

Breastfeeding Support in the Wake of Damning JAMA Editorials:



What Should I Believe?

Wednesday
February 15, 2017
11:00 AM - 12:00 PM
Central Standard Time

CHAMPS Wednesday Webinar Series

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- I have no relevant financial relationships with the manufacturer(s) of any commercial product(s) and/or provider of commercial services discussed in this CME activity.
- I do not intend to discuss an unapproved/investigative use of a commercial product/device in my presentation.

Learning Objectives



1. Understand the difference between a published study and an opinion piece
2. Explain concerns raised about safety and the Ten Steps [JAMA Pediatr. 2016;170(10)]
3. Define practices that support safe implementation of the Ten Steps using AAP safe sleep guidelines.
4. Describe concerns raised about systematic “Interventions Intended to Support Breastfeeding” [JAMA 2016; 316(16)]
5. Define the evidence to support the Baby-Friendly Hospital Initiative

JAMA Opinion Pieces



Opinion

VIEWPOINT

Unintended Consequences of Current Breastfeeding Initiatives

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Promoting and supporting breastfeeding during the postpartum period has been an important and appropriate priority for maternity units in recent years. The Ten Steps to Successful Breastfeeding of the Baby-Friendly Hospital Initiative have been implemented by an increasing number of hospitals as the standard of care for optimally supporting breastfeeding from birth to hospital discharge.¹ As some or all of these steps are increasingly being promoted as standard of care by government agencies (eg, the Centers for Disease Control and Prevention) and by The Joint Commission, it is important to be certain that the basis for the recommendations has been documented in reproducible scientific studies and that the benefits of the practices recommended outweigh the risks. Unfortunately, there is now emerging evidence that full compliance with the 10 steps of the initiative may inadvertently be

and co-bedding.² Furthermore, a recent publication from the American Academy of Pediatrics observed that lawsuits have surfaced in US hospitals attributed to unexpected respiratory arrest in apparently healthy newborns during early skin-to-skin care and cautioned that this practice needs to be balanced with the need to implement safe sleep practices with monitoring of infants during skin-to-skin care unless direct observation takes place.⁴

While breastfeeding undoubtedly has many benefits, 24-hour rooming-in, which is a key component of the initiative, may have unintended consequences in the perinatal period. In order to ensure that the benefits of the practices recommended outweigh the risks, it is important to be certain that the basis for the recommendations has been documented in reproducible scientific studies and that the benefits of the practices recommended outweigh the risks. Unfortunately, there is now emerging evidence that full compliance with the 10 steps of the initiative may inadvertently be

August 2016, JAMA Peds publishes Unsolicited “Viewpoint” Counter “Viewpoint” published By AAP Section on Breastfeeding

Opinion

EDITORIAL

Interventions Intended to Support Breastfeeding: Updated Assessment of Benefits and Harms

Valerie Flaherman, MD, MPH; Isabelle Von Kohn, MD, PhD

In this issue of *JAMA*, the US Preventive Services Task Force (USPSTF) has updated its recommendations on primary care interventions to support breastfeeding.¹ Based on the accompanying evidence review by Patnode and colleagues,² who evaluated studies conducted in settings classified as having very high human development,^{1,2} the USPSTF concluded that, based on fair-to-good-quality studies, there is adequate evidence to recommend primary care interventions to support breastfeeding.

reported that there was no consistent association between system-level interventions and any beneficial outcomes. Certification by BFHI was specifically evaluated in 2 studies^{4,5} with concurrent control groups from 5 US states and was not associated with increased breastfeeding duration; a study from Australia,⁶ not included in the evidence review, reported similar results. The evidence review by Patnode and colleagues noted that many before-and-after studies without a concurrent control group show an association between system-level interventions and breastfeeding outcomes; the authors excluded these because of their study design.

