

## Obstetrics and Periodontal Therapy

### Data Dictionary

Baseline (Visit 1) = 13-16 weeks gestation


Visit 2 = 17-20 weeks gestation



Visit 3 = 21-24 weeks gestation

Visit 4 = 25-28 weeks gestation

Visit 5 = 29-32 weeks gestation

Position	Variable	Variable Label	Units	Codes
1	PID	Participant ID		First digit indicates enrollment center (1 = NY, 2 = MN, 3 = KY, 4 = MS); Next 4 digits are sequential; Sixth digit is a check digit; There are no missing data
2	Clinic	Enrollment center		NY = Harlem Hospital MN = Hennepin County Center; KY = University of Kentucky; MS = University of Mississippi Medical Center; There are no missing data
3	Group	Randomized treatment assignment		T = Intervention; C = Control; There are no missing data
<b>Baseline Risk Factors (variables 4-28)</b>				
4	Age	Age of participant at baseline	years	There are no missing data
5	Black	Black participant (self-identified)		Yes; No; There are no missing data
6	White	White participant (self-identified)		Yes; No; There are no missing data
7	Nat Am	Native American participant, incl. Latin Americans with aboriginal origin (self-identified)		Yes; No; There are no missing data
8	Asian	Asian participant (self-identified)		Yes; No; There are no missing data

9	Hisp	Hispanic participant (self-identified)		Yes; No; Blank = Missing (participant declined to respond)
10	Education	Education level of participant		LT 8 yrs = Less than 8 years; 8-12 yrs = 8 to 12 years; MT 12 yrs = More than 12 yrs; There are no missing data
11	Public Asstce	Public Assistance: Whether a government agency paid for the delivery		Yes; No; There are no missing data
12	Hypertension	Whether participant had chronic hypertension at baseline		Yes; No; There are no missing data
13	Diabetes	Whether participant had diabetes at baseline (self-reported)		Yes; No; There are no missing data
14	BL Diab Type	Baseline Diabetes Type: Type of diabetes, for participants having diabetes at baseline (self-reported)		Type I; Type II; Blank = No diabetes at baseline (variable 13 = No)
15	BMI	Body-Mass Index 	kg/m <sup>2</sup>	Blank = Missing
16	Use Tob	Self-reported participant history of tobacco use		Yes; No; Blank = Missing
17	BL Cig/Day	Self-reported number of cigarettes per day for those with tobacco use history		Blank = Missing (variable 16 = Yes or blank) or non-smoker (variable 16 = No)
18	Use Alc	Self-reported participant history of alcohol use		Yes; No; Blank = Missing
19	BL Drks/Day	Self-reported number of drinks per day for those with alcohol use history		Blank = Missing (variable 18 = Yes or blank) or non-drinker (variable 18 = No)
20	Drug Add	Self-reported participant history of drug addiction		Yes; No; Blank = Missing
21	Prev preg	Any previous pregnancy		Yes; No; There are no missing data
22	N prev preg	Number of previous pregnancies for those with any previous pregnancy		Blank = Missing (variable 21 = Yes) or no previous pregnancies (variable 21 = No)

23	Live PTB	Previous live preterm birth for those with any previous pregnancy	Yes; No = No previous live preterm birth (variable 21 = Yes) or no previous pregnancies (variable 21 = No)
24	Any stillbirth	Previous <u>stillbirth</u> 	Yes; No = No previous stillbirth (variable 21 = Yes) or no previous pregnancies (variable 21 = No)
25	Spont ab	Previous spontaneous abortion	Yes; No; Blank = Missing (variable 21 = Yes) or no previous pregnancies (variable 21 = No)
26	Induced ab	Previous induced abortion	Yes; No; Blank = Missing (variable 21 = Yes) or no previous pregnancies (variable 21 = No)
27	Any live ptb sb sp ab in ab	Any previous live pre-term birth, stillbirth, spontaneous abortion, or induced abortion	Yes; No = No live pre-term birth/stillbirth/abortion (variable 21 = Yes) or no previous pregnancies (variable 21 = No)
28	N living kids	Number of living children the subject had at baseline	Blank = Missing (variable 21 = Yes) or no previous pregnancies (variable 21 = No)
<b>Variables Describing Periodontal Therapy (variables 29-32)</b>			
29	Tx comp?	Whether treatment plans were completed by participants in treatment group	Yes = Completed; No = Not completed; Und = Some therapy (unknown whether completed); Blank = Withdrew from treatment (variable 3 = T) or no periodontal therapy (variable 3 = C)
30	Local anes	Whether any local anesthetic used during periodontal therapy for participants in treatment group	Yes; No = No local anesthetic used or <u>withdrew from</u> treatment (variable 3 = T);  Blank = No periodontal therapy (variable 3 = C)

