MetaAnalysis – Systematic Review Potential PURL Review Form PURL Jam Version

PURLs Surveillance System Family Physicians Inquiries Network

SECTION 1: Identifying Information for Nominated Potential PURL [to be completed by PURLs Project Manager]

- A. Citation: Ciardulli A, Saccone G, Anastasio H, Berghella V. Less-Restrictive Food Intake During Labor in Low-Risk Singleton Pregnancies: A Systematic Review and Meta-analysis. Obstet Gynecol. 2017 Mar;129(3):473-480. doi: 10.1097/AOG.000000000001898. Review. PubMed PMID: 28178059.
- B. Link to PubMed Abstract: https://www.ncbi.nlm.nih.gov/pubmed/?term=28178059
- C. First date published study available to readers: March 2017
- D. PubMed ID: 28178059
- E. Nominated By: Emily White Van Gompel
- F. Institutional Affiliation of Nominator: University of Chicago
- G. Date Nominated: 2/10/2017
- H. Identified Through: Obstetrics & Gynecology
- I. PURLs Editor Reviewing Nominated Potential PURL: Corey Lyon
- J. Nomination Decision Date: 2/15/2017
- K. Potential PURL Review Form (PPRF) Type: Systematic Review
- L. Assigned Potential PURL Reviewer: Dean Seehusen
- M. Reviewer Affiliation: Eisenhower Army Medical Center
- A. Abstract: OBJECTIVE:

To evaluate benefits and harms of food intake during labor.

DATA SOURCES:

Electronic databases such as MEDLINE and ClinicalTrials.gov were searched from their inception until October 2016.

METHODS OF STUDY SELECTION:

We included randomized trials comparing a policy of less-restrictive food intake with a policy of more restrictive food intake during labor. The primary outcome was the mean duration of labor. Meta-analysis was performed using the random-effects model of DerSimonian and Laird to produce summary treatment effects in terms of either a relative risk or a mean difference with 95% confidence interval (CI).

TABULATION, INTEGRATION, AND RESULTS:

Ten trials, including 3,982 laboring women, were included. All the studies involved laboring singletons considered at low risk because they had no obstetric or medical complications that would increase the likelihood of cesarean delivery. In three studies, women were allowed to select from a low-residue diet throughout the course of labor. One study had honey date syrup as the allowed food intake. Five studies had carbohydrate drinks as food intake in labor. The last one was the only trial that allowed unrestrictive food intake. In the included studies, all women in the intervention group were allowed the assigned food intake until delivery, whereas women in a control group were allowed only ice chips, water, or sips of water until delivery. A policy of less-restrictive food intake was associated with a significantly shorter duration of labor (mean difference -16 minutes, 95% CI -25 to -7). No other benefits or harms in obstetric or neonatal outcome were noticed. Regurgitation during general anesthesia and Mendelson

syndrome did not occur in either group.

CONCLUSION:

Women with low-risk singleton pregnancies who were allowed to eat more freely during labor had a shorter duration of labor. A policy of less-restrictive food intake during labor did not influence other obstetric or neonatal outcomes nor did it increase the incidence of vomiting. Operative delivery rates were similar.

B. Pending PURL Review Date: 9/19/2017

SECTION 2: Critical Appraisal of Validity [to be completed by the Potential PURL Reviewer]

- A. What types of studies are included in this review? RCTs
- B. What is the key question addressed by this review? Summarize the main conclusions and any strengths or weaknesses.

Duration of labor. Women allowed a less restricted diet had a statistically significant shorter duration of labor (16 minutes; 95% CI = 7-25 minutes) than women in control groups that were restricted to ice or water during labor.

- C. Study addresses an appropriate and clearly focused question. Adequately addressed Comments:
- D. A description of the methodology used is included. Well covered Comments:
- E. The literature is sufficiently rigorous to identify all the relevant studies. Well covered Comments:
- F. Study quality is assessed and taken into account. Well covered Comments:
- G. There are enough similarities between selected studies to make combining them reasonable. Adequately addressed

Comments: The diet allowed in the studies did vary widely.

- H. Are patient oriented outcomes included? If yes, what are they? Yes. Duration of labor. Other maternal outcomes such as c/s rate, operative vaginal delivery, vomiting, general anesthesia, Mendelson syndrome. Neonatal outcomes such as APGAR scores.
- I. Are adverse effects addressed? If so, how would they affect recommendations? N/A
- J. Is funding a potential source of bias? If yes, what measures (if any) were taken to ensure scientific integrity?
 No.

- K. To which patients might the findings apply? Include patients in the metaanalysis and other patients to whom the findings may be generalized. Low risk women with singleton pregnancies in labor.
- L. In what care settings might the findings apply, or not apply? L&D
- M. To which clinicians or policy makers might the findings be relevant? Any L&D provider following low risk women in addition to anesthesiologists, nurse anesthetists, and pediatricians.

SECTION 3: Review of Secondary Literature
[to be completed by the Potential PURL Reviewer]
[to be revised by the Pending PURL Reviewer as needed]

Citation Instructions: For up-to-date citations, use style modified from

http://www.uptodate.com/home/help/faq/using_UTD/index.html#cite & AMA style. Always use Basow DS on editor & current year as publication year.

