

A DESCRIPTION OF INTIMATE HYGIENE PRACTICES DURING PREGNANCY IN A
COHORT OF WOMEN IN JOHANNESBURG

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Medicine in Obstetrics and Gynaecology Johannesburg May 2025.

DECLARATION

I, Josef Locher, hereby declare that this Dissertation Report is of my own unaided work. I am submitting this research report for the degree Master of Medicine (in the submissible format with my protocol and extended literature review) in the branch of Obstetrics and Gynaecology at the University of the Witwatersrand, Johannesburg. This research report has not been submitted before for any degree or examination at this or any other university.



(Signature of candidate)

May 2025

ABSTRACT

Background: Intimate hygiene practices during pregnancy can influence maternal and neonatal health outcomes. Limited data exist on these practices among South African women. This study aimed to characterise intimate hygiene practices among pregnant women in Johannesburg and examine associations with demographic factors and preterm birth.

Methods: A secondary analysis was conducted on data from 18,076 pregnant women enrolled in the Group B Streptococcus Correlates of Protection Cohort Study in Johannesburg, South Africa. Participants completed questionnaires detailing their intimate hygiene practices, including frequency, methods, and products used. Statistical analyses assessed the prevalence of these practices, their association with demographic characteristics (age, race, education, occupation, dwelling type, parity, and HIV status), and preterm birth outcomes.

Results: The mean age was 28.4 years (range 18–49). Most participants were Black (16,811; 93.0%), single (14,541; 80.4%), unemployed (11,691; 64.7%), and resided in urban areas (12,782; 70.7%). They reported a median intimate cleaning frequency of 14 times per week (IQR 8–14). Vaginal washing was reported by 6,312 women (34.9%). Among those who undertook vaginal washing, 62.5% used fingers, 35.7% used a cloth, and 0.4% used other objects. Over half (9,653; 53.3%) practiced douching, and 8,743 (48.4%) added products to their bathwater.

Race was significantly associated with adding bathwater products ($p < 0.00001$). White women (39; 44.3%) had the highest proportion adding products. Tertiary-educated mothers were more likely to add products (396; 27.0%, $p = 0.0041$). Students had the highest rate of product use (154; 28.7%, $p = 0.0018$). Urban participants were more likely to add products (1,994; 25.2%) than semi-urban women (768; 23.2%, $p = 0.025$).

Douching was also significantly associated with race ($p < 0.00001$), with the “Other” category (67; 65.1%) reporting the highest rate. Women with no schooling had the highest douching rate (53.2%, $p = 0.0006$). Semi-urban mothers douched the most frequently (4,757; 53.4%, $p < 0.00001$). Marital status was significantly associated with douching ($p < 0.00001$), with the highest prevalence among single women (6,658; 45.8%). Occupation was also significantly associated with douching ($p = 0.016$), with students having the highest douching prevalence (154; 28.7%).

A significant association was observed between gestational age and the addition of products to bathwater for deliveries between 34 and <37 weeks compared to term deliveries ($p = 0.045$). Women who did not add products were more likely to deliver at term, while those who added products had a higher likelihood of delivering preterm. For deliveries <34 weeks compared to 34–<37 weeks, women who did not add products were more likely to deliver at 34–<37 weeks ($p = 0.02$).

For deliveries at <34 weeks compared to 34–<37 weeks, women who douched were more likely to deliver at <34 weeks, while those who did not douche had higher proportions of deliveries at 34–<37 weeks ($p = 0.035$).

In the combined preterm category (<37 weeks) compared to term deliveries, a statistically significant association was observed ($p = 0.035$), with women who douched being more likely to

deliver preterm. Although some early preterm categories were more frequent among those who douched, overall no consistent statistically significant associations were found between hygiene practices and preterm birth outcomes.

Conclusion: Intimate hygiene practices are prevalent among pregnant women in Johannesburg and are significantly associated with various demographic factors. While some associations with preterm birth were identified, no consistent significant association was established, warranting further studies.

Keywords: intimate hygiene, pregnancy, preterm birth, vaginal microbiome, douching, maternal health, South Africa

ACKNOWLEDGEMENTS

I would like to thank my family and my late parents for their unconditional love and support.

Thank you to Dr Wise and Dr Strehlau my supervisors, for their guidance. Thank you Prof Libhaber for assistance with the statistical analysis.

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LIST OF ABBREVIATIONS

ANC - Antenatal Clinic

BMDH - Bheki Mhlangeni District Hospital

BV - Bacterial Vaginosis

CD - Cluster of Differentiation

CHBAH - Chris Hani Baragwanath Academic Hospital

GBS - Group B Streptococcus

HREC - Human Research Ethics Committee

IL - Interleukin

L. - Lactobacillus

PID - Pelvic Inflammatory Disease

PTB - Preterm Birth

RMMCH - Rahima Moosa Mother and Child Hospital

STI - Sexually Transmitted Infection

VIDA - Vaccine and Infectious Disease Analytics Research Unit

WITS - University of the Witwatersrand

**JOURNAL ARTICLE (Formatted for the European Journal of Obstetrics and
Gynaecology and Reproductive Biology)**

**A DESCRIPTION OF INTIMATE HYGIENE PRACTICES DURING PREGNANCY IN A
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ABSTRACT

Background: Intimate hygiene practices during pregnancy can influence maternal and neonatal health outcomes. Limited data exist on these practices among South African women. This study aimed to characterise intimate hygiene practices among pregnant women in Johannesburg and examine associations with demographic factors and preterm birth.

Methods: A secondary analysis was conducted on data from 18,076 pregnant women enrolled in the Group B Streptococcus Correlates of Protection Cohort Study in Johannesburg, South Africa. Participants completed questionnaires detailing their intimate hygiene practices, including frequency, methods, and products used. Statistical analyses assessed the prevalence of these practices, their association with demographic characteristics (age, race, education, occupation, dwelling type, parity, and HIV status), and preterm birth outcomes.

Results: The mean age was 28.4 years (range 18–49). Most participants were Black (16,811; 93.0%), single (14,541; 80.4%), unemployed (11,691; 64.7%), and resided in urban areas (12,782; 70.7%). They reported a median intimate cleaning frequency of 14 times per week (IQR 8–14). Vaginal washing was reported by 6,312 women (34.9%). Among those who undertook vaginal washing, 62.5% used fingers, 35.7% used a cloth, and 0.4% used other objects. Over half (9,653; 53.3%) practiced douching, and 8,743 (48.4%) added products to their bathwater.

Race was significantly associated with adding bathwater products ($p < 0.00001$). White women (39; 44.3%) had the highest proportion adding products. Tertiary-educated mothers were more likely to add products (396; 27.0%, $p = 0.0041$). Students had the highest rate of product use (154; 28.7%, $p = 0.0018$). Urban participants were more likely to add products (1,994; 25.2%) than semi-urban women (768; 23.2%, $p = 0.025$).

Douching was also significantly associated with race ($p < 0.00001$), with the “Other” category (67; 65.1%) reporting the highest rate. Women with no schooling had the highest douching rate (53.2%, $p = 0.0006$). Semi-urban mothers douched the most frequently (4,757; 53.4%, $p < 0.00001$). Marital status was significantly associated with douching ($p < 0.00001$), with the highest prevalence among single women (6,658; 45.8%). Occupation was also significantly associated with douching ($p = 0.016$), with students having the highest douching prevalence (154; 28.7%).

A significant association was observed between gestational age and the addition of products to bathwater for deliveries between 34 and <37 weeks compared to term deliveries ($p = 0.045$). Women who did not add products were more likely to deliver at term, while those who added products had a higher likelihood of delivering preterm. For deliveries <34 weeks compared to 34–<37 weeks, women who did not add products were more likely to deliver at 34–<37 weeks ($p = 0.02$).

For deliveries at <34 weeks compared to 34–<37 weeks, women who douched were more likely to deliver at <34 weeks, while those who did not douche had higher proportions of deliveries at 34–<37 weeks ($p = 0.035$).

In the combined preterm category (<37 weeks) compared to term deliveries, a statistically significant association was observed ($p = 0.035$), with women who douched being more likely to

deliver preterm. Although some early preterm categories were more frequent among those who douched, overall no consistent statistically significant associations were found between hygiene practices and preterm birth outcomes.

Conclusion: Intimate hygiene practices are prevalent among pregnant women in Johannesburg and are significantly associated with various demographic factors. While some associations with preterm birth were identified, no consistent significant association was established, warranting further studies.

Keywords: intimate hygiene, pregnancy, preterm birth, vaginal microbiome, douching, maternal health, South Africa

Introduction and Background

Vaginal hygiene practices during pregnancy are used to different degrees and can impact maternal health as well as foetal and neonatal outcomes (1, 2). However, limited data exist, particularly in the South African context, describing and comparing the various hygiene products and cleaning methods used by pregnant women. Globally, it has been reported that pregnant women use a range of vaginal hygiene practices to clean the vulva and vagina (1, 2).

A balanced vaginal microbiome is dominated by *Lactobacillus* spp., which acidifies the vaginal environment and helps protect against pathogens (1, 2). A *Lactobacillus*-depleted microbiome has been linked to various adverse health outcomes, including bacterial vaginosis (BV), an increased risk of sexually transmitted infections, and preterm birth (PTB) (3, 4, 5). The latter two have been associated with intimate hygiene practices, many of which are practiced without sufficient evidence of health benefits (3, 5, 6). The most extensively studied practice is vaginal douching, defined as washing inside the vagina with water or another solution, which is known to cause vaginal dysbiosis—alteration in microbial balance leading to disrupted function—predisposing individuals to pelvic inflammatory disease (PID), BV, and PTB (5,7). The role of intimate hygiene products in either preventing or contributing to maternal colonisation with Group B *Streptococcus* (GBS) has been described (7). This is of particular public health importance given the severe consequences of neonatal GBS infection.

A study describing intimate hygiene practices, demographic associations and hygiene products used by pregnant women in the South African setting could help assess how these contribute to maternal and neonatal health, including preterm birth associations, thereby informing potential interventions and health education programs.

Methodology

We conducted a retrospective analysis of data from maternal-infant dyads collected during a neonatal follow-up cohort study investigating immunological correlates of protection against invasive Group B streptococcus (ClinicalTrials.gov ID NCT06431217).

Study Population

The primary study enrolled pregnant women either through recruitment at antenatal clinic visits, during the early stages of labour, or during the postpartum period prior to hospital discharge. A total of 18,076 pregnant women were enrolled during 2019-2020.

Study Setting

The primary study was conducted at Rahima Moosa Mother and Child Hospital (RMMCH) and a referring clinic (Discovers Clinic); Chris Hani Baragwanath Academic Hospital (CHBAH) and surrounding clinics (Lillian Ngoyi Clinic, Diepkloof, Mofolo, Michael Maponya, Zola, Itereleng and Chiawelo Clinic); and Bheki Mhlange District Hospital (BMDH) in the City of Johannesburg, South Africa.

Study Procedure

Informed consent and data collection sheets were completed by trained Research Assistants. Study participation was offered to all presenting women and study enrolment occurred unless participation was declined, or the study team was unable to obtain informed consent. The primary study involved no active follow-up unless GBS-related adverse events were identified in the mother-infant dyad.

A questionnaire comprising demographic, pregnancy and health information was completed. Questions were asked in a non-judgemental manner and patients put at ease to ensure information accurately reflected practices.

Data were analysed to determine the prevalence of intimate hygiene practices and their associations with the use of specific products, as well as demographic and preterm birth associations. Data for this study was obtained from an existing database and a secondary data analysis was conducted.

