

# From evidence to methods in integrative mental health care

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# Evolution of health care toward medical pluralism

- Strong historical role of non-conventional medical practices in U.S. health care
- Changing consumer demands related to cultural and demographic trends (Eisenberg 2001; Astin 1998)
- Growing use of CAM reflects an increasingly consumer-driven health care environment

# Conventional Rx in Psychiatry

10% of adults take conventional drugs for depressed mood, anxiety, schizophrenia and other mental health problems (Ohayon 2002).

# Efficacy issues

- One half of psychiatric patients fail to respond or respond *partially* to conventional Rx (Dubin 2004).
- Patients who fail to respond to conventional Rx sometimes benefit from non-conventional or integrative Rx.

# Conventional Rx—issues

- Conventional Rx of depression, anxiety and schizophrenia have limited *effectiveness* and significant adverse effects (Leo 1999; Schatzberg 1997; Moncrieff 2004; Thase 2002; Sussman 2004).
- Risks associated with prescription antidepressants may exceed desired therapeutic effects (Keitner 2004).

# Conventional Rx—issues

- Growing public concerns over safety and cost of new drugs, especially among indigent patients and elderly (Moran 2004).
- Outpatient mental health services constrained by managed care/HMOs approach: infrequent, brief and impersonal sessions for “medication management” only (Dubin 2004).

# Context for non-conventional Rx

Growing public demand

Increasing professional interest

# The average CAM user

- Is better educated than non-CAM users
- has generally poorer overall health status than non-CAM users
- has a holistic orientation to health
- expresses strong commitments to personal growth or spirituality
- probably has a history of chronic pain, *anxiety* or back problems
- *is satisfied with conventional health care and uses conventional treatments concurrently*

# Use of CAM is growing rapidly

- Estimated CAM use rates probably *under-represent* actual uses (*many* not reported and *most* not covered)
- Use of CAM therapies increased by 25% between 1990 and 1997 and continues to grow rapidly (Eisenberg 1997; 2001)
- One third of all U.S. adults (72 million) used a non-conventional Rx in 2002 (Tindle 2005).

# Rapid growth in CAM use

- Two thirds of these used only one modality, and over 40% reported using two or more approaches in the previous year (Tindle 2005).
- When prayer is regarded as a “treatment” almost two thirds of adults use non-conventional therapies (Barnes 2004).

# Factors driving increasing uses of CAM in mental health

- Fewer new drugs in pipeline
- Increasing costs of new drugs Increasing concerns over safety
- Concerns over efficacy of conventional Rx
- Emerging evidence for CAM Rx
- Growing public and physician interest and institutional openness in medical training

# Changing popular attitudes

- Most patients believe non-conventional Rx are *effective* in spite of limited evidence for a postulated mechanisms of action and, in many cases, little or no evidence of efficacy (Furnham 2000).
- One fourth of U.S. adults who use any non-conventional approach believe that conventional medical treatments they have tried for the same problem are *ineffective* (Barnes 2004).

# Unresolved issues in CAM Rx

- Most non-conventional Rx *not* validated as effective or safe
- Over 60% of non-drug Rx use *not* disclosed to physicians (Eisenberg et al. 1999)
- Approx 10% of U.S. adults take prescription medications together with herbal remedies or high-dose vitamins
- *Unknown risks of serious toxicities and interactions*

# Physicians referring to CAM providers

- One fourth of U.S. adults who use any non-conventional Rx for a medical or mental health problem *do so on the advice of a physician or other medical professional* (Barnes 2004).

# Physicians training in CAM

- Half of U.S. physicians believe that acupuncture, chiropractic and homeopathy rest on valid medical principles and refer patients these therapies (Astin 1998b).
- Western M.D.s are becoming certified in one or more areas of non-conventional medicine including massage, acupuncture, herbal medicine and homeopathy (Astin 1998b; Ernst 1995).

# Evolution in medical training

- **The Consortium of Academic Health Centers for Integrative Medicine** has 28 medical school members and is bringing core competencies of integrative medical practice into mainstream medical education in medical schools and residency training programs (Kligler 2004).

# CAM practitioners learning about Western medicine

- Training requirements for Chinese medical practitioners, herbalists, homeopaths and others include basic courses in Western medical theory, human physiology and anatomy.