31	Topical Anest	Whether any topical anesthetic used during periodontal therapy for participants in treatment group		Yes; No = No topical anesthetic used or withdrew from treatment (variable 3 = T); Blank = No periodontal therapy (variable 3 = C)
32	Tx time	Total treatment time for participants in treatment group	hours	Blank = Withdrew from treatment (variable 3 = T and variable 29 = blank) or no periodontal therapy (variable 3 = C)

### Essential Dental Care (variables 33-36)


33	EDC necessary?	Whether patient required <sup>1</sup> essential dental care (EDC)		Yes; No; Blank = Missing
34	Completed EDC	Did patient complete EDC before 20 weeks gestational age?		Yes; No; Blank = Missing
35	N extractions	Number of teeth extracted during EDC	0-20, integer	Blank = Missing
36	N perm restorations	Number of permanent restorations carried out as a part of EDC	0-18, integer	Blank = Missing

### Periodontal Summaries (variables 37-68)

37	N qualifying teeth	Number of teeth meeting OPT (Obstetrics and Periodontal Therapy Study) criteria for having periodontal disease at baseline		There are no missing data
38	BL GE	Whole-mouth average gingival index at baseline		Silness-Löe Gingival Index: Higher value indicates more severe inflammation; 0 = Normal gingiva; There are no missing data
39	BL %BOP	Fraction of sites <sup>2</sup> <u>bleeding on probing</u> at baseline		There are no missing data
40	BL PD avg	Whole-mouth average pocket depth at baseline	mm	There are no missing data
41	BL %PD>4	Fraction of sites <sup>2</sup> with pocket depth $\geq$ 4mm at baseline		There are no missing data

42	BL %PD>5	Fraction of sites <sup>2</sup> with pocket depth $\geq$ 5mm at baseline		There are no missing data
43	BL CAL avg	Whole-mouth average clinical attachment level at baseline	mm	There are no missing data
44	BL %CAL>2	Fraction of sites <sup>2</sup> with clinical attachment level $\geq$ 2 mm at baseline		There are no missing data
45	BL %CAL>3	Fraction of sites <sup>2</sup> with clinical attachment level $\geq$ 3 mm at baseline		There are no missing data
46	BL Calc I	Whole-mouth average calculus index at baseline.		Simplified Oral Hygiene Index (OHI-S): Higher value indicates more calculus; 0 = No calculus present; There are no missing data
47	BL PI I	Whole-mouth average plaque index at baseline		Silness-Löe Plaque Index: Higher value indicates more abundant plaque; 0 = No plaque in gingival area; There are no missing data.
48	V3 GE	Whole-mouth average gingival index at visit 3		Silness-Löe Gingival Index: Higher value indicates more severe inflammation; 0 = Normal gingiva
49	V3 %BOP	Fraction of sites <sup>2</sup> bleeding on probing at visit 3		Blank = Missing
50	V3 PD avg	Whole-mouth average pocket depth at visit 3	mm	Blank = Missing
51	V3 %PD>4	Fraction of sites <sup>2</sup> with pocket depth $\geq$ 4mm at visit 3		Blank = Missing
52	V3 %PD>5	Fraction of sites <sup>2</sup> with pocket depth $\geq$ 5mm at visit 3		Blank = Missing
53	V3 CAL avg	Whole-mouth average clinical attachment level at visit 3	mm	Blank = Missing
54	V3 %CAL>2	Fraction of sites <sup>2</sup> with clinical attachment level $\geq$ 2 mm at visit 3		Blank = Missing
55	V3 %CAL>3	Fraction of sites <sup>2</sup> with clinical attachment level $\geq$ 3 mm at visit 3		Blank = Missing

