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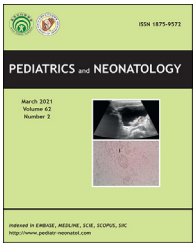

Original Article

The BaSICS (Baby Skin Integrity Comparison Survey) study: A prospective experimental study using maternal observations to report the effect of baby wipes on the incidence of irritant diaper dermatitis in infants, from birth to eight weeks of age

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Key Words
Infant diaper dermatitis (IDD);
Nappy rash;
Maternal observation;
Smartphone application;
Brand comparison

Background: Baby wipes have been shown to be safe and effective in maintaining skin integrity when compared to the use of water alone. However, no previous study has compared different formulations of wipe. The aim of the BaSICS study was to identify any differences in incidence of irritant diaper dermatitis (IDD) in infants assigned to three different brands of wipe, all marketed as suitable for neonates, but which contained varying numbers of ingredients.
Methods: Women were recruited during the prenatal period. Participants were randomly assigned to receive one of three brands of wipe for use during the first eight weeks following childbirth. All participants received the same nappies. *Participants* reported their infant's skin integrity on a scale of 1—5 daily using a bespoke smartphone application. Analysis of effect of brand on clinically significant IDD (score 3 or more) incidence was conducted using a negative binomial generalised linear model, controlling for possible confounders at baseline. Analysts were blind to brand of wipe.
Results: Of 737 women enrolled, 15 were excluded (admitted to neonatal intensive care, premature or other infant health issues). Of the 722 eligible babies, 698 (97%) remained in the study for the full 8-week duration, 24.6% of whom had IDD at some point during the study. Mothers using the brand with the fewest ingredients reported fewer days of clinically significant nappy rash (score$\geq$3) than participants using the two other brands ($p = 0.002$ and $p < 0.001$). Severe IDD (grades 4 and 5) was rare (2.4%).

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Conclusions: Rarity of severe IDD suggested that sensitive formula baby wipes are safe when used in cleansing babies from birth to eight weeks during nappy changes. The brand with fewest ingredients had significantly fewer days of clinically significant IDD. Daily observations recorded on a smartphone application proved to be a highly acceptable method of obtaining real-time data on IDD.

Clinical Trial registration: This study was not designed or registered as a clinical trial as no intervention in normal patterns of infant care took place. Mothers who had already decided to use disposable nappies and a baby wipe product agreed to observe and report on their infants' skin condition; in return they received a 9-week supply of free nappies and wipes.

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1. Background

Irritant diaper dermatitis (IDD, also known as nappy rash) is a skin condition characterised by inflammation in the buttocks, groin and perineum. It is caused by contact with urine and faeces combined with the friction of the nappy rubbing against the skin[1] and is one of the most common skin complaints in infancy, although international prevalence estimates show a wide range in rates of IDD.[2–9] Healthcare providers have traditionally recommended water with cloth wipes or cotton wool for cleaning babies' nappy areas; however, two seminal studies have shown no greater skin irritation where baby wipes were used.[10,11] Moreover, baby wipes were associated with a decrease in skin irritation compared to cloth wipes[10] and parents reported that baby wipes were more convenient to use than cotton wool and water.[11] Both of these studies recommended further research into the impact of baby wipes on infant skin, especially studies comparing different formulations of baby wipes.[10,11]

Baby wipe formulations have improved significantly in the last 40 years: abrasive ingredients, such as isopropanol are no longer added, and many brands exclude perfume, as recommended by the National Institute for Health and Care Excellence.[12–14] The brands used in this study were marketed as being mild enough for newborn skin, but they differed in their number of ingredients. Brand three contained two ingredients,[15] while brands one and two each had more than three times as many.

2. Methods

2.1. Design

The Baby Skin Integrity Comparison Survey (BaSICS) research was a prospective experimental study designed to compare three different brands of baby wipes using maternal observations of the incidence of IDD in infants from birth to eight weeks of age. Greater Manchester was selected as the study site due to its multi-ethnic demographic profile. Pregnant women expecting single, healthy, term babies were recruited during the prenatal period by direct contact or advertising in hospital antenatal clinics and on social media.

