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Evidence Based Medicine

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Evidence Based Practices in Mental Health
What is it, and what is it NOT
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Evidence Based Medicine

- Conscientious explicit and judicious use of current best evidence in making decisions about the care of individual patients. David Sackett M.D.
- What is new is a structured process to help choose the best available interventions Anna Donald M.D. 2004
- Evaluate the *quality* of the evidence

Evidence Based Medicine

- Best scientific evidence should be used to make clinical decisions
- Evidence should be adjusted for individual patient and local circumstances
- Patients have a right of self-determination based on
  - Accurate information regarding disease, interventions, adverse effects and outcomes
  - Their own values and preferences regarding interventions and outcomes
- Clinicians should have the appropriate clinical expertise to work with clients to deliver EBM

Drake 2003

Evidence Based Medicine

- What is the chance of rolling a 6 on a six-sided die?
- Until the renaissance, people followed Greek thinking that the chance was 50-50

Evidence Based Medicine

1. Define a structured question about target population or outcome
2. Search the literature about sources of data
3. Evaluate the data for
   - Methodological rigor
   - Relevance to the question
4. Analyze the resulting data to answer the question posed

Anna Donald 2004

Evidence Based Medicine

- Asks “what is the chance that…benefits or harms people
- Rather than how or why

  Helpful in deciding what might work, but not in deciding how a patient might feel today

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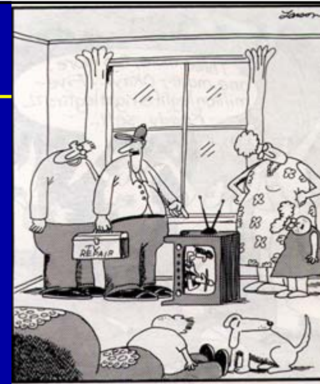
Evidence Based Medicine

Evidence Based Medicine

1. Ask an answerable question
2. Find the best evidence
3. Critically appraise the evidence
4. Act on the evidence
5. Evaluate your performance


"Well, here's your problem, Mr. Schueler."

1. Formulate the question

- Define the client group involved
  - What are the most important characteristics of the group?
- What is the problem or intervention
- Time frame
- Outcomes of interest

Sackett et al

Answerable questions

Is Clubhouse or ACT likely to be most effective for my client who is a man with co-morbid schizophrenia and alcohol dependence?

Answerable questions

In a client similar to mine:

- 42 y.o man who has had schizophrenia 14 years
- Used to work, has a University degree
- Supportive parents now deceased
- Currently using alcohol extensively
- On SSI

Comparison intervention

Clubhouse program

- With internal case management and MD service
- With good medication monitoring
- With active work support program
- (with very stable, well trained staff, hopeful recovery orientation)

ACT program

- 24 hour crisis coverage
- integrated AODA and vocational services

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Answerable questions

What would count as "improvement"

- Decreased hospital recidivism
- Competitive employment
- Decreased alcohol use
- Improved subjective sense of quality of life

2. Find the best evidence

Search the literature

- Searching a data base
  - Medline
  - Cochrane reviews
  - Individual studies Vs meta-analysis
- Hierarchy of evidence

Sackett et al

What is the best evidence available to answer *this* question?

- Controlled research
  - Multiple double blind randomly controlled
  - Randomly controlled trials
  - Single controlled trial
- Quasi-experimental trial-controls but not random assignment
- Multiple program descriptions/ good outcomes measures
- Single program descriptions with good outcome measures
- Consensus statement from "experts"
- Anecdotal examples of programs that "seem to work"

3. Assess quality of evidence

- How many studies with how many subjects
- How big was the effect
  - Statistical significance
  - Clinical significance
- What were the adverse effects
- How similar is the evidence to the current client or current clinical situation

Assess the article or data using CAT [Clinically Appraised Topic]

- Is the study design valid
- What are the results
  - Likelihood of this being a chance finding
  - Power of the difference--is the different clinically important
- Is this relevant to my population
  - How important is the finding
  - How applicable is the finding

Sackett et al

Exercise # 1
EBM syllabi http://www.cebm.utoronto.ca/syllabi/

- You are responsible for psychiatric services to homeless people in an inner city. Many of your patients suffer from schizophrenia. Although the outpatient clinic seems to help, resettling the patients from the hostel to alternative accommodation often results in failure.
- You want to know if there is a model of service that will make it more likely for resettlement to be successful .
- Clinical question: "In homeless patients with schizophrenia, is there an intervention that will reduce the rates of homelessness following resettlement?

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Preventing recurrent homelessness among mentally ill men: a "critical time" intervention after discharge from a shelter.

Susser E, Valencia E, Conover S, Felix A, Tsai WY, Wyatt RJ.

OBJECTIVES:
- prevent homelessness in people with severe mental illness
- Provide bridge between institutional and community care.