One included study presented good-quality evidence that

October 2016 JAMA publishes Solicited “Editorial” to Comment on USPSTF Updated Recommendations

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Opinions are NOT Studies



- Peer reviewed journals have multiple formats to publish opinions of well-known (and some not-so-well-know) researchers/authors
- Opinion pieces are often controversial...even inflammatory... so **people want to read them**
- Just like the media, controversial opinion pieces sell
- Media often (erroneously) picks up on opinion pieces as a “new study”
- Result: public is misled

Backlash of Letters-to-the-Editor



- Multiple “on-line first” letters-to-the-editor of JAMA Pediatrics
- Published January 30, 2017, and more keep pouring in.
 - Mothers are informed and may opt out
 - BFHI has worked to increase breastfeeding
 - There are strategies to improve safety
 - No evidence that the number of deaths has increased with the Ten Steps
 - Failure to disclose formula industry sponsorship of one of the authors

See more detail on our website:

www.champsbreastfeed.org/jama_pediatrics_responses.html

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For Today



I will NOT focus on:

- Authors conflict of interests
- Formula company sponsorship
- Non-disclosure

I WILL focus on:

- Content of their arguments and where they fall short
- Evidence based support for exclusive breastfeeding
- Safe Implementation of the BFHI

Key Points in the JAMA Viewpoint By Joel Bass, MD, et al.



- Bass, et al asserts that the Ten Steps is a rigid and dangerous set of regulations that may lead to death in newborns (leading to SUPC)
- Bass implies that hazards of rooming-in, skin-to-skin, and avoidance of formula may not be overcome by safe practices
- Finally, Bass disagrees with the Surgeon General Call To Action to accelerate the implementation of the BFHI and instead believes the evidence supports retracting this recommendation

VIEWPOINT

Unintended Consequences of Current Breastfeeding Initiatives

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Promoting and supporting breastfeeding during the postpartum period has been an important and private priority for maternity units in recent years. Ten Steps to Successful Breastfeeding of the Baby-Friendly Hospital Initiative have been implemented at an increasing number of hospitals as the standard of care for optimally supporting breastfeeding from admission to hospital discharge.¹ As some or all of these steps are increasingly being promoted as standard of care by government agencies (eg, the Centers for Disease Control and Prevention) and by The Joint Commission, it is important to be certain that the basis for the recommendations has been documented in reproducible scientific studies and that the benefits of the practices recommended outweigh the risks. Unfortunately, there is now emerging evidence that full compliance with the 10 steps of the initiative may inadvertently

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While breastfeeding exclusivity (step 6) and 24-hour rooming in (step 7) have demonstrated benefits in the postpartum period, these practices may also engender risk. An overly rigid insistence on these steps in order to comply with Baby-Friendly Hospital Initiative criteria may inadvertently result in a potentially exhausted or sedated postpartum mother being persuaded to feed her infant while she is in bed overnight,

No Evidence that SUPC
is a “Consequence” of
“Breastfeeding Initiatives”

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Sudden Unexpected Postnatal Collapse (SUPC)



- Sudden collapse in previously vigorous spontaneously breathing newborn with five minute APGAR>8
- Gestational age >35 weeks
- Incidence 2.6-38/100,000
- One third occur in first 2 hours, 1/3 between 2 and 24 hours and final 1/3 between 1-7 days of life
 - Herlenius and Kuhn. Trans Stroke Res 2013;4:236-47
- Another study suggests 73% occur in first 2 hours
 - Becher J-C, et al. Arch Dis Chil Fetal Neonatal Ed 2012;97:F30-4

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Is SUPC Increasing because of the BFHI? NO EVIDENCE



- MA vital statistics implied cases of SUPC are on the rise, but not coincident with hospitals designated as Baby-Friendly
- Bass et al reported the % of diagnostic codes occurring within first 28 days (14%), first 5 days (35.1%), and newborn period (22.2%) (denominator is all SIDS)
- Fails to recognize that SIDS is declining overall (first year of life) so proportion of cases within 1 month may appear higher
- New York did a similar review, with addition of 9 new Baby-Friendly hospitals and NO increase in SIDS and ZERO cases of neonatal (birth-1 month) death between 2012 and 2014

“...full compliance with the 10 steps of the initiative may inadvertently be promoting potentially hazardous practices and/or having counterproductive outcomes.”



NOT TRUE...it is not the “full compliance” that compromises safety...it is the poor compliance with The Ten Steps.

