

# COMPLEMENTARY MEDICINE – WHAT IS THE EVIDENCE?

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Dr. Shandis Price, MD, CCFP

Hot Topics in Primary Care

Friday October 13, 2017

# Faculty/Presenter Disclosure

- **Faculty:** Dr. Shandis Price, MD, CCFP
- **Relationships with commercial interests:**
  - **Not Applicable**

# Mitigating Potential Bias

- Not Applicable

# Objectives

- Define Complementary and Alternative Medicine (CAM)
- Define Integrative Medicine
- Discuss and explore different resources to review evidence of various supplements/CAM therapies
- Briefly review some common complementary therapies and evidence for their use
- Discuss an approach to patient care in the context of complementary therapies

# Complementary and Alternative Medicine (CAM)

- Definition:
  - Group of diverse medical and health care systems, practices and products that are not currently considered to be a part of conventional medicine

# Definitions (cont' d)

- Conventional medicine
  - Medicine as practiced by medical doctors and other allied health professionals (PT's, psychologists, nurses)
- Complementary therapies
  - Therapies used **together with** conventional medicine
- Alternative therapies
  - Therapies used **in place of** conventional medicine
- Integrative Medicine
  - Bringing conventional and complementary approaches together in a coordinated way

# CAM Therapies

- Biologically Based practices
  - Herbs
  - Dietary supplements
  - Foods/nutrition
  - Vitamins
- Mind-body therapies
  - Hypnosis
  - Guided imagery
  - Meditation
  - Yoga
  - Tai Chi / Qi Gong
  - Relaxation exercises
- Manual therapies
  - Massage
  - Chiropractic
  - Osteopathy
- Whole medical systems
  - Traditional Chinese Medicine / Acupuncture
  - Ayurveda
  - Naturopathic medicine
  - Homeopathy
- Energy medicine
  - Reiki
  - Therapeutic Touch

# CAM Therapies (continued)

- Some evidence may exist for some of these therapies, but there are many questions that still need to be answered by well-designed studies
  - Safety
  - Efficacy
- List of CAM therapies keeps changing, as those therapies proven to be safe and effective become adopted by conventional medicine

# How often are CAM therapies used by patients?

- National US survey 2012
  - Trends in use of Complementary Health Approaches 2002-2012 (updated 2002, 2007, 2012)
    - Any CAM therapy – 33.2%
    - Dietary Supplements – 17.7%
    - Deep Breathing Exercises – 10.9%
    - Yoga, Tai Chi, Qi Gong – 10.1%
    - Chiropractic/Osteopathic – 8.4%
    - Meditation – 8%
    - Massage – 6.9%
    - Homeopathy – 2.2%
    - Acupuncture – 1.5%
    - Naturopathy – 0.4%

# Health Canada – Natural Health Products

- Health Canada Survey (2010)
  - 73% have used a NHP (71% in 2005)
- Natural Health Products (NHP's)
  - Vitamins and minerals
  - Herbal remedies
  - Homeopathic medicines
  - Traditional medicines eg. TCM, Ayurvedic
  - Probiotics
  - Fatty acids (eg. Omega 3, 6, 9)

# NHP - Safety

- “natural” does not always equal safe
- Herb-drug interactions
- Manufacturing issues
  - Contamination, ingredients incorrect
- Unproven claims on bottle
- Possible side-effects/allergic reactions
  - 12% of people using NHP's have experienced adverse side effects (Health Canada 2010)

# Regulation of NHP's

- “Natural Health Products Regulations” – in place as of January 1, 2004 - Health Canada
  - Licensing requirements for the manufacture, packaging, labeling and importation of NHP's for sale in Canada
  - Labeling and packaging requirements
  - Good manufacturing practice standards
  - Evidence supporting health claims is reviewed by Health Canada

# Licensing of NHP's

- Licensed Natural Health Products Database
  - Contains information about NHP's licensed to be sold in Canada
  - NPN number
    - “Natural Product Number”
    - equivalent of DIN number for Rx and OTC medications
  - DIN-HM for homeopathic remedies

# Licensing of NHP's (continued)

- If has an NPN or DIN-HM number:
  - The product has been evaluated by Health Canada and found “safe and effective under the recommended conditions of use”
  - States the product is licensed and authorized for sale in Canada by the Natural and Non-prescription Health Products Directorate (NNHPD)

