A New Paradigm For MS Care—Optimizing Health Through the Integration of Lifestyle, Alternative, and Conventional Medicine

Allen C. Bowling, MD, PhD
Colorado Neurological Institute (CNI)

Conflict/Disclosure Information

- Research, consulting, advising, speaking
  - Acorda, Bayer, Biogen-Idec, EMD-Serono, Genzyme, Novartis, Pfizer, Questcor, Teva Neuroscience
  - American Academy of Neurology, Center for Disability Services, Consortium of MS Centers, Evergreen Health, Mandell Center for Multiple Sclerosis, National MS Society, ProCE
- Royalties
  - Demos Medical Publishing
Summary

• Features of Paradigm
  – Five underlying concepts
• Application of Paradigm
  – Evidence-based evaluation of many different lifestyle and unconventional therapies
• Translation into Clinical Practice
  – Seven-step approach

“New Paradigm”

• Types of Therapies
• Conditions That are Relevant to MS
• Whole Body Health
• Clinician-Patient Interaction
• Interpretation and Use of Evidence
Lifestyle and Unconventional Medicine
Under-Recognized and Under-Utilized Tools in the MS Toolbox

• Lifestyle Medicine
  – Daily habits and practices, such as diet and exercise, that are incorporated into conventional medical care in order to prevent or treat disease

Lifestyle Medicine

• Typical “lifestyle diseases”
  – DM, obesity, high blood pressure, heart disease, cancer
  – Studies
    • 2009—Potsdam Study (“EPIC,” Arch Int Med, 169, 1355-1362)
      – N=23,153 Germans, prospective cohort study
      – End points: type 2 DM, MI, stroke, and cancer
      – 4 lifestyle factors: smoking, physical activity, healthy diet, BMI<30
      – All 4 factors: 78% lower risk of disease
      – 1 factor: 49% lower risk
    • 2004—Mokdad et al (JAMA, 291, 1238-1245)—similar findings
    • 1993—McGinnis and Foege (JAMA, 270, 2207)
      – About half of US deaths premature: due to modifiable risk factors: primary 3 plus alcohol, microbial exposure, toxic agents, firearms, sexual behavior, MVAs, illicit use of drugs
Lifestyle Medicine

- Atypical “lifestyle diseases”
  - Autoimmune diseases: MS, RA, psoriasis, IBD, type I DM
  - Lifestyle and MS
    - Direct Effect: Risk or severity affected by lifestyle factors, such as physical activity, tobacco, salt and vitamin D intake
    - Indirect Effect: Quality of life and disability affected by typical lifestyle diseases

MS, “Other” Diseases, and Lifestyle
MS, “Other” Diseases, and Lifestyle

MS

LIFESTYLE

OTHER DISEASES

MS

LIFESTYLE

OTHER DISEASES

MS

LIFESTYLE

OTHER DISEASES
MS, “Other” Diseases, and Lifestyle

- MS
- LIFESTYLE
- OTHER DISEASES
  - Obesity → Arthritis, Heart Disease
  - High Calorie and Fat Intake
Comorbidities and MS

- Mental: depression 50%, anxiety 36%
- Physical: hyperlipidemia, hypertension, arthritis, IBS, chronic lung disease
- Impact of comorbidities in MS
  - Increased disability with increased number of physical comorbidities
  - More rapid disability progression
    - Musculoskeletal conditions
    - HTN, hypercholesterolemia, DM, PVD
  - Lower HRQOL with more comorbidities

Lifestyle and Unconventional Medicine

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• Unconventional Medicine
  – Also known as complementary and alternative medicine (CAM)
  – Therapies that are generally not taught in medical schools or provided in hospitals

Complementary and Alternative Medicine (CAM)

• Relatively high use
  – General Population: about 40%
  – MS: about 50-70%
  – Most CAM is used in conjunction with conventional medicine: 80-90%

• May be beneficial, ineffective, harmful

• Reasons for use in MS
  – Not as a cure
  – Relieve symptoms, increase control, improve health, account for mind-body-spirit
Which Approach and Which Clinician Are in Which Category/Compartment?