- Furthermore, there is NO evidence that the number of sentinel events such as SUPC have increased
- Skin-to-skin care is evidence-based

Evidence for Skin to Skin: Mother



- Decreases maternal stress and improves paternal perception of stress in the relationship with baby
- Depression scores and salivary cortisol levels lower over the first month among postpartum mothers providing SSC
- Enhances opportunity for early first breastfeed, which in turn leads to more readiness to breastfeed, organized suckling pattern, and more success in exclusive and overall breastfeeding

Safe Positioning for SSC



To cite: Feldman-Winter L, Goldsmith JP, AAP COMMITTEE ON FETUS AND NEWBORN, AAP TASK FORCE ON SUDDEN INFANT DEATH SYNDROME. Safe Sleep and Skin-to-Skin Care in the Neonatal Period for Healthy Term Newborns. *Pediatrics*. 2016;138(3):e20161889

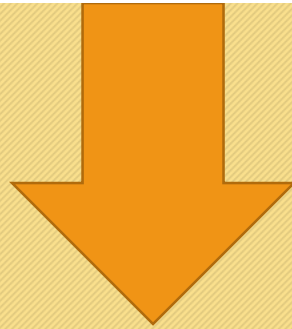
1. Infant's face can be seen
2. Infant's head is in "sniffing" position
3. Infant's nose and mouth are not covered
4. Infant's head is turned to one side
5. Infant's neck is straight, not bent
6. Infant's shoulders and chest face mother
7. Infant's legs are flexed
8. Infant's back is covered with blankets
9. Mother-infant dyad is monitored continuously by staff in the delivery environment and regularly on the postpartum unit
10. When mother wants to sleep, infant is placed in bassinet or with another support person who is awake and alert

Bass et. Al. “mothers should have continuous skin-to-skin contact after birth until completion of the first feeding,... a time period when direct continuous observation by medical care professionals is not likely to occur...”



AAP Clinical Report recommends
“continuous observation” during SSC
in the first hour(s)

Bass et. al. “In order to comply with ...BFHI... inadvertently result in a potentially exhausted or sedated postpartum mother and persuade to feed her infant... when she is not physically able to do so safely. This may result in prone positioning or co-sleeping ...in direct contraindication to the Safe Sleep Recommendations of the NIH. In addition, co-sleeping poses a risk for the newborn falling out of bed, ...also possible that unsafe sleep practices modeled in the hospital may continue at home.”



- Good nursing care supports moms to feed safely
- Recommend safe sleep positioning and to avoid bed-sharing while maintaining room sharing
- There are devices that help to do this safely

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Step 7: 24-hour Rooming-in



- Consistent with contemporary models of Family-Centered Care
- Leads to improved patient satisfaction
- Leads to optimal outcomes for healthy dyads as well as those with higher risk including neonatal abstinence
- Provides more security, avoids abductions or switches, leads to decreased infant abandonment



**Delivery hospital
bedside sleeping
arrangements**



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Bass, Et. Al. “... NO allowable exceptions for newborn conditions...” [for non-exclusive breastfeeding...supplementing with formula]



The authors are referring to the Joint Commission Core Measure (PC-05). The rationale for “no exceptions” was to standardize measurement. There are expected (medically indicated) exceptions and this accounts for the 10%, given that the goal is 90% exclusive breast milk feeding.

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Step 6: Avoidance of Infant Formula, unless medically indicated



- Understand physiology and define medical indications to supplement
- Determine if nurse and/or physician needs to order supplements with formula
- Revise protocols

“Justification for breastfeeding exclusivity is based on a 1998 WHO review of the evidence for the Ten Steps...however that review included evidence that when **supplementation was given for a medical indication there was no adverse effect ...on duration of breastfeeding...**”



- NO! The justification for exclusive breastfeeding is the myriad of health effects for baby and mom that are undermined by supplementation.
- There is also evidence of the detrimental effect of supplementation on duration and exclusivity of breastfeeding (RCT by Howard).
- And of course supplement... if medically necessary.

