



NESTLÉ S.A.

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Vevey, April 4th 2018

Dear Dr. P. Gertler, et al.,

We acknowledge receipt of your report "*Mortality from Nestlé's Marketing of Infant Formula in Low and Middle-Income Countries*" (LMIC) dated March 29th, 2018. We would like to thank you for giving us the opportunity to review it and to share our comments before it is submitted for publication. We share your dedication to putting science and rigorous quantification analysis at the core of the dialogue on optimal infant and young child nutrition during the 1st 1000 days.

Looking back at the period your study covered, Nestlé has learnt a great deal from its experience in the marketing of breastmilk substitutes (BMS). Subsequent to the WHO International Code on the Marketing of Breastmilk Substitutes (the WHO Code) in 1981, we voluntarily released in 1982 our first Policy concerning its implementation. We have regularly updated our Policy and our latest updated [Policy and Procedures](#) in 2017 continue to follow the FTSE4Good Index criteria on the marketing of BMS, whose immediate focus is on the 152 countries where there is the greatest risk to infants and young children in terms of malnutrition and children mortality. If these countries have adopted policies and regulations more stringent than our Policies and Procedures, Nestlé complies with the applicable national policies.

We believe that breast-milk is the best nutritional choice for an infant as breastfeeding plays a critical role in a baby's growth and development. That is why we promote and support the WHO infant feeding recommendation of exclusive breastfeeding for the first 6 months of life and complementary feeding alongside continued breastfeeding up to 2 years and beyond, and why we are committed to supporting breastfeeding and optimal nutrition for infants and young children in the 1st 1000 days of life. We have converted our words into action by opening 4613 breastfeeding rooms in India, Bangladesh and China for public use and 339 breastfeeding rooms on Nestlé sites globally as of the end of 2017. The [Nestlé Maternity Protection Policy](#) adopted in 2015 offers new mothers up to six months maternity leave.



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We have reviewed your draft paper and would recommend caution to be exercised in interpreting the data contained in the paper in its current version. In the annex to this letter, we provide our comments regarding the methodology of the analysis, and some suggestions, focusing on a few key areas in order to contribute to the peer-review exercise this scientific paper needs to go through. We hope you will find these constructive.

We believe that the paper could be significantly strengthened by reviewing and including actual data of infant formula usage and frequency of consumption rather than a proxy based on commercial reports. We also provide recommendations for a greater use of available Demographic and Health Surveys (DHS) data.

We would like to engage in a collaboration with you and contribute to your effort by providing additional factual and quantitative information to strengthen the qualitative and quantitative inputs into the model. We have always found such dialogue and collaboration to be the most constructive way to move forward.

Yours sincerely

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ANNEX

Manuscript: Mortality from Nestlé's Marketing of Infant Formula in Low and Middle-Income Countries

**Jesse Anttila-Hughes, Lia C.H. Fernald, Paul J. Gertler, Patrick Krause, Bruce Wydick
March 29, 2018**

Overall objectives, aims, and conclusions

The authors state their objective as carrying out “first causal estimates of the effect on infant mortality of Nestlé’s entrance into LIMC formula markets for the both population overall, and for vulnerable subpopulations believed to be most at risk.” They conclude that in the population studied (*18 ‘treated’ countries vs 28 ‘control’ countries, for a total sample of 2,478,842 children in 46 countries*) the ‘availability’ of Nestlé infant formula (*as determined by the time a country is included in Nestlé’s annual corporate report*) had “no statistically significant average impact on infant mortality for the population as a whole”. However, infant formula ‘availability’ had a significantly negative effect on mortality of infants born in households that used surface water and that this effect did not change with mother’s education and wealth. The authors’ hypothesis, although not specifically stated, is that there is an association (potential causality and impact that can be estimated) between:

- the initiation of market and sales activities of Nestlé in a country,
- and an increase in infant mortality, regardless of which year this activity began, in a span of approximately 50 years (1966-2014),

The authors suggest that the mechanism for the causal relationship would likely be that these marketing and sales activities led to greater inappropriate formula use (in quantity and in quality with unsanitary water), leading to greater mortality.

Study Population and Country allocation

The methods rely on a comparison of ‘differences in differences’ and an assessment between ‘treated’ and ‘control’ countries. Thus criteria for group allocation, correct allocation and the representativity of these countries as ‘treated’ and ‘controls’, are critical if generalizations and calculations of attributable mortality are to be made. The approach taken by the authors raises some significant concerns:

1. It may help for the clarity of the manuscript to state the criteria for allocating a country as a ‘control’ more clearly or explicitly. It appears the dates of available annual Nestlé reports are the single criteria, but major markets are not included in either ‘treated’ or ‘control’ group (India, Malaysia) nor countries which were LMIC more than 45 years ago (Mexico, Brazil). These are major populations that can significantly change estimates and results.
2. Regarding proxy criteria for group allocation: The criteria for assigning a country into the ‘treatment’ or ‘control’ group is that formula ‘became available’, or Nestlé ‘began selling formula’ in that county. In addition, the proxy for ‘availability’ as well the timing on which the ‘difference in difference’ analysis relies on, was that Nestlé included this country as a market in which it sold infant formula products in its annual Corporate report. The paper indeed notes the ‘limitations’ of using only Nestlé ‘data’ (only Annual Report dates) and of no other manufacturer, and no data on ‘intensity’ of the marketing or its penetration, nor on formula use.’



