

Do pacifiers increase the risk of nosocomial diarrhoea? A cohort study

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ABSTRACT

Design: Prospective cohort study.

Setting: Teaching paediatric hospital—Instituto de Medicina Integral Prof. Fernando Figueira (IMIP), Recife, Northeast Brazil.

Participants: 378 of 536 infants admitted in paediatric wards from April to October 2009 were daily assessed during hospital stay until the first episode of nosocomial diarrhoea (ND), death or discharge. Infants with community-acquired diarrhoea, respiratory or haemodynamic instability and who stayed in hospital for <24 h were excluded.

Primary and secondary outcome

measures: Incidence and risk factors for ND and rates of pacifier faecal contamination.

Results: 33 ND episodes occurred in 378 infants, with a cumulative incidence of 8.7% and density of 11.25/1000 patients-day. ND occurred in 8.2% (16/194) of pacifier users compared with 9.2% (17/184) in non-users (adjusted OR=0.88, 95% CI 0.43 to 1.80). In multivariate logistic regression analysis, duration of oxygen use (OR=1.61; 95% CI 1.18 to 2.20) and days of antimicrobial use (OR=1.62, 95% CI 1.34 to 1.94) were associated with higher risk of ND, whereas being breast fed (OR=0.40, 95% CI 0.17 to 0.93) and each day of hospital stay (OR=0.65, 95% CI 0.53 to 0.80) were protective factors. Faecal coliforms were isolated in 16% (27/169) of tested pacifiers, 77.8% of which had more than 100 000 CFU/ml. The probability of a child remaining free of an episode of diarrhoea up to the seventh day of hospitalisation in the ward was 91.2% (95% CI 87.7% to 94.9%). The log-rank test showed no statistical difference between pacifier users and non-users.

Conclusions: ND is a frequent healthcare-associated infection in paediatric wards, but the use of pacifiers during the stay in hospital does not seem to affect the incidence of ND in infants in many settings where the burden of diarrhoea is still high.

INTRODUCTION

Nosocomial diarrhoea (ND) in children is associated with increased morbidity, mortality and length and cost of hospital stay.¹ Low adherence to hand washing facilitates person to person spread of diarrhoea pathogens in

ARTICLE SUMMARY

Article focus

- Healthcare-associated infections in paediatric hospital.
- ND incidence.
- Influence of pacifier use and ND in hospitalised children.

Key messages

- Pacifier use is common in paediatric wards and ND is a frequent healthcare-associated infection in hospitalised infants.
- The use of pacifiers during hospital stay does not seem to affect the incidence of ND in infants in a high diarrhoea burden setting. Breast feeding reduces the incidence of ND in infants in a high diarrhoea burden setting.

Strengths and limitations of this study

- The study did not assess microbial aetiology of ND and, due to limited isolation facilities, infants admitted with community-acquired diarrhoea were not routinely segregated in this study setting.
- To our knowledge, this is the first report of a hospital-based prospective cohort designed to investigate the association of pacifier use and the risk of ND in infants.

hospital settings, but indirect transmission also plays a role. Potential sources of transmission include water, food or contaminated surfaces such as toys or bed linen, as well as bottle and pacifier teats.² Despite controversy surrounding the recommendation of pacifier use, their use is very common in paediatric wards.³ Previous reports have investigated pacifier use and the risk of diarrhoea in community settings,⁴ but we could find no well-designed studies looking into pacifier use and hospital-acquired diarrhoea. This report investigates the association of pacifier use and the risk of ND in a cohort of children from Recife, Brazil.

METHODS

This was a hospital-based prospective cohort study of children aged >28 days and <2 years

old who were admitted to the Instituto de Medicina Integral Prof. Fernando Figueira (IMIP) in Recife, Northeast Brazil. IMIP is a publically funded teaching hospital that has three paediatric wards for children <2 years old. Each ward has an area of 25 m² within which nine cradles and nine chairs (for accompanying parents). In each ward, there is a sink with constantly supplied running chlorinated water, liquid soap and disposable paper towels. For the healthcare workers, disposable latex gloves are used for patient handling during procedures when there is risk of exposure to body fluids. Children admitted to hospital for causes other than diarrhoea were consecutively enrolled between April and October 2009.