Ethical clearance was obtained for both the primary and sub-study from the University of the Witwatersrand Human Research Ethics Committee (181110, 30 November 2018 and M230781, 20 November 2023, respectively).

Study Objectives

The secondary data analysis aimed to describe the demographic and obstetric characteristics of participants and examine their intimate hygiene practices, including the types of products and objects used, how they were used, and the frequency of these practices. It also explored associations between intimate hygiene practices and demographic factors such as occupation, education level, type of dwelling, and area of residence. Finally, the study investigated whether the use of products in bathwater or douching was associated with the risk of preterm birth.

Statistical Analysis

Data collected from the primary study were entered into a secure database by data capturers. The data were cleaned as permitted by time and staff availability. The transfer of unidentified data was conducted via Wits VIDA Microsoft Sharepoint, a secure data transfer platform. Data were kept in single datasheet and kept secure. The statistical analysis was performed using Statistica software (version 14.0). Data variables included demographics such as age, race, education, occupation and dwelling type; health and pregnancy data such as HIV status, parity, gestational age at delivery and intimate hygiene practices (frequency of washing, douching, washing inside the vagina, and the use of various hygiene products). Demographics and obstetric related characteristics of the participants are described using: counts, frequency, medians and a descriptive table; description of the products and objects that the participants reported using to clean the vagina and vulva are reported as rates and ranges of the rates of use for the different products; frequency of the participants' cleaning practices are described as rates, ranges, medians, and interquartile ranges (IQR); a description of the participants use of products added to bath water with rates and ranges.

Chi-Square was used to calculate p values for douching and associated preterm birth, for adding products to bathwater and preterm birth, and demographics and hygiene practice associations. A p value < 0.05 was considered statistically significant. Missing data due to incomplete questionnaires is a limitation which could result in incorrect comparison results.

Results

The cohort comprised 18076 pregnant women, with a mean age of 28.4 years (range 18–49). Individuals under 18 years were excluded due to consent constraints. The population was predominantly Black (93.0%), with smaller proportions identifying as Coloured, White, Asian, or Other.

Most participants were single (80.4%) and had completed primary or secondary schooling (82.9%). Only 13.2% had tertiary education, and a minority (2.6%) reported no formal schooling. Unemployment was common, just under two thirds (64.7%), and the majority of partners were unemployed (72.5%).

Urban residence predominated (70.7%), and nearly all participants planned to remain in Johannesburg post-delivery (96.6%). Singleton pregnancies accounted for the vast majority (96.3%), with a median gestational age of 37.8 weeks. Term deliveries (≥ 37 weeks) occurred in 73.5% of cases, while 20.6% were preterm (< 37 weeks), including 7.0% classified as early preterm (< 34 weeks).

HIV prevalence in the cohort was 26.0%, while 71.5% were HIV-negative. Most participants (85.5%) tested negative for syphilis, although 13.3% had an unknown result. Rhesus positivity was observed in 89.2% of women; status was unknown or unreported for 9.0%.

Regarding reproductive history, 27.9% were nulliparous, and 30.5% had one prior birth. Median parity and gravidity were both 2. (Table 1).

Table 1: Maternal demographics of all women included in the primary study

Age (years)	
Median (IQR)	28.4 (23.97-33.52)
Range	18-49
Race	n (%)
Black	16 811 (93.0)
Coloured	886 (4.9)
White	103 (0.6)
Asian	98 (0.5)
Other	87 (0.5)
Missing	91 (0.5)
Marital Status	n (%)
Single	14541 (80.4)
Married	3386 (18.7)
Divorced	51 (0.3)
Other	30 (0.2)
Missing	68 (0.4)
Level of Education	(n, %)
Schooling (Primary/Secondary)	14989 (82.9)
Tertiary	2386 (13.2)
None	466 (2.6)
Missing	235 (1.3)
Occupation of Mother	(n, %)
Unemployed	11691 (64.7)
Employed	5049 (27.9)
Self-Employed	887 (4.9)
Student	343 (1.9)
Missing	106 (0.6)
Occupation of Father	(n, %)
Unemployed	13099 (72.5)
Employed	1585 (19.8)
Self-Employed	991 (5.5)
Student	210 (1.2)
Missing	91 (1.1)
Dwelling	(n, %)
Urban	12782 (70.7)
Rural	4757 (26.3)
Semi-Urban	290 (1.6)
Blank	247 (1.4)
Residence After Delivery	
Johannesburg	17455 (96.6)
Outside Johannesburg	207 (1.2)
Missing	414 (2.3)
Number of Babies	
Singleton	17413 (96.3)
Twins	645 (3.6)
Triplets	18 (0.1)
Gestational Age (Weeks) at Delivery	(n, %)
>= 37	13868 (73.6)
34 - <37	2574 (13.7)
< 34	1317 (7.0)

Missing	316 (1.7)
HIV Status	(n, %)
Negative	12919 (71.5)
Positive	4698 (26.0)
Unknown	121 (0.7)
Missing	337 (1.9)
Syphilis Results	(n, %)
Negative	15447 (85.5)
Unknown	2412 (13.3)
Positive	217 (1.2)
Rhesus Status	(n, %)
Positive	16116 (89.2)
Negative	336 (1.9)
Unknown	239 (1.3)
Missing	1385 (7.7)
Parity	(n, %)
0	5040 (27.9)
1	5517 (30.5)
2	3855 (21.3)
3	1626 (9.0)
4	503 (2.8)
5+	268 (1.5)
Missing	1267 (7.0)
Median	2
Pregnancy Number (Gravidity)	(n, %)
1	4254 (23.5)
2	5127 (28.4)
3	3982 (22.0)
4	2106 (11.7)
5+	1339 (7.4)
Missing	1277 (7.1)
Median	2

The data revealed an average intimate cleaning frequency of 11.6 times per week, with a median frequency significantly higher at 14 times per week (IQR 8-14). Washing inside the vagina was reported by 34.9% - using fingers (21.9%), a cloth (12.5%) or another object (0.13%).

Just over half (53.3%) of patients practiced douching during pregnancy. Douching refers to the deliberate flushing of the vaginal canal using liquid solutions, often with devices such as bottles or syringes, while washing inside the vagina involves manual internal cleaning using fingers or cloths, sometimes with water or soap, and was described to the participants as such. Soap was used more commonly than antiseptic solutions, 77.0 % vs. 9.4%, respectively. Two thirds (65.6%) of the women reported using Sunlight soap. The commonest antiseptic solutions were Dettol (7.0%) and Savlon (2.4%). Other products such as Betadine and Vagisil were used much less frequently, with

rates of 0.04% and 0.03%, respectively, while a variety of other products accounted for an additional 4%. Two or more products were used by 9.6% of participants.

The addition of products to bathwater was reported by almost half of the cohort (48.4%). The main products added to bathwater included Dettol, used by 5.6% of the cohort, followed by Savlon (2.4%), and bubble bath solutions (3.5%) (Table 2).

Table 2: Hygiene Practices

Washing Practice	(n, %)
Wash inside vagina	6312 (34.9)
Do not wash inside vagina	5421 (30.0)
Missing	6343 (35.1)
Method of Washing inside Vagina	(n, %)
Fingers	3949 (62.5)
Cloth	2255 (35.7)
Other	24 (0.4)
Missing	11848
Frequency of Washing (times per week)	(n, %)
1-3	200 (1.8)
4-7	1637 (14.8)
8-14	5523 (49.9)
15-21	113 (1.0)
22+	5 (0.1)
Missing	10598 (32.4)
Median (IQR)	14 (8-14)
Douching	(n, %)
Yes	9653 (53.3)
No	8423 (46.7)
Douching	(n, %)
Antiseptic Solutions	
Dettol	558 (7.0)
Savlon	189 (2.4)
Betadine	3 (0.1)
Soap	
Sunlight	4520 (56.3)
Protex	708 (8.8)
Lux	441 (5.5)
Lifebuoy	348 (4.3)
Dove	157 (2.0)
Cream	
Vagisil	3 (0.1)
Other	331 (4.1)

Number of products used	(n, %)
Two Products	637 (7.9)
Three Products	99 (1.2)
More Than 3 Products	29 (0.4)
Adding Products to Bathwater	(n, %)
Yes	2829 (15.7)
No	8743 (48.4)
Missing	6504 (36.0)
Product Added to Bathwater	(n, %)
Soap with Savlon	436 (2.4)
Bubble bath	637 (3.5)
Soap with Dettol	1,004 (5.6)

Dettol, Savlon, Betadine, Sunlight, Protex, Lux, Lifebuoy, Dove and Vagisil are all registered trademarks.

Significant associations were observed between several demographic variables and the addition of products to bathwater (Table 3). Race was strongly associated ($p < 0.00001$); although most users were Black women, the highest within-group use was among White (44.3%) and Coloured (30.7%) participants. Educational level ($p = 0.0041$) and occupation ($p = 0.0018$) were also significantly associated: mothers with tertiary education and students showed the highest proportional use (27.0% and 28.7%, respectively), although most users came from women with primary or secondary schooling due to their greater representation.

Urban residence was associated with greater use of bath additives (25.2%) compared to semi-urban (23.2%) and rural areas (19.1%) ($p = 0.025$). Parity ($p = 0.008$) and age group ($p = 0.032$) were also associated: women with high parity (e.g. parity 7; 33.3%) and those aged 40–49 (26.9%) had the highest proportional use. No significant associations were found with marital status ($p = 0.1423$) or HIV status ($p = 0.911$).

Table 3: Association of demographics and adding products to bathwater

Demographics	N	Products Not Added to Bathwater (%)	Products Added to Bathwater (%)	p-Value
Race (n, %)				<0.00001
Black	10667	8115 (76.1)	2552 (23.9)	
Coloured	623	432 (69.3)	191 (30.7)	
White	88	49 (55.7)	39 (44.3)	
Asian	67	49 (73.1)	18 (26.9)	
Other	69	51 (73.9)	18 (26.1)	
Marital Status				0.1423
Single	9028	6836 (75.7)	2192 (24.3)	
Married	2455	1849 (75.3)	606 (24.7)	
Divorced	15	11 (73.3)	4 (26.7)	
Other	37	22 (59.5)	15 (40.5)	

Level of Education				0.0041
Schooling				
Primary/Secondary	9633	7298 (75.8)	2335 (24.2)	
Tertiary	1468	1072 (73.0)	396 (26.9)	
None	307	240 (78.2)	67 (21.8)	
Occupation of Mother				0.0018
Unemployed	7477	5725 (76.6)	1752 (23.4)	
Employed	3287	2428 (73.9)	859 (26.1)	
Self-Employed	208	152 (73.1)	56 (26.9)	
Student	537	383 (71.3)	154 (28.7)	
Dwelling				0.025
Urban	7928	5934 (74.9)	1994 (25.2)	
Rural	152	123 (80.9)	29 (19.1)	
Semi-Urban	3313	2545 (76.8)	768 (23.2)	
Parity				0.008
0	3425	2560 (74.7)	865 (25.3)	
1	3836	2921 (76.2)	915 (23.9)	
2	2642	2005 (75.9)	637 (24.1)	
3	1124	831 (73.9)	293 (26.1)	
4	330	273 (82.7)	57 (17.3)	
5	108	77 (71.3)	31 (28.7)	
6	30	27 (90.0)	3 (10.0)	
7	6	4 (66.7)	2 (33.3)	
Age				0.032
<20	756	578 (76.5)	178 (23.5)	
20-29	6003	4481 (74.6)	1522 (25.9)	
30-39	4200	3230 (76.9)	970 (23.1)	
40-49	517	378 (73.1)	139 (26.9)	
HIV-Status				0.911
Negative	8363	6313 (75.5)	2050 (24.5)	
Positive	2927	2210 (75.5)	717 (24.5)	

p-values calculated using the chi-square test

Douching was significantly associated with several demographic variables (Table 4). Race ($p < 0.00001$) showed strong variation: the highest within-group prevalence was among participants identifying as “Other” (65.1%), followed by White (56.3%), Coloured (55.3%), Asian (49.0%), and Black women (46.5%). Marital status was also significant ($p < 0.00001$); married women were more likely to douche (52.9%) than single women (45.8%).