Example: Auth I. Title of article. {insert author name if given, & search terms or title.} In: Basow DS, ed. UpToDate [database online]. Waltham, Mass: UpToDate; 2009. Available at: http://www.uptodate.com. {Insert date modified if given.} Accesses February 12, 2009. [whatever date PPRF reviewer did their search.}

For DynaMed, use the following style:

Depression: treatment {insert search terms or title}. In: DynaMed [database online]. Available at http://www.DynamicMedical.com. Last updated February 4, 2009. {Insert date modified if given.} Accessed June 5, 2009. {search date}

A. DynaMed excerpts

- a. "oral nutrition"
 - i. allow unrestricted drinking clear liquids and sucking on ice chips as needed throughout labor (1, 2, 3)
 - ii. isotonic drinks may help prevent ketosis and are preferable to water(1, 2)
 - iii. in United States, solid foods are typically limited during labor in order to reduce risk for aspiration should surgical intervention/general anesthesia be required, but overall risk is low^(1, 3)
 - iv. some experts allow women who have not received opioids or developed other risk factors for general anesthesia to eat a light diet, such as yogurt or sherbet^(1, 3)
- B. DynaMed citation: Title. Management of Routine Labor. A Chisholm, Z Fedorowicz, A Ehrlich. In: DynaMed. Available at: access date www.DynamicMedical.com Last Updated: Mar 2017. Accessed: Sep 2017.
- C. Bottom line recommendation or summary of evidence from DynaMed (1-2 sentences) Liquid intake, especially isotonic liquids and clear liquids, should be unrestricted during routine labor. Given the low risk of aspiration, some physicians may choose to allow soft solids.

However, other patients' with higher risk of aspiration may require stricter diets.

- D. UpToDate excerpts Nothing found.
- E. UpToDate citation/ Always use Basow DS as editor & current year as publication year. Access date Title. Author. In: UpToDate [database online]. Available at: http://www.uptodate.com. Last updated: . Accessed n/a
- F. Bottom line recommendation or summary of evidence from UpToDate (1-2 sentences) n/a
- G. Other excerpts (USPSTF; other guidelines; etc.)

 ACOG: (from Dyna Med) American College of Obstetricians and Gynecologists (ACOG) recommendations for oral intake during labor in women with uncomplicated labor: moderate amounts of clear liquid may be given orally, including water, fruit juice without pulp, carbonated drinks, clear tea, black coffee, sports drinks. For women with risk factors for aspiration (such as morbid obesity, diabetes, or difficult airway) may require additional restriction on oral intake

A Cochrane review of this question found no evidence to support dietary restriction during labor.

- H. Citations for other excerpts Singata M, Tranmer J, Gyte GM. Restricting oral fluid and food intake during labour. The Cochrane Database of Systematic Reviews 2013, Issue 8. Art. No.: CD003930. doi: 10.1002/14651858.CD003930.pub3.
- I. Bottom line recommendation or summary of evidence from Other Sources (1-2 sentences) There is no justification for restricting laboring women's diet.

SECTION 4: Conclusions

[to be completed by the Potential PURL Reviewer]
[to be revised by the Pending PURL Reviewer as needed]

- A. **Validity**: Are the findings scientifically valid?
- B. If **A** was coded 4, 5, 6, or 7, please describe the potential bias and how it could affect the study results. Specifically, what is the likely direction in which potential sources of internal bias might affect the results?
- C. Relevance: Is the topic relevant to the practice of family medicine and primary care practice, including outpatient, inpatient, obstetrics, emergency and long-term care? Are the patients being studied sufficiently similar to patients cared for in family medicine and primary care in the US such that results can be generalized?

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- D. If **C** was coded 4, 5, 6, or 7, please provide an explanation.
- E. **Practice changing potential**: If the findings of the study are both valid and relevant, are they not a currently widely accepted recommendation among family physicians and primary care clinicians for whom the recommendation is relevant to their patient care? Or are the findings likely to be a meaningful variation regarding awareness and acceptance of the recommendation?
- F. If **E** was coded as 1, 2, 3, or4, please describe the potential new practice recommendation. Please be specific about what should be done, the target patient population and the expected benefit.

Allowing more than just ice or water to laboring low risk women with singleton pregnancies.

G. Applicability to a Family Medical Care Setting:

Is the change in practice recommendation something that could be done in a medical care setting by a family physician (office, hospital, nursing home, etc.), such as a prescribing a medication, vitamin or herbal remedy; performing or ordering a diagnostic test; performing or referring for a procedure; advising, education or counseling a patient; or creating a system for implementing an intervention? 1 (definitely could be done in a medical care setting)

H. If **G** was coded as a 4, 5, 6, or 7, please explain.

I. Immediacy of Implementation:

Are there major barriers to immediate implementation? Would the cost or the potential for reimbursement prohibit implementation in most family medicine practices? Are there regulatory issues that prohibit implementation? Is the service, device, drug, or other essentials available on the market? 1 (definitely could be immediately applied)

J. If I was coded 4, 5, 6, or 7, please explain why.

K. Clinically meaningful outcomes or patient oriented outcomes:

Do the expected benefits outweigh the expected harms? Are the outcomes patient oriented (as opposed to disease oriented)? Are the measured outcomes, if true, clinically meaningful from a patient perspective?

4 (uncertain)

L. If **K** was coded 4, 5, 6, or 7 please explain why.

16 minutes of shorter labor duration is not clinically meaningful. Yet, there are potential benefits from allowing a less restrictive diet to include patient satisfaction, less maternal exhaustion. This study did not look at these types of outcomes.

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- M. In your opinion, is this a pending PURL?
 - 1. Valid: Strong internal scientific validity; the findings appear to be true. The most serious outcomes was underpowered.

- 2. Relevant: Relevant to the practice of family medicine.
- 3. Practice Changing: There is a specific identifiable new practice recommendation that is applicable to what family physicians do in medical care settings and seems different than current practice.
- 4. Applicability in medical setting. Easily implemented on all L&Ds.
- 5. Immediacy of implementation Could be implemented tomorrow.
- N. Comments on your response for question M.

Highly restrictive diets are currently common practice was started without any evidence that it was effective. There is reason to believe there are at least some benefits to changing the practice and no demonstrated evidence that changing the practice would cause harm.