# Disclosure of CAM use to medical practitioners

- Patients often don't tell physicians about their CAM use
  - Rates of non-disclosure of CAM use range from 23-72%
- Reasons for non-disclosure of CAM use:
  - Concern about negative response from medical practitioner
    - Fear that practitioner wouldn't continue to treat them
    - Fear that practitioner wouldn't be supportive of their CAM use
    - Fear that practitioner may give negative response and dissuade them from using the CAM therapy
  - Perception that physician had little knowledge of CAM therapies, so didn't think they needed to know if patient using them
  - Medical practitioner didn't ask about CAM use or seemed uninterested

# Why is it important for physicians to ask about CAM therapy use?

- Safety
  - Adverse effects
  - Herb-drug interactions
  - Quality concerns
  - Delay of conventional treatment
- Potential benefits of CAM therapies
- Better understand patient's beliefs and concerns about their health care decisions
- Lack of openness to communication re CAM therapies may lead to:
  - Decreased trust in the therapeutic relationship
  - Patient use of potentially harmful, ineffective or expensive CAM therapies
- Discussing CAM use is not the same as promoting it

# Resources for CAM Therapies

- Health Canada website – Natural Health Products
  - regulations
- Natural Medicines database
- NCCIH – National Center for Complementary and Integrative Health
  - National Institutes of Health, U.S. Department of Health and Human Services
  - Website: [www.nccih.nih.gov](http://www.nccih.nih.gov)
- American Family Physician
  - [www.aafp.org](http://www.aafp.org) - “fact sheets” for supplements
- Lexicomp: Lexi-Interact
- PubMed

# Natural Medicines Database

- Previously called Natural Standard
- Access through U of M libraries
- Paid subscription
- *“Natural Medicines is impartial; not supported by any interest group, professional organization or product manufacturer”.*

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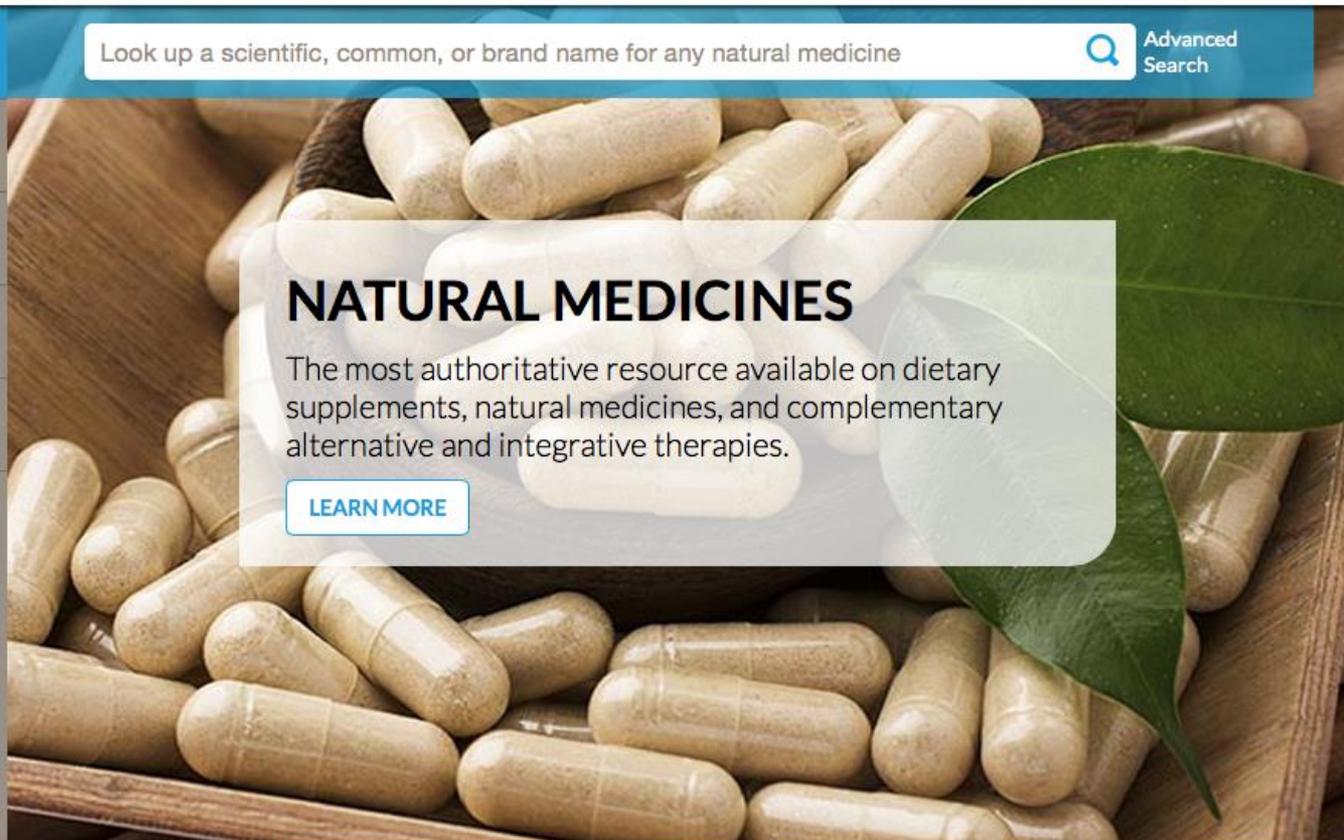
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# NCCIH