Accompanying parents or guardians were asked if pacifiers were brought to hospital and children were observed daily. The use of any pacifier during the hospital stay was the main exposure measure, while the first episode of ND was the main outcome measure. Children presenting—diarrhoea after <72 h or who were hospitalised for <24 h, those admitted for community-acquired diarrhoea and those presenting with haemodynamic or respiratory instability were excluded.

ND was defined as liquid stools for more than 12 h, with or without fever or vomiting, and no likely non-infectious cause that was acquired after 72 h of admission.¹

The possible factors associated with nosocomial infectious diarrhoea were as follows: socioeconomic variables (per capita income of family, mother's level of education), sex and age (≤ 6 months), nutritional status (considering ≤ -2 weight/age z-score WHO curve 2007),⁵ low weight at birth (<2500 g), prematurity (<37 weeks gestational age), breast feeding, finger sucking habit, use of baby bottles and rotavirus vaccination status (Rotarix® GlaxoSmithKlineBiologicals Laboratory, oral vaccine, attenuated monovalent (G1P [8], strain RIX4414)). Other exposure factors investigated during hospitalisation and before the occurrence of the outcome or discharge were use of medication (antibiotics, antiemetics, glucocorticoids, sedatives/analgesics, H₂ blockers), fasting (feeding withdrawn due to gastric residues) and use of common invasive procedures (central venous catheter, urinary catheter, gastric tube, oxygen therapy by nasal catheter). The length of stay (LOS) and the patient-days of use of medication or devices were measured up to the occurrence of first-onset episode of diarrhoea, discharge from hospital or death.

Data from the medical and nursing charts and those from direct observation were recorded in a standardised form by a research nurse and research assistant on a daily basis until discharge. Changes in exposure factors, clinical condition or diarrhoeal episodes were recorded.

A sample size calculation was performed using EpiInfo V.3.5.1. To inform power calculations, we did use local

ward survey data that found that a third of the mothers of babies hospitalised in the weeks prior to study enrolment reported pacifier use. Assuming a 9% frequency of ND in non-exposed children, 354 children would be required to detect a difference of 20% in the risk of diarrhoea, with 80% statistical power and a 5% level of significance. To allow for possible losses, 378 children were enrolled.

Data were entered in duplicate, and statistical analyses were performed using STATA V.9.1. ORs were described with 95% CIs and each variable was controlled for LOS. Use of pacifiers and variables associated with the risk of diarrhoea at a level of $p < 0.2$ in bivariate analysis were selected for inclusion in the multivariate model. A backward stepwise procedure was followed to obtain adjusted OR in multivariate logistical regression. The R software V.2.6.0 was used for survival analysis (The R Foundation for Statistical Computing).

To assess colonisation by faecal coliforms, pacifier teats were immersed in brain–heart-infusion media. Specimens were immediately taken to the hospital microbiology laboratory and plated on to MacConkey and Hektoen Enteric Agar (Himedia Laboratories, Mumbai, India). Isolates with appropriate colonial morphology were subcultured and confirmed to be oxidase-negative Gram-negative bacilli. TSI (Triple Sugar Iron Agar) and SIM (Sulfide Indole Motility) tests were used to differentiate *Klebsiella spp.* from other enteric bacilli according to the Clinical and Laboratory Standards Institute guidelines.⁶

The study was approved by IMIP's Research Ethics Committee and all parents or guardians had signed a consent form.

RESULTS

Throughout the study period, 378 of 536 infants fulfilled the eligibility criteria. Fifty-six (10.4%) children with community-acquired diarrhoea, 90 with either respiratory or haemodynamic instability; five who stayed in hospital for <24 h were excluded. There were seven losses (1.3%) due to failure to obtain informed consent.

The cohort of 378 infants was followed for a total of 2932 patient-days. There was a predominance of male (59%), and the median age was 4.1 months (IQR 2–9.6 months). Children came from a low socioeconomic status with median family income (monthly) per capita of U\$64.87 (IQR 32.49–93.23) and maternal schooling of 9 years (IQR 7–12 years) among those with ND and 8 years for those without diarrhoea (IQR 6–12 years). Fifty-five per cent (208/378) of children were being breast fed (either exclusively or mixed) at the time of admission to hospital. The median duration of exclusive breast feeding was 2 months.