56	V3 Calc I	Whole-mouth average calculus index at visit 3		Simplified Oral Hygiene Index (OHI-S): Higher value indicates more calculus; 0 = No calculus present; Blank = Missing
57	V3 PI I	Whole-mouth average plaque index at visit 3		Silness-Löe Plaque Index: Higher value indicates more abundant plaque; 0 = No plaque in gingival area; Blank = Missing
58	V5 GE	Whole-mouth average gingival index at visit 5		Silness-Löe Gingival Index: Higher value indicates more severe inflammation; 0 = Normal gingiva; Blank = Missing
59	V5 %BOP	Fraction of sites <sup>2</sup> bleeding on probing at visit 5		Blank = Missing
60	V5 PD avg	Whole-mouth average pocket depth at visit 5		Blank = Missing
61	V5 %PD>4	Fraction of sites <sup>2</sup> with pocket depth $\geq 4$ mm at visit 5		Blank = Missing
62	V5 %PD>5	Fraction of sites <sup>2</sup> with pocket depth $\geq 5$ mm at visit 5		Blank = Missing
63	V5 CAL avg	Whole-mouth average clinical attachment level at visit 5	mm	Blank = Missing
64	V5 %CAL>2	Fraction of sites <sup>2</sup> with clinical attachment level $\geq 2$ mm at visit 5		Blank = Missing
65	V5 %CAL>3	Fraction of sites <sup>2</sup> with clinical attachment level $\geq 3$ mm at visit 5		Blank = Missing
66	V5 Calc I	Whole-mouth average calculus index at visit 5		Simplified Oral Hygiene Index (OHI-S): Higher value indicates more calculus; 0 = No calculus present; Blank = Missing

67	V5 Pl I	Whole-mouth average plaque index at visit 5		Silness-Löe Plaque Index: Higher value indicates more abundant plaque; 0 = No plaque in gingival area; Blank = Missing
68	N PAL sites	Number of sites for which attachment loss increased from baseline by $\geq 3$ mm.	sites	0 = No sites; Blank = Missing
<b>Obstetrical Outcomes (variables 69-77)</b>				
69	Birth outcome	Birth outcome		Elective abortion; Live birth; <u>Lost to FU = Lost to</u>  <u>Follow-Up</u> ; Non-live birth = Stillbirth or spontaneous abortion; There are no missing data
70	Preg ended < 37 wk	Whether the pregnancy ended before gestational age 37 weeks (259 days)		Yes; No; Blank = Lost to Follow-Up
71	GA at outcome	Gestational age at end of pregnancy, or at mother's last follow-up visit if lost to follow-up	days	There are no missing data
72	Birthweight	Infant birth weight at time of birth, abstracted from obstetrical records	grams	Blank = Missing
73	Fetal/congenital anomaly	Fetal/congenital anomaly identified at birth or during pregnancy?		Yes; No; There are no missing data
74	Apgar1	Apgar score, a summary of a newborn infant's "Appearance, Pulse, Grimace, Activity, Respiration" at 1 minute Score interpretation: $\leq 3$ : Critically low 4-6: Fairly low $\geq 7$ : Normal	1-10, integer	Blank = Missing
75	Apgar5	Apgar score at 5 minutes	1-10, integer	Blank = Missing
76	Any SAE?	Whether participant experienced any serious adverse events (e.g. lost pregnancies)		Yes; No; There are no missing data
77	GA @ 1st SAE	Gestational age of first SAE (serious adverse event).	days	259 = No SAE (variable 76 must = No); There are no missing data


