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Supplements and Vasculitis

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University of Pennsylvania

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Note: These are just some of the slides from the original presentation.

The full video version of this lecture with all of the slides will be featured on the VF Website in September 2019.

Patient Educational Information on Dietary Supplements and Medical Marijuana

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Conflicts of Interest and Disclosures

- **Jennifer Trofe-Clark has no conflicts of interest to disclose**

- **I will be providing some educational information in this presentation regarding medical marijuana/cannabis, but cannot provide any recommendations regarding its use in a specific patient.**
  - Questions should be discussed on a case by case basis with your provider.

Learning Objectives

- Describe patterns of dietary supplement use in the United States
- Understand perceptions and misconceptions of dietary supplement use
- Demonstrate practical steps for vasculitis providers, care-givers and patients to have an open discussion about dietary supplement use and medical marijuana/cannabis

Dietary Supplement Definition

- **Dietary supplements are defined by the Dietary Supplement Health and Education Act (DSHEA) as a product (other than tobacco) intended to supplement the diet, that contains one or more of the following dietary ingredients:**
  - **Vitamins**
  - **Minerals**
  - **Herb or botanical**
  - **Amino Acids**
  - **a dietary substance for use by man to supplement the diet by increasing the total dietary intake**
  - **a concentrate, metabolite, constituent, extract, or combination of any ingredient**

Dietary and Supplement Health and Education Act of 1994
https://ods.od.nih.gov/About/DSHEA_Wording.aspx Accessed July 19, 2019

Dietary Supplements and Patient Perceptions

- They are natural, so they must be safe.
- They help to balance my body against medication effects.
- They are not actually medications, so my provider shouldn't care if I use them.
- My providers have bias against supplements because they want me to buy expensive prescription medications instead.
- I feel better knowing I am taking something natural versus more medications.

Question 1

- **What percent of adults in the United States in 2018 reported using a dietary supplement?**
  - **A) 25%**
  - **B) 50%**
  - **C) 75%**
  - **D) 100%**

Dietary Supplement Use Among Us

- 75% of Americans took a dietary supplement in 2018
  - 98% reported using vitamin/mineral supplements
  - 41% reported using herbal/botanical supplements

- Demographics of supplement use (from 2015 and 2018 data)
  - Women > Men
  - College > High School
  - Older > Younger
  - Chronic illness > Acute Illness
  - Patient with stroke, obesity, arthritis, breathing problems
  - Use of over the counter medications > none
  - Use of mail order pharmacy

2018 Council for Responsible Nutrition. Consumer Survey on Dietary Supplements: www.crnusa.org/CRNConsumerSurvey, accessed July 18, 2019

Question 2

- The Food and Drug Administration reviews all dietary supplements to make sure they are safe before manufacturers market them to the public

- A) True
- B) False

What's the Big Difference?

Regulatory Standard	FDA* Approved Medications	Herbal Supplements
Premarket notification	Required	Not Required
Proof of efficacy	Required	Not Required
Proof of safety	Required	Not Required
Post approval surveillance	Required	Required *Manufacturer to notify FDA within 15 days of receiving an serious adverse event report from consumer*
Good Manufacture Practice	Required	Required
Disease treatment claims	Allowed via Approval	Not Allowed *Has disclaimer on label stating this has not been evaluated by the FDA and is not intended to dx, cure, prevent or treat any disease*

FDA: Federal Drug Administration

R. Corey et. al., Nutrition in Clinical Practice 2014; 29: 322-31

Supplement Adverse Effects

- **Based on national representative surveillance data from 63 Emergency Departments (ED) in the United States from 2004-2013**
  - Estimated 23,000 ED visits/year attributed to adverse events from supplements
    - Included ingestion in unsupervised children
  - Estimated 2,154 hospitalizations annually
- **Review of FDA's Center for Drug Evaluation and Research (CDER), Tainted Products Marketed as Dietary Supplements Database 2007-2016**
  - 776 adulterated dietary supplements were identified and 146 different companies were implicated
    - 157 (20.2%) adulterated products had > 1 unapproved ingredient

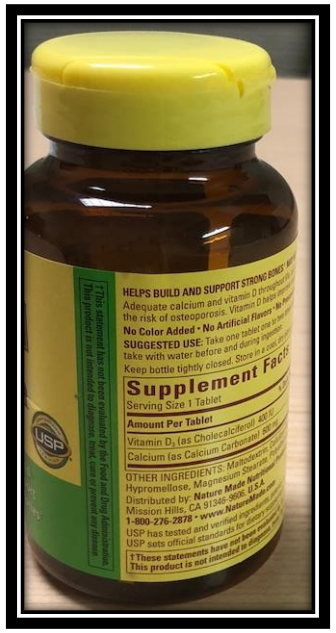
Geller AI, et al, NEJM 2015; 373: 1531-40, Tucker J et al. JAMA Network Open 2018;1(6):e183337

Types of Drug-Drug Interactions

- Pharmacodynamic
  - Supplement and medication have additive or effects that work against each other
    - Red Yeast Rice + statin (pravastatin) = additive effect
    - Echinacea + immunosuppressant = work against each other
- Pharmacokinetic
  - Supplements may affect how prescription medications are absorbed distribution, broken down in the body and elimination from the body.
    - Absorption of prescription medication may be increased or decreased
    - Supplement may compete with drug binding sites or change how "fast" the prescription medication is broken down or eliminated

Independent Verification of Supplements

- Look for independent verification processes:
  - United States Pharmacopeia (USP®) verified mark means the product:
    - *Contains the ingredients listed on the label in the declared amounts*
    - *Does not contain harmful levels of specified contaminants*
    - *Will break down/release in the body in a specific amount of time*
    - *Made according to FDA Good Manufacturing Practices*
- Alternative independent verifications review examples:
  - NSF® International
  - ConsumerLabs.Com®
  - UL®



USP Verified Mark Website. https://www.usp.org/verification-services/verified-mark accessed July 19, 2019
NSF Website. http://info.nsf.org/Certified/Dietary/ accessed July 19, 2019
ConsumerLabs.Com Website. https://www.consumerlab.com/ accessed July 19, 2019
UL Website. https://crs.ul.com/en/services/validation-and-verification/ accessed July 19, 2019

Question 3

- Have you ever had a discussion with your vasculitis provider(s) about dietary supplements you may currently be using or are thinking about using?