Educational level ($p = 0.0006$) and maternal occupation ($p = 0.016$) were significantly associated. Women with no schooling had the highest douching prevalence (53.2%), while employed women (47.7%) had the highest among occupational groups. Dwelling type ($p < 0.00001$) also showed variation, with semi-urban women most likely to douche (53.4%) compared to rural (41.0%) and urban participants (44.7%).

Parity did not demonstrate a significant association with douching; proportions were consistent across parity levels. Age group was significantly associated ($p = 0.0215$), with higher douching rates observed among women aged 20–29 (47.8%) and 30–39 (46.5%). No significant association was found with HIV status ($p = 0.27$) (Table 4).

Table 4: Association of Demographics and Douching

Demographics	Total (N)	No Douching (%)	Douching (%)	p-Value
Race				<0.00001
Black	16811	8991 (53.5)	7820 (46.5)	
Coloured	886	396 (44.7)	490 (55.3)	
White	87	38 (43.7)	49 (56.3)	
Asian	98	50 (51.0)	48 (49.0)	
Other	103	36 (35.0)	67 (65.1)	
Marital Status				<0.00001
Single	14541	7883 (54.2)	6658 (45.8)	
Married	3386	1594 (47.1)	1792 (52.9)	
Divorced	30	18 (60.0)	12 (40.0)	
Other	51	26 (51.0)	25 (49.0)	
Level of Education				0.0006
Schooling				
Primary/Secondary	14989	7903 (52.7)	7086 (47.3)	
Tertiary	2386	1330 (55.7)	1056 (44.3)	
None	466	218 (46.8)	248 (53.2)	0.016
Occupation of Mother				
Unemployed	11691	6156 (52.7)	5535 (47.3)	
Employed	5049	2642 (52.3)	2407 (47.7)	
Self-Employed	343	191 (55.6)	152 (44.4)	
Student	887	512 (57.7)	375 (42.3)	<0.00001
Dwelling				
Urban	12782	7068 (55.3)	5714 (44.7)	
Rural	290	171 (59.0)	119 (41.0)	
Semi-Urban	4757	2214 (46.6)	2543 (53.4)	
P value<0.00001				0.19
Parity				
0	5040	2570 (50.9)	2470 (49.1)	
1	5517	2686 (48.7)	2831 (51.3)	
2	3855	1894 (49.2)	1961 (50.8)	

3	1626	792 (48.7)	834 (51.3)	
4	503	256 (50.9)	247 (49.1)	
5	268	84 (50.6)	82 (49.4)	
6	44	22 (50.0)	22 (50.0)	
7	7	1 (14.3)	6 (85.7)	
Age				0.0215
<20	588	40 (57.8)	248 (42.2)	
20-29	8907	4652 (52.2)	4255 (47.8)	
30-39	7240	3846 (53.5)	3394 (46.5)	
40-49	1210	666 (55.0)	544 (45.0)	
HIV-Status				0.027
Negative	12919	6804 (52.6)	6115 (47.4)	
Positive	4698	2515 (53.6)	2183 (46.4)	

In terms of the association between adding products to the bathwater and/or douching and gestational age at delivery. The following results were found:

Addition of Products to Bathwater

A significant association was found between gestational age and product use for deliveries between 34–<37 weeks compared to term ($p = 0.045$). Women who did not add products were more likely to deliver at term (90.9%) than those who did (9.2%). Conversely, among those delivering between 34–<37 weeks, product use was more common (7.5%) compared to the term group.

A stronger association was observed when comparing <34 weeks and 34–<37 weeks ($p = 0.02$): 10.6% of women who added products delivered before 34 weeks, while 7.5% delivered between 34–<37 weeks. Those who did not add products were more likely to deliver later within the preterm range.

However, when preterm deliveries (<37 weeks) were combined and compared to term, the association was not statistically significant ($p = 0.341$), despite a slightly higher frequency of product use among preterm deliveries (8.5%) than term (9.2%).

Douching

No significant association was observed between douching and deliveries at <34 weeks compared to term ($p = 0.097$), though a greater proportion of women who douched delivered early (38.1%) than those who did not (61.9%).

In contrast, the comparison between <34 weeks and 34–<37 weeks showed a significant association ($p = 0.035$): women who douched were more likely to deliver at <34 weeks (38.1%) than at 34–<37 weeks (41.9%). Those who did not douche had higher proportions of later preterm births.

When preterm deliveries were combined, douching remained significantly associated ($p = 0.035$), with 40.6% of preterm births occurring in women who douched compared to 59.4% in those who did not.

Combined Practices (Products and Douching)

No significant associations were observed when combining product use and douching. Among women delivering at <34 weeks, 17.6% engaged in both practices compared to 18.0% at term ($p = 0.56$). Similarly, no significant differences were seen between <34 and 34–<37 weeks ($p = 0.548$), or 34–<37 weeks and term ($p = 0.414$). While trends suggested that dual-practice users were somewhat more likely to deliver early, these associations did not reach statistical significance (Table 5).

Table 5: Association between adding products to the bathwater and/or douching and gestational age at delivery

Gestational Age at Delivery (Weeks)	No products added to bathwater	Only products added to bathwater	P-value	No douching	Only douching	P value	No products added to bathwater or douching	Products added to bathwater and douching	P-value
<34 ≥37	607 6683	72 674	0.242	735 7332	453 5022	0.097	607 6883	129 1514	0.56
34-<37 ≥37	1291 6683	104 674	0.045	1336 7332	963 5022	0.278	1291 6883	275 1514	0.414
<34 34-<37	607 1291	72 104	0.02	735 1336	453 963	0.035	607 1291	129 275	0.548
<37 ≥37	1898 6683	176 674	0.341	2071 7332	1416 5022	0.035	1898 6683	404 1514	0.328

Discussion

Demographics and Obstetric Characteristics of Participants

The demographic profile of this large cohort—primarily young, predominantly Black, with a median age in the late 20s, and a high rate of unemployment—parallels trends observed in antenatal populations across Sub-Saharan Africa (SSA), particularly within public healthcare settings (8,9,10). Studies in urban South Africa reveal that most women attending antenatal care are single, unemployed, and have a primary or secondary education, reflecting limited socioeconomic opportunities (9,10). Similar demographic structures are seen in other low- and middle-income countries (LMIC), where limited education and economic hardship often shape health-related behaviours, including hygiene practices (4,11, 12). Lower educational levels are commonly linked to traditional hygiene practices and a lack of formal guidance on safe practices, as highlighted in a Tanzanian study where less-educated women were more likely to engage in internal cleansing (13). This practice frequently occurs within cultural contexts where internal cleansing is perceived as essential for maintaining cleanliness, adhering to societal norms regarding femininity, or enhancing sexual health (13). In contrast, high-income countries (HIC) generally report broader access to healthcare, where socioeconomic status influences access to specific hygiene products and adherence to medical recommendations (14,15,16,17). These recommendations include: avoid douching: (can disrupt the natural balance of vaginal bacteria and may lead to infections); use mild, unscented products (harsh soaps, antiseptics, and scented products can alter the vaginal pH and irritate sensitive tissues); maintain regular hygiene practices (regular bathing with appropriate cleansing of the external genital area helps maintain hygiene (16,17)). However, overuse of feminine hygiene products, such as deodorant sprays and wipes, is discouraged due to potential adverse effects on the vaginal mucosal biome; wear breathable, non-irritating clothing (cotton underwear and avoiding tight-fitting clothing can help prevent moisture buildup and irritation, promoting a healthy vaginal environment) (16,17).

Products Reported for Vaginal and Vulval Cleaning

Participants frequently used household products, including Sunlight soap and Dettol for intimate hygiene. This finding aligns with studies across SSA, where economic constraints and cultural beliefs often lead to the use of accessible, multi-purpose products for intimate hygiene (18,19). In Ghana, for instance, 60% of pregnant women reported using household soaps, attributing their choices to accessibility and cultural norms (3). The use of antiseptic solutions like Dettol is similarly widespread in SSA, where a study in Cameroon showed that over 40% of women used antiseptics, perceiving them to prevent infections (4). In contrast, HICs report a preference for commercially marketed, pH-balanced washes and sprays, largely due to product availability and targeted advertising (20,21). This contrast reflects regional and economic disparities in product choices for intimate hygiene.

Objects Used for Vaginal and Vulval Cleaning

Approximately one-third of participants reported using fingers or cloths for internal cleansing, consistent with practices in SSA where internal cleansing is culturally associated with health maintenance (13). Studies in Nigeria and Tanzania indicate that over 40% of women practice

internal cleansing, driven by beliefs about cleanliness and infection prevention (13,22). In HICs, public health campaigns generally discourage internal cleansing, especially during pregnancy, due to associations with BV, PID, and other complications (16,17,23). For instance, U.S. guidelines advise against internal cleansing to protect the vaginal microbiome and reduce the risk of adverse pregnancy outcomes (17). Despite these guidelines, some women in HICs continue to engage in internal cleansing, though rates are lower than those in LMICs (24).

Frequency of Cleaning Practices

Participants reported frequent intimate cleaning, with some women washing up to 14 times per week. This finding is consistent with urban SSA studies, where cultural beliefs about cleanliness and purity contribute to frequent washing (12,25). In KwaZulu-Natal, for instance, over 60% of pregnant women reported daily or near-daily washing due to beliefs linking hygiene with health (12). In contrast, HICs recommend less frequent washing, as frequent intimate washing can disturb vaginal pH and microbiome balance. Public health advice in the United Kingdom, for instance, promotes minimal washing to preserve beneficial microbiota and reduce infection risk (15).

Methods of Product Use

The study showed that products were often added to bathwater or applied directly, reflecting a blend of traditional and adaptive hygiene practices common in LMICs. Kenyan studies indicate that nearly 50% of pregnant women add antiseptics to bathwater, perceiving it as a way to ensure cleanliness (26). This practice contrasts with HICs, where healthcare providers discourage adding antiseptics to bathwater due to risks of irritation and microbiome disruption. Canadian guidelines, for example, advise against this practice during pregnancy to protect vaginal health and reduce potential complications (16,27). These regional differences underscore varying levels of healthcare guidance and cultural influences on hygiene practices during pregnancy.

Associations Between Hygiene Practices and Demographic Characteristics

Significant associations were observed between demographic factors and hygiene practices, particularly race, education, age, occupation, and residence type. Women with tertiary education levels were more likely to add products to bathwater compared to those with primary or secondary education, while unemployed women had slightly lower rates of douching compared to employed women. Additionally, semi-urban mothers were more likely to add products to bathwater and to report douching compared to urban or rural mothers. This is in contradiction to findings in Tanzania and Nigeria where low socioeconomic status increased these practices (13,26). However, women with no formal education were more likely to douche. Urban residence was linked to a greater likelihood of using bath additives, likely due to increased exposure to product marketing (13,26). These associations suggest that cultural norms, in addition to socioeconomic factors, influence intimate hygiene practices in SSA. While several associations reached statistical significance, the large sample size increases the likelihood of detecting minor differences that may lack clinical

relevance, and applies to all of the associations found in this study. Statistical significance in this context does not necessarily equate to a meaningful effect size or actionable difference in clinical practice. Interpretation should therefore consider both the magnitude of association and biological plausibility when assessing potential implications for maternal health.

