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What does the Evidence Say: How to Understand, Interpret and Support Evidence Based Practices in Breastfeeding

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Sherri Mendelson, PhD, RNC, CNS, IBCLC

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Why Do You Do What You Do?

- What is Your Role in Health Care
- Provision of education
- Encouragement of best practice for patients and colleagues
- Patient support
- Improvement of community health

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Cultivation of Spirit of Inquiry

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- A spirit of inquiry: attitude in which questions are encouraged about existing practices; allows lactation care providers to feel comfortable with questioning current methods of practice and challenging these practices to create improvements and change.
  - Always question current practices.
  - Integrate EBP as higher standard/mission/philosophy and include competencies for EBP.
  - Recognition of use of EBP.

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Objectives

At the conclusion of this presentation the participants will be able to:

- Interpret the results of lactation studies based on two different research studies
- Communicate two key aspects of a research report that can be used to support evidence-based practice
- Differentiate research-based literature from non-research-based literature

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What is Evidence-Based Lactation Care?

- **Evidence-based lactation care** is an approach to making quality decisions and providing lactation care based upon personal clinical expertise in combination with the most current, relevant **research** available on the topic. This approach is using evidence based practice (EBP) as a foundation. EBN implements the most up to date methods of providing care, which have been proven through appraisal of high quality studies and statistically significant research findings.

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Goal of Evidence-Based Lactation Care

- To improve the health and safety of mothers and babies while also providing care in a cost-effective manner to improve the outcomes for both the patient and the healthcare system. It is a process founded on the collection, interpretation, appraisal, and integration of valid, clinically significant, and applicable research.

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Evidence Based Practice

- The evidence used to change practice or make a clinical decision can be separated into **levels of evidence** that differ in type of study and level of quality. To properly implement evidence-based lactation care, the **knowledge of the person providing care**, the **patient's preferences**, and **multiple studies of evidence** must all be collaborated and utilized in order to produce an appropriate solution to the task at hand.

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What is the Evidence?

- Levels of Evidence

- Level I: Evidence from a systematic review of all relevant randomized controlled trials (RCT's), or evidence-based clinical practice guidelines based on systematic reviews of RCT's
- Level II: Evidence obtained from at least one well-designed Randomized Controlled Trial (RCT)
- Level III: Evidence obtained from well-designed controlled trials without randomization, quasi-experimental
- Level IV: Evidence from well-designed case-control and cohort studies
- Level V: Evidence from systematic reviews of descriptive and qualitative studies
- Level VI: Evidence from a single descriptive or qualitative study
- Level VII: Evidence from the opinion of authorities and/or reports of expert committees

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Melnyk and Fineout-Overholt

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The Steps in the EBP Process

Assess	**Start with the patient -- a clinical problem or question arises from the care of the patient**
Ask	**Construct a well built clinical question derived from the case**
Acquire	**Select the appropriate resource(s) and conduct a search**
Appraise	**Appraise that evidence for its validity (closeness to the truth) and applicability (usefulness in clinical practice**
Apply	**Return to the patient -- integrate that evidence with clinical expertise, patient preferences and apply it to practice**
Evaluate	**Evaluate your performance with this patient/patient group**

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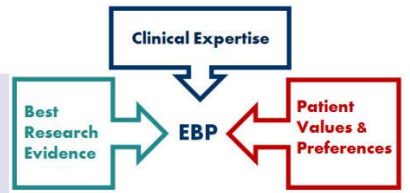
What Do you Know?

- What are three pieces of knowledge that you teach many of the mothers you care for?



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What Does the Study Tell You

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What Was the Study Looking At?