- A) Yes
- B) No

Having "the Supplement Talk"

Information patients & providers both thought were important about supplements

- **Supplements taken**
- **Advice**
- **Interactions**
- **Benefits/Adverse Drug Events**
- **Safety**
- **Directions**
- **Indications**
- **Alternative therapies**
- **Efficacy**
- **Evidence**
- **Patient expectations**

- Example of comment from patient focused on:
  - *Wanting to know if the information heard from friends/family was accurate*
  - *For providers to discuss risks and benefits of a particular supplement, in their opinion*

- Example of comment from provider focused on:
  - *Concern for dietary supplements not being FDA regulated*
  - *Not knowing what is in the supplement and needing to tell the patient that they don't know what it is*

Tarn DM, et. al, J Gen Intern Med 2014; 29: 1242-9

Discussion Points for Dietary Supplement Use Talk

- **Nonjudgmental and unbiased assessment with open dialogue**
  - **Why are you taking it?**
  - **Who recommended you to take it?**
  - **When did you start taking it?**
  - **How much and how often are you taking it?**
  - **How has it benefited you?**
  - **Do you feel it has harmed you?**

Anastasi JK, et. al, JNP, 2011(7); 1;29-35

Dietary Supplement Assessment

- **Provider should assess interaction potential with other medications/supplements**
  - Pharmacokinetic/Pharmacodynamic

- **Assess for supplement safety**
  - U.S. Pharmacopeial Convention http://www.usp.org/dietary-supplements/overview
  - Report adverse events via FDA Medwatch Online Voluntary Reporting Form
    - https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home
  - Contact manufacturer for further information
  - Providers can also review databases such as Micromedex® and LexiComp®

- **If supplement use deemed appropriate, choose an independent certified product with one of the following certifications whenever possible:**
  - USP® Verified Mark
  - ConsumerLab.Com®
  - NSF® International
  - UL®

- **Supplement use/questions should be addressed at every visit**

Patient Resources on Dietary Supplements

- Food and Drug Administration Consumer Resource on Dietary Supplements

http://www.fda.gov/Food/DietarySupplements/UsingDietarySupplements/ucm109760.htm (accessed July 19, 2019)

- NIH: National Center for Complementary and Integrative Health

https://nccih.nih.gov/health/know-science/how-medications-supplements-interact (accessed July 19, 2019)

- US Department of Agriculture

https://www.nutrition.gov/dietary-supplements/herbal-supplements

(accessed July 19, 2019)

- US National Library of Medicine: Medline Plus: Herbs and Supplements

https://medlineplus.gov/druginfo/herb_All.html (accessed July 19, 2019)

Medical Marijuana

- **Currently 34 states in the US, the District of Columbia, Guam and Puerto Rico allow for comprehensive medical marijuana/ cannabis programs.**

- **Medical marijuana/cannabis comes in different forms including pill, oil, topical, nebulization/vaporization (including dry leaf/plant form), tincture and liquid dosage forms.**
  - **Pharmacokinetics vary with different formulations**

- **Medical marijuana/cannabis is only approved for certain medical conditions and vary by state**
  - **Additionally allowable formulations for the inpatient setting may vary with institutions.**

National Conference of State Legislatures. http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx accessed July 19, 2019

Patient Education for Medical Marijuana/Cannabis

- **Patients should be encouraged to have open discussion with their providers regarding their use of medical marijuana/cannabis**

- **Prescribed medical marijuana/cannabis should only come from a licensed distributor**
  - **Limit exposure to contaminated or adulterated products**

- **Patients should adhere to the prescribed schedule**
  - **Use only product type prescribed and notify provider when this changes**

Provider Education for Medical Marijuana/Cannabis

- **Review formulation of medical marijuana/cannabis patient is using at every visit**
  - **Continually screen for drug-drug interactions with medical marijuana/cannabis and:**
    - **Over the counter medications**
    - **Dietary supplements**
    - **Prescription medications**
  - **Perform lab monitoring as clinically indicated**
  - **Work closely with certified physicians or dispensaries for questions**

- **Providers and patients will need ongoing education as practices, policies, and laws surrounding medical marijuana/cannabis continue to change**

- **Ongoing well-designed research is necessary to help guide future practice**

Bridgeman MB. Medical Cannabis. In: Murphy JE, Lee MW, eds. Pharmacotherapy Self-Assessment Program, 2019 Book 2. *Current Issues in Pharmacotherapy*. Lenexa, KS: American College of Clinical Pharmacy, 2019: 57-79.

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Take Home Points

1) Educate yourself about dietary supplements and potential risks
   - Natural does not equal safe

2) Keep up to date with state changes regarding medical marijuana/cannabis

3) Have an ongoing open dialogue with your providers regarding use of dietary supplements and medical marijuana/cannabis

4) If providers deemed dietary supplement appropriate for patient to use, choose an independent verified brand (USP®, NSF®, ConsumerLab®, UL®) whenever possible

5) Report any dietary supplement adverse effects to Food and Drug Administration (FDA)

http://www.fda.gov/Food/DietarySupplements/ReportAdverseEvent/

Thank you for listening!

Questions?

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