Breastfeeding and Infant Health: Why you may not want to randomize even if you could

Hector Cebolla Boado, María Jiménez-Buedo, Leire Salazar

Mechanisms in Medicine Canterbury, July2017

Why breastfeeding?

- Wide consensus over its benefits backed almost universally:
 - Pediatricians and health authorities
 - WHO
 - 'lactivism'
- Increasing adoption of breastfeeding and of exclusive breastfeeding as the default feeding option in the first months/years
- -A closer look on current evidence over benefits suggests that public and private campaign efforts may not be justified. Evidence is:

Contradictory

Observational.

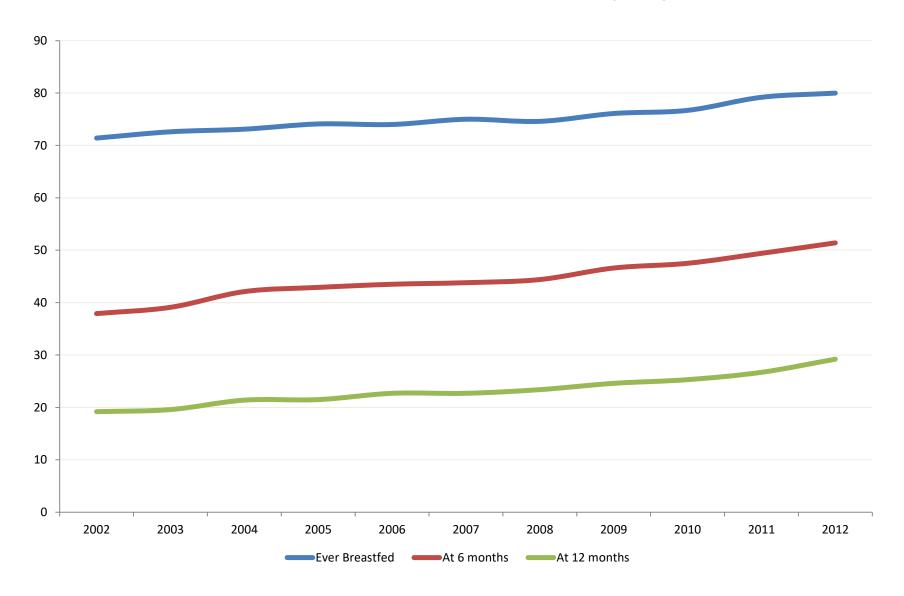
-But would randomization solve most problems?

NO

Country	Ever breastfed	Exclusive	Months	Any at 6 months
Norway	99	70	3	80
Slovenia	97			
Sweden	98	60	4	72
Luxembourg	90	26	4	41
Austria	93	60	3	55
Lithuania	98	41	3	31
Latvia	92	63	3	46
Czech Rep	96			53
Netherlands	81	30	3	37
Germany	96	33	4	48
Estonia	82			40
Poland	71	31	3	
Portugal	90	52	3	29
France	65			
Belgium	72	25	3	25
Ireland	46			
Italy	91	47	3	47
Switzerland	92			41
N. Zealand	88	56	3	
Cyprus	79	52	3	
Denmark	98	48	3	
Greece	86			
Slovak Rap.	92	57	4	
Spain	76	44	3	40
UK	81	13	3	25
Finland	93	51	3	60
Japan	97	38	3	
Hungary	96	62	4	
Canada	90	52	3	54
Iceland	98	48	4	65
Australia	96	39	3	60
Malta	62			
US	75	35	3	44

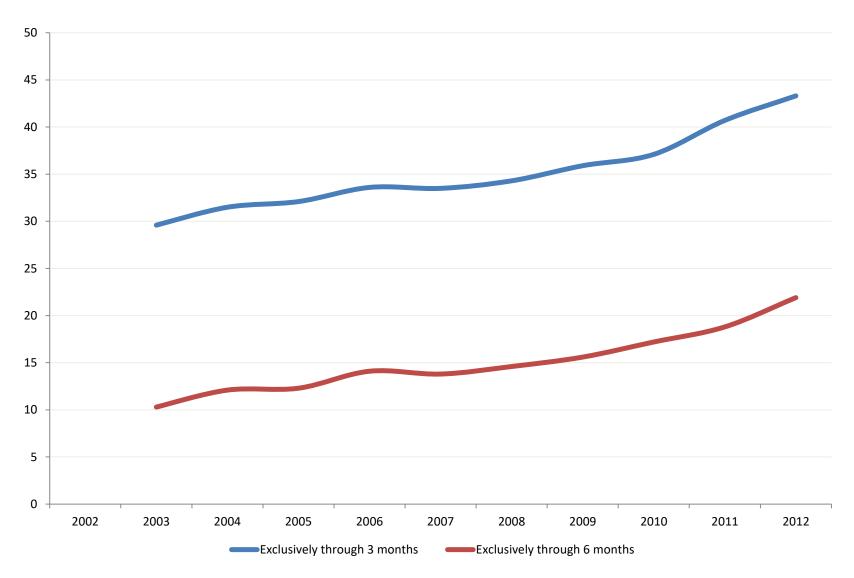
Source: 2012 "Nutrition in the First 1,000 Days". Save the Children