Risks of Supplementation

Mom

- Decreases confidence
- Decreases milk removal leading to increased autocrine control and decreased milk synthesis
- Leads to premature weaning



Baby

- Increases risk of short and long term disease
- Changes microbiology and immuno-biology of gut

Dyad

- Interferes with effective latch
- Decreases hormonal stimulation via afferent nerve receptors

Father and Family

- Bottle/formula feeding
- Caring for sick child

“Another issue is the ban on pacifier use (step 9). Compliance requires mothers be educated that pacifiers interfere with the development of optimal breastfeeding, but, strong evidence that pacifiers have a protective effect against SIDS.

...because a substantial number of SUPC events Occur during the first week of life this recommendation is difficult to defend.”



- There is **NO evidence** that pacifiers reduces the risk of SUPC, a distinct disease from SUID/SIDS
- There is evidence that pacifiers may interfere with early establishment of breastfeeding (despite Cochrane review)

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy
of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN™

Safe Sleep and Skin-to-Skin Care in the Neonatal Period for Healthy Term Newborns

Lori Feldman-Winter, MD, MPH, FAAP, Jay P. Goldsmith, MD, FAAP, COMMITTEE ON FETUS
AND NEWBORN, TASK FORCE ON SUDDEN INFANT DEATH SYNDROME

AAP Clinical Report published same day
As Bass Editorial (coincidence??)

Pediatrics. October 2016;138(3)

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AAP Summary Recommendations



1. Standardize practices of SSC
2. Standardize sequence of events after delivery
3. Document maternal and newborn assessments and any changes in condition
4. Direct observation in delivery room
5. Position the newborn to avoid airway obstruction
6. Conduct frequent assessments
7. Assess level of maternal fatigue
8. Avoid bed-sharing
9. Promote supine sleep for all infants
10. Train health care personnel in standardized methods of providing SSC and rooming-in

Key Points in the Editorial by Valerie Flaherman, MD, et al.



- Flaherman exaggerates the negative results of the USPSTF review of the evidence to support systematic interventions to support breastfeeding
- She goes further to say the harms of systematic interventions outweigh the potential benefits
- Recommends against exclusive breastfeeding (early limited formula use)

What is the USPSTF?



- An independent panel of experts in primary care and prevention that systematically reviews the evidence of effectiveness and develops recommendations for clinical preventive services
- A panel of primary care physicians and epidemiologists
- Funded, staffed, and appointed by the U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality.
- Does Not consider Cost of interventions

JAMA Editorial invited companion piece to USPSTF Report



Clinical Review & Education

JAMA | US Preventive Services Task Force | EVIDENCE REPORT

Primary Care Interventions to Support Breastfeeding Updated Evidence Report and Systematic Review for the US Preventive Services Task Force

Carrie D. Patnode, PhD; Michelle L. Haninger, PhD; Caitlyn A. Songor, MPH; Leslie A. Perdue, MPH; Evelyn P. Whitlock, MD

Purpose to update 2008 interventions to support breastfeeding

Recommendation: B level evidence

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System Level Interventions: Summary



| Number of Studies | Study Quality | Findings |
|------------------------------------|-------------------|--|
| 9 studies: 7 RCTs 2 pre/post | Good: 6 Fair:3 | No evidence for “BFHI accreditation” and policies for breastfeeding support groups, minimizing mother-baby separation, on duration of any or exclusive breastfeeding for 16 weeks. |

“One large observational study found a statistically significant higher rate of breastfeeding initiation and exclusive breastfeeding at 4 weeks in women with lower education”

Problems with System Level Analyses



- Excluded PROBIT study from Belarus because it was done in a developing country.
- Hawkins first study from Maine done in environments where the control group may have already been very supportive, despite not achieving BFHI designation
- Excluded non-RCT studies, and those with no comparison group, mainly pre-post studies on the basis of “single hospital & retrospective” for BMC studies, and Cooper study examining the impact of removing industry bags because of disclosed problem of poor implementation and staff giving out free formula
- Excluded study of residency curriculum (controlled trial of physician/resident education) not considered system level!
There was a comparison group!