# Use rates of non-drug Rx in mental health

- Use of *any* non-drug Rx significantly greater among persons diagnosed with *any* psychiatric disorder (Unutzer et al, 2000)
- Most users of non-drug Rx for mental health problems also use conventional Rx (Eisenberg 1998; Unutzer et al 2000)
- Patients with severe depression or severe anxiety disorders use non-drug Rx *most* often (Unutzer et al 2000; Davidson et al 1998)

## Patients see non-drug Rx comparable to conventional treatments

- Two thirds of patients with panic attacks rated non-drug Rx and drug Rx as equally effective (Kessler et al 2001)
- One half of patients with severe depression rated non-drug Rx and drug Rx as equally effective (Ibid)

# Widely used non-conventional treatments in mental health care

- Relaxation techniques (20%) and “spiritual healing” (10%) are the most commonly used non-pharmacological Rx for mood and anxiety disorders (Kessler et al 2001)
- Herbs, megavitamins, homeopathy and naturopathic Rx are used by 10% of patients with panic attacks or severe depression (Kessler et al 2001)

## People who use non-conventional Rx for mental health *also* use conventional Rx

- Two thirds of patients who use *any* non-drug Rx for severe anxiety or depression also see a mental health professional (Kessler 2001)
- 90% see a psychiatrist while self-treating with one or more non-drug therapies or seeing a CAM practitioner

# Integrative mental health care

*Toward a middle ground*

# Premises

- Integrative mental health care is now the *de facto standard approach* used by the majority of mentally ill patients in the U.S.
- *Context*—limited conventional choices, increasing safety and efficacy concerns
- Decisions about non-drug Rx are made with little or no evidence
- There is no established methodology for planning integrative treatments

# Integrative perspective

- *Many* conventional Rx are often beneficial and safe
- *Some* conventional Rx are not effective and have significant safety problems
- *Many* non-conventional Rx are beneficial and safe
- *Some* non-conventional Rx are not effective and have significant safety issues

# Context for integrative Rx

- Limitations of conventional Rx of mental illness invites rigorous evaluation of promising non-conventional Rx
- Integrative healthcare is patient-centered and individualized (*not treatment-centered*).
- Integrative medicine engages the patient's active participation to improve wellness rather Rx of a "disorder" (Barrett 2003).

# Context for integrative Rx

- Integrative medicine offers a reasonable “*middle way*” in mental health care incorporating advantages of conventional and non-conventional approaches while ideally minimizing limitations and risks of either approach alone.

# From evidence to methods

- Legal and ethical issues
- *Levels* of evidence
- Methodology
- Integrative Rx of depression
- Resources

# Legal and ethical issues

- At present there is no clear ethical or legal framework that defines the scope of practice for physicians or non-conventionally trained healthcare providers who treat patients using alternative or integrative approaches (Adams 2002; Cohen 1998).

# Legal and ethical: scope of practice

- Any healthcare provider has a *legal and ethical duty* to his or her patients.
- This duty includes the demonstration of professional competence when treating patients, and the exercise of sound judgment when referring a patient for consultation with another healthcare provider.

# Legal and ethical: scope of practice

- Western physicians who use alternative or integrative treatments should learn of any applicable restrictions imposed by the State Medical Board on the scope of medical practices within their medical sub-specialty.
- Medical practices regarded as *legitimate* in one State jurisdiction may be cause for probation or other disciplinary action in other States.

# Legal-ethical: making referrals

- When a patient's medical or mental health problem is outside of the scope of a clinician's expertise and experience, the clinician is ethically obligated to refer the patient to an appropriate and competent provider.

# Legal-ethical: making referrals

- When a non-conventionally trained practitioner is the primary health care provider it is appropriate to refer a patient to his or her primary care physician *when there is a question of an unaddressed medical problem* that cannot be adequately addressed by methods available to the practitioner.

# Legal-ethical: making referrals

- When an M.D. refers a patient to non-conventional practitioner s/he *assumes liability for negative outcomes resulting from the referral, including harmful effects of treatment.*
- Physicians should *refer patients to non-conventionally trained practitioners only after confirming good reputation and qualified to practice specialty.*

# CAM Rx categories

- Biological (eg, herbs, vitamins, Omega-3s)
- Somatic (exercise, massage)
- Mind-body practices (yoga, taichi)
- Rx based on *scientifically validated* forms of energy or information (light, sound, electricity)
- Rx based on *postulated* forms of energy or information not validated by current Western science (qigong, Reiki, prayer)

# Levels of evidence

- **Substantiated**—positive systematic review and widely used
- **Provisional**—at least 3 large well designed studies and widely used
- *Possibly effective*—few small studies, inconsistent findings and not widely used

# Methodology

- Based on evidence (not *strictly* EBM)
- SI/HI or acute medical problem refer to ER
- Review patient history
  - Conventional Rx
  - Non-drug Rx
- Derive *ideal* Rx plan
- Modify to *realistic* Rx plan