Association of Hygiene Practices with Preterm Birth

Several hygiene practices were associated with an increased risk of preterm birth. Adding products to bathwater in this cohort was associated with preterm delivery in those with a GA of 34–<37 weeks, suggesting a possible impact on early delivery. Douching was similarly associated with preterm births at <34 and 34–<37 weeks. Findings from SSA studies that connect douching with vaginal dysbiosis and elevated infection risk (28,29,30), and studies from HICs that have linked douching with BV and preterm birth, underscores concerns over the potential risks of such practices during pregnancy (2,14,31).

Pregnant vs. Non-Pregnant Comparison

While this study did not include non-pregnant women, studies from non-pregnant SSA populations reveal similar hygiene practices, though frequencies and product types may vary. In Soweto, South Africa, non-pregnant women reported similar cleansing methods but at lower frequencies than their pregnant counterparts, suggesting that pregnancy may heighten hygiene behaviours (10,19).

Limitations

The absence of a non-pregnant control group limits the ability to determine whether the observed hygiene practices and their associations with outcomes are specific to pregnancy or reflect broader population behaviours. Self-reported data introduce the potential for recall and social desirability bias, particularly for sensitive practices such as douching or intravaginal washing. Missing data for some variables may have introduced bias or reduced statistical power in subgroup analyses. Moreover, the cross-sectional nature of hygiene practice reporting limits causal inference regarding their relationship with gestational outcomes.

Conclusion

This study underscores the widespread prevalence of intimate hygiene practices among pregnant women in this population, reflecting deeply rooted cultural norms, accessibility of products, and individual socioeconomic circumstances. Practices such as douching, internal vaginal washing, and the use of antiseptic solutions like Dettol highlight the intersection of traditional beliefs and modern influences on hygiene practices.

The observed associations between hygiene practices and demographic characteristics, as well as with specific preterm birth categories, suggest that these practices are shaped by a complex interplay of cultural, social, and environmental factors. Although no consistent link with overall preterm birth outcomes was found, the potential disruption of the vaginal microbiome by certain practices raises concerns about increased vulnerability to infections and related pregnancy complications.

Future research is essential to unravel the causal mechanisms underlying the relationship between intimate hygiene practices and pregnancy outcomes. Understanding how these practices impact the vaginal microbiome and subsequent health risks could inform targeted interventions, ultimately improving maternal and neonatal health in diverse cultural and socioeconomic contexts.

Acknowledgements

Prof E. Libhaber, School of Clinical Medicine and Health Sciences Research Office, University of the Witwatersrand, Johannesburg, South Africa, for reviewing and guidance with the statistical analysis.

Conflict of Interest

None to declare by all researchers.

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APPENDICES

Appendix A: Approved Research Protocol



UNIVERSITY OF THE
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A DESCRIPTION OF INTIMATE HYGIENE PRACTICES DURING PREGNANCY IN A COHORT OF WOMEN IN JOHANNESBURG

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1. Abbreviations

ANC - Antenatal Clinic

BMDH - Bheki Mhlangeni District Hospital

BV - Bacterial Vaginosis

CD - Cluster of Differentiation

CHBAH - Chris Hani Baragwanath Academic Hospital

GBS - Group B Streptococcus

HREC - Human Research Ethics Committee

IL - Interleukin

L. - Lactobacillus

PID - Pelvic Inflammatory Disease

PTB - Preterm Birth

RMMCH - Rahima Moosa Mother and Child Hospital

STI - Sexually Transmitted Infection

VIDA - Vaccine and Infectious Disease Analytics Research Unit

WITS - University of the Witwatersrand

2. Introduction and Background

Vaginal hygiene practices during pregnancy are used to different degrees, and can affect maternal health as well as foetal and neonatal outcomes (1,2). However, there are limited data available, particularly in the context of South Africa, describing and comparing the different hygiene products and cleaning methods used by pregnant women. Worldwide, pregnant women use a variety of vaginal hygiene practices to clean their vulva and vagina, and studies have been done to assess these practices and their subsequent effects (1,2).

A balanced vaginal microbiome is dominated by *Lactobacillus* species, which acidifies the vaginal environment and helps to protect against pathogens (1,2). The hallmark of a balanced vaginal microbiome is characterised by one dominated by *Lactobacillus* species, which acidifies the vaginal environment and helps to protect against invading pathogens (2).

A *Lactobacillus* depleted microbiome has been linked to a variety of adverse health outcomes, including bacterial vaginosis (BV), an increased risk of sexually transmitted infections (STIs) and preterm birth (PTB)(1,3,4). The latter two have been associated with intimate hygiene practices, many of which are practiced without sufficient evidence of benefit to health (1,3,4). The most extensively studied practice is vaginal douching, which is known to cause vaginal dysbiosis, which predisposes to pelvic inflammatory disease (PID), BV, and PTB (5,6). Neonatal complications from Group B streptococcus infection originating from maternal vaginal colonisation is a major health issue worldwide, with few studies assessing the role of intimate hygiene products in either preventing or contributing to maternal colonisation (7).

A study describing intimate hygiene practices performed, and hygiene products used by pregnant women in the South African setting would aid in assessing how these contribute to

maternal and new-born health and allow for interventions and health education programs to be implemented.

3. Literature Analysis

There are limited data available on the prevalence of vaginal hygiene practices in pregnant women.

Vaginal Hygiene Practices

Vaginal hygiene practices encompass a wide range of behaviours and techniques employed by women during pregnancy to maintain cleanliness, comfort and overall vaginal health. These practices can include internal cleansing, external washing, intravaginal insertion of substances, and the use of various products (8,9). Data collected from a cohort in KwaZulu-Natal described the prevalence and types of vaginal hygiene practices among non-pregnant women (8). This study found the majority of participants (90.2%) to have engaged in at least one vaginal hygiene practice, with 34.8% engaging in two or more practices (8). Internal cleansing was found to be common, with most women cleansing their vaginas twice daily using objects such as a cloth or paper (8). The motivations behind these practices include achieving cleanliness, reducing odour, and vaginal drying. External genital washing was also prevalent among the participants, with motivations extending beyond hygiene, including wellness and feminine identity (8).

The methods used in vaginal hygiene practices during pregnancy vary among different populations and regions globally. Data from non-pregnant women in Soweto, Gauteng, reported women to engage in a variety of practices, including vigorous washing outside the vagina, washing with water or alternative substances, using fingers or other objects for intravaginal cleansing, and even the insertion of traditional medications intravaginally (10).

Objects reported as being used during the process of vaginal cleaning included paper, cloth, sponges and cotton wool, and conventional medications, gels, lubricants and creams, including haemorrhoid creams, were also commonly used by the women (10). These findings emphasise the diverse range of methods employed in vaginal practices and highlight the need for further investigation into the motivations, cultural factors and potential health implications associated with these practices (10).

Multi-country reviews, including those conducted in Tete (Mozambique), Yogyakarta (Indonesia), Chonburi (Thailand), and KwaZulu-Natal (South Africa), have provided insights into the global landscape of vaginal hygiene practices in non-pregnant women (11,12). These reviews have shown that external washing is a common practice across these regions, with the motivation centred around cleanliness and odour reduction (11,12). In Yogyakarta self-treatment of suspected infections was also reported as a motivation for external washing (11). Intravaginal cleansing was found to be more prevalent in African regions compared to Thailand and Indonesia, particularly in Tete and KwaZulu-Natal, where it was the most prevalent practice (11). Women in these regions engaged in intravaginal cleansing for hygiene purposes, maintaining wellness and relieving genital symptoms (11). Furthermore, in Chonburi the traditional practice of vaginal steaming or smoking was found to be common and was associated with wellness maintenance and feminine identity, especially during the postpartum period (11).

In Cameroon the most common practice for vulval cleaning among pregnant women was the use of non-irritating agents. Antiseptic solutions, either alone or in combination with water, were preferred for vaginal cleaning (9). These findings emphasise the importance of considering cultural and regional variations in vaginal practices of women in these regions, and their potential impact on maternal and neonatal health outcomes.

Vaginal Hygiene Products

A wide array of products is used by pregnant and non-pregnant women for vaginal hygiene purposes. In addition to commercially manufactured and advertised products, a survey conducted in Canada revealed the utilisation of products for the genital area but not intended or marketed for such use (13). These products include douches, wipes, washes, sprays, powders, moisturisers, lubricants, deodorant suppositories and tablet suppositories for vaginal infections (13). Respondents also reported using products such as hand sanitisers, body lotions, baby oil, baby wipes and shaving cream in the genital area (13). It is important to note that certain products, particularly douches and scented deodorants, have raised concerns due to potential risks to vaginal health, including irritation, dysbiosis and infection (6,13,14). Medical organisations, including the United States Office of Women's Health and the Canadian Women's Health Network, advise against the use of these products, citing them as unnecessary for vaginal cleansing and having the potential for irritation (15,16). These recommendations align with the understanding that vaginal secretions are indicative of good physiological health, and the use of cleansing products may disrupt the natural balance of the vaginal microbiome (14).

Additionally, the survey revealed the utilisation of homemade or non-proprietary vaginal douches among a subset of respondents (13). These homemade douches included various substances such as medicated creams, sprays, gels, cooking oils, yogurt (topical and suppositories), garlic clove suppositories, probiotic suppositories, prescription suppositories, depilatory creams and petroleum jelly(13). The use of such products may vary among individuals based on cultural beliefs, personal preferences and perceived benefits (13).

It has been found that Afro-Caribbean immigrants in the United Kingdom are more likely to wash the vulva with bubble bath or antiseptic compared with Caucasian women (12). Other studies have documented the use of soaps, body-washes, foam, premoistened wipes, powders, and deodorant sprays (1,12). However, the motivations and potential consequences associated with the usage of these non-conventional products warrant further investigation (12,13).

Vaginal Microbiome and its Importance

The vaginal microbiome undergoes fluctuations in composition due to various internal and external factors (1,12). Internal factors such as age, hormonal shifts and infections, along with external factors like vaginal hygiene practices, sexual intercourse, antibiotic use and hormone replacement therapy, impact the milieu of the vaginal microbiome (1,12). It has been shown that there is vaginal microbiome variation among different ethnic groups in the United States, with Asian and White women tending to have a higher prevalence of *Lactobacillus* dominance (80.2% and 89.7%, respectively) compared to Hispanic and Black women (59.6% and 61.9%, respectively). (17) These differences may be partially attributed to variances in vaginal hygiene practices across ethnicities (17). Furthermore, specific *Lactobacillus* species, such as *L. jensenii*, have been found to be more prevalent in women of Asian and Caucasian ethnicity, while *L. gasseri* is absent in samples from Black women (17). During pregnancy, the vaginal microbiome undergoes distinct changes. A longitudinal study conducted on full-term, uncomplicated pregnancies revealed that the vaginal microbiome exhibits low diversity, with *L. crispatus* and *L. iners* dominating throughout pregnancy (2,17). *Lactobacillus* dominance during pregnancy regardless of ethnicity has been found in a study conducted in the United Kingdom (17). The abundance of *Lactobacilli* during

pregnancy contributes to a reduction in vaginal pH and an increase in vaginal gland secretions, which act as a protective barrier against pathogenic microbes (2,17). These changes provide a favourable environment for a healthy pregnancy (2,17).