E3. Study design: Not RCT for individual-level intervention; not RCT, controlled before-after, or prospective cohort study for system-level policies

Take Away from System Level Support Evidence



- Why not recommend system level support given the effect in women with low levels of education?
 - Missed opportunity
- Each of the Ten Steps has its own body of evidence, and each may be considered system level, but not included in the evidence based review.
 - For example, training resident physicians
- PROBIT Study only true RCT available and the population may be generalized to the US even at this time. There is no question to us in the field that BFHI increases overall and exclusive breastfeeding.
 - However, we need to repeat PROBIT in the US...maybe the next best thing to do with CDC/NIH funding

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Flaherman Editorial



“...In contrast to the evidence supporting individual-level interventions, among 9 fair to good system-level intervention studies (BFHI-2 studies), there was NO consistent association between intervention and beneficial outcomes.”

Not True- there was evidence for women with low education...

Discounts relationship in women with low levels of education

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Flaherman Editorial



“...BFHI may be beneficial for specific groups of mothers. Using clinical judgment individualized for each mother and infant may result in better outcomes than following a rigid system of practices...”

Really??
Are we really going to recommend
differential treatment for women with
low education?

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Flaherman Editorial



“...In addition, 2 controversial areas (...avoidance of pacifiers and avoid feedings other than breastmilk) could present **potential risk** associated with system-level interventions...”

The majority of research demonstrates the importance of an exclusively breastfed diet, thus “avoiding feedings other than breast milk” is hardly controversial.

Flaherman Editorial: Regarding Pacifiers



“...evidence has been building that infant use of a pacifier may be associated with a reduced risk of SIDS, the most common cause of post-neonatal death in the US....

Cochrane review reached conclusion that avoidance of pacifiers was not associated with any negative breastfeeding outcomes...

Routine counseling to avoid pacifiers may be ethically problematic...”



Post-neonatal
=
1 mo-1 year

But...Cochrane review only examined outcomes after the first few months of life when weaning may have already occurred.

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PRAMS Study in 10 States



Kair LR. *Breastfeeding Medicine* 2017

Practices that will decrease any breastfeeding: [*=effect on exclusivity too]

- not breastfed in 1st hour (4)
- mom did not begin to bf in hospital (5)
- **supplementation with formula*** (6)
- not breastfeeding on demand (8)
- giving all moms pumps* (5+)
- not giving discharge phone number to call (10)
- **using pacifier*** (9) [NOT NICU]
- *staff provided bf education & helped mom learn to bf** (3 & 5)

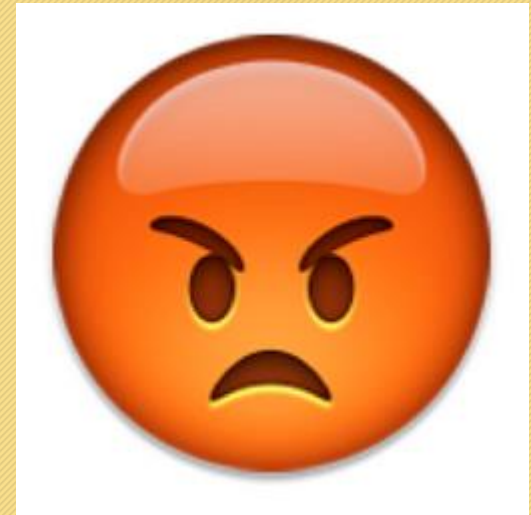
Note: rooming in (7) made no difference; sample gift packs (6-The Code) had an effect on exclusive breastfeeding only

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Flaherman Editorial



“...controversial area involves use of feedings other than breastmilk. Counseling to avoid giving infants any food or drink other than breastfeeding during the newborn period...step 6...Three randomized trials have examined the effectiveness of avoiding giving newborns any food or drink other than breastmilk...none showed a beneficial effect...on breastfeeding duration...”



- Avoidance of supplementation in the newborn period is to achieve **better health outcomes, a protective microbiome, and less disease.**
- Avoidance of supplementation to achieve longer breastfeeding duration is a secondary outcome, and has been shown (previous slide).
- Evidence cited (hers) was NOT reviewed by the USPSTF for quality.