Thirty-three of the 378 infants developed ND (8.7%) with an incidence density of 11.3 per 1.000 patient-days. Table 1 shows the distribution of infants with and without ND according to the factors reported at admission and observed during hospitalisation. Almost half of

Table 1 Frequency distribution and bivariate analysis of the association between intrinsic and extrinsic factors and the occurrence of nosocomial diarrhoea (ND) in infants paediatric wards at IMIP, from 1 April to 31 October 2009

| Variables | All infants N=378 | Patients with ND n=33 | Patients without ND n=345 | OR (95% CI)* | p Value |
|---|----------------------|-----------------------------|---------------------------------|---------------------|-------------|
| | n (%) | n (%) | n (%) | | |
| Intrinsic factors | | | | | |
| Pacifier user in the hospital | 194 (51.3) | 16 (48.5) | 178 (51.6) | 0.88 (0.43 to 1.80) | 0.72 |
| Bottle feeding | 281 (74.3) | 21 (64.0) | 260 (75.4) | 0.57 (0.27 to 1.21) | 0.15 |
| Finger sucking habit | 36 (9.5) | 3 (9.0) | 33 (9.6) | 0.95 (0.27 to 1.32) | 0.94 |
| Rotavirus vaccination | 173 (45.8) | 16 (48.5) | 157 (45.5) | 0.87 (0.43 to 1.80) | 0.73 |
| Age ≤6 months | 234 (62.0) | 21 (64.0) | 213 (61.7) | 1.09 (0.52 to 2.29) | 0.82 |
| Sex, male | 223 (59.0) | 21 (64.0) | 202 (58.5) | 1.25 (0.59 to 2.62) | 0.56 |
| Low weight at birth | 61 (16.1) | 5 (15.1) | 56 (16.2) | 0.92 (0.34 to 2.48) | 0.87 |
| Prematurity | 67 (17.7) | 6 (18.2) | 61 (17.7) | 1.03 (0.41 to 2.61) | 0.94 |
| Breast feeding | 208 (55.0) | 12 (36.4) | 196 (56.8) | 0.43 (0.20 to 0.90) | 0.03 |
| Nutritional status, weight/age z-score ≤-2 | 56 (14.8) | 6 (18.2) | 50 (14.5) | 1.3 (0.50 to 3.34) | 0.59 |
| Extrinsic factors | | | | | |
| Use of devices or medication | | | | | |
| Central venous catheter | 31 (8.2) | 6 (18.2) | 25 (7.2) | 2.96 (1.06 to 8.23) | 0.04 |
| Peripheral venous catheter | 281 (74.3) | 25 (75.8) | 256 (74.2) | 1.08 (0.47 to 2.49) | 0.85 |
| Gastric tube | 86 (22.7) | 12 (36.4) | 74 (21.4) | 2.1 (0.986 to 4.53) | 0.06 |
| Oxygen therapy by nasal catheter | 48 (12.7) | 6 (18.2) | 42 (12.2) | 1.59 (0.62 to 4.13) | 0.34 |
| Antibiotic | 264 (69.8) | 25 (75.8) | 239 (69.3) | 1.38 (0.60 to 3.16) | 0.44 |
| Corticoids | 113 (29.9) | 11 (33.3) | 102 (29.7) | 1.19 (0.55 to 2.54) | 0.66 |
| Gastric acid H2 blockers | 54 (14.2) | 6 (18.2) | 48 (14.0) | 1.36 (0.53 to 3.52) | 0.52 |
| Prolonged fasting | 73 (19.3) | 6 (18.2) | 67 (19.4) | 0.91 (0.36 to 2.30) | 0.84 |
| | Median (IQR) | Median (IQR) | Median (IQR) | | |
| LOS, patient-days† | 266 (4–10) | 6 (4–10) | 6 (4–9) | 1.00 (0.97 to 1.04) | 0.83 |
| Device utilisation, patient-days of use† | | | | | |
| Central venous catheter | 177 (0–0) | 0 (0–0) | 0 (0–0) | 1.09 (0.97 to 1.23) | 0.14 |
| Peripheral venous catheter | 856 (0–3) | 2 (1–3) | 2 (0–3) | 0.98 (0.84 to 1.13) | 0.76 |
| Gastric tube | 465 (0–0) | 0 (0–2) | 0 (0–0) | 1.10 (0.98 to 1.22) | 0.09 |
| Oxygen therapy by nasal catheter | 125 (0–0) | 0 (0–0) | 0 (0–0) | 1.32 (1.04 to 1.68) | 0.02 |
| Antibiotic | 1449 (0–6) | 7 (1–11) | 2 (0–6) | 1.49 (1.28 to 1.74) | 0.00 |
| Corticoids | 408 (0–1) | 0 (0–1) | 0 (0–1) | 1.04 (0.92 to 1.18) | 0.50 |
| Gastric acid H2 blockers | 344 (0–0) | 0 (0–0) | 0 (0–0) | 1.03 (0.93 to 1.13) | 0.61 |
| Prolonged fasting | 145 (0–0) | 0 (0–0) | 0 (0–0) | 0.95 (0.71 to 1.28) | 0.75 |