2.2. Sample size calculation

Sample size calculations indicated that in order to detect a difference between a prevalence of 15% of IDD in one brand of baby wipe versus 5% in another brand, 166 participants were required per arm (total 498, assuming power of 80% and a type I error rate of 5%). Assuming a 70% retention rate the study aimed to recruit 700 women.

2.3. Randomisation

Mothers and babies were assigned to receive one of three brands of wipes using block randomisation: all mothers received the same brand of disposable nappies. Researchers involved in analysis of the data were blind to the baby wipe brand. It was not possible to blind participants as this would have necessitated re-packaging the wipes, which could have compromised the quality of the contents.

2.4. Procedure

An initial 'starter pack' containing a week's supply of nappies and wipes was delivered to all participants when they registered onto the study from 34 weeks of pregnancy. This ensured that mothers had an adequate supply of their assigned wipes for use immediately after their baby's birth. Subsequently, nappies and wipes were delivered to participants' homes by courier as soon as they self-activated into the study by completing their first survey, and then at roughly 2-week intervals throughout the study period. Each mother received nine weeks' supply of free nappies and wipes and in return completed a short daily survey from the day of their baby's birth, up to eight weeks of age (Appendix). Mothers' daily observations were recorded using a bespoke smartphone application: a paper version of the survey tool was made available for the small number of participants who preferred this method ($n = 3$).

2.5. Statistical analysis

The main outcome of interest was the incidence of significant IDD in the sample, and comparisons of incidence among the three groups. IDD was measured on a scale of 1–5, with grade 1 indicating an absence of redness or rash,

grade 2 some redness and a mild rash, grade 3 the point at which broken skin and discomfort were evident, and grades 4 and 5 being more severe (Appendix). The outcome of 'clinically significant IDD' was set at grade 3 or greater. Data were analysed using SPSS and Stata. Univariate comparisons among wipe brands and sample characteristics were compared using ANOVA, chi-square and Kruskal–Wallis tests, depending on variable type. Analyses of effect of brand on IDD incidence used a negative binomial generalised linear model with a log link, controlling for possible confounders at baseline.[16]

3. Results

3.1. Sample characteristics

Recruitment continued until 737 women were enrolled onto the study. Fifteen babies were ineligible at the time of birth (eight required a stay in neonatal intensive care, one was born premature, two had other infant health issues, and four were excluded on multiple criteria), leaving 722 women and their babies able to start the study. Retention was far higher than expected, with only 24 participants dropping out, leaving an analysis population of 698 women completing the study (96.7%), confirming the validity and acceptability of the study methods. Attrition was similar across the three groups, with 11 participants dropping out from group one, 8 from group two, and 5 from group three ($\chi^2 = 2.25$, $p = 0.32$).

Brand 1 was used by 233 participants, 227 used Brand 2, and 238 used Brand 3. Group numbers varied because: i) participants were assigned to a brand during the prenatal period, but some babies were subsequently ineligible; ii) rates of attrition were slightly different across groups; and iii) the original randomisation did not start with exactly equal numbers because of the block randomisation process.

Table 1 shows demographic characteristics and details of the infant care and cleaning routines of the analysis population, and for each group. The average age of mothers at their infant's birth was 32.0 years (SD = 5.12), and just over half (51.9%) of the infants were male. Just less than half (49.0%) of the infants were their mothers' first child and just under half (49.6%) of the infants were born by normal vaginal birth. Ethnicity was determined using UK government census classifications; 75% of mothers in this sample self-identified as White, 15% Asian, 5% Black, 3% Mixed race, and 1% as Other ethnic group. Comparison with Greater Manchester population data[17] showed that there was a greater proportion of people from ethnic minorities in the sample (23.3%), compared to the wider population (16.4%; $\chi^2 = 25.36$, $p < 0.001$). This may have been due to differences in age ranges: census data includes people of all ages, whereas our sample consisted of only women of childbearing age.

More than half of participants (52.1%) changed their infants' nappies approximately every 3 h, and most (58.7%) bathed their infants once every 2–3 days. Many (79.4%) used non-biological laundry detergent, and two thirds of participants (66.9%) reported the use of skin cream on their infant's nappy area at some point during the study. A minority (13.8%) of infants received antibiotics at some point during the study. There were no between-group differences in any of the characteristics shown in Table 1.