% of children breastfed (US)



Source: Centers for Disease Control and Prevention.

% of children exclusively breastfed (US)



Source: Centers for Disease Control and Prevention.

Alleged benefits of breastfeeding

- Breastfeeding benefits for infants
 - Higher I.Q.
 - Lower risk of Sudden Infant Death Syndrome
 - Lower incidence of food allergies
 - Lower incidence of asthma
 - Lower incidence of eczema
 - Lower incidence of obesity
 - Lower incidence of type II diabetes
 - Lower incidence of ear infections (acute otitis media)
 - Lower incidence of respiratory infections
 - Lower incidence of gastrointestinal infections
 - Lower incidence of necrotizing enterocolitis in premature babies



good things you need to know about exclusive* breastfeeding



and protects baby against disease with antibacterial agents.

provides all nutrients baby needs for the first 6

emergencies.

clean and safe source of food, especially in



child grow strong and intelligent.



"While breastfeeding may not seem the right choice for every parent, it is the best choice for every baby."

~Amy Spangler

have better hearing

due to lower

infections

incidence of ear



bonds

mother and child



months.

the mother's risk of ovarian and breast



helps

space pregnancies, a natural method of birth control.



saves money

by not having to buy infant formula and feeding equipment.



protects

the environment wit no need for packag ing and disposal.

The Breastfed Toddler

Breastfed toddlers have

Higher intellectual and glossier, healthier hair, Protein cognitive aptitude compared is a major functional and to formula fed peers and structural component of hair peers breastfed for a shorter cells and is essential for growth amount of time. and repair. After 12 months 448 ml (15 ounces) of breastmilk provides 45% of a toddler's protein requirements in its

most natural form.

Taste Buds

Breastfed toddlers are less likely to be fussy eaters. However, even if they go through a fussy period, breastfed toddlers still get their taste buds stimulated by the range of flavors in their

> um is a mineral that thens bones. After 12 hs 448 ml (15 ounces) astmilk provides 36% ddler's calcium



Independence

Teeth

Breastfeeding is part of meeting a child's dependency needs, and this is the key to helping the child achieve independence. Children who achieve independence at their independence than children forced into independence prematurely

As the eye is similar to the brain in

breastfed toddlers have stronge

75% of a toddler's vitamin A

by the retina of the eye and is

necessary for both low-light (scotopic vision) and color vision

Thumb sucking is less likely to

occur in breastfed toddlers so

increased duration of nursing

actually improves the dental arch

their teeth are less likely to

become misaligned. Also

vision. Also at 12 months 448 ml

(15 ounces) of breastmilk provides

requirements. Vitamin A is needed

regards yo nervous tissue,

Toddlers who are breastfed for extended periods of time tend to have leaner bodies with less risk of obesity.

Portability

Breastfed toddlers are easier to travel with. Nursing is far more convenient than carrying around feeding cups and paraphernalia, and can be a wonderful way of providing reassurance in unfamiliar surroundings

*exclusive means 100% breastmilk, no water, no solid food, nothing else.



The possibilites are endless...

Stash your Breastmilk for a sick day.