- Lifestyle Medicine
- Unconventional Medicine
- Conventional Medicine
  - Specialization and sub-specialization

“Dis-Integrated Approaches”
“Dis-Integrated Approaches”

Integrated Approach:
“Integrative Medicine”

• Integration (decompartmentalization) of lifestyle, unconventional, and conventional medicine
Integrated Approach: “Integrative Medicine”

- Integration (decompartmentalization) of lifestyle, unconventional, and conventional medicine
- ALSO
  - Emphasizes health and wellness of the whole person
  - Supportive clinician-patient relationship

Challenges with Lifestyle and Unconventional Medicine

- Books and other written material
  - Extremely variable quality
- Products and CAM/lifestyle practitioners
  - Exaggerated claims, profits, limited neuro knowledge
- Conventional health providers
  - Little or no training/knowledge, unappealing or repulsive, limited time/resources especially with MS rx advances, reimbursement issues, no medicolegal implications, different mindset and skill set
“Give it to me straight, Doc. How long do I have to ignore your advice.”
“New Paradigm”

- Types of Therapies
- Conditions That are Relevant to MS
- Whole Body Health
- Clinician-Patient Interaction
- Interpretation and Use of Evidence

Levels of Evidence: American Academy of Neurology

- Class I
  - Randomized, controlled, objective outcome
  - Extra criteria: concealed allocation, primary outcome clearly defined, exclusion and inclusion criteria clearly defined, adequate accounting for dropouts and crossovers
- Class II: lacks one criterion
- Class III: all other controlled trials with independent outcome assessment
- Class IV: all other studies
Levels of Evidence: AHRQ Report, 2002

• Agency for Healthcare Research and Quality
  – Agency within US Dept of Health and Human Services
• 2002 review (West et al, Systems to rate the strength of scientific evidence: Summary. In AHRQ Evidence Report Summaries 47).
  – Many methods: 49 for RCTs, 19 for obs. studies
  – Many not well designed for clinical recommendations
    • One size does not “fit all,” especially with “less traditional” bodies of evidence
    • Too focused on individual studies, overly complex
    • Rigid hierarchy: simplistic, misunderstand meaning of evidence

Levels of Evidence

• “It is what you feel in your own body and mind that is the most important thing, and it is very easy for doctors and patients to forget that. I believe that a little of what you fancy does do you good!”
  Elizabeth Forsythe, MD
• “Studies which have not ‘proven’ the treatment to be beneficial but which suggest a major benefit look much more interesting when you actually have the disease, especially when the treatment has other health benefits as well...Despite [its] effectiveness, lifestyle change is often not promoted.”
  George Jelinek, MD
Levels of Evidence

• “I have practiced evidence-based medicine for several decades and am very familiar with the rating systems for clinical trial evidence. I also have MS. When considering therapeutic options for my MS, I am interested in Class IV studies with less than 10 patients. I am also interested in trials with MS relevance that are conducted in people with conditions other than MS. I have benefitted significantly from the rational use of low-risk therapies that have limited evidence for efficacy in MS, such as yoga, meditation, and massage.”

HH

Ratings

- **Essential**
  - Benefits far outweigh risks

- **Worth Considering**
  - Some indication of benefit, little or no risk

- **Uncertainties**
  - Uncertainties about safety and/or effectiveness

- **Avoid or Limit Use**
  - Significant safety concerns and/or risks greatly outweigh benefits
Summary

• Features of Paradigm
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**Ratings**

*Essential* Benefits far outweigh risks

<table>
<thead>
<tr>
<th>Alcohol abstention or moderate use</th>
<th>Salt in recommended amounts</th>
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<tbody>
<tr>
<td>Exercise</td>
<td>Tobacco none</td>
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<td>Fiber in recommended amounts</td>
<td>Vitamin B12 supplements if vitamin B12 deficient</td>
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<td>Gluten restriction in celiac disease</td>
<td>Weight management</td>
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**Weight Management and Obesity**

- Obesity and MS risk
  - Increased risk with childhood/adolescent obesity
- Obesity in those with MS
  - No clear effect on disease course
  - May provoke MS symptoms
    - Fatigue, sleep, bladder, depression
  - Multiple possible “indirect” effects
    - Increased risk for other diseases that may negatively affect those with MS
Weight Management and Obesity