The impact of the vaginal microbiome extends beyond maternal health and has implications for neonatal immunity and long-term health outcomes (18). Evidence suggests that the vagina may serve as a source of microbes that can reach the placenta, amniotic fluid and foetus through translocation across the choriodecidual plate. Microbes present in the maternal vagina are believed to play a critical role in programming neonatal immunity (18).

Differences in immune profiles have been observed between infants delivered vaginally and via caesarean section, indicating the potential influence of the vaginal microbiome in immune education during early life (18). The specific microbial composition of the maternal vagina during pregnancy has also been linked to variations in infant immunity even before passage through the vaginal canal during delivery. Newborns whose mothers were vaginally colonised with *Lactobacillus* during pregnancy demonstrated altered immune responses, with higher levels of CD45RO+ cells and reduced IL-12 in cord blood, showing that lactobacilli in the maternal vagina impact foetal immune development (18). The presence of certain maternal vaginal microbes (especially *Ureaplasma urealyticum*) was associated with risk for wheezing in children at 4–5 years of age (18).

The mechanisms of this interaction remain unknown, but could be due to bacterial metabolites,

ascending organisms or simply that women's vaginal microbiota is largely dependent on that of

the gut microbiome (18).

Studies have shown that douching and the use of feminine hygiene products can disrupt the natural balance of the vaginal microbiome, particularly affecting lactobacillus species (19). Additionally, hygiene practices have been associated with the prevalence of conditions such as bacterial vaginosis, candidiasis and trichomoniasis (3,4). Commercial antiseptic products and douches have been strongly linked to an increased risk of bacterial vaginosis (3,4).

Vaginal hygiene practices during pregnancy encompass a range of methods and products. These practices exhibit regional and cultural variations, as observed in South Africa and other countries. Understanding the prevalence, motivations, sociodemographic factors, maternal and neonatal disease epidemiology, and the consequences of these practices is essential for developing effective strategies to promote maternal and neonatal health and well-being. Additionally, it highlights the need for further research to explore the impact of vaginal hygiene practices on the vaginal microbiome and the potential implications for maternal and neonatal outcomes.

4.1. Aim

To conduct a secondary analysis of maternal vaginal hygiene practices during the antenatal period using data obtained from the GBS Correlates of Protection (CoP) Study, which investigated immunological correlates of protection against invasive Group B streptococcus disease in infants less than 90 days of age.

4.2. Objectives

To assess vaginal hygiene practices in the antenatal period using the following data collected from an obstetric history questionnaire:

1. To describe the demographics and obstetric related characteristics of the participants.
2. To describe what products the participants reported using to clean the vagina and vulva.
3. To describe what objects the participants reported using to clean the vagina and vulva.
4. To describe the frequency of the participants cleaning practices.
5. To describe how the products were used by the participants.

5. Methodology

5.1. Study Design

Data for this study will be obtained from an existing database and a secondary data analysis will be conducted. It will be a retrospective study on the data that were collected prospectively.

Primary Study

The study entitled: “Investigating for immunological correlates of protection against invasive Group B *streptococcus* disease in infants less than 90 days of age” was conducted during 2019-2020. The study Principal Investigator (PI) is Prof. Shabir Madhi and co-PI Dr Stephanie Jones from the Wits VIDA Research Unit, Johannesburg.

Primary objective:

Determine the infant GBS Alp 1N, RibN, AlpCN and Alp 2/3N protein specific serum IgG antibody level predictive of 80% and 90% risk reduction of invasive GBS disease between 0-89 days of age for the combined “cohort” and “retrospectively enrolled” cases.

Endpoint: A threshold of infant serum IgG antibody concentrations, specific for Alp 1N, RibN, AlpCN and Alp 2/3N associated with a risk reduction of 80% and 90% on invasive GBS due to isolates expressing the homologous protein (i.e. Alp1, Rib, AlpC and Alp 2/3).

Secondary Objectives:

Infant Secondary Objectives:

1. Determine the infant GBS Alp 1N, RibN, AlpCN and Alp 2/3N protein (N-terminals) specific serum IgG antibody level associated with 80% and 90% reduced risk of invasive GBS disease between 0-89 days of age, stratified for “cohort” and “retrospectively enrolled” cases.

Endpoint: A threshold of infant GBS Alp 1N, RibN, AlpCN and Alp 2/3N protein (N-terminals) specific serum IgG antibody level associated with 80% and 90% reduced risk of invasive GBS disease between 0-89 days of age, stratified for “cohort” and “retrospectively enrolled” cases.

2. Determine the infant GBS Alp 1N, RibN, AlpCN and Alp 2/3N protein (N-terminals) protein specific serum IgG antibody levels associated with 80% and 90% reduced risk of invasive GBS disease for cohort and retrospectively enrolled cases combined, stratified by GBS-EOD and GBS-LOD. Endpoint: A threshold of infant GBS Alp 1N, RibN, AlpCN and Alp 2/3N protein (N-terminals) protein specific serum IgG antibody levels associated with 80% and 90% reduced risk of invasive GBS disease for cohort and retrospectively enrolled cases combined, stratified by GBS-EOD and GBS-LOD.

3. Determine the infant GBS Alp 1, Rib, AlpC and Alp 2/3 protein opsonophagocytic activity (OPA) titre associated with 80% and 90% reduced risk invasive GBS disease between 0-89 days of age for the combined “cohort” and retrospectively enrolled cases. Endpoint: A threshold of infant GBS Alp 1, Rib, AlpC and Alp 2/3 protein opsonophagocytic activity (OPA) titre associated with 80% and 90% reduced risk invasive GBS disease between 0-89 days of age for the combined “cohort” and retrospectively enrolled cases.

Maternal Secondary Objectives:

1. Determine the maternal GBS Alp 1N, RibN, AlpCN and Alp 2/3N protein specific Alp 1N, RibN, AlpCN and Alp 2/3N protein serum IgG antibodies associated with 80% and 90% reduced risk of invasive GBS disease in their infants between 0-89 days of age. Endpoint: A threshold for maternal GBS Alp 1N, RibN, AlpCN and Alp 2/3N protein specific Alp 1N, RibN, AlpCN and Alp 2/3N protein serum IgG antibodies associated with 80% and 90% reduced risk of invasive GBS disease in their infants between 0-89 days of age.

2. Determine the maternal GBS Alp 1N, RibN, AlpCN and Alp 2/3N protein serum IgG antibodies associated with 80% and 90% reduced risk of invasive GBS disease in their infants stratified by GBS-EOD and GBS-LOD. Endpoint: A threshold of maternal GBS Alp 1N, RibN, AlpCN and Alp 2/3N protein serum IgG antibodies associated with 80% and 90% reduced risk of invasive GBS disease in their infants stratified by GBS-EOD and GBS-LOD

3. Determine the maternal GBS capsular serum IgG antibody levels associated with 80% and 90% reduced risk of invasive GBS disease for the composite of all Alp protein types.

Endpoint: A threshold for maternal GBS capsular serum IgG antibody levels associated with 80% and 90% reduced risk of invasive GBS disease for the composite of all Alp protein types.

4. Determine the maternal GBS Alp 1, Rib, AlpC and Alp 2/3 protein opsonophagocytic activity (OPA) titre associated with 80% reduced odds of invasive GBS disease between 0-89 days of age for the combined “cohort” and retrospectively enrolled cases. Endpoint: Estimated odds of disease for infants with maternal GBS serotype specific Alp 1, Rib, AlpC

and Alp 2/3 protein titres above a threshold and estimated odds of disease for infants with maternal GBS Alp 1, Rib, AlpC and Alp 2/3 protein specific OPA titres below the threshold.

Study Setting

Rahima Moosa Mother and Child Hospital (RMMCH) and surrounding clinics (Discovers Clinic), Chris Hani Baragwanath Academic Hospital (CHBAH) and surrounding clinics (Lillian Ngoyi Clinic, Diepkloof, Mofolo, Michael Maponya, Zola, Itereleng and Chiawelo Clinic) and at Bheki Mhlangeni District Hospital (BMDH) in the City of Johannesburg, South Africa.

5.2 Study Population

The primary study enrolled pregnant women either through recruitment at antenatal clinic (ANC) visits, during the early stages of labour or during the postpartum period prior to discharge. Study participation was offered to all presenting women and study enrolment occurred unless study participation was declined, or the study team was unable to obtain informed consent. Screening and enrolment took place at Rahima Moosa Mother and Child Hospital (RMMCH) and surrounding clinics (Discovers Clinic), Chris Hani Baragwanath Academic Hospital (CHBAH) and surrounding clinics (Lillian Ngoyi Clinic, Diepkloof, Mofolo, Michael Maponya, Zola, Itereleng and Chiawelo Clinic) and at Bheki Mhlangeni District Hospital (BMDH) in the City of Johannesburg, South Africa. In order to reach the target study population of 15 000 for the primary study, recruitment took place during working hours in ANCs as well as afterhours and over weekends in labour wards. Informed consent and data collection sheets were completed by trained Research Assistants. The primary study involved no active follow-up unless GBS-related adverse events were identified in the mother-infant dyad.

The sample size was calculated to detect an 80% and 90% reduction in the risk of EOD or LOD by serotype Ia or III among infants, with 80% power, based on the ratio of cases to controls with maternal antibody levels above a specified titre versus the ratio of cases to controls with antibody levels below the specified protective titre. Calculations were based on method described by Walter for matched case control studies.

Secondary analysis

From the above described population, all the women with a complete questionnaire on the vaginal hygiene practices subsection will be included.

The variables describing the demographics, obstetric characteristics including HIV status, and vaginal practices of the mothers included in the study will be extracted from the database (see Appendix 1: Data Collection Sheet. GBS CoP database access approved by principal investigator Prof S Madhi).

5.3. Data Analysis and Management

Data collected from the primary study were entered into a secure database by data capturers. The data were cleaned as permitted by time and staff availability. Permission to obtain data from the existing database has been obtained from the database holder – Prof S Madhi (Appendix 3). Data variables required for this secondary analysis were requested from the senior database manager/statistician at Wits VIDA. The transfer of unidentified data was conducted via a secure data transfer platform. The data are saved as a password protected document and only the researcher and supervisors have access to the data. Access to the database will be from RMMCH. Data collected from the database will be kept in single datasheet and kept secure.

The planned statistical analysis for each objective is described below:

- Objective 1: Demographics, cultural background and obstetric related characteristics of the participants: counts, frequency and a descriptive table.
- Objective 2: Describe the products that the participants reported using to clean the vagina and vulva: rates, and ranges and medians of the rates of use for the different products.
- To describe what objects the participants used to clean the vagina: rates, and ranges and medians of the rates of object use.
- On average, how many times per week? To describe the frequency of the participants cleaning practices: rates, ranges and medians.
- To describe the participants use of products added to bath water: rates, ranges and medians.

6. Ethics

Wits University Human Research Ethics Committee approved the primary study (HREC reference number: 181110, 30 November 2018). Application for Wits HREC waiver will be done prior to initiation of this secondary data analysis. National Health Research Database (NHRD) study registration will be completed prior to study start.

7. Timeline (Gantt chart)

	2023						2024				
	July	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May

Literature review											
Protocol Preparation											
Protocol submission											
HREC application											
Data Collection											
Data Analysis											
Prepare publication											
Submit to journal											
Prepare WITS submission											

8. Funding

Costs will be expected to be minimal for this analysis. Potential costs include statistician fees (estimated R3000) and article publication charges. Regarding publication charges: article processing charges are covered partially or fully for researchers who choose to publish open access in journals under the publishers who have an agreement with Wits University, and the article will be submitted to one of these publishers, preferably Science Direct (Elsevier) associated journals, where no charge is made. If unable to find a publisher that doesn't charge, The Wits School of Clinical Medicine offers MMED funding that will be applied for

(maximum R25000 for research related funding), and covers conference fees (Local conference registration fee: up to R8 000 maximum. International conference registration fee: up to R16 000 maximum).

