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The following slides were presented during the educational portion of IFFGD's 2020 Virtual Advocacy Event. To view this presentation and the all videos available during this program, please visit https://bit.ly/Adv_Edu.

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An Introduction to Supplements for Gastrointestinal Disorders

Jordan Shapiro, MD
Assistant Professor of Gastroenterology
Baylor College of Medicine
Houston, TX

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Disclosures

- Nothing to disclose

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Disclaimers

- The content is not intended to be a substitute for professional medical advice. Always seek the advice of your physician/qualified health provider with any questions you may have regarding a medical condition.
- I will use CAM (complementary and alternative medicine), though we will discuss a proposed name change
 - Similar to FGIDs and DGBIs

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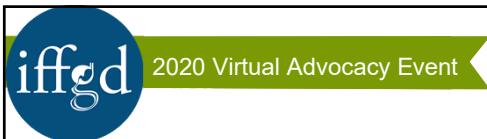
Objectives

- Introduction to complementary and alternative medicine (CAM)
- Challenges and concerns regarding supplement use
- Updates on a few supplements used for GI disorders
- How I approach supplement use

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Introduction to CAM

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What is CAM?

- “A group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine.” (NCCAM 2002)

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What's in a name?

- Complementary vs alternative vs integrative medicine
 - Complementary: used with conventional medicine
 - Alternative: used in place of conventional medicine
 - Integrative: blends all options, evidence-based, holistic view of health

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3 categories of CAM

- Natural products/supplements
 - E.g. – psyllium, probiotics, aloe vera, peppermint oil, Iberogast, turmeric, glutamine, melatonin, artichoke leaf extract
- Mind-body medicine
 - E.g. – cognitive behavioral therapy, gut-directed hypnosis, diaphragmatic breathing, yoga
- Traditional/newer medicinal systems
 - E.g. – Ayurveda, Traditional Chinese Medicine, functional medicine

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How common is CAM use?

- General population: 30 to 45%
- GI conditions:
 - Functional GI disorders: 35%
 - Irritable bowel syndrome (IBS): 21-73%
 - Inflammatory bowel disease (IBD): 21-60%
 - Chronic liver disease: 27%

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Predictors of CAM use

- Female
- Higher education
- Poorer health status
- Holistic orientation to health
- Interest in spirituality and personal growth psychology
- NOT dissatisfaction with conventional medicine

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Why do patients with GI disorders use CAM?

- Failure of conventional therapies to alleviate symptoms
- Desire for “natural” approach
- Sense of control
- Health promotion (as opposed to mere treatment of disease)

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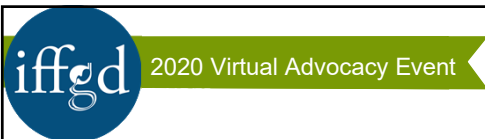
Disclosure of CAM use to physicians

- A minority of CAM use is physician recommended
- Most CAM is started without consultation with a physician
- CAM use is often NOT disclosed to physicians (30 to 80%)
- Disclosure varies by type of CAM use
 - More common with yoga (65%) and meditation (64%)
 - Less common with **herbs and/or supplements** (25%) and acupuncture (36%)
- Reasons for nondisclosure
 - Physicians not asking about it (57%)
 - Respondents believing physicians did not need to know about their use (46%)
 - Least often due to past (2%) or potential (3%) discouragement by physicians

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Concerns and controversies surrounding supplement use

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For some supplements, there are known risks

- Direct side effects
- Indirect side effects
 - Interactions with medications
 - Deferment of other proven treatments
 - Cost
 - Supplement burden



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For many supplements, risks are unknown

- Not knowing that something is bad (or how bad it is) doesn't mean it is good.

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Why are we still in the dark?

- There are currently over 80,000 herbs and dietary supplements on the market
- Federal law does not require supplements to be proven safe by the FDA before marketing
- Little regulation/standardization to verify what's in the bottle
 - E.g., melatonin dose ranged from -83 to +478% of labeled dose
- Research limitations:
 - Lack of rigor (i.e., blinding, randomization, controls, FDA endpoints)
 - Lack of funding
 - NIH (NCCIH) funded studies often not published and/or negative
 - Combination therapies
 - Vague/extremely broad mechanisms of action

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Physicians are not trained in use of CAM

- There is no standardized training/education on CAM therapies
- Bravewell Collaborative (2002 to 2015)
 - Philanthropic-driven push to get CAM into medical schools
 - 56 total member institutions by the end
 - Funded almost 100 Integrative Medicine fellowships at University of Arizona

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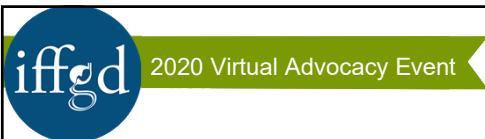
Non-scientific arguments in favor of supplements

- Appeal to tradition/antiquity (argumentum ad antiquitatem)
- “My friend/celebrity/Dr.TV said it cured their _____.”
- “I got the more expensive one” or “I bought this at my _____’s office.”
- “It had anti-inflammatory, analgesic, and immune-stimulating properties.”
 - Assumption that in vivo (test-tube/lab) result = in vitro (human) result
- “They didn’t use the whole herb/plant.”