- Obesity-associated diseases and MS
  - Obesity increases risk of arthritis, diabetes, heart disease, high blood pressure, high cholesterol
  - All of these conditions are associated with more rapid progression of disability in MS
  - The greater the number of other medical conditions in MS, the lower the quality of life
Salt

- One of single greatest dietary harms to health
- Average American: 4,000 mg/day
- Recommended amount: 1,500-2,300 mg/day
- High salt intake increases disease risk
  - High blood pressure, heart disease, stroke, congestive heart failure, kidney disease
- Effect of 1,200 mg decrease in salt intake in US
  - Dramatic decrease in death/disability
  - 150,000 lives and $10-24 billion saved annually

Salt

  - 3 different articles
  - Increased salt conditions: increased production of pro-inflammatory T$_{h17}$ cells and more severe EAE
- Correale et al (*J Neurol Neurosurg Psych*, 2014)
  - Medium salt intake: 2.75-fold increased attack risk
  - High salt intake: 3.95-fold increased attack risk, 3.4-fold increased risk of new MRI lesion, 8 more T2 lesions
MS

LIFESTYLE
Salt Intake

??

OTHER DISEASES
Heart Disease, Stroke, Blood Pressure

Ratings

Essential
Benefits far outweigh risks

Worth Considering
Some indication of benefit, little or no risk

Uncertainties
Uncertainties about safety and/or effectiveness

Avoid or Limit Use
Significant safety concerns and/or risks greatly outweigh benefits
Ratings

**Worth Considering** Some indication of benefit, little or no risk

- Acupuncture
- Biofeedback
- Caffeine
- Chiropractic for low back pain
- Coffee
- Cooling therapy
- Cranberry
- Guided imagery
- Hippotherapy
- Hypnosis
- Massage
- Meditation
- Mindfulness
- Multivitamins
- Music therapy

- Pets
- Pilates method/
  PhysicalMind method
- Prayer and spirituality
- Psyllium
- SAMe
- Tai chi/Qi Gong
- Therapeutic horseback riding
- Valerian
- Vitamin D
- Yoga
Vitamin D

• Deficiency or insufficiency
  – 50% or more of general population
• Many possible causes
  – Sunscreen
  – Sun avoidance
  – Obesity
  – Decreased intake of fortified foods

Vitamin D: Clinical Studies

• Definite causality: bone health
• Associations (observational studies)
  – MS: risk, attacks, disability progression, symptoms
  – More than 20 other conditions: other autoimmune, cancer, cardiac, lung, psychiatric
• MS intervention studies
  – Variable results
  – Current “score:” YES 3, NO 3
Can Modest Doses or High Normal Levels be Toxic?

- Vitamin D supplements
  - Toxicity with very high doses: "intoxication," "hypervitaminosis D"
  - Emerging concerns with chronic, moderately high doses or levels (? reverse J-shaped curve)
    - All-cause mortality, some cancers (eg pancreatic), heart disease risk, fractures, falls
    - ? More than 4,000 IU daily or 55ng/ml

Ratings

**Uncertainties** Uncertainties about safety and/or effectiveness

| ALCAR | Alpha-lipoic acid | Amino acids | Antioxidant vitamins | Aromatherapy | Aspartame avoidance | Ayurvedic supplements | Bee pollen | Chiropractic for neck pain and conditions other than low back pain | Coenzyme Q10 | Craniosacral therapy | Creatine | Feldenkrais | Fish oil | Garlic | Ginkgo | Ginsengs | Glucosamine | Gluten restriction generally | Goldenseal | Grape seed extract | Homeopathy | Inosine |
Uncertainties

Inosine
Lecithin
Low dose naltrexone (LDN)
Magnets
Marijuana
Melatonin
Oligomeric proanthocyanidins (OPC)
Padma 28
Paleolithic diet
Probiotics
Prokarin
Propolis
Pycnogenol
Raw honey
Reflexology
Resveratrol
Royal jelly
St. John’s wort
Stinging nettle
Swank diet
Therapeutic touch
Threonine
Tragerwork