Potential Budget Costs	Estimated Cost in Rand
Statistician Fees	3,000
Article Publication Charges (Open Access)	0
Article Publication Charges (Elsevier Journals)	0
Article Publication Charges (Other Publishers)	To be determined
MMED Funding (Research Related)	Up to 25,000
Conference Fees (Local)	Up to 8,000
Conference Fees (International)	Up to 16,000
Total Maximum Cost	R52,000

9. Limitations

Missing data: as this is a secondary analysis, not all data or variables may have been gathered in the primary study.

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11. Appendix

1. Data Collection Sheet
2. Wits HREC approval for primary study
3. Permission letter from database holder
4. Appointment of supervisor form

Appendix F: Guidelines for the European Journal of Obstetrics and Gynaecology and Reproductive Biology

Guide for Authors

About the journal

Aims and scope

An Official journal of the [European Urogynaecological Association \(EUGA\)](#), le [College National des Gynecologues et Obstetriciens Francais \(CNGOF\)](#), the [European Board and College of Obstetrics and Gynaecology \(EBCOG\)](#) and the [European Association of Perinatal Medicine \(EAPM\)](#).

The *European Journal of Obstetrics & Gynecology and Reproductive Biology* has an open access companion journal [European Journal of Obstetrics & Gynecology and Reproductive Biology: X](#) which has the same aims and scope, editorial board and peer-review process. To submit to *European Journal of Obstetrics & Gynecology and Reproductive Biology: X* visit <https://www.editorialmanager.com/eurox/default.aspx>

The *European Journal of Obstetrics & Gynecology and Reproductive Biology* provides a forum for scientific and clinical professional communication in **obstetrics** and **gynecology** throughout Europe and the world.

The *European Journal of Obstetrics & Gynecology and Reproductive Biology* publishes articles, reviews, short communications, letters to the editor and expert opinions.

Fields covered include **obstetrics, prenatal diagnosis, maternal-fetal medicine, perinatology, general gynecology, gynecologic oncology, uro-gynecology, reproductive medicine, infertility, reproductive endocrinology, sexual medicine and reproductive ethics**. The *European Journal of Obstetrics & Gynecology and Reproductive Biology* provides a forum for scientific and clinical professional communication in **obstetrics** and **gynecology** throughout Europe and the world.

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As well as invited articles we welcome submitted reviews on topics of current interest in obstetrics and gynecology. Reviews are allowed a

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Expert Opinions

These are generally "invited" by the Editor-in-Chief but submission may be considered, with a maximum of 2000 words, 20 citations and 2 figures or 2 tables.

Research articles

For details, see below: "General Requirements for the preparation of manuscripts". There is a limit of 2500 words (excluding title page, abstract and references), 10 figures and 10 tables. The reference list should not exceed 3 pages.

Letters to the Editor are limited to a maximum of 600 words (excluding references, names and addresses of the signers, and the phrase "to the Editor").

Only one type of letter will be considered for publication:

Letter to the Editor - Brief Communication giving a brief case presentation or short report of a pertinent clinical observation. Please use the correct format following the criteria: max 600 words, max 5 references, max 1 table or 1 figure, no abstract, no keywords, no headings. The information must be presented as a true Letter, e.g. starting with "Dear Editor, we found that... etc." Brief communications that do not meet this criteria will be returned to the author.

Announcements of major meetings and other significant activities should be sent to the Editor-in-Chief.

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3. Final approval of the version to be submitted.

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- sexual orientation

- disability or health condition

We recommend avoiding the use of descriptors about personal attributes unless they are relevant and valid. Write for gender neutrality with the use of plural nouns ("clinicians, patients/clients") as default. Wherever possible, avoid using "he, she," or "he/she."

No assumptions should be made about the beliefs of readers and writing should be free from bias, stereotypes, slang, reference to dominant culture and/or cultural assumptions.

These guidelines are meant as a point of reference to help you identify appropriate language but are by no means exhaustive or definitive.

Reporting sex- and gender-based analyses

There is no single, universally agreed-upon set of guidelines for defining sex and gender. We offer the following guidance:

- Sex and gender-based analyses (SGBA) should be integrated into research design when research involves or pertains to humans, animals or eukaryotic cells. This should be done in accordance with any requirements set by funders or sponsors and best practices within a field.
- Sex and/or gender dimensions of the research should be addressed within the article or declared as a limitation to the generalizability of the research.
- Definitions of sex and/or gender applied should be explicitly stated to enhance the precision, rigor and reproducibility of the research and to avoid ambiguity or conflation of terms and the constructs to which they refer.

We advise you to read the [Sex and Gender Equity in Research \(SAGER\) guidelines](#) and the [SAGER checklist](#) (PDF) on the EASE website, which offer systematic approaches to the use of sex and gender information in study design, data analysis, outcome reporting and research interpretation.

For further information we suggest reading the rationale behind and recommended [use of the SAGER guidelines](#).

Definitions of sex and/or gender

We ask authors to define how sex and gender have been used in their research and publication. Some guidance:

- Sex generally refers to a set of biological attributes that are associated with physical and physiological features such as

chromosomal genotype, hormonal levels, internal and external anatomy. A binary sex categorization (male/female) is usually designated at birth ("sex assigned at birth") and is in most cases based solely on the visible external anatomy of a newborn. In reality, sex categorizations include people who are intersex/have differences of sex development (DSD).

- Gender generally refers to socially constructed roles, behaviors and identities of women, men and gender-diverse people that occur in a historical and cultural context and may vary across societies and over time. Gender influences how people view themselves and each other, how they behave and interact and how power is distributed in society.

Jurisdictional claims

Elsevier respects the decisions taken by its authors as to how they choose to designate territories and identify their affiliations in their published content. Elsevier's policy is to take a neutral position with respect to territorial disputes or jurisdictional claims, including, but not limited to, maps and institutional affiliations. For journals that Elsevier publishes on behalf of a third party owner, the owner may set its own policy on these issues.

- Maps: Readers should be able to locate any study areas shown within maps using common mapping platforms. Maps should only show the area actually studied and authors should not include a location map which displays a larger area than the bounding box of the study area. Authors should add a note clearly stating that "*map lines delineate study areas and do not necessarily depict accepted national boundaries*". During the review process, Elsevier's editors may request authors to change maps if these guidelines are not followed.
- Institutional affiliations: Authors should use either the full, standard title of their institution or the standard abbreviation of the institutional name so that the institutional name can be independently verified for research integrity purposes.

Studies in humans and animals

Authors must follow [ethical guidelines](#) for studies carried out in humans and animals.

Studies in humans

Work which involves the use of human subjects should be carried out in accordance with the World Medical Association Declaration of Helsinki: [Ethical principles for medical research involving human subjects](#).

Manuscripts should follow the [International Committee of Medical Journal Editors \(ICMJE\) recommendations](#) for the conduct, reporting, editing and publication of scholarly work in medical journals and aim to be representative of human populations in terms of sex, age and ethnicity. [Sex and gender terms](#) should be used correctly, as outlined by WHO (World Health Organization).

Manuscripts must include a statement that all procedures were performed in compliance with relevant laws and institutional guidelines and have been approved by the appropriate institutional committee(s). The statement should contain the date and reference number of the ethical approval(s) obtained.

Manuscripts must also include a statement that the privacy rights of human subjects have been observed and that informed consent was obtained for experimentation with human subjects.

This journal will not accept manuscripts that contain data derived from unethically sourced organs or tissue, including from executed prisoners or prisoners of conscience, consistent with recommendations by [Global Rights Compliance on Mitigating Human Rights Risks in Transplantation Medicine](#). For all studies that use human organs or tissues, sufficient evidence must be provided that these were procured in line with [WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation](#). The source of the organs or tissues used in clinical research must be transparent and traceable. If your manuscript describes organ transplantation you must additionally declare within the manuscript that:

- autonomous consent free from coercion was obtained from the donor(s) or their next of kin.
- organs and/or tissues were not sourced from executed prisoners or prisoners of conscience.

Studies in animals

All animal experiments should comply with [ARRIVE \(Animal Research: Reporting of In Vivo Experiments\) guidelines](#).

Studies should be carried out in accordance with [Guidance on the operation of the Animals \(Scientific Procedures\) Act 1986](#) and associated guidelines, [EU Directive 2010/63 for the protection of animals used for scientific purposes](#) or the [NIH \(National Research Council\) Guide for the Care and Use of Laboratory Animals \(PDF\)](#) or those of an equivalent internationally recognized body.

The sex of animals, and where appropriate, the influence (or association) of sex on the results of the study must be indicated and a statement included in your manuscript that such guidelines as listed above have been followed.

Registration of clinical trials

Clinical trials must be registered in a public trials registry in accordance with [International Committee of Medical Journal Editors \(ICMJE\) clinical trials guidelines](#) and as a condition of publication in this journal. Purely observational studies, in which the assignment of the medical intervention is not at the discretion of the investigator, do not require registration.

Some key excerpts from the guidelines include:

- Trials must be registered at or before the onset of patient enrolment.
- The clinical trial registration number should be included at the end of the article abstract.
- A clinical trial is defined as any research study that prospectively assigns human participants, or groups of humans, to one or more health-related interventions to evaluate the effects of health outcomes.
- Health-related interventions include any intervention used to modify a biomedical or health-related outcome such as drugs, surgical procedures, devices, behavioural treatments, dietary interventions, and process-of-care changes.
- Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

Writing and formatting

File format

We ask you to provide editable source files for your entire submission (including figures, tables and text graphics). Some guidelines:

- Save files in an editable format, using the extension .doc/.docx for Word files and .tex for LaTeX files. A PDF is not an acceptable source file.
- Lay out text in a single-column format.
- Remove any strikethrough and underlined text from your manuscript, unless it has scientific significance related to your article.
- Use spell-check and grammar-check functions to avoid errors.

We advise you to read our [Step-by-step guide to publishing with Elsevier](#).

Title page

You are required to include the following details in the title page information:

- Article title. Article titles should be concise and informative. Please avoid abbreviations and formulae, where possible, unless they are established and widely understood, e.g., DNA).
- Author names. Provide the given name(s) and family name(s) of each author. The order of authors should match the order in the submission system. Carefully check that all names are accurately spelled. If needed, you can add your name between parentheses in your own script after the English transliteration.
- Affiliations. Add affiliation addresses, referring to where the work was carried out, below the author names. Indicate affiliations using a lower-case superscript letter immediately after the author's name and in front of the corresponding address. Ensure that you provide the full postal address of each affiliation, including the country name and, if available, the email address of each author.
- Corresponding author. Clearly indicate who will handle correspondence for your article at all stages of the refereeing and publication process and also post-publication. This responsibility includes answering any future queries about your results, data, methodology and materials. It is important that the email address and contact details of your corresponding author are kept up to date during the submission and publication process.
- Present/permanent address. If an author has moved since the work described in your article was carried out, or the author was visiting during that time, a "present address" (or "permanent address") can be indicated by a footnote to the author's name. The address where the author carried out the work must be retained as their main affiliation address. Use superscript Arabic numerals for such footnotes.