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- What is the study looking at or testing
  - The question
  - The purpose
- What is already known
  - Review of the literature
  - Background
  - Related concepts

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Who is Involved

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- Who was studied
  - Who is the population and who is the study group
- How many were studied
- How did the participants get included in the study

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How Was the Study Conducted

- Methods-
  - Tools used-are they valid and reliable
    - Are they valid and reliable for the group being studied
  - Qualitative or quantitative
  - Experimental or quasi-experimental
  - Systematic review versus meta-analysis

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How Were the Data Analyzed

- Methods for data analysis
  - Are they appropriate
- Were they tested for significance
  - Where was the level of significance set
  - Is this appropriate for the risk

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The Results

- Did the results match the research question
- Are the results significant
- Are the results within the level of confidence

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Level of Significance

- Level established by the researcher prior to data analysis-usually at the beginning of the study
- Definition:
  - Risk of making a Type 1 error

Type 1 Error

- Rejection of the null hypothesis when it is true
- Researcher concludes that there is a relationship between two variables when there is not
  - Example: Study is examining whether having a smiley-face sticker on the meal tray increases mothers' exclusive breastfeeding. The study finds that the smiley-face sticker works. When the study is repeated with two similar populations with a larger sample it is not found to work.
  - Why was there a type 1 error?

How to Set the Level of Significance

- How important is it to avoid a type 1 error?
  - Important (always) but not life threatening
  - Life threatening

Setting Significance Level

- Significance set at p<.01; .001; .0001
  - The risk of a type 1 error is lower
  - The risk of finding no significance when it is really there is higher- Type 2 error
- Significance set at p<.05
  - Type 1 error is higher
  - Type 2 error is lower

Meaning of the Level of Significance

- P<.05
  - If you reject the null hypothesis (conclude that there is a significant relationship between groups) you will be wrong 5/100 times and correct 95/100 times
- P<.01
  - If you reject the null hypothesis (conclude that there is a significant relationship between groups) you will be wrong 1/100 times and correct 99/100 times
- P<.001
  - If you reject the null hypothesis (conclude that there is a significant relationship between groups) you will be wrong 1/1000 times and correct 999/1000 times

Risk in Research Conclusions

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- When is lowering the risk of a type 1 or type 2 error important?
  - Potential for harm to mother or baby?
  - Increased cost with no benefit?
  - Closing programs that actually are beneficial?

What Are the Conclusions

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- Do the conclusions match the question
- Do the conclusions match with the data analysis and results
- Are the conclusions useful for practice

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Are There Limitations

- Are they included
- Do you see limitations that were not mentioned
- Do the limitations invalidate the findings

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Translation into Practice

- How much evidence does it take?
  - What is the risk to mother/baby by not translating something valid into practice
    - Demand feeding versus every four hours
- How much risk is involved if you are wrong?
  - What is the risk to mother/baby by translating something invalid into practice
    - Allowing HIV mothers to breastfeed

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WHEN DO YOU NEED A TRANSLATIONAL RESEARCH STUDY

- When your population is different than the study population
- When the evidence is conflicting
- When there is solid evidence but you cannot convince the practitioners (physicians, nurses, administration, etc.)
  - Systematic Review that demonstrates appropriateness
  - Professional Guidelines

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Postpartum Depression and Breastfeeding

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JOGNN November-December 2016 45(6):760-771

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Objective To determine if symptoms of postpartum depression and postpartum weight varied according to the level of **breastfeeding** among women of Mexican origin at 1 month and 6 months postpartum.

Design Secondary quantitative analysis to study the differences in postpartum weight and depression among the mothers in the study who breastfed and those who did not.

Setting A heavily Hispanic community located in a major Southwestern U.S. city.

Participants Women of Mexican origin (N = 150) who enrolled during their third trimesters in a local Special Supplemental Nutrition Program for Women, Infants, and Children clinic and were followed for 6 months.

Methods Weight was measured at 1 month and at 6 months postpartum at home visits with validated digital scales. **Breastfeeding** was measured according to World Health Organization criteria and recorded after monthly phone calls. Depression was measured at home visits at 1 month and 6 months with the Edinburgh Postnatal Depression Scale

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JOGNN November-December 2016 45(6):760-771

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Results At 6 months postpartum, participants who did not breastfeed had the highest scores on the Edinburgh Postnatal Depression Scale; participants who breastfed nonexclusively had the lowest scores (p =.067). At both time points, there was a significant difference in weight (p = .017) between women who were doing any **breastfeeding** and women who were not **breastfeeding**.