- National Center for Complementary and Integrative Health
  - Website: [www.nccih.nih.gov](http://www.nccih.nih.gov)
  - National Institutes of Health
  - U.S. Department of Health and Human Services
  - Mission
    - “ to define, through rigorous scientific investigation, the usefulness and safety of complementary and integrative health interventions and their roles in improving health and health care”



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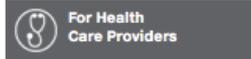
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Americans Are in Pain: Analysis of Data on the Prevalence and Severity of Pain from National Survey (August 11, 2015)

Study of Milk Thistle's Effects Highlights a Two-Phase Process (July 17, 2015)

Lack of Knowledge Is One Reason People Don't Use Complementary Health Approaches (June 18, 2015)

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- NIH framework points the way forward for building national, large-scale research cohort, a key component of the President's Precision Medicine Initiative (NIH; 09/17/15)
- Message From the Director: What We Don't Know About Supplement-Drug Interactions (09/17/15)
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- Aloe vera
- Alopecia Areata
- Alpha Lipoic Acid
- Alpha-linolenic Acid
- Alzheimer's Disease
- Amino Acids
- Androstenedione (Andro): FDA Warning (FDA; 03/11/04)
- Antibiotic-associated Diarrhea: See** Efficacy & Safety of Probiotics: Unanswered Questions
- Antioxidants
- Anxiety
- Appetite Suppressant: See** SmartLipo365 Issues Voluntary Nationwide Recall of Smart Lipo Due to Undeclared Sibutramine, Desmethylsibutramine, and Phenolphthalein (FDA; 06/03/15)
- Aristolochic Acid: See** Herbal Science International, Inc. Recalls Twelve Dietary Herbal Supplements Nationwide Because of Possible Health Risk Associated with Ephedra, Aristolochic Acid and Human Placenta (FDA;

### L

- L-Arginine (MedlinePlus)
- L-Tryptophan
- Labor Pain
- Lactoferrin
- Laetrile (Amygdalin)
- Lavender
- Lemon or Lemon Balm: See** Aromatherapy May Make Good Scents, But Does It Work? (04/01/08)
- Licorice Root or Glycyrrhizin
- Light Therapy
- Liver Disease
- Lobelia
- Low-back Pain
- Lung or Pulmonary Disease
- Lutein
- Lycium (MedlinePlus)
- Lycopene (MedlinePlus)
- Lyme Disease: See** Bismacine Not Approved for Use (FDA; 07/21/06)

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- Magnets
- Malaria: See** Message From the Director: Ancient Practice Meets Modern Science (10/04/11)
- [Manganese \(MedlinePlus\)](#)
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- D** Marvelon (CAN) (CYP3A4 Substrates (High risk with Inducers))  
St John's Wort
- D** Marvelon (CAN) (Estrogen Derivatives (Contraceptive))  
St John's Wort
- D** Marvelon (CAN) (Progestins (Contraceptive))  
St John's Wort
- B** Marvelon (CAN) (Estrogen Derivatives (Contraceptive))  
Amoxicillin (Penicillins)