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Flaherman Editorial



“Exclusivity ...may not be free of potential harm...women have scant colostrum ...and no production for 4-7 days, and ...is associated with risk of Hyperbilirubinemia, dehydration, and readmission...”

Really??

Exclusive breastfeeding is more harmful than formula supplementation?

I don't think so, that is NOT supported by the evidence.

Yes, colostrum volume is scant, but that is normal physiology, and newborns are born to manage this. They are supposed to lose weight, initially.

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Point/Counterpoint



- Flaherman claims newborns should not lose $\geq 5\%$ before 48 hours or they need a supplement, claims this supplementation limits further use of formula at 1 week.



One Study

Pediatrics. 2013
Jun;131(6):1059-65

But...multiple studies have documented HARMS of Supplementation

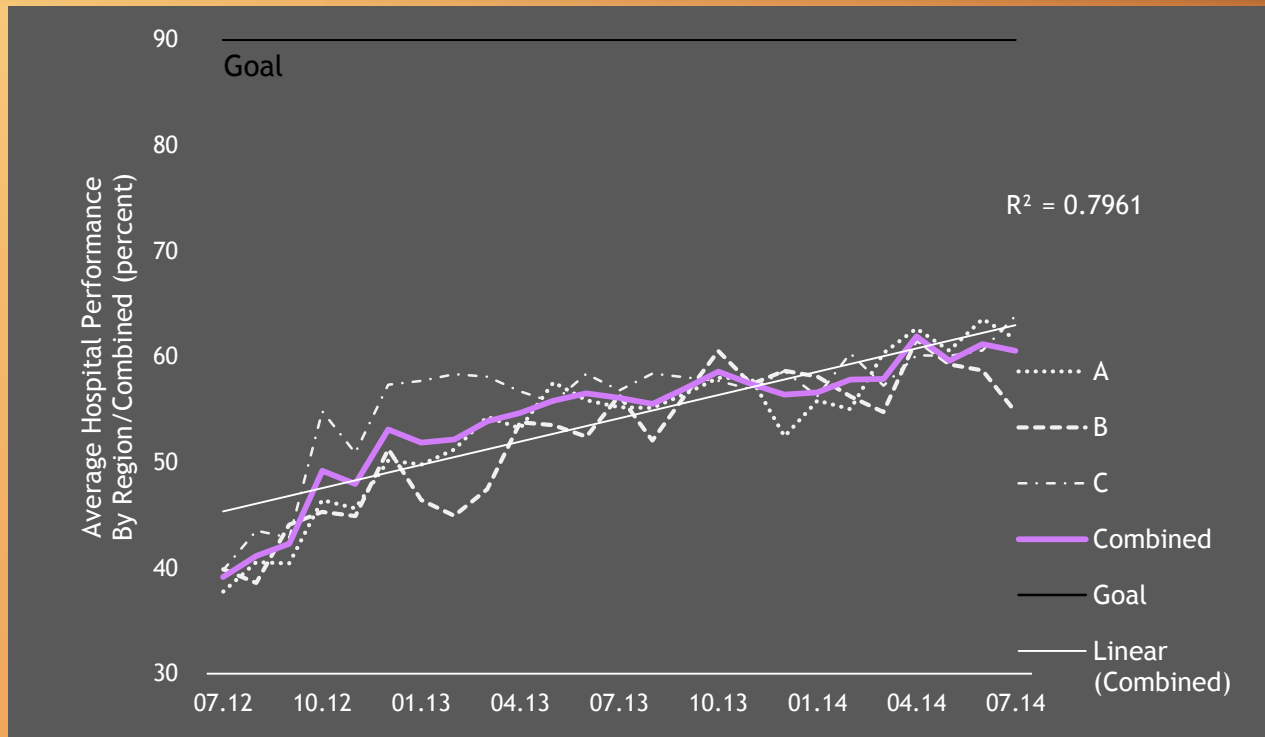
- Changes to the microbiome
- Increase risk of disease
- Infections
- Cancer
- Premature weaning

How do we measure BFHI-system level outcomes?