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Highlights of a few common GI supplements

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Ginger

- Proposed mechanism of action:
 - Inhibits acetylcholine and serotonin signaling (similar to Zofran/ondansetron)
- Evidence for efficacy:
 - Prevention of post-operative nausea/vomiting
 - Few individual studies with positive findings, pooled analyses showed no difference
 - Nausea/vomiting of pregnancy
 - “Can be considered as a nonpharmacologic option” (Level C evidence – mostly expert consensus/opinion)
 - Prevention of chemotherapy-induced nausea/vomiting
 - No difference between ginger and placebo groups
- Dose:
 - 250mg to 1.5 grams per day in dried/extract forms in capsule/tablet form
- Risks:
 - Bleeding (inhibits platelets), drug interactions, heartburn, mouth irritation, mutagenicity

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Peppermint

- Proposed mechanism of action:
 - Calcium channel blockade (smooth muscle relaxant/antispasmodic)
- Evidence for efficacy:
 - Functional dyspepsia and irritable bowel syndrome
 - Several studies demonstrating improvement in global symptoms
 - Recent randomized controlled trial for IBS showed improvements in abdominal pain, discomfort, and IBS severity but not FDA-approved endpoints at 8 weeks
- Dose:
 - IBGard®: 2 90-mg capsules daily, 0.2-0.4 mL of the oil
- Risks:
 - Heartburn, diarrhea, nausea, vomiting, allergic skin reaction, asthma exacerbation, atrial fibrillation

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Turmeric (curcumin)

- Proposed mechanism of action:
 - Anti-inflammatory and analgesic properties
- Evidence for efficacy:
 - Irritable bowel syndrome
 - Systematic review of 5 studies concluded no significant improvement in symptoms
 - Inflammatory bowel disease
 - Add-on therapy for mild-to-moderate ulcerative colitis, but AGA guideline makes “no recommendation” based on an updated systematic review which failed to show a benefit
- Dose:
 - 1 to 3 grams of curcumin extract daily (turmeric is 3% curcumin by weight)
- Risks:
 - Nausea, constipation, headache

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Probiotics

- AGA:
 - No recommendation for Crohn's, ulcerative colitis, IBS, or treatment of *C.difficile*
 - Limit use to clinical trials
 - If taking, should consider stopping
 - Recommend against for children or adults with acute gastroenteritis
 - Specific instances in which patients may benefit from specific probiotics
 - Preterm, very low birthweight infants to prevention necrotizing enterocolitis, sepsis, and all-cause mortality
 - Prevention or maintenance of remission of pouchitis
 - Prevention of *C.difficile* in patients receiving antibiotics

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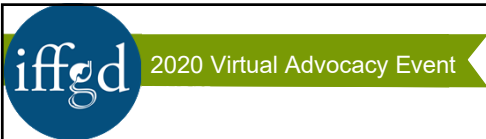
Cannabis

- Cannabinoids: phyto-, endo-, and synthetic (dronabinol/Marinol®)
- Proposed mechanism of action:
 - Cannabinoids inhibit excitatory nerves in the intestines, analgesic properties
- Evidence for efficacy:
 - FDA approved for weight loss in HIV/AIDs and for refractory chemotherapy-induced nausea/vomiting
 - All 4 studies in irritable bowel syndrome used dronabinol and none assessed symptom improvement
- Dose:
 - dronabinol: 2.5 or 5 mg twice daily
- Risks:
 - All about the THC:CBD ratio
 - Most likely predictor of admissions for IBS was cannabis use disorder
 - Cannabis hyperemesis syndrome

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How I approach supplement use

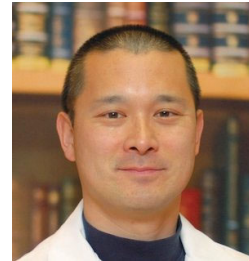
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My general approach to CAM

- “Always leave patients with hope.”

William D. Chey, MD
University of Michigan



- Start with the notion that CAM use is well-intended and serving a purpose
 - “I’m so glad you’re actively seeking solutions to improve your health.”
- Patients may find success with therapies that we cannot explain
 - It okay to be skeptical, concerned about supplement safety, AND thankful patients are better.
 - “I am so glad you found something that worked. I’d like to talk about a

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Ask (providers) and tell (patients)

- Any CAM use?
- Specific CAM therapies used (past, present, intended future)?
- How patients became interested/aware of CAM therapies?
- Effectiveness of CAM therapies for specific symptoms?
- Any adverse events related to CAM therapies?

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Guiding a trial of supplement use

1. Define the duration of a treatment trial. In most cases, a trial of 2-4 weeks should be adequate. Limit to one supplement at a time. If already on, consider a supplement holiday.
2. To the best of your ability, align your and your patient's treatment expectations.
3. Help the patient to understand optimal dose, timing, and frequency of any recommended supplement.
4. Inform patients of potential adverse events and any known drug-supplement interactions, noting that lack of information does not guarantee safety.

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Summary

- The spectrum of CAM therapies is vast
 - Natural products (supplements), mind-body medicine, systems of healing
- CAM use is common, often not discussed, but is well-intended
- There are direct/indirect risks of CAM and challenges providers may face in supporting/guiding its use
- Given the relative lack of regulation, standardization, and rigorously conducted clinical trials with many CAM therapies...
...patient-provider communication is critical to maximize safety and maintain hope

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2020 Virtual Advocacy Event

Thank You

Questions:

jordan.shapiro@bcm.edu

 @drjshapiro

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