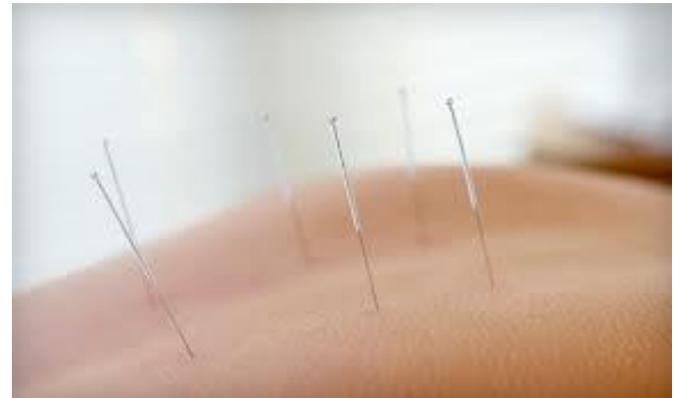
**DISCLAIMER:** Readers are advised that decisions regarding drug therapy must be based on the independent judgment of the clinician, changing information about a drug (eg, as reflected in the literature and manufacturer's most current product information), and changing medical practices.

# Complementary Therapies with Evidence for use

- Several complementary therapies have evidence for use for some common primary care problems
  - Acupuncture
  - Yoga
  - Meditation / Mind-body
  - Probiotics
  - St.John's Wort
  - Fish oil / omega-3

# Acupuncture

- Insertion of thin needles into specific locations (acupoints) along meridians (energy pathways)
- Based on theory of Qi (vital energy) flowing along meridians
  - Blockage of Qi leads to disease/problem
  - Acupuncture stimulates acupoints to relieve blockage of Qi
- Widely practiced by many different practitioners
  - Acupuncturists
  - Physicians
  - Physiotherapists
  - Dentists



# Acupuncture – Chronic Pain

- Acupuncture and Chronic Pain: Individual Patient Data Meta-Analysis (Vickers et al., Arch Int Med, 2012)
  - 29 RCT's and 17,922 patients
  - Acupuncture effective for back and neck pain, OA, chronic headache and shoulder pain
    - Significant differences between true and sham acupuncture, but differences are modest
    - Total effects of acupuncture are clinically relevant and include:
      - Effects of correct needling procedure
      - Non-specific physiologic effects of needling
      - Non-specific psychological effects (placebo effect)

# Acupuncture – Neck Pain

- Acupuncture for Neck Disorders
  - (Trinh et al., Cochrane Database of Systematic Reviews, 2016)
  - Acupuncture relieves pain better than sham acupuncture or inactive treatment at short-term follow-up (moderate-quality evidence)

# Acupuncture – Migraine Prevention

- Cochrane review: Acupuncture for the prevention of episodic migraine (Linde et al., 2017)
  - Compared to usual care:
    - Acupuncture decreased headache frequency by at least half in 41% of acupuncture group vs. 17% of no acupuncture group (NNT=4)
  - Compared to sham acupuncture:
    - Acupuncture had small but statistically significant reduction in headache frequency compared to sham acupuncture (NNT=10)
  - Compared to prophylactic drug treatment:
    - Acupuncture decreased h/a frequency statistically more than prophylactic medication
- Bottom Line:
  - “The available evidence suggests that a course of acupuncture consisting of at least six treatment sessions can be a valuable option for people with migraine.”
- Strength of evidence:
  - Moderate

# Acupuncture – Low Back Pain

- Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline from the American College of Physicians. (Qaseem et al., *Ann Intern Med.* 2017)
  - Acupuncture:
    - Chronic low back pain – moderate effect
    - Acute low back pain – small effect
  - Quality of evidence: moderate

# Mind-Body Therapies

- NCCIH definition:
  - “practices that employ a variety of techniques designed to facilitate the mind's capacity to affect bodily function and symptoms”



# Types of Mind–Body Therapies

- Relaxation and Stress reduction
  - Progressive muscle relaxation
  - Breathing exercises
- CBT
- Meditation
- Guided imagery
- Yoga
- Tai Chi / Qi gong
- Hypnosis
- Biofeedback

# Yoga

- Widely practiced
- Exercises involving controlled breathing, physical postures and meditation
- Some evidence for:
  - Back pain
  - Depression
  - HTN
  - Stress/Wellbeing



(Field, 2016)