- USPSTF looked at breastfeeding initiation and continuation (exclusive and any)...how well can this be measured? How reliable are these data?
- What about Baby-Friendly designation and implementation of the Ten Steps? How can we say it does or does not work when we don't have valid or reliable methods to measure how well any of the steps are implemented?
- Is designation the best method to determine that these practices have been adopted?
- Should each of the Ten Steps be studied independently or as a group intervention?

Some Positive News About BFHI: NICHQ Best Fed Beginnings

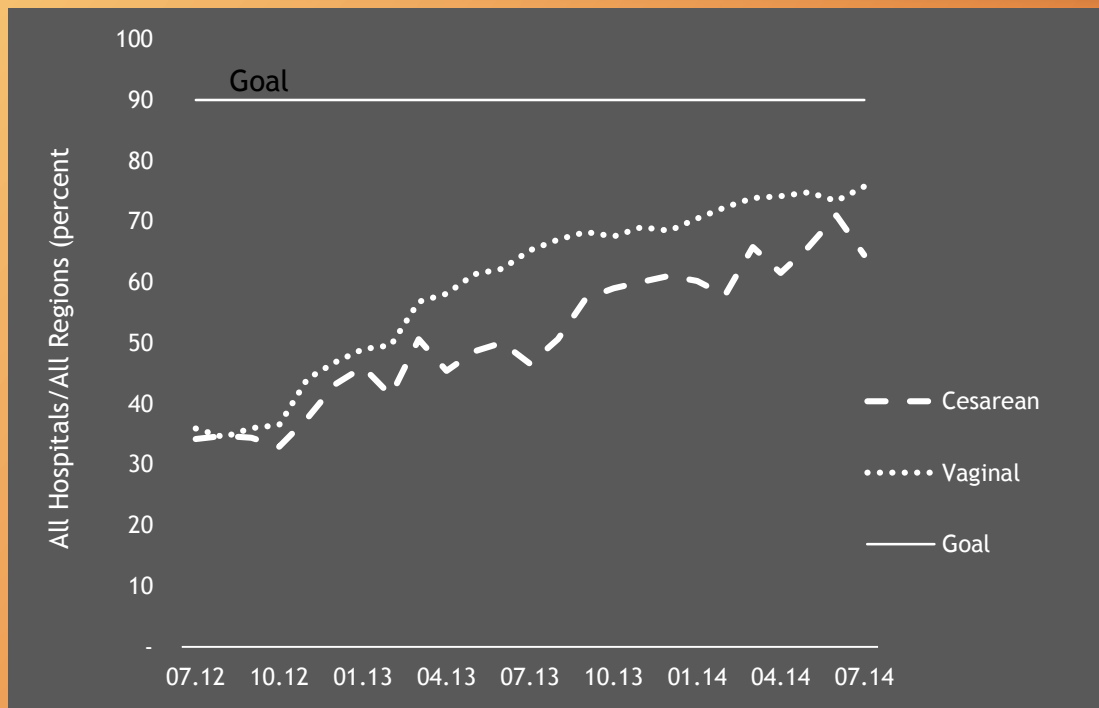


Hospital reported
data among 89
US Hospitals
2012-2014

Exclusive breastfeeding increased from
39% to 61% ($p < .001$)