*OR adjusted for LOS to until first-onset episode of diarrhoea, discharge or death. p values of less than 0.2 are shown in bold numbers.

†Patient-days until first-onset episode of ND, discharge or death.

IMIP, Instituto de Medicina Integral Prof. Fernando Figueira; LOS, length of stay.

the infants (51.4%) enrolled at this cohort study (194/378) used a pacifier during their stay in hospital. The rate of pacifier use in breastfed babies was 65% (135/208) and 35% for non-breastfed babies (59/170). Pacifier users presented 8.2% (16/194) of hospital-acquired diarrhoea compared with 9.2% (17/184) at non-users (time adjusted bivariate analysis OR=0.88, 95% CI 0.43 to 1.80). There were no differences between median LOS for pacifier users (6 days, IQR 4–10 days) and non-users (6 days, IQR 4–9 days). Twelve (3%) children died during follow-up, two of whom had ND.

In multivariate logistic regression analysis (table 2), risk and protective factors for nosocomial diarrhoea, controlled for LOS, were duration of oxygen by nasal catheter use (OR=1.61, 95% CI 1.18 to 2.20), days of antimicrobial use (OR=1.62, 95% CI 1.34 to 1.94), being breast fed during the hospitalisation (OR=0.40, 95% CI

0.17 to 0.93), each day on hospital stay (OR=0.65, 95% CI 0.53 to 0.80) and pacifier user (OR=1.03, 95% CI 0.43 to 2.47).

The likelihood of a child remaining free of ND for each day of stay in the paediatric ward was estimated using the Kaplan–Meier method, and the curves for pacifier users and non-users were drawn (figure 1). The probability of a child remaining free of an episode of diarrhoea up to the seventh day of hospitalisation in the ward was 91.2% (95% CI 87.7% to 94.9%). The log-rank test showed no statistical difference between pacifier users and non-users.

One hundred and sixty-nine (87.1%) of 194 pacifiers were available for culture, 16 belonged to the infants with diarrhoea and 153 for those without diarrhoea. Faecal coliforms were isolated in 16% (27/169) of samples. Among the infants with diarrhoea, in only one

Table 2 Multivariate analysis of the risk factors for occurrence of ND in IMIP paediatric ward, from 1 April to 31 October 2009

| Variables | OR (95% CI) | p Value |
|--|---------------------|---------|
| Days of use of oxygen therapy (nasal catheter) | 1.61 (1.18 to 2.20) | 0.003 |
| Days of use of antibiotics | 1.62 (1.34 to 1.94) | 0.000 |
| Breast feeding | 0.40 (0.17 to 0.93) | 0.034 |
| LOS in paediatric ward* | 0.65 (0.53 to 0.80) | 0.000 |
| Pacifier user | 1.03 (0.43 to 2.47) | 0.936 |

*OR controlled by LOS until onset of ND, discharge or death. IMIP, Instituto de Medicina Integral Prof. Fernando Figueira; ND, nosocomial diarrhoea; LOS, length of stay.

pacifier was isolated a coliform (6.3%) and 16.0% within those without diarrhoea (p=0.47).

DISCUSSION

Despite the high costs and morbidity associated with ND, the frequent use of pacifiers by children admitted to hospital and the potential of enteropathogens colonising pacifiers, this is, to our knowledge, the first report to prospectively assess the role of pacifiers in ND. The risk of ND in children between 29 days and <2 years of age at IMIP paediatric wards during the 6-month study period was not different in children who were classified as pacifier users versus children who did not use a pacifier.