Abstract

You are required to provide a concise and factual abstract which does not exceed 250 words. The abstract should briefly state the purpose of your research, principal results and major conclusions. Some guidelines:

- Abstracts must be able to stand alone as abstracts are often presented separately from the article.
- Avoid references. If any are essential to include, ensure that you cite the author(s) and year(s).

- Avoid non-standard or uncommon abbreviations. If any are essential to include, ensure they are defined within your abstract at first mention.

Keywords

You are required to provide 1 to 7 keywords for indexing purposes. Keywords should be written in English. Please try to avoid keywords consisting of multiple words (using "and" or "of").

We recommend that you only use abbreviations in keywords if they are firmly established in the field.

Highlights

You are encouraged to provide article highlights at submission.

Highlights are a short collection of bullet points that should capture the novel results of your research as well as any new methods used during your study. Highlights will help increase the discoverability of your article via search engines. Some guidelines:

- Submit highlights as a separate editable file in the online submission system with the word "highlights" included in the file name.
- Highlights should consist of 3 to 5 bullet points, each a maximum of 85 characters, including spaces.

We encourage you to view example [article highlights](#) and read about the benefits of their inclusion.

Math formulae

- Submit math equations as editable text, not as images.
- Present simple formulae in line with normal text, where possible.
- Use the solidus (/) instead of a horizontal line for small fractional terms such as X/Y.
- Present variables in italics.
- Denote powers of e by exp.
- Display equations separately from your text, numbering them consecutively in the order they are referred to within your text.

Tables

Tables must be submitted as editable text, not as images. Some guidelines:

- Place tables next to the relevant text or on a separate page(s) at the end of your article.
- Cite all tables in the manuscript text.
- Number tables consecutively according to their appearance in the text.
- Please provide captions along with the tables.
- Place any table notes below the table body.
- Avoid vertical rules and shading within table cells.

We recommend that you use tables sparingly, ensuring that any data presented in tables is not duplicating results described elsewhere in the article.

Figures, images and artwork

Figures, images, artwork, diagrams and other graphical media must be supplied as separate files along with the manuscript. We recommend that you read our detailed [artwork and media instructions](#). Some excerpts:

When submitting artwork:

- Cite all images in the manuscript text.
- Number images according to the sequence they appear within your article.
- Submit each image as a separate file using a logical naming convention for your files (for example, Figure_1, Figure_2 etc).
- Please provide captions for all figures, images, and artwork.
- Text graphics may be embedded in the text at the appropriate position. If you are working with LaTeX, text graphics may also be embedded in the file.

Artwork formats

When your artwork is finalized, "save as" or convert your electronic artwork to the formats listed below taking into account the given resolution requirements for line drawings, halftones, and line/halftone combinations:

- Vector drawings: Save as EPS or PDF files embedding the font or saving the text as "graphics."
- Color or grayscale photographs (halftones): Save as TIFF, JPG or PNG files using a minimum of 300 dpi (for single column: min. 1063 pixels, full page width: 2244 pixels).
- Bitmapped line drawings: Save as TIFF, JPG or PNG files using a minimum of 1000 dpi (for single column: min. 3543 pixels, full page width: 7480 pixels).

- Combinations bitmapped line/halftones (color or grayscale): Save as TIFF, JPG or PNG files using a minimum of 500 dpi (for single column: min. 1772 pixels, full page width: 3740 pixels).

Please do not submit:

- files that are too low in resolution (for example, files optimized for screen use such as GIF, BMP, PICT or WPG files).
- disproportionally large images compared to font size, as text may become unreadable.

Figure captions

All images must have a caption. A caption should consist of a brief title (not displayed on the figure itself) and a description of the image. We advise you to keep the amount of text in any image to a minimum, though any symbols and abbreviations used should be explained.

Provide captions in a separate file.

Color artwork

If you submit usable color figures with your accepted article, we will ensure that they appear in color online.

Please ensure that color images are accessible to all, including those with impaired color vision. Learn more about [color and web accessibility](#).

For articles appearing in print, you will be sent information on costs to reproduce color in the printed version, after your accepted article has been sent to production. At this stage, please indicate if your preference is to have color only in the online version of your article or also in the printed version.

Generative AI and Figures, images and artwork

Please read our policy on the use of generative AI and AI-assisted tools in figures, images and artwork, which can be found in Elsevier's [GenAI Policies for Journals](#). This policy states:

- We do not permit the use of Generative AI or AI-assisted tools to create or alter images in submitted manuscripts.
- The only exception is if the use of AI or AI-assisted tools is part of the research design or methods (for example, in the field of biomedical imaging). If this is the case, such use must be described in a

reproducible manner in the methods section, including the name of the model or tool, version and extension numbers, and manufacturer.

- The use of generative AI or AI-assisted tools in the production of artwork such as for graphical abstracts is not permitted. The use of generative AI in the production of cover art may in some cases be allowed, if the author obtains prior permission from the journal editor and publisher, can demonstrate that all necessary rights have been cleared for the use of the relevant material, and ensures that there is correct content attribution.

Supplementary material

We encourage the use of supplementary materials such as applications, images and sound clips to enhance research. Some guidelines:

- Cite all supplementary files in the manuscript text.
- Submit supplementary materials at the same time as your article. Be aware that all supplementary materials provided will appear online in the exact same file type as received. These files will not be formatted or typeset by the production team.
- Include a concise, descriptive caption for each supplementary file describing its content.
- Provide updated files if at any stage of the publication process you wish to make changes to submitted supplementary materials.
- Do not make annotations or corrections to a previous version of a supplementary file.
- Switch off the option to track changes in Microsoft Office files. If tracked changes are left on, they will appear in your published version.

We recommend you upload research data to a suitable specialist or generalist repository. Please read our guidelines on [sharing research data](#) for more information on depositing, sharing and using research data and other relevant research materials.

Video

This journal accepts video material and animation sequences to support and enhance your scientific research. We encourage you to include links to video or animation files within articles. Some guidelines:

- When including video or animation file links within your article, refer to the video or animation content by adding a note in your text where the file should be placed.
- Clearly label files ensuring the given file name is directly related to the file content.

- Provide files in one of our [recommended file formats](#). Files should be within our preferred maximum file size of 150 MB per file, 1 GB in total.
- Provide "stills" for each of your files. These will be used as standard icons to personalize the link to your video data. You can choose any frame from your video or animation or make a separate image.
- Provide text (for both the electronic and the print version) to be placed in the portions of your article that refer to the video content. This is essential text, as video and animation files cannot be embedded in the print version of the journal.

We publish all video and animation files supplied in the electronic version of your article.

For more detailed instructions, we recommend that you read our guidelines on [submitting video content to be included in the body of an article](#).

Research data

We are committed to supporting the storage of, access to and discovery of research data, and our [research data policy](#) sets out the principles guiding how we work with the research community to support a more efficient and transparent research process.

Research data refers to the results of observations or experimentation that validate research findings, which may also include software, code, models, algorithms, protocols, methods and other useful materials related to the project.

Please read our guidelines on [sharing research data](#) for more information on depositing, sharing and using research data and other relevant research materials.

For this journal, the following instructions from our [research data guidelines](#) apply.

Option B: Research data deposit, citation and linking

You are **encouraged** to:

- Deposit your research data in a relevant data repository.
- Cite and link to this dataset in your article.
- If this is not possible, make a statement explaining why research data cannot be shared.

Data statement

To foster transparency, you are required to state the availability of any data at submission.

Ensuring data is available may be a requirement of your funding body or institution. If your data is unavailable to access or unsuitable to post, you can state the reason why (e.g., your research data includes sensitive or confidential information such as patient data) during the submission process. This statement will appear with your published article on ScienceDirect.

Read more about the importance and benefits of providing a [data statement](#).

Data linking

Linking to the data underlying your work increases your exposure and may lead to new collaborations. It also provides readers with a better understanding of the described research.

If your research data has been made available in a data repository there are a number of ways your article can be linked directly to the dataset:

- Provide a link to your dataset when prompted during the online submission process.
- For some data repositories, a repository banner will automatically appear next to your published article on ScienceDirect.
- You can also link relevant data or entities within the text of your article through the use of identifiers. Use the following format: Database: 12345 (e.g. TAIR: AT1G01020; CCDC: 734053; PDB: 1XFN).

Learn more about [linking research data and research articles in ScienceDirect](#).

Research Elements

This journal enables the publication of research objects (e.g. data, methods, protocols, software and hardware) related to original research in [Elsevier's Research Elements journals](#).

Research Elements are peer-reviewed, open access journals which make research objects findable, accessible and reusable. By providing detailed descriptions of objects and their application with links to the original research article, your research objects can be placed into context within your article.

You will be alerted during submission to the opportunity to submit a manuscript to one of the Research Elements journals. Your Research Elements article can be prepared by you, or by one of your collaborators.

Article structure

Article sections

- Divide your article into clearly defined and numbered sections. Number subsections 1.1 (then 1.1.1, 1.1.2, ...), then 1.2, etc.
- Use the numbering format when cross-referencing within your article. Do not just refer to "the text."
- You may give subsections a brief heading. Headings should appear on a separate line.
- Do not include the article abstract within section numbering.

Theory and calculation

The theory section should lay the foundation for further work by extending the background you provided in the introduction to your article. The calculation section should represent a practical development from a theoretical basis.

Glossary

Please provide definitions of field-specific terms used in your article, in a separate list.

Footnotes

We advise you to use footnotes sparingly. If you include footnotes in your article, ensure that they are numbered consecutively.

You may use system features that automatically build footnotes into text. Alternatively, you can indicate the position of footnotes within the text and present them in a separate section at the end of your article.

Acknowledgements

Include any individuals who provided you with help during your research, such as help with language, writing or proof reading, in the acknowledgements section. Acknowledgements should be placed in a separate section which appears directly before the reference list. Do not include acknowledgements on your title page, as a footnote to your title, or

anywhere else in your article other than in the separate acknowledgements section.

Author contributions: CRediT

Corresponding authors are required to acknowledge co-author contributions using [CRediT \(Contributor Roles Taxonomy\)](#) roles:

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Not all CRediT roles will apply to every manuscript and some authors may contribute through multiple roles.

We advise you to read [more about CRediT](#) and [view an example of a CRediT author statement](#).

Funding sources

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List funding sources in this standard way to facilitate compliance to funder's requirements:

Funding: This work was supported by the National Institutes of Health [grant numbers xxxx, yyyy]; the Bill & Melinda Gates Foundation, Seattle, WA [grant number zzzz]; and the United States Institutes of Peace [grant number aaaa].

It is not necessary to include detailed descriptions on the program or type of grants, scholarships and awards. When funding is from a block grant or other resources available to a university, college, or other research institution, submit the name of the institute or organization that provided the funding.

If no funding has been provided for the research, it is recommended to include the following sentence:

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Appendices

We ask you to use the following format for appendices:

- Identify individual appendices within your article using the format: A, B, etc.
- Give separate numbering to formulae and equations within appendices using formats such as Eq. (A.1), Eq. (A.2), etc. and in subsequent appendices, Eq. (B.1), Eq. (B. 2) etc. In a similar way, give separate numbering to tables and figures using formats such as Table A.1; Fig. A.1, etc.

References

References within text

Any references cited within your article should also be present in your reference list and vice versa. Some guidelines:

- References cited in your abstract must be given in full.
- We recommend that you do not include unpublished results and personal communications in your reference list, though you may mention them in the text of your article.
- Any unpublished results and personal communications included in your reference list must follow the standard reference style of the journal. In substitution of the publication date add "unpublished results" or "personal communication."
- References cited as "in press" imply that the item has been accepted for publication.