3.2. Main outcomes analysis

The percentage of mothers who reported at least one day of clinically significant IDD (grade 3 or above) was 24.6%. Brand 3 had the lowest proportion of babies with significant IDD (n = 46; 19%), followed by brand 1 (n = 59; 25%) and brand 2 (n = 67; 30%). The distribution of the number of days with significant nappy rash by brand is shown in Fig. 1. Severe IDD (grades 4 and 5) was rare (2.4% of babies). There were no reports of any problems such as allergic reactions that required medical attention. Overall the average nappy rash score was 1.43 and the average number of days with no rash was 34 out of 55 study days.

A univariate analysis (Table 2) of clinically significant IDD showed a highly significant brand effect. For one day of clinically significant nappy rash with Brand 3, the rash would have lasted 1.48 days (95% CI: 1.15–1.90) with Brand 1 ($p = 0.002$) and 1.69 days (95% CI: 1.32–2.17) with Brand 2 ($p < 0.001$). Other potential factors included the gender of the baby (females having a lower rate of rash, incidence rate ratio (IRR) 0.77, 95% CI: 0.63–0.94, $p = 0.011$) and parity (second or subsequent babies had a higher rate: IRR 1.24, 95% CI: 1.04–1.51, $p = 0.033$). Each year increase in maternal age was associated with a 1.02 (95% CI: 1.00–1.04) increase in the rate of significant nappy rash ($p = 0.039$). Those with above average annual household income (>£30,000) had a higher rate of rash than those reporting below average household income (IRR 1.74, 95% CI: 1.38–2.18, $p = <0.001$). Babies whose mothers were of mixed ethnicity had a lower rate of rash (IRR 0.29, 95% CI: 0.13–0.66, $p = 0.003$) compared to babies of White mothers.

A second set of models tested each covariate in turn while controlling for brand. Gender of the baby, parity, and household income remained significant. A multivariate forwards stepwise regression model produced similar results for the primary analysis. The brand of wipe remained a significant predictor of number of days of rash, with the use of Brand 2 having a significantly higher rate of rash (IRR 1.70, 95% CI 1.31–2.22, $p < 0.001$) compared to Brand 3 and although Brand 1 also had a higher rate of rash compared to Brand 3, this was no longer statistically significant (IRR 1.22, 95% CI: 0.93–1.60, $p = 0.152$). Compared to first babies, subsequent babies had a higher rate of rash (IRR 1.89, 95% CI: 1.50–2.38, $p < 0.001$) and those with above average household incomes also had a higher rate of IDD (IRR 2.59, 95% CI: 1.97–3.41).

3.3. Fidelity to treatment

Fidelity was measured by number of days of using only the allocated brand of baby wipe for cleaning the nappy area. In total, 59.5% of participants reported 100% fidelity to their allocated brand of wipe. A further 28.3% used a different cleaning method on between 1 and 5 days: 12.2% reported using a different cleaning method on more than 5 days, and 2% reported using a different method on more than 10 days. The

Table 1 Sample characteristics.

