#### Dietary and Herbal Supplement Use in Rural Communities Implications for Child Health Outcomes

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## Lecture Roadmap

- Dietary Supplements (DS) definitions, history, regulation, disclosure, sales
- Epidemiology of DS use in children: national, next rural
- Addressing the research gaps (models of types of studies)
- Promising DS
- Recommendations for future research (safety and efficacy)

DS USE IN CHILDREN HAS POTETIAL PROMISES AND PITFALLS

LITTLE IS KNOWN ABOUT DS USE IN RURAL CHILDREN

# Defining Dietary Supplement

## Usage Data: A Historical Perspective

- **2000 B.C.** *Here, eat this root.*
- **1000 B.C.** *That root is heathen, say this prayer.*
- **1850** A.D. That prayer is superstition, drink this potion.
- **1940** A.D. That potion is snake oil, swallow this pill.
- **1985** A.D. *That pill is ineffective, take this antibiotic.*
- **2**000 A.D. *That antibiotic is artificial.* Here, eat this root.

How are herbs and dietary supplements regulated in the United States?

## Dietary Supplement Health and Education Act (DSHEA)

- Dietary supplements can be marketed without testing efficacy
- Safety need not be proved before marketing
- Require good manufacturing practices
- Structure/function product claims allowed
- Label claims do not require extensive evidence
- FDA approval not needed for marketing claims

#### **DSHEA's Definition of Dietary Supplements**

- Product (other than tobacco) that contains one or more of the following dietary ingredients:
  - a vitamin, mineral, herb or other botanical, or amino acid
  - a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients

### **Complexity of Supplements**

Multiple combinations of ingredients Many different types of products Teas, tinctures, capsules, shakes/drinks.... Products moved beyond clinical conditions Traditional medicines or cultural uses indigenous systems of medicine and healing often prominent in developing countries

#### What parents navigate...



# What about dietary supplements use in children today?



# Where Do We Find Pediatric Dietary Supplements?

- Teas (Kitchen)
- Soft and sport drinks
- Children's vitamins
- Infant formula
- Sports fitness products
- Weight loss/gain products
- Medicinal OTCs

- Personal care
  - hair care
  - bath preparations
  - skin care
- Tinctures
  - Essential oils

#### Start with the Parents in Rural Settings

Natural therapies, folk, and home remedies are a long-established component of the lives of rural populations
DS use is high in ADULTS
High in chronic health conditions and less availability of conventional health care services.

 Wardle, J., Lui, C.-W. and Adams, J. (2010), The Journal of Rural Health. doi: 10.1111/j.1748-0361.2010.00348.x Where is the data on dietary supplement use children in rural communities?

#### Prevalence Dietary Supplements



Dietary supplement use among infants, children, and adolescents in the U.S., 1999-2002 (NHANES)

- 32 % used dietary supplements
- 38 % non-Hispanic white; 22 % Mexican American;
   19 % non-Hispanic black
- Most common Multivitamins / minerals (18%).
- DS contain 29% Ascorbic acid, 26% retinol, 26% vitamin D, 21% calcium, and iron (19%)
  - Picciano, M. F. et al. Arch Pediatr Adolesc Med 2007;161:978-985.

Prevalence and SE (error bars) of dietary supplement use among infants, children, adolescents, and adults in the past 30 days



Picciano, M. F. et al. Arch Pediatr Adolesc Med 2007;161:978-985.



# Significant Findings

Supplement use was associated with:

- Families with higher income
- Smoke-free environment
- Lower body mass index (BMI)
- Less daily recreational screen time
  - Picciano, M. F. et al. Arch Pediatr Adolesc Med 2007;161:978-985.

# What about herb use in children in the United States?

#### Most Common Natural Products Among Children\* - 2007



\*Percentages among children who used natural products in the last 30 days.

Source: Barnes PM, Bloom B, Nahin R. CDC National Health Statistics Report #12. Complementary and Alternative Medicine Use Among Adults and Children: United States, 2007. December 2008.

Echinacea 37.2 %; Fish oil 30.5 %; Combination Herbal 17.9 %; Flaxseed 16.7 %

Biologically Based Therapies (HERBS and special diets)

- Correlated with:
  - Being a child (OR 1.60 [1.03, 2.51]) or an adolescent (OR 2.15 [1.35, 3.44])
  - Living in the West (OR 1.89 [1.24,2.90])
  - Having parents who are college educated (OR 3.55 [1.88, 6.69])
  - Non-Hispanic blacks and Hispanics (OR 0.60 [0.37, 0.96] OR 0.62 [0.40, 0.95])
  - Birdee G. Pediatrics. 2010 Feb;125(2):249-56.