Conclusion Breastfeeding, even if not exclusive, contributed to lower depression scores and significantly lower postpartum weight among this sample of Mexican American women.

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Examples of Evidence or Lack Thereof

Prenatal Stress, Anxiety, and Depressive Symptoms as Predictors of Intention to Breastfeed Among Hispanic Women

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- ***Background:*** Studies on the relationship between prenatal psychosocial risk factors and breastfeeding are sparse, particularly in Hispanic women.

Tabassum Z. Insaf, Renée Turzanski Fortner, Penelope Pekow, Nancy Dole, Glenn Markenson, and Lisa Chasan-Taber. Journal of Women's Health. August 2011, 20(8): 1183-1192. doi:10.1089/jwh.2010.2276.

Prenatal Stress, Anxiety, and Depressive Symptoms

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- Evaluated this association among 424 participants in *Proyecto Buena Salud*, an ongoing prospective cohort of pregnant Hispanic women in Western Massachusetts. The Perceived Stress Scale (PSS), the State-Trait Anxiety Inventory (STAI), and the Edinburgh Postnatal Depression Scale (EPDS) were administered by bilingual interviewers in early pregnancy (mean 13.6 weeks gestation) and midpregnancy (mean 25.7 weeks gestation). Information on sociodemographic, behavioral, and acculturation factors was also collected. Breastfeeding intention was abstracted from medical records. Poisson regression was used to calculate prevalence risk ratios (PRR) and 95% confidence intervals (CI).

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Prenatal Stress, Anxiety, and Depressive Symptoms

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- ***Results:*** A total of 274 (64.6%) women reported a positive intention to breastfeed. In multivariate analyses, women in the highest quartile of perceived stress (PRR 0.76, 95% CI 0.62-0.94) in early pregnancy and highest quartile of anxiety in early pregnancy (PRR 0.66, 95% CI 0.54-0.81) and midpregnancy (PRR 0.80, 95% CI 0.64-1.00) were less likely to intend to breastfeed compared to women in the lowest quartile.

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Prenatal Stress, Anxiety, and Depressive Symptoms

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- Women who had at least probable minor depression (EPDS score ≥13) (PRR 0.79, 95% CI 0.65-0.95) or probable major depression (EPDS score ≥15) (PRR 0.77, 95% CI 0.62-0.96) during midpregnancy were less likely to intend to breastfeed compared to women without depressive symptoms. Similarly, women with persistent depressive symptoms over pregnancy were 24%–33% less likely to intend to breastfeed compared to women without depressive symptoms.

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Prenatal Stress, Anxiety, and Depressive Symptoms

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- ***Conclusions:*** Psychosocial risk factors during pregnancy are important predictors of breastfeeding intention among Hispanic women.
- So-what do we do with this?
  - Find women who are pregnant and depressed and make them breastfeed?
  - Assume that women that choose not to breastfeed are depressed and leave them alone?
  - Put women that choose not to breastfeed into therapy?

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What Do You Recommend for Sore Nipples

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- Cabbage leaves
- Tea bags
- Lanolin
- Air-drying
- Expressed breast milk
- Breast shells
- Nipple shields

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What is the Evidence

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- Research has demonstrated that warm water compresses can be as effective as commercial products such as ointments and shells in relieving nipple pain (Buchko et al., 1994; Pugh et al., 1996).
- Lactation consultants have anecdotally reported positive outcomes on sore nipples from the use of virgin coconut oil, but no studies could be located that used virgin coconut oil on sore or damaged nipples.

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Painful Nipples-Cochrane Review

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- We found four trials of good methodological quality involving 656 women, which evaluated five different interventions including glycerine pads, lanolin with breast shells, lanolin alone, expressed breast milk, and an all-purpose nipple ointment. All studies included education to position the infant at the breast correctly as part of routine care to both intervention and control groups.