### Additional Risk Factors Identified During Pregnancy (variables 78-100)

78	Bact vag	Whether mother had bacterial vaginosis during pregnancy	Yes; No; Blank = Missing
79	Gest diab	Whether mother had gestational diabetes during pregnancy	Yes; No; Blank = Missing
80	Oligo	Whether mother had <u>oligohydramnios</u> during pregnancy	Yes; No; Blank = Missing
81	Polyhyd	Whether mother had <u>polyhydramnios</u> during pregnancy	Yes; No; Blank = Missing
82	Gonorrhea	Whether mother had gonorrhea during pregnancy	Yes; No; Blank = Missing
83	Chlamydia	Whether mother had chlamydia during pregnancy	Yes; No; Blank = Missing
84	Strep B	Whether mother had strep B colonization during pregnancy	Yes; No; Blank = Missing
85	Traumatic Inj	Whether mother had a traumatic injury during pregnancy	Yes; No; Blank = Missing
86	UTI	Whether mother had a UTI (urinary tract infection) during pregnancy	Yes; No; Blank = Missing
87	Pre-eclamp	Whether mother had pre-eclampsia, a pregnancy condition characterized by high blood pressure and associated with fetal growth restriction	Yes; No; Blank = Missing
88	Mom HIV	HIV status of mother during pregnancy	Yes = HIV-positive; No = HIV-negative or unknown (question answered but HIV status at delivery not recorded); Blank = Missing (question not answered)
89	BL Anti-inf	Did participant report use of anti-inflammatory medication at or $\leq$ 6 months before baseline?	0 = No; 1 = Yes; There are no missing data
90	BL Cortico	Did participant report use of corticosteroids at or $\leq$ 6 months before baseline?	0 = No; 1 = Yes; There are no missing data



91	BL Antibio	Did participant report use of antibiotics at or $\leq$ 6 months before baseline?	0 = No; 1 = Yes; There are no missing data
92	BL Bac-vag	Did participant report use of bacterial vaginitis treatments at or $\leq$ 6 months before baseline?	0 = No; 1 = Yes; There are no missing data
93	V3 Anti-inf	Did participant report use of anti-inflammatory medication between baseline and visit 3?	0 = No; 1 = Yes; Blank = Missing
94	V3 Cortico	Did participant report use of corticosteroids between baseline and visit 3?	0 = No; 1 = Yes; Blank = Missing
95	V3 Antibio	Did participant report use of antibiotics between baseline and visit 3?	0 = No; 1 = Yes; Blank = Missing
96	V3 Bac-vag	Did participant report use of bacterial vaginitis treatments between baseline and visit 3?	0 = No; 1 = Yes; Blank = Missing
97	V5 Anti-inf	Did participant report use of anti-inflammatory medication between visit 3 and visit 5?	0 = No; 1 = Yes; Blank = Missing
98	V5 Cortico	Did participant report use of corticosteroids between visit 3 and visit 5?	0 = No; 1 = Yes; Blank = Missing
99	V5 Antibio	Did participant report use of antibiotics between visit 3 and visit 5?	0 = No; 1 = Yes; Blank = Missing
100	V5 Bac-vag	Did participant report use of bacterial vaginitis treatments between visit 3 and visit 5?	0 = No; 1 = Yes; Blank = Missing

### Visit Attendance (variables 101-103)

101	# Vis Att	Visit attendance: Number of study visits attended AFTER baseline. Range: 0-5	There are no missing data
102	# Vis Elig	Number of visits for which participant was <u>eligible</u> (could become ineligible after miscarriage or early delivery). Range: 0-5 	There are no missing data