# Yoga and Low Back Pain

- A Systematic Review and Meta-analysis of Yoga for Low Back Pain (Cramer et al., *Clin J Pain*, 2013)
  - 10 RCT's, total 967 patients
  - Strong evidence for short-term effects on pain, back-specific disability and global improvement
  - Strong evidence for long-term effect on pain
  - Moderate evidence for long-term effect on back specific disability
  - No serious adverse events
- Conclusion: Yoga can be recommended as an additional therapy for patients with chronic low back pain

# Meditation

- A variety of techniques aimed to focus or control one's attention



# Meditation (cont'd)

- Meditation is generally used for:
  - Anxiety
  - Depression
  - Pain
  - Stress
  - Insomnia
  - Coping with emotional/physical symptoms associated with chronic illnesses
  - Overall health and well-being

# Mindfulness

- Mindfulness means paying attention in a particular way; On purpose, in the present moment, and nonjudgmentally.” ~*Jon Kabat-Zinn*
- Training in mindfulness is aimed at increasing one’s awareness of thoughts, emotions and maladaptive ways of responding to stress
  - Thus helping to learn to cope with stress in a healthier, more effective way

# Mindfulness and Physician wellness

- CME course for practicing physicians that focused on self-awareness
- Included 8-week mindfulness course
- Improvement in:
  - Personal well-being
  - Burnout (emotional exhaustion, depersonalization and personal accomplishment)
  - Mood
  - Attitudes associated with patient centered care
    - Krasner et. al. JAMA 2009;302(12):1338-40

# MBSR

- Mindfulness-Based Stress Reduction
  - 8 week structured program teaching mindfulness meditation
  - Help people manage stress, pain and illnesses
  - Courses offered several times a year through the Canadian Mental Health Association of Winnipeg

# Insomnia and Mind-Body Interventions

- Many different mind-body interventions have been shown to be beneficial for insomnia:
  - CBT
  - Hypnosis
  - Meditation
  - Guided imagery
  - Biofeedback
  - Yoga
  - Qi Gong/Tai Chi
  - Music therapy

(Kligler, 2016)

# CBT for Insomnia (CBT-I)

- Effective and recommended as first-line treatment for chronic insomnia
- Combination of cognitive and behavioral treatment strategies
  - Cognitive
    - changing patients' dysfunctional beliefs and attitudes about sleep and insomnia
  - Behavioural
    - stimulus control therapy, sleep restriction, relaxation training, sleep hygiene

# Insomnia and other Mind-Body Interventions

- RCT on mindfulness meditation (Black et al., *JAMA*, 2015)
  - Mindful awareness practices improved sleep quality in older adults with sleep disturbances (more than sleep hygiene education)
- Meta-analysis of patients with cancer and insomnia (Chiu et al., *J Clin Psychiatry*, 2014):
  - Yoga, meditation, hypnosis, MBSR and Qi Gong have moderate effect on improving sleep quality for up to 3 months
- Cochrane review (Jespersen, 2015)
  - Listening to music may be effective for improving sleep quality, and is safe and easy to administer

# Probiotics



# Probiotics

- Live microorganisms from food or supplements that are intended to have health benefits when consumed
- Most common types probiotics
  - *Lactobacillus* species
  - *Bifidobacterium* species
  - *Saccharomyces boulardii*
    - Nonpathogenic yeast

# Probiotics and Prevention of Antibiotic-Associated Diarrhea

- Probiotics for the Prevention and Treatment of Antibiotic-Associated Diarrhea: Systematic review and Meta-Analysis (Hempel et al., *JAMA*, 2012)
  - 63 RCT's, 11,811 participants
  - Statistically significant reduction in antibiotic-associated diarrhea with probiotic use
    - RR 0.58
    - NNT=13
  - Most studies used *Lactobacillus* species +/- other species

# Probiotics and pediatric AAD

- Cochrane review 2015
  - 23 studies (3938 participants)
  - Protective effect of probiotics in preventing AAD in children (moderate quality evidence)
    - *Lactobacillus rhamnosus*
    - *Saccharomyces boulardii*
  - Dose: 5-40 billion CFU/day
  - Pooled estimate RR 0.46 (95% CI 0.35 to 0.61)
  - NNT – 10 to prevent one case of diarrhea

# Probiotics and *C.difficile*

- Cochrane review, 2013
  - Review of 23 RCT's (4213 patients)
  - Moderate quality evidence that probiotics are safe and effective for preventing *C.difficile* associated diarrhea
  - Probiotics decreased risk of *C.difficile* associated diarrhea by 64% when given with antibiotics