• Gluten restriction generally
• Paleolithic diets
• Probiotics
Ratings

**Avoid or Limit Use**  Significant safety concerns and/or risks greatly outweigh benefits

- 5-HTP
- Androstenedione
- Ashwagandha
- Asian proprietary medicine
- Ayurvedic supplements
- Bee venom therapy
- Calcium EAP
- Candida treatment
- Chelation therapy
- Chinese herbal medicine
- Chronic cerebrospinal insufficiency (CCSVI)
- Colon therapy
- Dental amalgam removal
- DHEA
- Echinacea
- Enzyme therapy
- Germanium
- Hyperbaric oxygen
- Kava kava
- Protandim
- Spirulina
- Yohimbe
- Yohimbine

Supplements and Herbs with Potential Side Effects or Drug Interactions

- More than 200 different products
  - “Immune stimulation”
  - Significant toxicity
  - MS-relevant side effects
    - Fatigue, urinary irritation
  - MS-relevant drug interactions
Potentially Harmful Supplements

- Acanthopanax obovatus
- Alfalfa
- Alkanna
- Aloe
- Alpine ragwort
- American chestnut
- American ginseng
- American hellebore
- American pennyroyal
- Andrographis
- Androstenedione
- Angelica sinensis
- Angel’s trumpet
- Aristolochia fangchi
- Artemisia annua
- Artemisia myriantha
- Ashwagandha (Withania somnifera)
- Asiatic dogwood
- Asian ginseng
- Asparagus
<table>
<thead>
<tr>
<th>Potentially Harmful Supplements</th>
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<td>Acanthopanax obovatus</td>
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## Potentially Harmful Supplements

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<td>Hound's tongue</td>
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<td>5-HTP</td>
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</table>
Potentially Harmful Supplements

Wormwood
Xiao-chai-hu-tang
Yangjinhua
Yellow dock
Yerba mansa
Yohimbe or yohimbine
Zinc

Summary

• Features of Paradigm
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• Translation into Clinical Practice
  – Seven-step approach
Translation into Clinical Practice

• Current Standard of Care
  – DMTs and symptom management
  PLUS
• Five Concepts
  PLUS
• Lifestyle and Unconventional Medicine
  – “Essential” and “Worth Considering”

Seven Steps

• **Step 1** Disease-modifying medications
• **Step 2** Diet, dietary supplements, and weight management
• **Step 3** Physical activity
• **Step 4** Personal and social well-being
• **Step 5** Tobacco and alcohol use
• **Step 6** Prevention/management of other medical conditions
• **Step 7** Symptom management
Seven Steps to Integrate Lifestyle, Alternative, and Conventional Medicine

• Concepts
  – Typical Westernized lifestyle has adverse effects on MS and general health
  – Other medical conditions have adverse effects
  – Some of the most beneficial treatment approaches may be those that use “built-in resources” of human body and do not require any medications, supplements, devices, or technology

Seven Steps

• **Step 1** Disease-modifying medications
• **Step 2** Diet, dietary supplements, and weight management
• **Step 3** Physical activity
• **Step 4** Personal and social well-being
• **Step 5** Tobacco and alcohol use
• **Step 6** Prevention/management of other medical conditions
• **Step 7** Symptom management
Seven Steps:  
Many More Treatment Options  
• If DMT not appropriate, there are still 6 other steps to pursue  
  – Secondary or primary progressive  
  – Pregnancy/breastfeeding  
  – Other reason for not being on DMT

Seven Steps  
• Step 1  Disease-modifying medications  
• Step 2  Diet, dietary supplements, and weight management  
• Step 3  Physical activity  
• Step 4  Personal and social well-being  
• Step 5  Tobacco and alcohol use  
• Step 6  Prevention/management of other medical conditions  
• Step 7  Symptom management
Summary of Dietary Approaches

**Essential** Fiber in recommended amounts, gluten restriction in celiac disease, salt in recommended amounts, vitamin B12 supplements if deficient, weight management

**Worth Considering** “Healthful diet,” multivitamins, vitamin D and calcium

**Uncertainties** Gluten restriction generally, paleolithic diets, probiotics, many supplements including antioxidants and fish oil

**Avoid or Limit Use** Many many supplements, colon therapy, enzyme therapy

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Physical Activity

"What fits your busy schedule better, exercising one hour a day or being dead 24 hours a day?"