BENEFITS OF BREASTFEEDING



TO THE CHILD Starting breastfeeding in the first hour after birth improves

chances of a child to survive

reduction in the risk of death related to sepsis. pneumonia, diarrhoea

14 times more likely to survive the first six months of life than nonbreastfed children



TO THE MOTHER Starting breastfeeding in the first hour reduces mother's risk of death

breastfeed are less likely to become pregnant in the first six months following delivery and return to their pre-pregnancy

less postpartum depression and also have a lower risk of ovarian and breast cancers



une System

year of age, a child's ne system, in functioning at f adult level. The antibodies astmilk continue to provide ble protection during the er period. In fact, the nological benefits of tfeeding actually increase the second and third years

Limbs

Breastmilk is an excellent

painkiller the bumps and

toddlers and climbing

bruises that come along with

Hydration

Smoother and

more supple

Although breastfed toddlers are less likely to become ill. if they do get sick breastmilk can keep them hydrated when they can not tolerate other liquids.

www.mummiesnummies.com

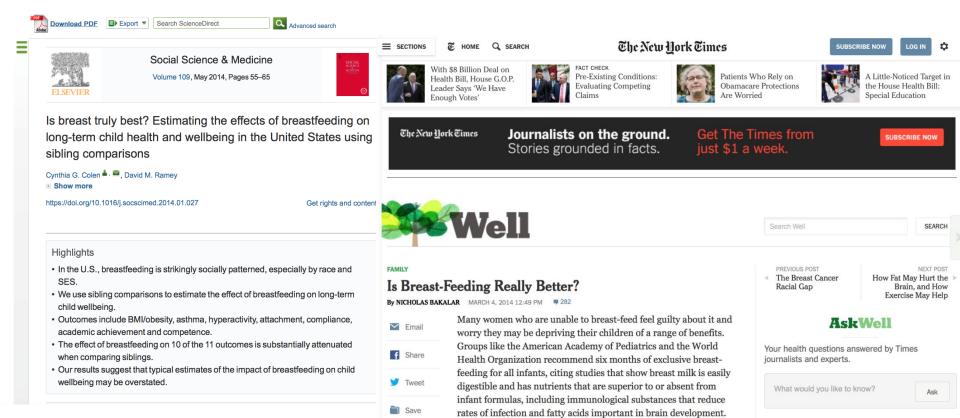
Other effects of breastfeeding and formula feeding

- B'feeding impact on mother's health:
 - postpartum depression
 - premenopausal breast cancer
 - ovarian cancer
 - retained gestational weight gain
 - type 2 diabetes
 - myocardial infarction
 - metabolic syndrome
- B'feeding risks for infants:
 - Increased risk of dehydration
 - Increased risk of hypoglycemia
 - Increased risk of neonatal Jaundice
 - Increased risks of anemia
 - Increased risk of failure to thrive (length, weight and head circumference)

Selection bias and overestimation of effects

"Selection to treatment" bias:

mother's (family/household) characteristics affect both the feeding choice and the infant's health



Strategies to minimize Selection Bias

- 1) Siblings studies: exploit intra-family variation
 - Limitation:
 - -Few databases
 - -Limited subsamples for discrepancies of breastfeeding across siblings
 - -selection bias within each discrepant cases
- 2) Other, "quasi-experimental" statistical methods:
 - e.g., Propensity Score Matching
 - e.g., Augmented probability weighting

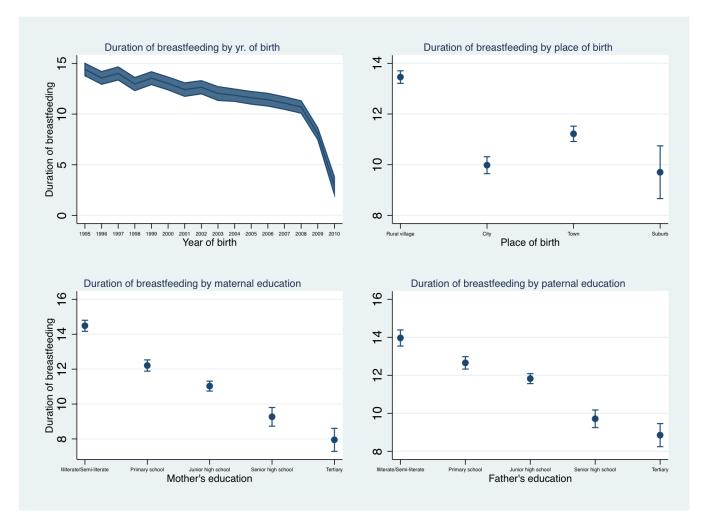
3) Strategic selection of cases:

Countries where BFers show an alternative route to selection to the treatment

-A distinct pattern of normativization. E.g., China

Breastfeeding in China

Duration of breastfeeding (in months) by various characteristics



Legend: Results from the estimation of separate HLM models (with province fixed effects) predicting the average duration of breastfeeding by family characteristics. Uncontrolled effects. Results available upon request.