# Probiotics - Dosing

- Children: 5-10 billion CFU's/day
- Adults: 10-20 billion CFU's/day
  
- Start probiotic within 72hrs of starting antibiotics and continue for 1 week after stopping Abx

# St. John's Wort

- *Hypericum perforatum*
- Mainly used for mild-moderate depression



# St. John's Wort and Depression

- Cochrane review (Linde et al., 2008)
  - Reviewed 29 studies including 5489 patients with depression that compared treatment with St. John's Wort to either placebo or standard antidepressants for 4-12 weeks
  - St. John's Wort superior to placebo in patients with major depression
  - Similar effectiveness as standard antidepressants
  - Fewer side effects than standard antidepressants
  - Most studies focused on mild-moderate depression rather than severe depression

# St. John's Wort – Dose and Safety

- Dosage
  - 300mg TID
  - Extracts standardized to 0.3% hypericin
- Safety
  - Generally safe
  - **Multiple** interactions with medications
    - Induces cytochrome P450 enzymes
  - Possible risk serotonin syndrome if use with SSRI's
  - Decreases effectiveness of OCP and some Abx

# Fish Oil



# Omega-3

- Multiple epidemiological studies and RCT's have shown omega-3 fatty acids to significantly:
  - Reduce risk of CV events
  - Reduce sudden death by cardiac arrhythmias
  - Reduce all-cause mortality in patients with known coronary heart disease

Kris-Etherton, Circulation, 2002  
Schwalfenberg, CFP, 2006

# American Heart Association Recommendations (2002)

**TABLE 5. Summary of Recommendations for Omega-3 Fatty Acid Intake**

Population	Recommendation
Patients without documented CHD	Eat a variety of (preferably oily) fish at least twice a week. Include oils and foods rich in $\alpha$ -linolenic acid (flaxseed, canola, and soybean oils; flaxseed and walnuts)
Patients with documented CHD	Consume $\approx 1$ g of EPA+DHA per day, preferably from oily fish. EPA+DHA supplements could be considered in consultation with the physician.
Patients needing triglyceride lowering	Two to four grams of EPA+DHA per day provided as capsules under a physician's care

# Side Effects

**TABLE 4. Risk for Side Effects From Ingestion of Omega-3 Fatty Acids**

	Gastrointestinal Upset	Clinical Bleeding	Fishy Aftertaste	Worsening Glycemia*	Rise in LDL-C†
Up to 1 g/d	Very low	Very low	Low	Very low	Very low
1 to 3 g/d	Moderate	Very low	Moderate	Low	Moderate
>3 g/d	Moderate	Low	Likely	Moderate	Likely

\*Usually only in patients with impaired glucose tolerance and diabetes.

†Usually only in patients with hypertriglyceridemia.

# AHA update (Circulation, 2011)

- Secondary prevention CV disease
  - “For all patients, it may be reasonable to recommend omega-3 fatty acids from fish or fish oil capsules (1 g/d) for cardiovascular disease risk reduction. (*Level of Evidence: B*)

- More recent meta-analyses show conflicting results:
  - No association of omega-3's with all cause mortality, CV death, sudden cardiac death, or stroke
    - Rizos et al. *JAMA*, 2012
    - Kwak et al. *Arch Int Med*, 2012
- Canadian Cardiology Society (2016) Lipid guidelines
  - Do not recommend use of omega-3 supplements to reduce CVD events
  - Pooled evidence from RCT's show benefit for lowering TG levels at high doses omega-3 (2-4g/day)

# Omega-3 - summary

- Encourage patients to eat fish
- Evidence for lowering TG's at high doses (2-4g/day)
- Current evidence doesn't support using omega-3 supplementation for CVD prevention
- Safe

# Approach to Patient Care and Complementary Therapies

- Complementary therapies commonly used
- Patients may not disclose CAM use to physicians
  - Always ask about supplement/CAM use as regular part of hx
- Know where to look for evidence/information about supplements and CAM therapies
  - Counsel patients effectively
  - Drug and non-drug therapies for any given condition
- Be open to communication re: CAM therapies

# Questions/Comments?

- [Shandis.Price@umanitoba.ca](mailto:Shandis.Price@umanitoba.ca)

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