State University, Fresno
 - Edward Mullen & Aron Shlonsky, Columbia University School of Social Work

Introductory Remarks

- Office for Special Populations Programs
- Office of Rural Mental Health Program
- Clinical Research: Monitoring Inclusion of Women and Minorities in Clinical Research
- Evidence Based Practices
- Practice Based Evidence

3

National Institute of Mental Health Associate Director for Special Populations Special Populations Programs



4

NIH Policy For The Inclusion Of Women And Minorities In Clinical Research

- NIH ensures that women and minorities are included in all human subject research;
- Phase III clinical trials inclusion of Women and minorities in numbers adequate to allow for valid analyses of differences in intervention effect;
- Cost is not allowed as an acceptable reason for excluding these groups; and,
- NIH initiates programs and support for outreach efforts to recruit and retain women and minorities and their subpopulations as volunteers in clinical studies

<http://orwh.od.nih.gov/inclusion.html>

5

Clinical Research: NIMH Inclusion Data FY 2005

OLD FORM

Female	58.15%
Male	40.76%
American Indian/Alaskan Native	0.50%
Asian	10.42%
Hawaiian/Pacific Islander	*
Black	9.39%
Hispanic	9.46%
White	67.61%
More Than One Race	*
Unknown/Other	2.62%
50,274 Participants (57 protocols)	

NEW FORM

Female	53.65%
Male	44.04%
American Indian/Alaskan Native	0.98%
Asian	8.71%
Hawaiian/Pacific Islander	0.37%
Black/African American***	20.56%
Hispanic**	7.49%
White	59.96%
More Than One Race	2.86%
Unknown/Not Reported (Race)	6.57%
Unknown/Not Reported (Ethnicity)	5.49%
404,072 Participants (921 Protocols)	

For Additional data:
<http://orwh.od.nih.gov/inclusion/increports.html>

6

NIMH Clinical Recruitment Policy

<http://www.nimh.nih.gov/researchfunding/nimhrecruitmentpolicy.cfm>

- Purpose: To ensure that realistic recruitment targets are established from the onset of a project, and that these targets are met throughout the course of the research
- Applies to all new awards for clinical research studies, single or multi-site, planning to enroll 150 or more human subjects

7

Elements of the Policy

- If application is in fundable range, applicant asked to provide cumulative recruitment milestones three times yearly to be included in terms and conditions of grant award
- Investigators must submit tri-yearly recruitment reports throughout recruitment period, due April 1, August 1, and December 1.

8

Elements of the Policy

- If recruitment falls significantly below milestones (below 85% of target), NIMH will consider taking one or more actions, depending on severity and duration of recruitment shortfalls.
- In the case of continuing shortfalls, NIMH, in accordance with PHS policy, will consider suspending, terminating or withholding support and in some instances, may choose to negotiate a phase-out of the award.
- For additional information:
 - <http://www.nimh.nih.gov/researchfunding/nimhrecruitmentpolicy.cfm>

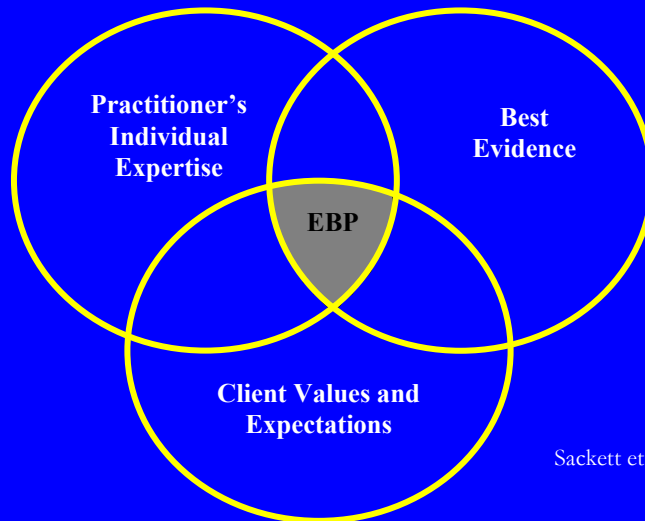
9

WHAT IS EBP?

- “Integration of the best research evidence with clinical expertise and patient (consumer) values” (Sackett, Straus, Richardson, Rosenberg, & Haynes, 2001)

10

The EBP Model



Sackett et al., 1997

11

Levels of Evidence

Level I -- Randomized Controlled Trials

Level II – 1 Well designed trials without randomization

2 Cohort or case control, preferably multi-site

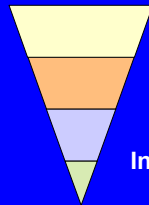
3 Multiple time series – with or without intervention

Level III -- Opinions of respected authorities, based on clinical experience; descriptive studies; case reports

From Yannacci, Jacqueline, Evidence-Based Practices: Definitions, Models and Issues, presentation at the NAMHPAC winter meeting, January 2005.