Physical Activity and MS

• Change in attitude about MS and exercise
  – Jimmie Heuga-pioneered exercise concept

• Many benefits
  – Physical: strength, walking, spasticity
  – Emotional: depression, anxiety, anger
  – Paradoxical: fatigue
  – Other MS symptoms: pain, cognitive function, sleeping difficulties, bowel, bladder, and sexual function
  – General health: osteoporosis, heart disease, stroke, high blood pressure, blood lipids, obesity, diabetes, cancer, risk of death
Unconventional Forms of Exercise

- **T’ai chi**
  - Two MS studies
    - Emotional and social function, gait, spasticity
  - Other studies
    - Anxiety, depression, fatigue, strength, sleep, cognition, pain

- **Yoga**
  - Class I study in MS: fatigue
  - 8 other MS studies
    - Anxiety, depression, gait, bladder function, pain, spasticity, quality of life

Summary of Physical Activity Approaches

- **Essential** Exercise
- **Worth Considering** Therapeutic horseback riding, Pilates, tai chi, yoga
- **Uncertainties** Feldenkrais, Tragerwork
- **Avoid or Limit Use** None

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### Ratings

**Essential** Benefits far outweigh risks

- Alcohol *abstention or moderate use*
- Exercise
- Fiber *in recommended amounts*
- Gluten restriction *in celiac disease*
- Salt *in recommended amounts*
- Tobacco *none*
- Vitamin B12 *supplements if vitamin B12 deficient*
- Weight management

### Ratings

**Worth Considering** Some indication of benefit, little or no risk

- Acupuncture
- Biofeedback
- Caffeine
- Chiropractic for low back pain
- Coffee
- Cooling therapy
- Cranberry
- Guided imagery
- Hippotherapy
- Hypnosis
- Massage
- Meditation
- Mindfulness
- Multivitamins
- Music therapy
- Pets
- Pilates method and PhysicalMind method
- Prayer and spirituality
- Psyllium
- SAMe
- Tai chi and Qi Gong
- Therapeutic horseback riding
- Valerian
- Vitamin D and calcium
- Yoga
Fatigue

• **Conventional**
  – Diagnostic evaluation
  – Lifestyle changes
  – Medications
    • Provigil/Nuvigil
    • Amantadine
    • Antidepressants
    • others

• **Unconventional/Lifestyle**
  – Possibly effective
    • Caffeine
    • Cooling
    • Exercise, tai chi, yoga
    • Mindfulness, meditation
    • Multiple others
  – Uncertain
    • Ginkgo biloba
    • Acetyl-L-carnitine
  – CAUTION!
    • Ginsengs, DHEA, androstenedione, spirulina
Gait Disorder

• **Conventional**
  – Physical Therapy
  – Dalfampridine (Ampyra)
  – Spasticity Rx
  – Assistive Devices

• **Unconventional/Lifestyle**
  – Possibly effective
    • Cooling
    • Hippotherapy
    • Pilates
    • Tai Chi
    • Yoga
    • Multiple others
Dealing with the Realities of Clinical Practice

- Brief, strong, supportive statements
- Focus on one issue per visit
- Refer patients to information resources
- Share or transfer responsibility/accountability
  - Other providers (PCPs), patients
- Change practice model: “Direct Care,” “Concierge Care”

References

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  - www.neurologycare.net
  - www.nationalmssociety.org
- Books
References

• Articles

• Articles
Acknowledgments

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- Julie Lawton
- Many people with MS
- National MS Society
- Consortium of MS Centers
- MS Foundation
- MS Association of America
- Teva Neuroscience, Biogen-Idec, EMD-Serono, Pfizer, Bayer
- HealthOne Foundation
- Denver Botanic Gardens
- Hudson Gardens
- Denver Medical Library