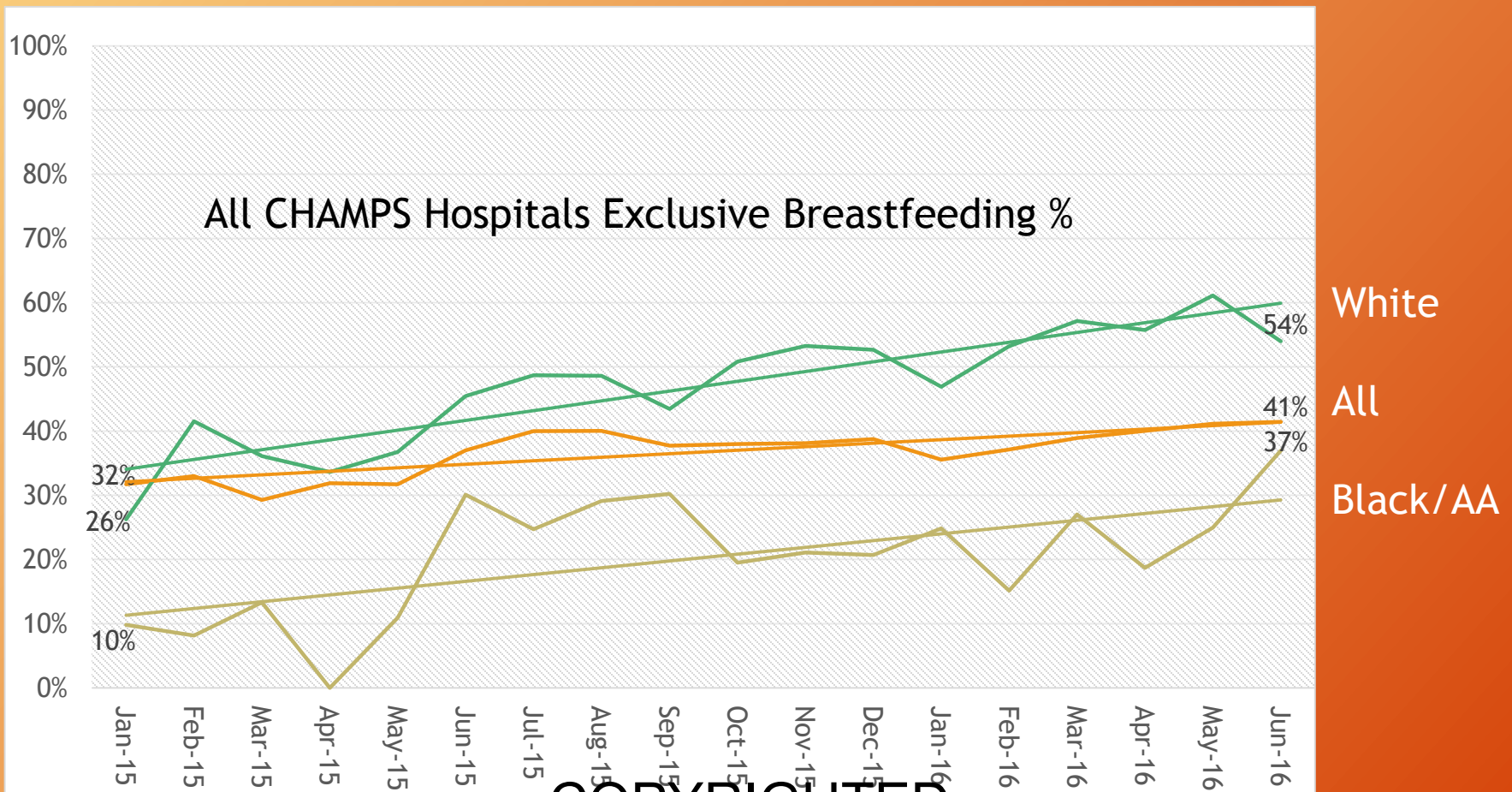
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Skin-Skin Contact is an outcome of importance, too



- SSC after vaginal births rose from 18% to 65% ($p < .001$).

Some More Positive News: CHAMPS



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Conclusions



- Don't believe everything you read!
- Yes, we need US studies, RCTs to document the benefits of BFHI
- ...or RCT's on each of the steps separately
- The BFHI is supported by the Surgeon General's Call to Action, the CDC, OWH, HHS and most State Health Departments
- The BFHI may be one way to reduce BF disparities
- The importance of an exclusive human milk diet cannot be overstated, the implications in individual health and population health are far reaching

An Editorial Gone Unnoticed



Opinion Editorial

In Support of Breastfeeding Support in Primary Care

Dimitri A. Christakis, MD, MPH

JAMA Peds December 2016

“I contend we should [be] draining the sea [of advisory directives] and selectively refilling [with] things for which there is sound evidence and proven value. If we were to take this approach, we might well add **breastfeeding support**, right after vaccinations.”

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