Linking to cited sources will increase the discoverability of your research.

Before submission, check that all data provided in your reference list are correct, including any references which have been copied. Providing

correct reference data allows us to link to abstracting and indexing services such as Scopus, Crossref and PubMed. Any incorrect surnames, journal or book titles, publication years or pagination within your references may prevent link creation.

We encourage the use of Digital Object Identifiers (DOIs) as reference links as they provide a permanent link to the electronic article referenced.

Web references

When listing web references, as a minimum you should provide the full URL and the date when the reference was last accessed. Additional information (e.g. DOI, author names, dates or reference to a source publication) should also be provided, if known.

You can list web references separately under a new heading directly after your reference list or include them in your reference list.

Data references

We encourage you to cite underlying or relevant datasets within article text and to list data references in the reference list.

When citing data references, you should include:

- author name(s)
- dataset title
- data repository
- version (where available)
- year
- global persistent identifier

Add [dataset] immediately before your reference. This will help us to properly identify the dataset. The [dataset] identifier will not appear in your published article.

Preprint references

We ask you to mark preprints clearly. You should include the word "preprint" or the name of the preprint server as part of your reference and provide the preprint DOI.

Where a preprint has subsequently become available as a peer-reviewed publication, use the formal publication as your reference.

If there are preprints that are central to your work or that cover crucial developments in the topic, but they are not yet formally published, you may reference the preprint.

Reference management software

Most Elsevier journals have their reference template available in popular reference management software products. These include products that support [Citation Style Language \(CSL\)](#) such as [Mendeley Reference Manager](#).

If you use a citation plug-in from these products, select the relevant journal template and all your citations and bibliographies will automatically be formatted in the journal style. We advise you to [remove all field codes](#) before submitting your manuscript to any reference management software product.

If a template is not available for this journal, follow the format given in examples in the reference style section of this Guide for Authors.

Journal specific information

Submitting your manuscript

Submission checklist

Before completing the submission of your manuscript, we advise you to read our submission checklist:

- One author has been designated as the corresponding author and their full contact details (email address, full postal address and phone numbers) have been provided.
- All files have been uploaded, including keywords, figure captions and tables (including a title, description and footnotes) included.
- Spelling and grammar checks have been carried out.
- All references in the article text are cited in the reference list and vice versa.
- Permission has been obtained for the use of any copyrighted material from other sources, including the Web.
- For gold open access articles, all authors understand that they are responsible for payment of the article publishing charge (APC) if the manuscript is accepted. Payment of the APC may be covered by the corresponding author's institution, or the research funder.

Suggest reviewers

To support the peer review process, we ask you to provide names and institutional email addresses of several potential reviewers for their manuscript. Some guidelines:

- Reviewers should not be colleagues or have co-authored or collaborated with you during the last three years.
- Do not suggest reviewers with whom you have competing interests.
- Suggest reviewers who are located in different countries or regions from yourself. This helps to provide a broad and balanced assessment of your work and to ensure scientific rigor.
- Consider diversity in your reviewer suggestions, such as gender, race and ethnicity and career stage.
- Do not suggest members of our Editorial Board.

The journal editors will take the final decision on whether to invite your suggested reviewers.

After receiving a final decision

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If your manuscript is more suitable for an alternative Elsevier journal, you may receive an email asking you to consider transferring your manuscript via the [Elsevier Article Transfer Service](#).

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You can choose to annotate and upload your edits on the PDF version of your article, if preferred. We will provide you with proofing instructions and available alternative proofing methods in our email.

The purpose of the proof is to check the typesetting, editing, completeness and correctness of your article text, tables and figures. Significant changes to your article at the proofing stage will only be considered with approval of the journal editor.

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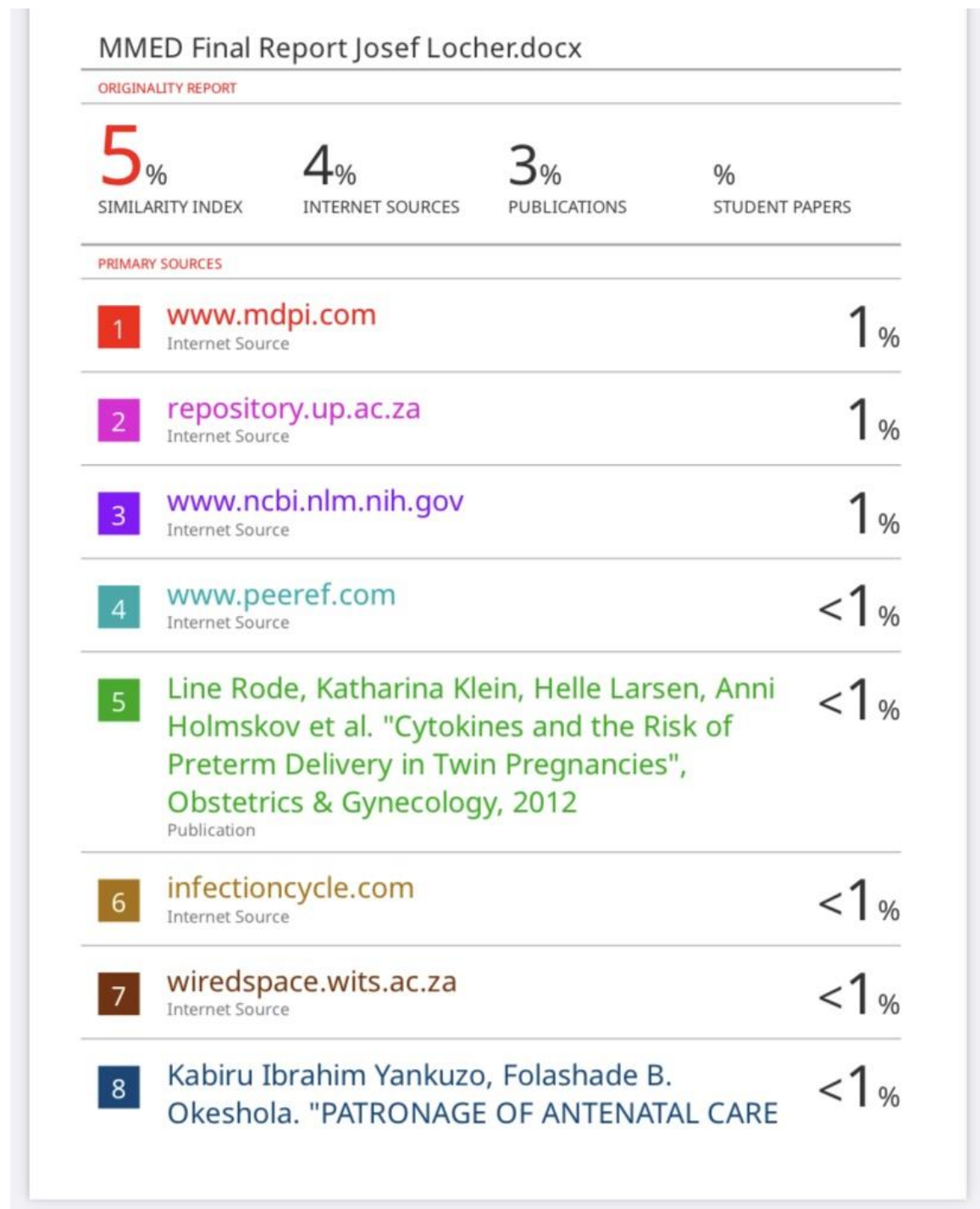
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Responsible sharing

We encourage you to share and promote your article to give additional visibility to your work, enabling your paper to contribute to scientific progress and foster the exchange of scientific developments within your field. Read more about how to [responsibly share and promote your article](#).

Appendix C: Turnitin Plagiarism Report



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Appendix H: Plagiarism Declaration

The University of the Witwatersrand, Johannesburg School of Clinical Medicine Senate

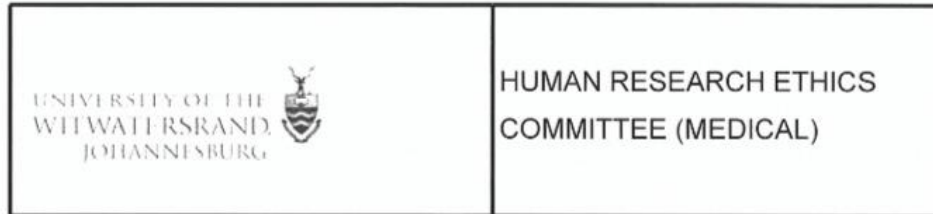
Plagiarism Policy Declaration by Students:

I, Josef Locher, student number: 0502444p, am a student for MMED (Obstetrics and Gynaecology). In the year 2025, I hereby declare the following: I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is totally wrong. I confirm that all the work submitted for assessment for the above course is my own unaided work except where I have explicitly indicated otherwise. I have followed the required conventions referencing the thoughts and ideas of others. I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.

Signature: 

Date: 08/05/2025

Appendix E: Ethics Approval Certificate



Office of the Deputy Vice-Chancellor (Research and Innovation)

TO: Dr J Locher
School of Clinical Medicine
Department of Obstetrics and Gynaecology
Medical School
University

E-mail: jaloher11@gmail.com

CC: Supervisor: Drs A Wise and R Strehlau
amyjulietwise@yahoo.co.uk
and <HREC-Medical Research Office@wits.ac.za>

FROM: Mr Iain Burns
Human Research Ethics Committee (Medical)
Tel: 011 717 1252

E-mail: Iain.Burns@wits.ac.za

DATE: 20 November 2023

REF: R14/49

PROTOCOL NO: **M230781** (This is your ethics application reference number. Please quote it in all enquiries, oral or written, relating to this study.)

PROJECT TITLE: *A description of intimate hygiene practices during pregnancy in a cohort of women in Johannesburg*

Please find attached the Clearance Certificate for the above project. I hope it goes well and that an article in a recognized publication comes out of it. This will reflect well on your professional standing and contribute to Government funding of the University.



M8Works2000/Iain0007/Clearscan.wps



R49 Dr J Locher

**HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M230781**

NAME: Dr J Locher **DEGREE:** MMed
(Principal and Co-Investigators)

DEPARTMENT: School of Clinical Medicine
Department of Obstetrics and Gynaecology
Medical School
University

PROJECT TITLE: *A description of intimate hygiene practices during pregnancy in a cohort of women in Johannesburg*

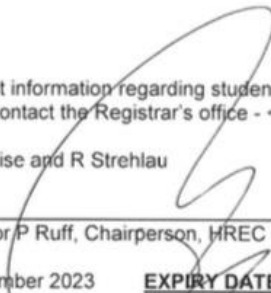
DATE CONSIDERED: Ad hoc

DECISION: Approved unconditionally

CONDITIONS: Sub-study under WHC Clearance No. 18/11/10

NOTE: If contact information regarding student study participants is required, please contact the Registrar's office - <Nicoleen.Potgieter@wits.ac.za>

SUPERVISOR: Drs A Wise and R Strehlau

APPROVED BY: 
Professor P Ruff, Chairperson, HREC (Medical)

DATE OF APPROVAL: 20 November 2023 **EXPIRY DATE:** 19 November 2028

This Clearance Certificate is valid for 5 years from the date of approval. An extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office secretariat on the 3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report** in the format available at <https://wits.ac.za/research/researcher-support/research-ethics/ethics-committees/>. This report is due annually, for the duration of the Clearance Certificate, beginning on the first anniversary of Date of Approval above. Unreported changes to the study may invalidate the clearance given by the HREC (Medical).

Signature of Principal Investigator

Date