Dennis, Jackson & Watson, 2014 39

Painful Nipples-Cochrane Review

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- Currently, there is not enough evidence to recommend any specific type of treatment for painful nipples among breastfeeding women. These results suggest that applying nothing or expressed breast milk may be equally or more beneficial in the short-term experience of nipple pain than the application of an ointment such as lanolin. One important finding in this review was that regardless of the treatment used, for most women, nipple pain reduced to mild levels approximately seven to 10 days' after giving birth (postpartum).

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Effect of Restricted Pacifier Use in Breastfeeding Term Infants For Increasing Duration of Breastfeeding (Review)

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Pacifier Use: Cochrane Review

- We updated the search on 30 June 2016. We identified three studies, with a total of 1915 babies. One study could not be included in the analysis and so findings are based on two studies involving 1302 infants. The mothers in the studies were motivated to breastfeed recruited immediately after birth and at two weeks of life, respectively. We found that unrestricted use of a pacifier did not affect the proportion of infants exclusive or partial breastfeeding at three and four months. The studies were remarkably consistent. We judged this to be *moderate-quality evidence*. There was no information on the effect of pacifier use on any breastfeeding difficulties experienced by the mothers, maternal satisfaction, infant crying and fussing and infant problems such as otitis media and dental malocclusion.

Jaafar, Ho, Jahanfar, & Angolkar, 2016

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Pacifier Use: Cochrane Review

- In motivated mothers, there is *moderate-quality evidence* that pacifier use in healthy term breastfeeding infants before and after lactation is established does not reduce the duration of breastfeeding up to four months of age. However, there is insufficient information on the potential harms of pacifiers on infants and mothers. Until further information becomes available on the effects of pacifiers on the infant, mothers who are well-motivated to breastfeed should be encouraged to make a decision on the use of a pacifier based on personal preference.

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Optimal Duration of Exclusive Breastfeeding (Review)

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Optimal Duration of Exclusive Breastfeeding: Cochrane Review

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- Infants who are exclusively breastfed for six months experience less morbidity from gastrointestinal infection than those who are partially breastfed as of three or four months, and no deficits have been demonstrated in growth among infants from either developing or developed countries who are exclusively breastfed for six months or longer. Moreover, the mothers of such infants have more prolonged lactational amenorrhea. Although infants should still be managed individually so that insufficient growth or other adverse outcomes are not ignored and appropriate interventions are provided, the available evidence demonstrates no apparent risks in recommending, as a general policy, exclusive breastfeeding for the first six months of life in both developing and developed-country settings.

Kramer & Kakuma, 2012

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Optimal Duration of Exclusive Breastfeeding: Cochrane Review

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- 23 independent studies meeting the selection criteria: 11 from developing countries (two of which were controlled trials in Honduras) and 12 from developed countries (all observational studies).

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What Do You Advise Regarding Supplementing

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New Evidence: Peanut Allergy

- 'There is now scientific evidence that health care providers should recommend introducing peanut-containing products into the diets of 'high-risk' infants early on in life (between 4 and 11 months of age) in countries where peanut allergy is prevalent because delaying the introduction of peanut can be associated with an increased risk of peanut allergy.''

AAP's endorsement August 2015

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New Evidence: Peanut Allergy

- The study in question, conducted in England and published in February in the *New England Journal of Medicine, involved 640 at-risk babies, ages 4-11 months. (Babies who develop severe eczema or an egg allergy in the first six months of life are considered high risk for a nut allergy.)*

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What to do with Conflicting Evidence

- Exclusive breastfeeding for 6 months
- AAP reaffirms its recommendation of exclusive breastfeeding for about the first six months of a baby's life, followed by breastfeeding in combination with the introduction of complementary foods until at least 12 months of age, and continuation of breastfeeding for as long as mutually desired by mother and baby.

Breastfeeding and the Use of Human Milk," published in the March 2012 issue of Pediatrics (published online Feb. 27), the American Academy of Pediatrics (AAP)

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Maintain Evidence Based Practice

- Know where to find best evidence
- Know how to examine the evidence
- Understand that the evidence changes over time
  - New findings
  - New circumstances
- Do not practice in a bubble!

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