# The integrative clinician must address five basic issues:

- Identifying the symptom pattern that is the focus of clinical attention
- Clarifying the patient's history of response to previous treatments for similar complaint
- Determining specific treatment approaches to consider
- Considering practical issues of cost, availability, patient preferences and values that determine the “shape” of a realistic and acceptable integrative strategy
- Establishing criteria for assessing outcomes

# Toward a methodology for integrative treatment planning

- Consider responses to previous Rx, practical constraints of location and cost, and preferences
- Begin with most substantiated approaches for target symptom(s)
- Systematically move from substantiated to provisional and possibly effective modalities

## Consider *possibly effective* Rx when

- More substantiated Rx have failed, are *refused, unavailable* or *unaffordable*
- Anecdotal evidence *suggests* a particular Rx may improve outcome
- While continuing a substantiated Rx that is *synergistic*.
- Always encourage patients to first try most substantiated Rx for target Sx

# Integrative Mental Health Care

Developing a realistic treatment plan

# Concepts

- **Safety foremost—low threshold for ER referral**
- Severe vs moderate Sx severity
- One core Sx vs two or more core Sx
- Biological (including drugs) vs non-biological Rx (psychotherapy, mind-body, somatic, energy-information)
- Sequential vs parallel Rx
- *Always assess compatibility before combining Rx*

# Emergency medical referral

- Medical problem is rapidly evolving or potentially life-threatening
- Patient is suicidal, homicidal or gravely disabled (PES evaluation and 5150)
- Patient is acutely intoxicated (EtOH or drugs)

# Non-urgent medical referral

- Un-diagnosed medical problem possibly confounding psychiatric DDx (eg, hypothyroidism, CAD, pulmonary dz, neurologic sx)
- Known medical problem poorly managed (non-compliance, patient refuses care)
- Alcohol or substance abuse

# Possibly effective Rx

- Follow “N of 1” protocol in order to obtain pertinent clinical information about the patient’s response at the early stages of treatment.

Safety

# Safety—*primum non nocere*

- *Where particular combinations of conventional or non-conventional treatments are associated with known safety problems, those treatments or combinations should be avoided, or implemented in a way that minimizes risk after written informed consent has been obtained.*

# General considerations

- Different safety issues for self-administered vs professionally-administered Rx.
- **Self-administered Rx** –review risks, give advice about reputable brands
- **Professionally administered Rx**—ongoing supervision to monitor for AEs, discuss progress/problems with CAM practitioner.

# Safety—general

- When recommending a natural product suggest specific *reputable brands*
- Useful resources for comparing brands: [www.consumerlab.com](http://www.consumerlab.com) and United States Pharmacopeia [www.usp-dsvp.org](http://www.usp-dsvp.org)
- Non-biological Rx have few safety problems and usually safe to combine with conventional or non-conventional biol. Rx

# Safety

- Always consult reliable resources before combining western herbs with conventional drugs
- Excellent resources on herbal and natural product safety include Bratman 2003; McGuffin 1997; Brinker 1998; Harkness 2003 (full citations in bibliography).

# Safety

- Provide handouts with basic information or a clearly written note listing common safety issues or AEs when a conventional Rx or natural product is taken alone or in combination with other biologically active substances, including herbals, natural supplements, and certain foods.

## *Limited safety data for integrative Rx*

- Limited information about potential interactions between many widely used natural products and conventional drugs.
- Integrative Rx combining medications and Chinese herbal medicines pose special problems (Lake 2004).

# One vs two or more *core* Sx

- Focus on Sx causing greatest distress or *impairment*
- When two or more core Sx consider targeting Sx most responsive to Rx
- Often practical to prioritize Rx plan by core sx (more severe then less severe)
- Use Rx that target two or more sx whenever possible (eg, exercise or SSRI for anxiety and depression)

# Single vs combined Rx

- Establish realistic Rx strategy focusing on core Sx
- Identify primary Rx targeting core Sx
  - Biological vs non-biological (eg, psychotherapy, mind-body, energy-information) vs integrative Rx
  - Conventional drug vs natural product vs combination

# Parallel vs Sequential approach when using more than one Rx

- Decision tree
  - One core sx vs two or more core sx
  - Symptom severity and urgency
  - Single modality is substantiated, available and preferred
  - Evidence for safety and efficacy when combining modalities
  - Risk of AEs when combining (biological) Rx vs. treatment delays when using single Rx in sequence
  - Patient motivation and resources

# Case vignette

*Integrative management of  
depression*

# Case vignette

- 57 year old retired stock broker
- Recovering alcoholic with 11 yrs sobriety
- Elevated cholesterol on statin
- First MDE age 18: fatigue, hopelessness, hypersomnolence, frequent SI (resolved without Rx after 3 months)
- Subsequent MDEs approx. every 3 to 5 years: vegetative sx, frequent SI

# Treatment Hx

- First treated age 30 Prozac 20mg with significant improvement but discontinued p. 1 yr due to sexual AEs and weight gain
- Recurring MDE 3 yrs later Zoloft 150mg, worsened, SI, hospitalized: LiCO<sub>3</sub> augmentation with significant improvement
- Discontinued Lithium after 3 months: tremor, weight gain, nausea.