12

Randomized Double-Blind Controlled Clinical Trial (RCT)



Find potential subjects, age limits, diagnosis

Exclude if patient has unusual symptoms or complicating illness, substance abuse, etc.

Informed consent (selects for motivated pts)



Randomize to treatment. Neither Patient nor Rater knows which group patient is in

Study Medicine

Active Comparator

Placebo

Analyze Data, Publish

13

Underlying Assumptions

- Since EBP's have demonstrated evidence of successful implementation and effective outcomes they are to be trusted with funding across and throughout the state and country
- Since EBP's have documented evidence of effectiveness with certain populations they will be equally effective with all ethnic populations upon which they yet to be tested

14

Real Concerns Regarding EBP's

- Lack of consideration of context--EBP's have typically been normed or standardized void of cultural context and realities
- Lack of demonstrated generalizability-the generalizability of EBP's to ethnic communities has not been substantially or systematically demonstrated especially in terms of their appropriateness, relevance, and applicability to Latinos, Asian-Pacific Islanders, and Native Americans
- Lack of description on how EBP's will ensure fidelity to their treatment model when engaging communities of color and in different contexts
- Blurring of definition of what constitutes an EBP
- EBP's are not necessarily developed to address existing disparities in access and utilization of services
- Costs incurred by community-based agencies and sustainability of EBP's

G. Aisenberg, Powerpoint Presentation, 2003

15

Merits of Evidence-Based Practice

- **Achieves defined outcomes sooner that last longer;**
 - **Avoids the adverse consequences of under or over serving (with cost implications);**
 - **Ethical;**
 - **Cost effective (though effective practice has costs);**
 - **Improves quality; helps define "best-practices"**
- ...this is "on average"; any specific individual or situation may be the exception.**

Source: Carter, B., & Adams, N. (7.05.05) Introduction to Applying Evidence-Based Practices. A CiMH Webcast

16

Does EBP Improve Health Care?

YES if properly used:

- Assures that providers, patients, and care planners have the best available information on which to base clinical decisions and to responsibly allocate resources;
- Guides treatment decisions;
- Funds legitimate treatment, not quackery.

S. Aguilar-Gaxiola, Powerpoint, 2005

17

Does EBP Improve Health Care?

NO if Misused, has potential to:

- Severely harm patients suffering from health disparities;
- Reduce healthcare use in one segment while increasing wasteful spending in other areas;
- Replace individualized health care with payer-mandated “cookie cutter” treatment;
- Deny legitimate care;
- Wreck the provider / patient relationship;
- Increase overhead of health practice and insurance benefit administration;
- Distort the scientific basis of health practice.

S. Aguilar-Gaxiola, Powerpoint, 2005

18

Practice Based Evidence

- Complementary paradigm to EBP which addresses many EBP criticisms
- Uses an evidence-base derived from routine practice settings rather than from efficacy studies.
- Engages practitioners in the collection and ownership of data and in analyses of that data which can inform their practice.
- Key components are **effectiveness** and **practice**
 - The effectiveness component does not provide strong causal attribution but addresses generalizability of results *across* particular services and settings.
 - The practice component addresses the agenda of analyzing results *within* a service or setting. That is, it gives the ability to drill down into the data to ascertain individual differences and variations in relation to client subgroups.

Evans, Connell, Barkham, Marshall, Mellor-Clark
Clin. Psychol. Psychother. 10, 374–388 (2003)

19

Ten Rules for Quality Mental Health Services

1. Informed Choice
2. Recovery Focus
3. Person Centered
4. Do No Harm
5. Free Access To Records
6. A System Based on Trust
7. A Focus On Cultural Values
8. Knowledge-Based
9. Partnership Between Consumer & Provider
10. Access to Services Regardless Of Ability To Pay

The National Association of Mental Health
Planning and Advisory Councils

20

Key Findings – Perceptions of Consumers in Developing and Implementing EBPs

- Consumer participation in EBP movement critical to its success.
- The EBP movement and mental health researchers should seek the participation of people with mental illness in all levels of EBP development
- EBPs must be linked to all aspects of living with a mental illness
- Current EBPs do not adequately address the needs of consumers
- The EBP movement does not incorporate the promising practices developed by consumers
- Consumers believe that consumer-led practices have a strong base of evidence