103	1st Miss Vis	First missed visit. No one missed the baseline visit, so this variable takes values 2, 3, 4, 5, 6, and 100 (no eligible visits missed)		There are no missing data
<b>Microbiological and Immunological Outcomes (variables 104 – 171)</b>				
104	OAA1	Serum IgG (immunoglobulin) antibodies to <i>A. actinomycetemcomitans</i> at baseline		. = No data available
105	OCR1	Serum IgG (immunoglobulin) antibodies to <i>C. rectus</i> at baseline		. = No data available
106	OFN1	Serum IgG (immunoglobulin) antibodies to <i>F. nucleatum</i> at baseline		. = No data available
107	OPG1	Serum IgG (immunoglobulin) antibodies to <i>P. gingivalis</i> at baseline		. = No data available
108	OPI1	Serum IgG (immunoglobulin) antibodies to <i>P. intermedia</i> at baseline		. = No data available
109	OTD1	Serum IgG (immunoglobulin) antibodies to <i>T. denticola</i> at baseline		. = No data available
110	OTF1	Serum IgG (immunoglobulin) antibodies to <i>T. forsythus</i> at baseline		. = No data available
111	OCRP1	Serum measure for C-reactive protein (CRP) at baseline		. = No data available
112	O1B1	Serum measure for Interleukin(IL)-1b at baseline		. = No data available
113	O61	Serum measure for Interleukin(IL)-6 at baseline		. = No data available
114	O81	Serum measure for Interleukin(IL)-8 at baseline		. = No data available
115	OPGE21	Serum measure for Prostaglandin E2 at baseline		. = No data available
116	OTNF1	Serum measure for tumor necrosis factor (TNF)-alpha at baseline		. = No data available
117	OMMP91	Serum measure for gelatinase (MMP9) at baseline		. = No data available
118	ETXU_CAT1	Serum endotoxin level at baseline		. = No data available
119	OFIBRIN1	Serum measure for fibrinogen at baseline		. = No data available

120	OAA5	Serum IgG (immunoglobulin) antibodies to <i>A. actinomycetemcomitans</i> at visit 5		. = No data available
121	OCR5	Serum IgG (immunoglobulin) antibodies to <i>C. rectus</i> at visit 5		. = No data available
122	OFN5	Serum IgG (immunoglobulin) antibodies to <i>F. nucleatum</i> at visit 5		. = No data available
123	OPG5	Serum IgG (immunoglobulin) antibodies to <i>P. gingivalis</i> at visit 5		. = No data available
124	OPI5	Serum IgG (immunoglobulin) antibodies to <i>P. intermedia</i> at visit 5		. = No data available
125	OTD5	Serum IgG (immunoglobulin) antibodies to <i>T. denticola</i> at visit 5		. = No data available
126	OTF5	Serum IgG (immunoglobulin) antibodies to <i>T. forsythus</i> at visit 5		. = No data available
127	OCRP5	Serum C-reactive protein (CRP) at visit 5		. = No data available
128	O1B5	Serum Interleukin(IL)-1b at visit 5		. = No data available
129	O65	Serum Interleukin(IL)-6 at visit 5		. = No data available
130	O85	Serum Interleukin(IL)-8 at visit 5		. = No data available
131	OPGE25	Serum Prostaglandin E <sub>2</sub> at visit 5		. = No data available
132	OTNF5	Serum tumor necrosis factor (TNF)-alpha at visit 5		. = No data available
133	OMMP95	Serum gelatinase (MMP9) at visit 5		. = No data available
134	ETXU_CAT5	Serum endotoxin level at visit 5		. = No data available
135	OFIBRIN5	Serum measure for fibrinogen at visit 5		. = No data available
136	BL DNA	Total amount of bacterial DNA extracted from plaque as a measure of total bacterial concentration at baseline	ng/mL	Blank = Missing
137	BL Univ	Count of all bacteria detected by universal primer at baseline		Blank = Missing
138	BL AA	Count of <i>A. actinomycetemcomitans</i> bacteria at baseline		Blank = Missing
139	BL PG	Count of <i>P. gingivalis</i> bacteria at baseline		Blank = Missing