	Full sample	Brand 1	Brand 2	Brand 3	Statistical test
Demographics					
N	698 (100%)	233 (33.3%)	227 (32.5%)	238 (34.1%)	$\chi^2 = 0.31, p = 0.86$
Mean (SD) age of mother at baby's birth	31.99 (5.12)	31.92 (5.37)	32.26 (4.84)	31.80 (5.14)	$F = 0.48, p = 0.62$
Gender of baby					
Male	361 (51.9%)	109 (46.8%)	124 (54.6%)	128 (53.8%)	
Female	334 (46.6%)	123 (52.8%)	101 (44.5%)	110 (46.2%)	$\chi^2 = 3.51, p = 0.17$
Undisclosed	3 (1.5%)	1 (0.4%)	2 (0.9%)	0	
Birthweight of baby					
Less than 2410 g	14 (2.0%)	2 (0.9%)	6 (2.6%)	6 (2.5%)	
2410 g—2919 g	93 (13.3)	39 (16.7%)	28 (12.3%)	26 (10.9%)	
2920 g—3628 g	366 (52.4%)	111 (47.6%)	116 (51.1%)	139 (58.4%)	
3629 g—4166 g	179 (25.6%)	68 (29.2%)	60 (26.4%)	51 (21.4%)	
4167 g—4706 g	41 (5.9%)	12 (5.2%)	16 (7.0%)	13 (5.5%)	
More than 4706 g	5 (0.7%)	1 (0.4%)	1 (0.4%)	3 (1.3%)	$H = 0.57, p = 0.75$
First baby					
Yes	342 (49.0%)	113 (48.5%)	103 (45.4%)	126 (52.9%)	
No	355 (50.9%)	119 (51.1%)	124 (54.6%)	112 (47.1%)	
Undisclosed	1 (0.1%)	1 (0.4%)	0	0	$\chi^2 = 4.68, p = 0.32$
Type of delivery					
Normal vaginal delivery	346 (49.6%)	110 (47.2%)	113 (49.8%)	123 (51.7%)	
Ventouse/forceps extraction	99 (14.2%)	30 (12.9%)	34 (15.0%)	35 (14.7%)	
Breech delivery	2 (0.3%)	1 (0.4%)	0	1 (0.4%)	
Caesarean section	251 (36.0%)	92 (39.5%)	80 (35.2%)	79 (33.2%)	$\chi^2 = 3.21, p = 0.78$
Household income					
Up to £25,000	177 (25.3%)	59 (25.3%)	66 (29.1%)	52 (21.8%)	
£25,000 - £50,000	206 (29.5%)	78 (33.4%)	63 (27.8%)	65 (27.3%)	
£50,000 - £75,000	186 (26.6%)	53 (22.7%)	64 (28.2%)	69 (28.9%)	
More than £75,000	90 (12.8%)	31 (13.3%)	24 (10.6%)	35 (14.7%)	
Undisclosed	39 (5.5%)	12 (5.2%)	10 (4.4%)	17 (7.1%)	$\chi^2 = 9.55. p = 0.30$
Mother's highest qualification					
No formal education	11 (1.6%)	2 (0.9%)	4 (1.8%)	5 (2.1%)	
GCSE or equivalent	62 (8.9%)	23 (9.9%)	19 (8.4%)	20 (8.4%)	
NVQ or equivalent	58 (8.3%)	11 (4.7%)	22 (9.7%)	25 (10.5%)	
A-level or equivalent	149 (21.3%)	59 (25.3%)	50 (22.0%)	40 (16.8%)	
Bachelor's degree or eq.	293 (42%)	98 (42.1%)	89 (39.2%)	106 (44.5%)	
Master's or PhD	118 (16.9%)	37 (15.9%)	42 (18.5%)	39 (16.4%)	
Other	7 (1.0%)	3 (1.3%)	1 (0.4%)	3 (2.1%)	$\chi^2 = 13.57, p = 0.33$
Mother's ethnicity					
White	536 (76.8%)	184 (79.0%)	174 (76.7%)	178 (74.8%)	
Black	30 (4.3%)	9 (3.9%)	14 (6.2%)	7 (2.9%)	
Asian	101 (14.5%)	32 (13.7%)	32 (14.1%)	37 (15.5%)	
Mixed	22 (3.2%)	4 (1.7%)	6 (2.6%)	12 (5.0%)	
Other	9 (1.3%)	4 (1.7%)	1 (0.4%)	4 (1.7%)	$\chi^2 = 9.82, p = 0.28$
Care and cleaning					
Frequency of nappy changing					
Hourly or more	19 (2.7%)	6 (2.6%)	7 (3.1%)	6 (2.5%)	
Every 2 h	175 (25.1%)	50 (21.5%)	63 (27.8%)	62 (26.1%)	
Every 3 h	364 (52.1%)	125 (53.6%)	123 (54.2%)	116 (48.7)	
Every 4 h	131 (18.8%)	48 (20.6%)	33 (14.5%)	50 (21.0%)	
Every 5 h or less	9 (1.3%)	4 (1.7%)	1 (0.4%)	4 (1.7%)	$H = 5.11, p = 0.08$
Bathing frequency					
Once daily or more often	202 (28.9%)	65 (27.9%)	71 (30.5%)	66 (27.7%)	
Once every 2—3 days	410 (58.7%)	133 (57.1%)	132 (56.7%)	145 (60.9%)	
Once per week or less often	86 (12.3%)	35 (15.0%)	24 (10.3%)	27 (11.3%)	$H = 1.70, p = 0.43$