Most infants in our cohort were pacifier user; however, there was no statistically significant association between pacifier use and the occurrence of nosocomial diarrhoea. Described by the terms ‘pacifier’, and regionally in northeastern Brazil as ‘comfort’, the use of pacifiers seems to be indicated in order to ‘pacify’ or ‘comfort’ the restless, especially suffering ill child.^{7,8} Randomised

clinical study investigated the effect of non-nutritive sucking (sucking of sterile water, sucrose or pacifier) as an analgesic during invasive procedures and has been shown that the use of a pacifier calms and modifies pain perception.⁹

The lack of an association between pacifier use and diarrhoea has been previously reported in a community setting. Tomasi *et al*⁴ performed a cross-sectional study in poor neighbourhoods of Pelotas, Brazil, and found no association between pacifier use and community-acquired diarrhoea, even though faecal coliforms were present in half of the tested pacifiers. The authors suggested that, in the highly contaminated environments where families from low socioeconomic backgrounds live, the added risk of using pacifiers would not significantly change the incidence of diarrhoea. This may also be true for the baby cradle environment in a busy and crowded hospital ward, where contamination vectors are likely to include the hands of professionals and associates, as well as food, water, utensils and hospital supplies.^{2,4}

The protective effect of breast feeding in ND, observed in this study (OR=0.40, 95% CI 0.17 to 0.93, p=0.03), corroborates the evidence from the literature on the protection of breast feeding in prevention of infections especially diarrhoeal diseases in the community.¹⁰⁻¹² The ND was an adverse event that occurred in the first days of hospitalisation.

Arguably, the relative importance of contaminated pacifiers could be different in settings with lower incidences of nosocomial gastrointestinal infection. Accompanying persons stay with their children for most of the time and it is not culturally acceptable to offer a child someone else’s pacifier, we deem as small the risk of an occasional unrecorded exposure. However, circumstances similar to the present study site are often found in many settings in low- and middle-income countries, where the burden of diarrhoea is highest. The present study suggests that, in isolation, measures to restrict the use of pacifiers in hospital are unlikely to affect the incidence of ND in such settings. Health professionals should thus focus on known effective measures, such as hand washing, and look for factors other than the use of pacifiers in their efforts to prevent spread of diarrhoeal pathogens in the hospital.^{2,13,14}

While the evidence-based benefits and risks of pacifiers should inform the policies of healthcare facilities as highlighted by the Unicef/WHO Baby-Friendly Hospital Initiative, it should be remembered that there are still controversial^{3,15} potentially adverse effects arising from the use of pacifiers in early weaning of breastfeeding infants.

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Contributors The listed authors have made the following contributions to this article: GCSS: substantial contributions to conception, design, acquisition, analysis and interpretation of data; drafting the article and revising it critically

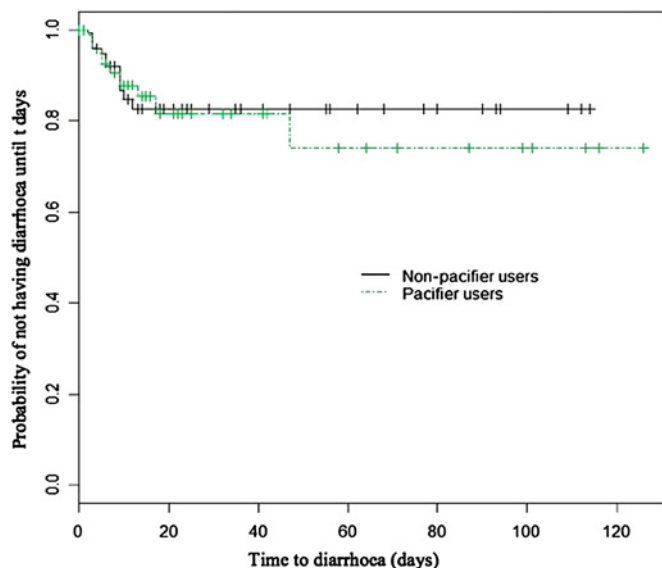


Figure 1 Stratified curve of time until occurrence of diarrhoea for the non-pacifier and pacifier users.