# Notable Findings

Delays in health care due to difficulties with access ■ OR 1.50 [1.07, 2.10] Medical conditions including: ■ insomnia (odds ratio 2.60 [1.76, 3.85]) fever (odds ratio 1.47, [1.08, 2.00]) reflux (odds ratio 1.72 [1.10, 2.69]) ■ sinusitis (odds ratio 1.45 [1.02, 2.05])

# What about the regional studies?

# Survey of WIC participants in Kansas and Wisconsin

#### ■ (N=2,562)

- Caregivers in WIC clinic completed a survey about herb use.
  38% caregivers and 35% children used herbs
- Of the caregivers who gave herbs to their children, 11% were from rural settings
- Herb use > Latino children (48.4%) and caregivers (43.4%)
- Aloe, chamomile, garlic, peppermint, lavender, cranberry, ginger, echinacea, St. Johns Wort, tea tree

Lohse, B. Volume 106, Issue 2, February 2006, Pages 227-237

### Survey in Southern Arizona

Families of 376 children who were receiving services in a regional facility that serves children with special health care needs

#### 19% used herbs

Sanders, et al. (2003). Use of Complementary and Alternative Medical Therapies Among Children With Special Health Care Needs in Southern Arizona. Pediatrics. 111 (3).

### North Carolina Behavioral Risk Factor Surveillance System

- 2001 population-based telephone survey adults (N 2982)
- 20% medicinal herbs in the past year.
  5% reported giving their children herbal medicines
- What is associated with giving their child a herb?
  - having taken medicinal herbs themselves
  - adults without health coverage anytime in the previous 12months

Wheaton et al. (2005). Annals of Epidemiology. 15 (9):678-685.

# What about special populations of children?

### **Kids with Chronic Illness**

- 505 chronically ill children and adolescents
  - Asthma, Cystic fibrosis
  - Diabetes
  - Cancer
  - Renal transplantations
  - Seizures
  - Rheumatological and neurobehavioral disorder

Ball SD, J Am Diet Assoc. Jan 2005

#### Kids with Chronic Illness: Results

- Mean age of 9.9 +/- 5.3 years
- 62% of the population used dietary supplements
  Only 20% of those using non-prescribed dietary supplements had discussed this use with the health care provider

What types of studies would be helpful to rural children and their families ?

#### Models of dietary supplements studies

To supplement or not to supplement?
 Dietary patterns – connections to obesity

Contribution of dietary supplements to nutrient adequacy among children in Hawaii

- Cross-sectional study. Children aged 8 to 11 years (n=185)
- A 24-hour food recall and a DS record
- Prevalence of dietary nutrient adequacy from foods alone (33% to 100%)
- Increased to 59% to 100% nutrient contribution when DS was included.
  - Martin CL. J. American Dietetic Association. 108(11):1874-80, 2008 Nov.

#### Models of dietary supplements studies

Diet patterns

 Pinpoint Specific vitamin and mineral deficiencies (vitamin D, calcium, iron)

#### Vitamin D (2003-2006) NHANES

- Diet, dietary supplement, and antacid use
- 1-3 y had the highest prevalence of meeting the AI from dietary and total calcium intakes.
- Females 14-18 y had the lowest prevalence of meeting the AI.
  - Bailey RL Journal of Nutrition. 140(4):817-22, 2010 Apr.

#### Models of dietary supplements studies

- Diet patterns and obesity
- Specific Vitamin and mineral deficiencies (vitamin D, calcium, iron)
- Safety of dietary supplements in children
  - Dietary supplement itself
  - Contamination or adulteration of the DS
  - Accidental ingestions

DS-related adverse events reported to the California Poison Control Centers

- 1183 telephone calls were retrieved
- DS exposure occurred in 438 children (53%).
- DS-related AEs were reported 134 children (28%).
- 84% intentional ingestion had a AE
- 16% accidental ingestion were reported a AE
  - Dennehy CE, American Journal of Health-System Pharmacy. 62(14) 2005

# **Promising Supplements**

#### Vitamin D and Calcium

- Omega 3 fatty acids
  - Fish oil, flax seeds
- Probiotics
- Cranberry
- Elderberry
- Ginger
- Chamomile
- Melatonin



#### **Evidence for Probiotics**

Lactobacillus GG reduced incidence and duration of diarrhea in children treated with antibiotics
Van Niel, C. Pediatrics, 109/4(678-684), 2002
Useful adjunct to rehydration therapy in treating acute infectious diarrhea in children
Allen. S. Cochrane Review, 2005

#### **Evidence for Cranberry**

- Jepson et al.- Cochrane review of ten clinical trials on the prevention of UTIs (n = 1049, five cross-over, five parallel group).
- Cran, cran-lingonberry juice versus placebo, juice or water were evaluated in 7 studies, and cran tablets versus placebo in four studies (1 study evaluated both juice and tablets).
- The authors found that products significantly reduced the incidence of UTIs at 12 months (RR 0.65, 95% CI 0.46 to 0.90) compared with placebo/control.
  - Jepson et al. Cochrane review, 2009

## Final Thoughts on Research Agenda

- Characteristics and diversity of DS use in children and families in the rural setting
- MORE Safety studies and Efficacy
- Design research tools to study DS/herbs in a culturally sensitive way understanding regional differences
- Mixed method designs

#### Conclusion

- DS use in children is common
- There is little data on DS use in children living in rural settings
  - Who, What, Where, Why
  - Connections to barriers to health care?
  - Safety?
  - Effectiveness?