(*continued on next page*)

Table 1 (*continued*)

	Full sample	Brand 1	Brand 2	Brand 3	Statistical test
Type of laundry detergent used					
Biological	68 (9.7%)	28 (12.0%)	21 (9.3%)	19 (8.0%)	
Non-biological	554 (79.4%)	176 (75.5%)	179 (78.9%)	199 (83.6%)	
Mixed	34 (4.9%)	11 (4.7%)	14 (6.2%)	9 (3.8%)	
Don't know	36 (5.2%)	16 (6.9%)	11 (4.8%)	9 (3.8%)	
No detergent used	6 (0.9%)	2 (0.9%)	2 (0.9%)	2 (0.8%)	$\chi^2 = 6.64, p = 0.58$
Skin cream used on nappy area	467 (66.9%)	149 (63.9%)	164 (72.2%)	154 (64.7%)	$\chi^2 = 0.73, p = 0.69$
Given antibiotics	96 (13.8%)	39 (16.7%)	32 (14.1%)	25 (10.5%)	$\chi^2 = 3.06, p = 0.22$

Categorical variables were analysed using the chi-square test ($\chi 2$), normally distributed continuous variables were analysed using ANOVA (F), and ordinal variables were analysed using Kruskall–Wallis tests (H).

other methods used were cotton wool and water (used at least once by 25.5% of participants), another brand of baby wipe (12.9%), water only (11.5%), or any other method (6.6%). There was no difference in fidelity between groups ($\chi^2 = 3.03$, $p = 0.22$).

4. Discussion

4.1. Main outcome

This research was designed to compare three brands of baby wipes in terms of their impact on IDD. One of the brands, Brand 3, contained fewer ingredients than the other two brands. Findings showed that babies who were cleansed with Brand 3 were less likely to have clinically significant IDD than those cleansed with the other two brands.

4.2. Strengths and limitations

As it was not possible to blind participants to the brands received, the potential for participants' observations of IDD to be biased based on previous perceptions or experience of brands of wipe is acknowledged. Measurement error, as a source of bias, was reduced by the use of real time (rather than retrospective) reports of IDD. The vast majority of those eligible for the study (97%) were retained and analysed and all participants contributed 55 days of continuous daily observations of their infants' skin condition. This high rate of retention and compliance with protocol was attributed to two factors: incentives in the form of free nappies and wipes, and the ease of use of the smartphone application, which reminded parents to submit daily observations and was simple and quick to use. The use of mothers' daily reports was innovative, imparting some important benefits. Previous UK studies of nappy rash have been based on either a single, retrospective survey of parents,[4,5] or