METHODS: 96 men with severe mental illness
- entering community housing from a shelter institution
- randomized to receive 9 months of a "critical time" intervention plus usual services or usual services only.

Primary analysis:
- mean # of homeless nights over 18-month
- survival curves were used.

RESULTS of Intervention to Decrease Homelessness

- 18-month follow-up period,
- Average 30 homeless nights the critical intervention Vs 91 for the usual services group.
- Survival curves: after 9-month period difference between the two groups continued.
- CONCLUSIONS: Strategies that focus on a critical time of transition may contribute to the prevention of recurrent homelessness among individuals with mental illness, even after the period of active intervention.

Preventing recurrent homelessness among mentally ill men: a 'critical time' intervention after discharge from a shelter.

Susser E, Valencia E, Conover S, et al. Am J Public Health 1997 Feb; 87: 256-62.

- Are the results of this single trial valid?
- Was the assignment of patients to treatments randomized?
- Were all patients who entered the trial accounted for?
- Were they analyzed in the groups to which they were randomized?
- Were the results both statistically and clinically significant?
- Was the population and context similar to yours?

POEMS
Patient Oriented Evidence that Matters

- Not simply about finding evidence of what works, but evidence that matters

  Kathryn Stewart
- Goal is not to normalize a blood abnormality
- "information mastery" concentrate on information that will make a difference

4. Act on the evidence

5. Assess the outcome of your action

- Did you act based on the information found?
  - If so, what was the outcome
    - How was this measured
    - Over what time frame
  - If not, why not?

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Evidence Based Medicine

Outcomes in Schizophrenia

- Positive symptoms
- Negative symptoms
- Ancillary symptoms (anxiety, depression, hostility)
- Cognitive impairments
- Functional impairments

All relatively independent of each other

Lehman et al 2003

EBM interventions for Schizophrenia: Antipsychotic Medications

- Antipsychotic medications decrease positive symptoms and relapse
  - Difficult to get clear evidence for other outcomes
  - Difficult to demonstrate superiority of second generation antipsychotics other than clozapine
  - SGA antipschotics may, or may not, decrease relapse
  - No data on use of more than one agent

Lehman et al 2003

Exercise # 3: Typical Vs Atypical Antipsychotics-

Are second generation antipsychotics (SGA) more effective than FGA?

Are all SGA equally effective?

Is the apparent increased efficacy of SGA correlated with the dose of the haloperidol comparater?

Davis, Chen and Glick
A Meta-analysis of the Efficacy of Second-Generation Antipsychotics
Arch of Gen Psych June 2003

Davis et al: Arch of Gen Psych 2003

Search of all clinical trials between Jan '53 and May 2002
- schizophrenia or schizoaffective disorder
- posters and other unpublished results included

- 124 randomized, controlled trials between FGAs and SGAs: total n = 18,272
- 18 comparisons between SGAs n = 2748

Assess study design and details

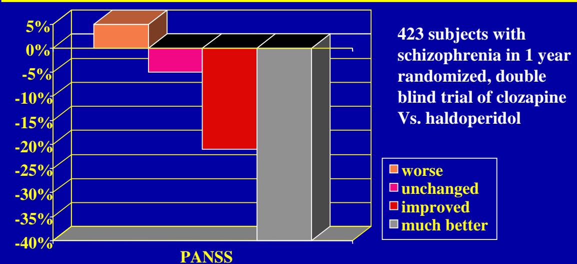
Summary:

Meta analysis of second generation antipsychotic medications Vs. first generation medications demonstrated little difference in outcomes

Consider

- Study population: who was in the studies?
- Intervention: dose, context
- Time course: how long is the study?
- Outcomes considered
- Were the subjects treatment resistant?

What change is clinically significant?



423 subjects with schizophrenia in 1 year randomized, double blind trial of clozapine Vs. haldoperidol

Cramer: Detecting Improvement in Quality of Life and Symptomatology in Schizophrenia: Quality of Life Newsletter, 2003

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Cochrane review of ACT

- Randomized clinical trials
- Compared ACT to std community care, hospital based rehabilitation service, or other case management
- People with severe mental illness 18-65
- Investigators defined the intervention as assertive community treatment

Cochrane review
ACT versus standard community care

- more likely to remain in contact with services \ (OR 0.51, 99%CI 0.37-0.70).
- less likely to be admitted to hospital (OR 0.59, 99%CI 0.41-0.85) and spent less time in hospital.
- significant and robust differences found on
  - i. accommodation status,
  - ii. employment and
  - iii. patient satisfaction.
- no differences on mental state or social functioning.