# Treatment Hx

- Subsequent therapeutic trials on Paxil, Serzone, Celexa, Lexapro, Effexor, with *initial* positive results
- Now on Remeron 15mg “munchies” and weight gain
- “They work for a while...then peter out”
- No previous CAM or integrative Rx
- Retired last year and moved to suburbs
- Found integrative clinic and “open” to new approaches

# Integrative Rx—Assessment and Formulation

- M.D./L.Ac. Does conventional assessment and Chinese medical assessment
- Med-psych, social and spiritual hx incl. detailed hx of previous conventional and CAM Rx
- Conventional Dx is MDE, recurrent, now with **moderate depressed mood, consider depressed mood due to low cholesterol**
- Chinese Dx (pulses, tongue) ascribes mood sx to **stagnant liver qi**
- Labs: serum total cholesterol and triglycerides, RBC folate level, and thyroid studies

# Integrative treatment planning

- Review of substantiated non-conventional approaches for moderate depressed mood suggests:
  - life style changes
  - Acupuncture
  - other therapies that improve *moderate depressed mood* when used alone or in combination with conventional Rx

# Treatment planning—patient preferences

- Patient skeptical about Chinese medicine which is *not* pursued
- Patient has *strong interest* in supplements and exercise
- Both approaches are beneficial for *moderate* depressed mood
- Both are available options, *affordable* and *realistic* for patient

## Treatment—initial integrative recommendations

- *Initial plan:* continue current dose of mirtazepine (15mg), start trial on adjunctive SAME with gradual taper to 400mg BID, vitamin supplements (B-12, folate), daily aerobic exercise, improved diet and regular stress management.
- Document informed consent of SAME trial p. reviewing AE risks

## 3 week follow-up

- “nothing is working...going downhill fast...”
- Still craving sweets, “sad” all the time, demoralized and not exercising
- RBC folate low-normal, serum total cholesterol 155mg/dl (low NL). Thyroid studies WNL.
- No change in Liver qi stagnation
- Takes B vitamins, SAME 200mg/am only (inferior brand)
- Working in garden, listening to music

# Modified plan

- Change to quality brand of SAMe and continue with initial titration schedule to 400mg BID
- Encourage daily work in garden and aerobic workouts if motivated
- Encourage listening to music for stress
- Review option of tapering/DC Remeron if significant response to SAMe

## 2 week follow-up

- Significantly “brighter”
- Exercising almost daily
- SAMe 400mg BID with mild GI distress
- “munchies” still a problem
- Family practice MD reduced statin dose, repeat total serum cholesterol now 180 (protective HDL/LDL ratio)

# One month follow-up

- Mood still improved
- Gradual weight loss
- Sustained exercise program
- Good compliance with SAME, minimal AEs
- Night-time craving sweets continues
- **New Rx recommendation:** hold Remeron pending continued euthymic mood while on maintenance SAME with B-vitamins

# On-going care

- Regular 4-6 week FU X 6 months then quarterly pending euthymic on present regimen
- Follow serum cholesterol q 6 months adjust statin PRN (DC pending cont'd weight loss)
- Serial Chinese energetic assessments (pulse dx)
- Maintenance SAME on-going (MDE recurrent)
- Encourage continued exercise, healthy diet and life-style changes
- Consider supportive psychotherapy

# Staying current

- In some cases strength of evidence for established Rx will have *increased* or *decreased*
- Before finalizing any integrative Rx plan review new research
- *Practitioner's responsibility to the patient is to ensure that treatment recommendations are based on the most current and most reliable information available.*

# Resources

- [www.APACAM.org](http://www.APACAM.org) Official site of APA CAM Caucus
- [www.IntegrativeMentalHealth.net](http://www.IntegrativeMentalHealth.net) My website, gateway to useful CAM sites
- [www.thieme.com/mentalhealth/index.html](http://www.thieme.com/mentalhealth/index.html) Companion site for *Textbook of Integrative Mental Health Care*, Lake J., Thieme (quarterly updates)

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