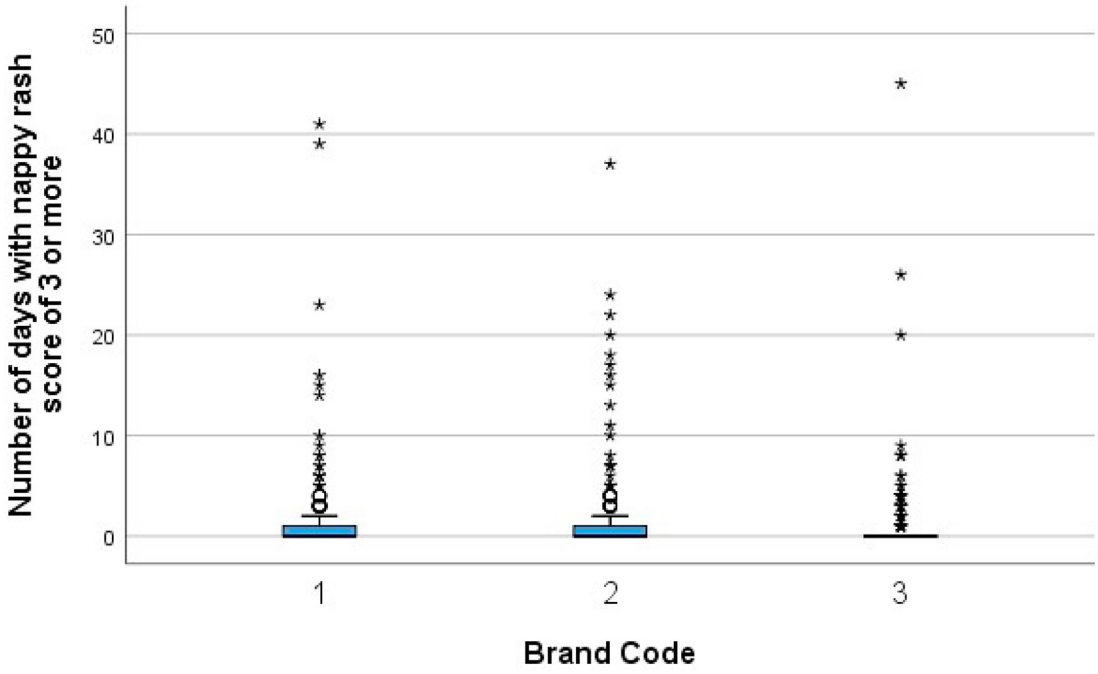

Fig. 1 Distribution of number of days of significant nappy rash by brand.

Table 2 Impact of brand of wipes and baseline covariates on number of days of significant rash.

	Univariate analysis		Univariate analysis (controlling for brand)		Multivariate analysis (n = 658)	
	IRR (95% CI)	P	IRR (95% CI)	P	IRR (95% CI)	P
Brand						
Brand 3	Ref		–			
Brand 1	1.48 (1.15–1.90)	0.002	–	–	1.22 (0.93–1.60)	0.152
Brand 2	1.69 (1.32–2.17)	<0.001	–	–	1.70 (1.31–2.22)	<0.001
Gender of baby						
Male	Ref					
Female	0.77 (0.63–0.94)	0.011	0.75 (0.61–0.92)	0.005	–	–
Parity						
First	Ref					
Subsequent	1.24 (1.02–1.51)	0.033	1.27 (1.04–1.55)	0.020	1.89 (1.50–2.38)	<0.001
Income (per year)						
<£30,000	Ref					
£30,000+	1.74 (1.38–2.18)	<0.001	1.78 (1.41–2.24)	<0.001	2.59 (1.97–3.41)	<0.001
Infant weight (g)						
<2410 g	Ref					
2410 g–4193 g	2.02 (0.87–4.70)	0.102	2.01 (0.86–4.7)	0.109	–	–
>4139 g	2.30 (0.92–5.75)	0.075	2.30 (0.91–5.81)	0.078	–	–
Mothers' age (years)						
	1.02 (1.00–1.04)	0.039	1.02 (1–1.04)	0.062	0.98 (0.95–1.00)	0.026
Ethnic Group						
White	Ref		Ref		Ref	
Black	1.41 (0.89–2.24)	0.144	1.29 (0.81–2.07)	0.286	2.52 (1.49–4.26)	0.001
Asian	1.29 (0.98–1.69)	0.068	1.32 (1.00–1.75)	0.048	1.71 (1.27–2.3)	<0.001
Mixed	0.29 (0.13–0.66)	0.003	0.30 (0.13–0.69)	0.004	0.16 (0.05–0.57)	0.004
Other	0.98 (0.4–2.37)	0.958	1.17 (0.48–2.86)	0.737	1.36 (0.54–3.38)	0.512

IRR Incidence Rate Ratio.
95% CI 95% confidence interval.

on a single or repeated assessment by a medical professional.[11] Although there have been studies with significantly larger sample sizes,[6] no other study has carried out this intensity of data collection for a large sample of babies. Mothers were able to report nappy rash daily, in real time, via a user-friendly interface on their smartphone, which contained reference diagrams for the assessment of IDD on a five-point scale. This allowed mothers to reflect daily on their baby's skin condition and cleaning routines using real-time methods of data collection, which are known to be more accurate than retrospective methods.[18] This has resulted in a set of IDD data that, to the authors' knowledge, is the most comprehensive to date for younger infants. The lack of direct professional involvement including trips to clinics may have helped to retain participants, contributing to the study's high completion rate.