140	BL TD	Count of <i>T. denticola</i> bacteria at baseline		Blank = Missing
141	BL TF	Count of <i>T. forsythus</i> bacteria at baseline		Blank = Missing
142	BL PI	Count of <i>P. intermedia</i> bacteria at baseline		Blank = Missing
143	BL CR	Count of <i>C. rectus</i> bacteria at baseline		Blank = Missing
144	BL FN	Count of <i>F. nucleatum</i> bacteria at baseline		Blank = Missing
145	BL S7	Sum of the 7 species-specific bacterial counts (variables 138-144) at baseline, rounded to 3 significant figures		Blank = Missing
146	V5 DNA	Total DNA extracted from subgingival plaque at visit 5	ng/mL	Blank = Missing
147	V5 Univ	Total Universal at visit 5		Blank = Missing
148	V5 AA	Count of <i>A. actinomycetemcomitans</i> bacteria at visit 5		Blank = Missing
149	V5 PG	Count of <i>P. gingivalis</i> at visit 5		Blank = Missing
150	V5 TD	Count of <i>T. denticola</i> bacteria at visit 5		Blank = Missing
151	V5 TF	Count of <i>T. forsythus</i> bacteria at visit 5		Blank = Missing
152	V5 PI	Count of <i>P. intermedia</i> bacteria at visit 5		Blank = Missing
153	V5 CR	Count of <i>C. rectus</i> bacteria at visit 5		Blank = Missing
154	V5 FN	Count of <i>F. nucleatum</i> bacteria at visit 5		Blank = Missing
155	V5 S7	Total bacterial counts for all 7 species (AA, PG, TD, TF, PI, CR, and FN) at visit 5		Blank = Missing
156	BL %AA	Percent of <i>A. actinomycetemcomitans</i> out of total DNA (variable 146) at baseline		Blank = Missing
157	BL %PG	Percent of <i>P. gingivalis</i> out of total DNA at baseline		Blank = Missing
158	BL %TD	Percent of <i>T. denticola</i> out of total DNA at baseline		Blank = Missing
159	BL %TF	Percent of <i>T. forsythus</i> out of total DNA at baseline		Blank = Missing

160	BL %PI	Percent of <i>P. intermedia</i> out of total DNA at baseline		Blank = Missing
161	BL %CR	Percent of <i>C. rectus</i> out of total DNA at baseline		Blank = Missing
162	BL %FN	Percent of <i>F. nucleatum</i> out of total DNA at baseline		Blank = Missing
163	BL %S7	Sum of the percents for the 7 species (AA, PG, TD, TF, PI, CR, and FN) at baseline		Blank = Missing
164	V5 %AA	Percent of <i>A. actinomycetemcomitans</i> out of total DNA at visit 5		Blank = Missing
165	V5 %PG	Percent of <i>P. gingivalis</i> out of total DNA at visit 5		Blank = Missing
166	V5 %TD	Percent of <i>T. denticola</i> out of total DNA at visit 5		Blank = Missing
167	V5 %TF	Percent of <i>T. forsythus</i> out of total DNA at visit 5		Blank = Missing
168	V5 %PI	Percent of <i>P. intermedia</i> out of total DNA at visit 5		Blank = Missing
169	V5 %CR	Percent of <i>C. rectus</i> out of total DNA at visit 5		Blank = Missing
170	V5 %FN	Percent of <i>F. nucleatum</i> out of total DNA at visit 5		Blank = Missing
171	V5 %S7	Sum of the percents for the 7 species (AA, PG, TD, TF, PI, CR, and FN) at visit 5		Blank = Missing

*Notes:*

1. Some centers provided EDC generously, offering it even when unnecessary. Therefore, some participants completed EDC (variable 34) even though EDC had not been deemed necessary (variable 33 = No).
2. “Fraction of sites” were obtained by dividing by a total of 168 max possible sites (6 sites per tooth, estimated 28 teeth per participant). The denominator varied slightly between participants, as some individuals had missing teeth or other differences.