From evidence to methods in integrative mental health care

Presented as a workshop

2007 APA Annual Meeting

May 22, San Diego

James Lake M.D.

www.IntegrativeMentalHealth.net

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 signicant 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 and United States Pharmacopeia 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: LiCO3 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 auggests:
  - 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 Official site of APA CAM Caucus
- www.IntegrativeMentalHealth.net My website, gateway to useful CAM sites
- www.thieme.com/mentalhealth/index.html Companion site for *Textbook of Integrative Mental Health Care*, Lake J., Thieme (quarterly updates)

Citations

- Bratman, S. & Girman, A.M. (2003). Mosby's Handbook of Herbs and Supplements and their Therapeutic Uses. St. Louis: Mosby, Inc
- Brinker, F. 1998. Herb Contraindications And Drug Interactions, Second Edition. Portland: Eclectic Medical Publications.
- McGuffin M, Hobbs C, Upton R, Goldberg A. 1997. Botanical Safety Handbook. Boca Raton: CRC Press.

Citations

- Eisenberg D Kessler R Foster C Norlock F Calkins D Delbanco T Unconventional medicine in the United States NEJM 1993;328:246-52.
- Eisenberg, D., Davis, R., Ettner, S, et al, Trends in alternative medicine use in the United States, 1990-1997: results of a follow-up national survey, JAMA November 11, 1998, 280:18, 1569-75.
- Ohayon M Lader M Use of psychotropic medication in the general population of France, Germany, Italy, and the United Kingdom J Clin Psychiatry 63:9;817-825, Sept 2002.

Citations

- Leo R Movement disorders associated with the serotonin selective reuptake inhibitors Jour Clin Psychiatry 57;449-54; 1999.
- Schatzberg AHaddad P Kaplan E Lejoyeux M Rosenbaum J Young A Zajecka J Serotonin reuptake inhibitor discontinuation syndrome: a hypothetical definition Jour of Clin psychiatry 58 [suppl7]:5-10, 1997.
- Keitner G Limits to the treatment of major depression Abstract no. 34 APA Annual Meeting, May, 2004, New York City

Citations

- Furnham A How the public classify complementary medicine: a factor analytic study Complementary Therapies in Medicine 8,82-87; 2000.
- Dubin W Clinical practices that lead to treatment resistance Abstract 81D, Symposium 81 Personality disorders: multiple perspectives in the understanding and treatment resistance, 2004 APA Annual Meeting, New York City, N.Y. Astin, J. Why Patients use alternative medicine, JAMA May 20, 1998a, 279:19, 1548-1553.
- Astin, J., Marie, A, Pelletier, K. et al A review of the incorporation of complementary and alternative medicine by mainstream physicians, Arch Intern Med, 158: Nov 23, 1998b, 2303-10. (NOTE: make slide on this also)

Citations

- Barnes P Powell-Griner E McFann K Nahin R Complementary and alternative medicine use among adults: United States, 2002 Seminars in Integrative Medicine 2:2; 54-71, 2004.
- Tindle H Davis R Phillips R Eisenberg D Trends in use of complementary and alternative medicine by U.S. adults: 1997-2002 Alt Ther Health Med 2005;11:1;42-49.
- Dubin W Clinical practices that lead to treatment resistance Abstract 81D, Symposium 81 Personality disorders: multiple perspectives in the understanding and treatment resistance, 2004 APA Annual Meeting, New York City, N.Y.

Citations

- Moran M Drug prices rise twice as fast as rate of inflation (see full citation in http://research.aarp.org/health/ib69_drugprices.pdf. Psychiatric News Aug 20, 2004, p. 18.
- Lake, J The integration of Chinese Medicine and Western medicine: focus on mental illness, Integrative Medicine Aug/Sept 2004 3(4):20-28
- Eisenberg, D Kessler R Van Rompay M Kaptchuk T Wilkey S Appel S et al perceptions about complementary therapies relative to conventional therapies among adults who use both: results form a national survey Ann Intern Med. 2001:135;344-351.

Citations

- Leo R Movement disorders associated with the serotonin selective reuptake inhibitors Jour Clin Psychiatry 57;449-54; 1999.
- Kessler R Soukup J Davis R Foster D Wilkey S et al The use of complementary and alternative therapies to treat anxiety and depression in the United States Am J Psychiatry 158:289-294;2001.
- Unutzer J Klap R Sturm R Young A Marmon T et al Mental disorders and the use of alternative medicine: results from a national survey Am J Psychiatry 157:1851-1857; 2000.

Citations

- Kliger B Maizes V Schachter S et al Core competencies in integrative medicine for medical school curricula: a proposal Acad Med 2004;79-521-531.
- Thase M Antidepressant effects: the suit may be small, but the fabric is real Prevention & Treatment 5:Article 32, 2002. available at journals.apa.org/prevention/volume5/toc-jul15-02.html.
- Sussman N The “file-drawer” effect: assessing efficacy and safety of antidepressants Primary Psychiatry July 2004 p. 12.

Citations

- Moncrieff J Wessely S Hardy R Active placebos versus antidepressants for depression (Cochrane Review) In: The Cochrane Library, Issue 2, 2004 Chichester, U.K. John Wiley & Sons, Ltd.
- Barrett B Marchand L Scheder J Plane M Maberry R Appelbaum D et al Themes of holism, empowerment, access and legitimacy define complementary, alternative and integrative medicine in relation to conventional biomedicine JACM 9;6:2003, 936-947.

Citations

- Astin, J. Why Patients use alternative medicine, JAMA May 20, 1998a, 279:19, 1548-1553.
- Astin, J., Marie, A, Pelletier, K. et al A review of the incorporation of complementary and alternative medicine by mainstream physicians, Arch Intern Med, 158: Nov 23, 1998b, 2303-10.