Cochrane Review;
ACT versus case management

- no data on numbers remaining in contact with services or on numbers admitted to hospital.
- People allocated to ACT consistently spent fewer days in hospital than those given case management.
- insufficient data to permit robust comparisons of clinical or social outcome.
- cost of hospital care was consistently less for those allocated to ACT, but ACT did not have a clear cut advantage when other costs were taken into account.

State of the evidence for people with schizophrenia

- ACT
  - Fidelity
  - What are the essential elements
  - Impact of social context and alternatives
  - Who does better in ACT, and who does not
  - Who does worse in ACT
  - When can people safely graduate

EBM interventions for Schizophrenia: Assertive Community Treatment

- Clear evidence that ACT decreases rehospitalization, if applied to people at high risk for hospitalization
- Cost-effective in high-risk high-cost clients

Lehman et al 2003

EBM interventions for Schizophrenia: Psycho-education family interventions

- Clearly effective in decreasing relapse
- May be culturally dependent
  - Multiple family groups more effective for Caucasians, but not with African-Americans

(McFarlane et al 1995)

Cultural issues

- Family psychoeducation produced ambiguous effects in a Latino population

Dixon et al Psych Serv 2001: 52-903-10

EBM interventions for Schizophrenia: Supported Employment

- Supported employment clearly leads to more employment
- Skills training helps specific functional impairments, but is situationally specific

Evidence based treatment of schizophrenia

- Antipsychotic medications
- Assertive community treatment
- Family psycho-education
- Supported employment
- Skills training
- Cognitive behavioral therapy
- Integrated Mental Health and AODA treatment

Lehman et al 2003

What about---

- Clubhouse programs
- Peer run/consumer programs
- Alternative models of case management
- Supported education
- Housing alternatives: group Vs individual
- Crisis intervention/hospital alternatives

Low intensity/low cost high quality services

- What models are available
- How to organize them
- Who does well, and who does not

Outcomes

- What counts as "doing better"
- How do we measure this/collect the data
- Outcomes that are easier to measure Vs outcomes that are "more important"
- Issues of Values

Outcomes

- Consumer satisfaction
- Work, housing
- Arrest, hospitalization
- Level of function
- Quality of life
- Amount of coercion used, financial payee, etc

Inputs that are not measured

- How we spend time
- Connection
- Patterns of prescribing

Concerns about EBM

- Research of limited relevance to clinical practice
  - Research already out of date
- Limited time to learn new skills
- Challenges professional autonomy
- Start up costs will be huge, even if they are eventually cost effective
- Requires letting go of services with well established constituencies

Essock et al 2003

Limits of EBM

Having no proof of difference, is NOT proof that no difference exists

- There is no proof that therapy A is any better than therapy B
- This is NOT proof that B is as good as A

Concerns about EBM

- Will only evidence based practice be funded
  - Ex: Innovative, consumer run services
- Will EBM prevent individualized treatment
  - Needs to include consumer preferences and consumer declines
- Will EBM, via emphasis on funded research, increase the power of researches and professionals
  - Peer to peer, consumer fun, family run
- What outcomes should be considered

Essock et al 2003

Concerns about EBM
Research of limited relevance to clinical practice

Shumway and Sentell evaluated 1076 articles published in 12 mental health journals in 1999

- 27 % evaluated interventions
- 64 % of these were pharmacological interventions
- 25 % of these included <31 patients
- 84 % were in specialty settings
- Only 4 % in public mental health settings

Psych Services June 2004

Problems with implementing EBM

Anecdotes are extremely powerful

- People estimate likelihood of an event by ease with which instances come to mind
  - Ex. Are there more words beginning with "r", or with "r" as the 3rd letter?

Tversky and Kahneman 1973

Problems with implementing EB

People do not use logic:

- Ex. A or B is always at least as frequent as A and B
  - MDs were asked to rank order symptoms of pulmonary embolism in a 55 y.o women
  - List included dyspnes (shortness of breath) and dyspnea + hemiparesis (one sided weakness) (Krishnan 2003)
  - More MDs chose the combination of symptoms than either one alone

Alternative to "evidence based"

- Business as usual
  - We have always done it that way
  - We "know" it works
  - We like it
  - Our client's like it, or there families' do
- Change is scary, hard, disruptive, takes resources
- You do not have to start with everything

Values and Culture

Do your patient and you have a clear assessment of their values and preferences?

Are they met by this regimen and its consequences?

Needs to be assessed in each patient

Evidence Based Medicine

- Asking answerable questions
- Finding the best evidence
- Critically appraising the evidence
- Acting on this evidence
- Evaluating the results of this change

Centre for Evidence Based Medicine
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Web sites

www.ebmentalhealh.com

http://www.cebm.utoronto.ca/
center for evidence based mental health, University of Toronto

http://www.cochrane.org/
cochrane reviews

http://www.cche.net/usersguides/main.asp
centre for health evidence

www.clinicalevidence.com
BMJ: Clinical Evidence in Mental Health