4.3. Prevalence of IDD

The prevalence of IDD in the first eight weeks of a baby's life observed in this study (24.6%) is close to one previous UK study,[5] which found a prevalence of 25% (based on a sample of 12,103 infants) and higher than another UK study,[4] whose prevalence rate was 16% (based on a sample of 532 infants). These differences may be methodological in origin, since IDD measurement techniques have not been consistent. Neither of these previous studies collected daily data, instead using retrospective questionnaires at four weeks[5] or up to two years of age.[4] It is therefore difficult to conclude that prevalence was high, low, or typical in this sample. It is also important to note the distinction between different degrees of IDD severity. In this study, the main outcome was based on clinically significant IDD, which was defined as grade 3 or higher on a 5-point scale. Severe IDD (grades 4 and 5) was rare (2.4% of participants reported any severe rash). Further studies should acknowledge IDD severity.

5. Conclusion

This large study of babies aged from birth to eight weeks, who had been randomly allocated different brands of wipe, is the first research to demonstrate that wipe formulation is related to incidence of clinically significant IDD. Babies who were cleaned with the brand with fewest ingredients had significantly fewer days of rash. However it is not possible to determine whether it was the exclusion or inclusion of a specific ingredient that causes this difference. The study methods were acceptable to caregivers, as demonstrated by the very high retention rate to the study, and the participants' willingness to contribute a comprehensive set of daily observations.

While predictors of IDD included gender, household income, parity and perhaps ethnicity, the research was not designed to answer the question as to why these

were significant. It would be valuable for further studies to explore factors such as cultural or biological differences, differences in patterns of care in second-time mothers, and why higher income is associated with increased rates of IDD. Dividing cultural from biological differences would necessitate a focus on the ethnicity of the infant, rather than that of the mother as was done in this study.

Further studies are recommended to evaluate nappy rash over a longer period, ideally up to the age of toilet-training. Since the participants in this study used only one brand of disposable nappy, future studies could explore the use of different brands or types of nappy including biodegradable and cloth nappies.

Authors' contributions

FMP, JL and PAC designed the study and wrote the study protocol. PAC wrote the data management plan (DAP) and the statistical analysis plan (SAP). JAJ managed the study, contributing to the writing of study documentation, particularly protocols for the distribution of supplies to participants. ADP carried out day-to-day fieldwork, did initial data analysis and prepared the research report for the commercial funders. AMCC and PAC carried out the main outcomes analysis. FMP edited the final research report to draft this article and all authors contributed to the final draft.

Ethics

University Ethical Approval was given for this study, identification code HSR1617-181 on 20.10.2017. National Research Ethics Service (NRES) approval was awarded on 20.02.2018, identified as IRAS project ID 235164, under REC reference 18/NE/0060.

Consent for publication

Participants were informed of the intention of publication of the study data but that no identifiers would link data to a named individual. All participants signed a consent form following a verbal explanation of the study and their part in it. Researchers provided all participants with documentation confirming this at the time of obtaining written consent.

Availability of data and materials

The data that support the findings of this study can be requested from Irish Breeze. Restrictions apply to the use of this data as the ownership of the quantitative data resides with the commercial funder under contractual obligations and thus are not publicly available. Data are however available from the authors upon reasonable request and with permission of Irish Breeze.

Declaration of competing interest

One of the authors, Dr. F MacVane Phipps, PI of the BaSICS study, is now retired but is being funded by Irish Breeze, Republic of Ireland on a daily lecturer rate, to enable participation in the writing team in order to facilitate publication of this article. Irish Breeze funded the study and their brand, WaterWipes, was Brand 3. The authors do not have permission to name the two comparison brands; these are products that are widely available, popular with mothers, and are advertised as gentle enough for use on new-born babies.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pedneo.2020.10.003.

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Abbreviations

BaSICS	Baby Skin Integrity Comparison Survey
IDD	Irritant diaper dermatitis
IRR	Incidence rate ratio
CI	Confidence intervals