Using the above criteria as a proxy for 'availability' rather than estimates of consumption in these populations can lead to significant error and/or bias when looking for associations, given how products such as infant formulas are introduced in different countries, then become available in retail stores or pharmacies, and ultimately are purchased and finally consumed. This is true for Nestlé as well as any other manufacturer's products. Amongst many relevant factors for which we can provide examples, the following factors can be drawn out:

- a. The initiation of market or sales activity in a country is a very poor and erratic representation of actual market penetration, market share, and consumption. This is even greater when only one manufacturer is considered. These differences can be major from market to market.
- b. This potential bias extends to allocation of 'control' countries. In many cases, formulas may be available, via distributors, and not direct sales (from Nestlé) or other Companies.
- c. Nestlé has not always been the first to enter a market, as in some 'control' countries, which can bias results depending on the penetration of such products. While Nestlé is the largest manufacturer of infant formulas, it does not have the majority of the overall share of formulas globally, which is distributed amongst many manufacturers.
- d. The inclusion of a country as Nestlé having marketing and sales activities per its annual reports, are also not always of starter (stage 1) infant formulas. In a number of countries, it is older child milk products that may have been introduced initially.
- e. Simple year of 'availability' and 'selling' for the first 3-5 years in one country, as a proxy for quantifying a potential effect (e.g. on child mortality) is greatly offset by the magnitude of changes and decisions in marketing and sales activities in other markets that have much bigger impact on infant exposure to formula. For instance, given population size and contributions to infant exposure the launch of a new formula brand in the Philippines or Malaysia would completely skew results. In practice, they would be best treated as 'treatment' rather than 'control' countries. Decisions on investment for innovations, new formulations, retail roll out, etc. have far greater effects on market than when sales operations are initiated.

All the above factors have a major impact on the dynamics of the formula market, and directly affect actual availability for purchase, and ultimately formula consumption, far beyond the 'proxy' of a date in an annual commercial report of one Company. The accuracy of these assumptions would have a significant effect on ultimately proving or disproving the paper's hypothesis. Infant formula availability and consumption frequency can be estimated, and would be a far better proxy for the causal estimation objective of this paper.

DHS data used

We also use DHS data to a great extent in our own research projects. We have carried out detailed analyses of infant formula feeding practices in these countries. Among other findings, our analysis of DHS data actually demonstrates the following:

- infant formula is the least used food type in LMICs;
- the infant feeding patterns show that a very large portion of water is often consumed on its own, more than in addition to infant formula or other substitutes;
- our analysis also evidenced that countries with the highest rates of surface water use were also the countries with low rates of infant formula feeding (around 6% in average).

The paper did not use or assess data on child morbidity. As the authors are aware, DHS is actually designed to understand the health status of the youngest child and morbidity is one of the main components of DHS (e.g. stunting, coughing, fever and diarrhea). Assessing morbidity with estimation of formula consumption in the various socio economic strata may reveal valuable



associations and strengthen causal estimation. It is also not clear which data was used for the period prior to the first DHS, which started in the mid 80's only.

The paper's results identify a significant increase in infant mortality in a sub-group of about 15% of the population studied (those depending on surface water), and not in the general population. The suggested mechanism for this is that this subgroup of parents / caregivers would:

- have access to infant formula retailers or pharmacies, and
- have the means of purchasing infant formula, and,
- prepare, and provide it to their infants, in a way that is unsafe given the quality of the water they have access to.

The paper seems to imply in various sections that infants who are not breastfed are automatically fed by infant formula, which is not always the case. In fact, this population is also the least likely to have access to retailers and pharmacies and to consider attempts to purchase and consume such products. Lastly, as mentioned above, countries with the highest rates of surface water use have also the lowest rates of infant formula feeding.

In summary: the paper draws conclusions derived from associations and comparisons of countries assigned to groups based on a very weak and unreliable proxy. The exercise would greatly benefit from estimations of actual infant formula availability and consumption frequency (Nestlé's or others) as well as the evolution and change of feeding patterns in LMICs. . Such data can be compiled, estimated, allow for appropriate associations and comparisons, and overall improve the quality of input into the model. We would be happy to collaborate to provide data may that help the strength and impact of this paper.

In addition, use of available DHS data on feeding practices for the countries studied would greatly enhance the rigor and strength of the study; also allowing appropriate comparisons and better estimation of the effect of formula availability and consumption. While not the original objective of the study, assessment of morbidity would be more likely to identify differences that could exist relative to infant formula consumption. We would also be happy to provide our assessments so far, some of which have been published, or help with improving these DHS inputs into the study model.