



## Removal of industry-sponsored formula sample packs from a hospital maternity service: Associated outcomes

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- None of the authors has any relevant financial relationships to disclose



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## Objectives

- To examine prospectively breastfeeding and practice outcomes associated with removal of industry-sponsored formula sample packs from the hospital.

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## Methods

- **Design:**
  - Prospective study
- **Setting:**
  - Large urban public teaching hospital.
- **Participants:**
  - Maternity patients enrolled from 6/2009 – 7/2010

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## Methods (cont.)

- For 6 months, control group discharged with industry-sponsored formula sample packs (standard of care)
- 1 month washout period
- 2<sup>nd</sup> 6 months, intervention group discharged with a University Hospital diaper bag
- Research assistants blinded to design called subjects weekly for 10 weeks to determine feeding practices.

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## Old vs. New Bags



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## Sample Size & Statistical Analysis

- 201 control and 201 intervention required for 80% power for a two-sided log-rank test of differences in breastfeeding between control and intervention groups.
- Kaplan-Meier survival curves were log-rank tested for control vs. intervention group in duration of *any* and *exclusive* breastfeeding
- Final curves analyzed over 56 days (dropout)

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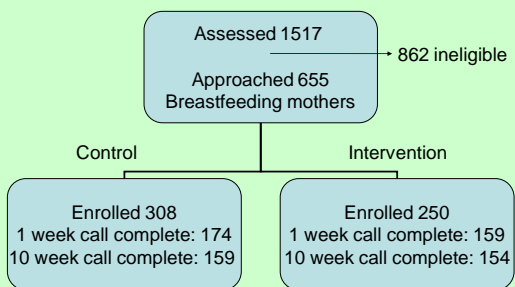
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## Enrollment Algorithm




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## Results

- There were no significant differences in demographic characteristics of mothers between control and intervention groups:
  - Race (1/3 each white, black, Hispanic, 6% Asian)
  - Place of birth (3/4 US born)
  - Education (20% less than HS graduate)
  - Maternal age (10% under 21 years, 40% over 30 years)

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## Results (cont.)

Mothers' Characteristics	N	Control N (%)	N	Intervention N (%)	P
Parity (N=527)	284		243		
First child		103 (36%)		87 (36%)	.381
Breastfed previous child(ren)		156 (55%)		142 (58%)	
Did not bf previous child(ren)		25 ( 9%)		14 (6%)	
Insurance (N=526)	284		242		
Public		164 (58%)		127 (53%)	.479
Private		115 (41%)		110 (46%)	
Other		5 ( 1%)		5 ( 2%)	

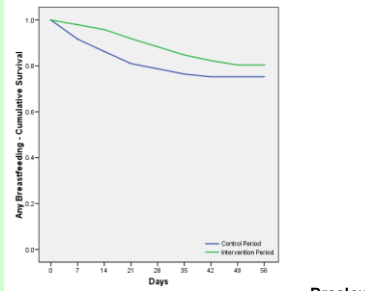
## Results (cont.)

Mothers' Characteristics	N	Control N (%)	N	Intervention N (%)	P
Marital status (N=527)	284		243		
Single/Other		168 (59%)		121 (50%)	.031
Married		116 (41%)		122 (50%)	
Ever smoked cigarettes (N=527)	284		243		
Yes		111 (39%)		73 (30%)	.030
No		173 (61%)		170 (70%)	

## Results (cont.)

Infant's characteristics		Control		Intervention	
Gestational age (N=527)	284		243		
36 - 37 6/7 weeks		21 (7%)		26 (11%)	.184
≥38 weeks		263 (93%)		217 (89%)	
Birth weight in grams - mean (SD) (N=527)	284	3337 (462)	243	3362 (459)	.522
Infant feeding in hospital (N=527)	284		243		
Exclusive breast milk		44 (15%)		47 (19%)	.244
Mixed fed		240 (85%)		196 (81%)	

Duration of Any Breastfeeding  
control (n=227) vs. intervention (n=211) periods



Breslow test, p=0.026

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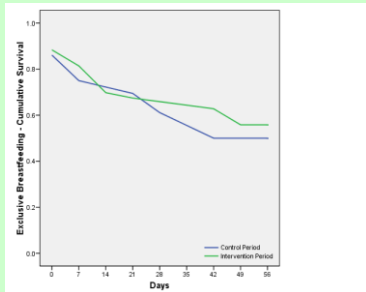
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Duration of exclusive breastfeeding control  
(n=36) vs. intervention (n=43) periods



Breslow test, p=0.589

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Results (cont.)

Data collected at 1 week				
Gave formula from the gift bag in first week of life (N=333)	174		159	
Yes	61 (35%)		30 (19%)	.001
No	113 (65%)		129 (81%)	

**But what is this all about??  
The hospital designed gift bag  
had no formula!**

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## Results (cont.)

Data collected at 10 weeks		Control	Intervention	
Received bottles from the hospital (N=313)**	159		154	
Yes		81 (51%)	86 (56%)	.385
No/Can't Remember		78 (49%)	68 (44%)	
Reported receiving formula in gift bag (N=250)	129		121	
Yes		106 (82%)	44 (36%)	<.001
No/Can't remember		23 (18%)	77 (64%)	

\*\*Received bottles of formula outside of gift bag

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## Conclusions

- Replacing industry-sponsored formula sample packs associated with increased duration of *any* but not exclusive breastfeeding
- Intervention group reported receiving formula in the discharge bags even when they were created without formula – how did it get there?

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## Conclusions

- Intervention group received bottles of infant formula at discharge
  - Hospital staff was stuffing the new bags with “hospital-use” ready-to-feed bottles
- Eliminating industry sponsored diaper bags should be combined with continued surveillance of formula for the intervention to have anticipated breastfeeding outcomes

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## Epilogue

- Staff was educated
- Hospital-use formula was placed in a controlled storage unit that required documentation and staff signature
- Addressed the common feeling that “we were only trying to help these poor mothers”

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## Thank you!

- To all of the mothers and families in Camden, NJ who participated in this study



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