for important intellectual content; final approval of the version to be published. MJGdM: substantial contributions to conception, design, analysis and interpretation of data; drafting the article and revising it critically for important intellectual content; final approval of the version to be published. JBC: substantial contributions to conception, design, analysis and interpretation of data; drafting the article and revising it critically for important intellectual content; final approval of the version to be published. ISS: substantial contributions to acquisition and analysis of data; revising the article critically for important intellectual content; final approval of the version to be published. GAPdS: substantial contributions to conception, design, analysis and interpretation of data; revising the article critically for important intellectual content; final approval of the version to be published. LSdL: substantial contributions to conception, design, analysis and interpretation of data; revising the article critically for important intellectual content; final approval of the version to be published.

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Competing interests None.

Ethics approval Ethic approval was provided by Comitê de Ética em Pesquisa em Seres Humanos do Instituto de Medicina Integral Prof. Fernando Figueira.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement There are no additional data available.

REFERENCES

- Horan TC, Gaynes RP. Surveillance of nosocomial infections. In: Mayhall CG, ed, *Hospital Epidemiology and Infection Control*. Philadelphia: Lippincott Williams & Wilkins, 2004:1659–702.
- Pittet D, Zerr DM, Posfay-Barbe KM. Infection control in paediatrics. *Lancet Infect Dis* 2008;8:19–31.
- Sexton S, Natale R. Risk and benefits of pacifiers. *Am Fam Physician* 2009;79:681–5.
- Tomasi E, Victoria CG, Post PR, et al. Uso de chupeta em crianças: contaminação fecal e associação com diarreia. *Rev Saúde Pública* 1994;28:373–9.
- WHO Multicentre Growth Reference Study Group. Development of a WHO growth reference for school-aged children and adolescents. *Bull World Health Organ* 2007;85:649–732.
- Clinical and Laboratory Standards Institute. *Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard*. Wayne: PA: NCCLS, 2003.
- Sertório SC, Silva IA. As faces simbólica e utilitária da chupeta na visão de mães. *Rev Saude Publica* 2005;39:156–62.
- Castilho SD, Rocha MAM. Uso de chupeta: história e visão multidisciplinar. *J Pediatr* 2009;85:480–9.
- Curtis SJ, Jou H, Ali S, et al. A randomized controlled trial of sucrose and/or pacifier as analgesia for infants receiving venipuncture in a pediatric emergency department. *BMC Pediatr* 2007;7:27.
- Araújo MFM, Ferreira AB, Gondim KM, et al. A prevalência de diarreia em crianças não amamentadas ou com amamentação por tempo inferior a seis meses. *Cienc Cuid Saude* 2007;6:76–84.
- Novak FR, Almeida JAG, Viera GO, et al. Coloostro humano: fontes naturais de probióticos? *J Pediatr (Rio J)* 2001;77:265–71.
- Anon. WHO Collaborative Study Team on the role of breastfeeding on the prevention of infant mortality. Effect of breastfeeding on infant and child mortality due to infectious diseases in less developed countries: a pooled analysis. *Lancet* 2000;355:451–5.
- Comina E, Marion K, Renaud FN, et al. Pacifiers: a microbial reservoir. *Nurs Health Sci* 2006;8:216–23.
- Cohen E, Austin J, Welstein M, et al. Care of children isolated for infection control: a prospective observational cohort study. *Pediatrics* 2008;122:411–15.
- O'Connor NR, Tanabe KO, Siadaty MS, et al. Pacifiers and breastfeeding. *Arch Pediatr Adolesc Med* 2009;163:378–82.