Randomization

Kramer's PROBIT study: Random allocation of BFHI training

 17,795 mothers at 32 sites. infants were followed up at 1, 2, 3, 6, 9, and 12 months of age.

Infants from the intervention sites were:

- more likely to be breastfed at 12 months
- more likely to be exclusively breastfed at 3 months and at 6 months
- Statistically significant reduction in the risk of gastrointestinal tract infections and of atopic eczema.
- No statistically significant reduction in respiratory tract infection.

- B'feeding benefits for infants
 - Higher I. Q.
 - Lower risk of SIDs
 - Lower incidence of food allergies
 - Lower incidence of asthma
 - Lower incidence of obesity
 - Lower incidence of type II diabetes
 - Lower incidence of ear infections (acute otitis media)
 - Lower incidence of respiratory infections
 - Lower incidence of eczema
 - Lower incidence of gastrointestinal infections
 - Lower incidence of necrotizing enterocolitis in premature babies

Recalcitrant selection bias

"Selection of the treated" bias:

- -child's characteristics affect the duration of treatment
 - -neonatal health is likely to predict b-feeding success
 - DOSE RESPONSE: DURATION OF BREASTFEEDING DEPENDS ON ITS SUCCESS.

Other, adjunct biases involved:

"Administration" bias:

administration of breastmilk is inseparable from mother's attention to baby, so effects of the two treatments can be confounded

"Self-fulfilling" bias:

induced adoption of treatment may not benefit infants for which breastfeeding is difficult, thus further biasing results

Breastfeeding

- Supply-demand system
 - Imperfect: unobservable characterististics of both mother (supply) and demand (infant) affect the b'feeding process
- Duration of b'feeding depends on mother's socioeconomic constraints and preferences but also, crucially, on the characteristics of the S-D dyad
 - S: Approximately 5-20% mothers have delayed lactogenesis II and unsufficient supply (lack of reliable data!)
 - D: No reliable data on the determinants of b'feeding ability in babies. Tied tongue, low muscle tone, etc.

Recalcitrant selection bias

"Selection of the treated" bias:

- -child's characteristics affect the duration of treatment
 - -neonatal health is likely to predict b-feeding success
 - DOSE RESPONSE: DURATION OF BREASTFEEDING DEPENDS ON ITS SUCCESS.

Other, adjunct biases involved:

"Administration" bias:

administration of breastmilk is inseparable from mother's attention to baby, so effects of the two treatments can be confounded

"Self-fulfilling" bias:

induced adoption of treatment may not benefit infants for which breastfeeding is difficult, thus further biasing results

Possible solutions:

Clinical studies in which milk and interaction can be separated (i.e. preterm children fed with mother's breast milk (in bottle), mother's breast milk from breast, donor's breast milk in bottle, compared with children fed with formula): very complex data-collecting process

and

- Close examination of the mother-child dyad: further understanding is needed of the mechanics of breastfeeding:
 - a complex supply-demand system
- Randomization is not only impractical and/or unethical.
 - It could exacerbate selection problems

Breastfeeding

- Supply-demand system
 - Imperfect: unobservable characterististics of both mother (supply) and demand (infant) affect the b'feeding process
- Duration of b'feeding depends on mother's socioeconomic constraints and preferences but also, crucially, on the characteristics of the S-D dyad
 - Approximately 5-20% mothers have delayed lactogenesis II and unsufficient supply (lack of reliable data!)
 - No reliable data on the determinants of b'feeding ability in babies. Tied tongue, low muscle tone, etc.
- Notwithstanding these factors, pro-breastfeeding campaigns are targeted UNIVERSALLY

Discussion:

Heterogeneous effects and current promotion strategies

- Benefits are targeted (i.e. preterm babies, developing countries, etc), and modest but recommendations are universal.
- No evidence that benefits are due to exclusive breastfeeding; yet, policy focuses on exclusiveness.
- The aim of universality can endanger vulnerable babies and mothers.

Breastfeeding and Infant Health: Why you may not want to randomize even if you could

Hector Cebolla Boado, María Jiménez-Buedo, Leire Salazar

Mechanisms in Medicine Canterbury, July2017

THANK YOU

Discussion

In light of this evidence and its flaws, can this be considered strong evidence? No

Formulation of policy recommendations based on weak medical evidence, uncritical reception from policy makers.

This applies to other topics in public health, but also outside the health domain.