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

| | Item No | Recommendation |
|------------------------------|----------------|--|
| Title and abstract | 1 | (a) Indicate the study’s design with a commonly used term in the title or the abstract |
| | a b | Ok. The study design (prospective cohort) has been included in the title and the abstract on pages 1 and 3 respectively. |
| | | (b) Provide in the abstract an informative and balanced summary of what was done and what was found |
| | | Ok. Methods and main findings have been included in the abstract on page 3. |
| Introduction | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported Ok. Brief scientific background and rationale are presented on page 3. |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses Ok. Objectives and the pre-specified hypotheses can be found on page 4. |
| Methods | | |
| Study design – | 4 | Present key elements of study design early in the paper Ok. The study design is indicated at the end of introduction (page 4) and in the first sentence in the Methods section (page 4). |
| Setting - | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection Ok. Every topic listed above has been included in the 1 st paragraph of Methods section (page 4). |
| Participants (a) | 6 | (a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up The eligibility criteria, sources and methods of selection and follow up are explained on page 4. |
| | | (b) For matched studies, give matching criteria and number of exposed and unexposed Not applicable. |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable Outcomes, exposures, predictors, potential confounders and effect modifiers are now given on pages 4 and 5. Diagnostic criteria for diarrhoea are given on page 4. |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group Sources of data and details of measurement are described on page 4. |
| Bias | 9 | Describe any efforts to address potential sources of bias Efforts to address potential sources of bias are described on page 4. |
| Study size | 10 | Explain how the study size was arrived at The sample size is explained on page 5 – 3 rd paragraph. |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why. Quantitative variables have now been categorized, as described on pages 4 and 5. |

| | | |
|---------------------|-----|--|
| Statistical methods | 12 | <p>(a) Describe all statistical methods, including those used to control for confounding A multivariate logistic regression (backwards stepwise procedure) was used, as described on page 7 and summarized in Table 2.</p> <hr/> <p>(b) Describe any methods used to examine subgroups and interactions</p> <hr/> <p>(c) Explain how missing data were addressed There were no missing data</p> <hr/> <p>(d) If applicable, explain how loss to follow-up was addressed Not applicable</p> <hr/> <p>(e) Describe any sensitivity analyses Not applicable</p> |
| Results | | |
| Participants | 13* | <p>(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. There were 536 admissions of age-eligible children during the enrolment period. Fifty-six children with community-acquired diarrhea, 90 with either respiratory or hemodynamic instability, 5 who stayed in hospital for <24 hours were excluded. Seven further children were not included as they had no available parent to give consent and were considered losses for the study.</p> <hr/> <p>(b) Give reasons for non-participation at each stage See above.</p> <hr/> <p>(c) Consider use of a flow diagram See the description above (13 a)</p> |
| Descriptive data | 14* | <p>(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders Characteristics of study participants are described on 2nd paragraph of Result section on page 6.</p> <hr/> <p>(b) Indicate number of participants with missing data for each variable of interest There were no missing data for the variables of interest.</p> <hr/> <p>(c) Summarise follow-up time (eg, average and total amount) During the 7-month period of the cohort, 378 children were followed up for a total of 2932 patient-days. The median length of stay for pacifier-users was 6 (IQI 4-10) and for non-users 6 (IQI 4-9).</p> |
| Outcome data | 15* | <p>Report numbers of outcome events or summary measures over time Incidence of nosocomial diarrhea for pacifier-users and non-users (8.2 and 9.2%, respectively; $p=0.94$)</p> |
| Main results | 16 | <p>(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included For each variable the Odds ratio in the bivariate analysis was adjusted for length of stay in the ward.</p> <hr/> <p>(b) Report category boundaries when continuous variables were categorized See pages 4 and 5.</p> <hr/> <p>(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period Not applicable.</p> |
| Other analyses | 17 | <p>Report other analyses done—eg analyses of subgroups and interactions, and</p> |

| | | |
|--------------------------|----|--|
| | | sensitivity analyses Not applicable. |
| Discussion | | |
| Key results | 18 | Summarise key results with reference to study objectives There were no differences in the risk (time adjusted OR=1.03, 95% CI 0.43-2.47) or incidences of nosocomial diarrhea between pacifier-users and non-users (8.2 and 9.2%, respectively; $p=0.94$). |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias The present study suggests that, in isolation, measures to restrict the use of pacifiers in hospital are unlikely to affect the incidence of nosocomial diarrhoea in such settings. |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence Health professionals should thus focus on known effective measures, such as hand-washing, and look at factors other than the use of pacifiers in their efforts to prevent the spread of diarrheal pathogens in the hospital. |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results The similar circumstances of busy and crowded wards such as the one covered by this study are often found in many settings in low- and middle-income countries, where the burden of diarrhea is high. |
| Other information | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based This study was funded by the Instituto de Medicina Integral Prof. Fernando Figueira – IMIP, through its institutional Fund for Education and Research. |

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at <http://www.strobe-statement.org>.