specified outcomes between randomization groups using an intent-to-treat approach.

RESULTS: 800 women were randomized between Feb 2018 and Jan 2020. Baseline characteristics were similar between treatment groups. Adherence to study drug was high in both groups (98%) and delivery outcomes were ascertained for all 800 participants. The primary outcome occurred in 36 (9.02%) participants assigned to 17P and 36 (8.98%) assigned to placebo (risk difference = 0.05; 95% CI: -3.92, 4.01). In a pre-specified analysis excluding provider-initiated PTB phenotypes, 25 (6.36%) women randomized to 17P delivered spontaneously before 37 weeks compared to 26 (6.63%) of those receiving placebo (risk difference = -0.27; 95% CI: -3.72, 3.18). The timing of antiretroviral therapy initiation relative to conception did not affect the risk of the primary outcome nor did it modify the effect of the intervention. Related adverse events were low and occurred at similar rates between the study groups.

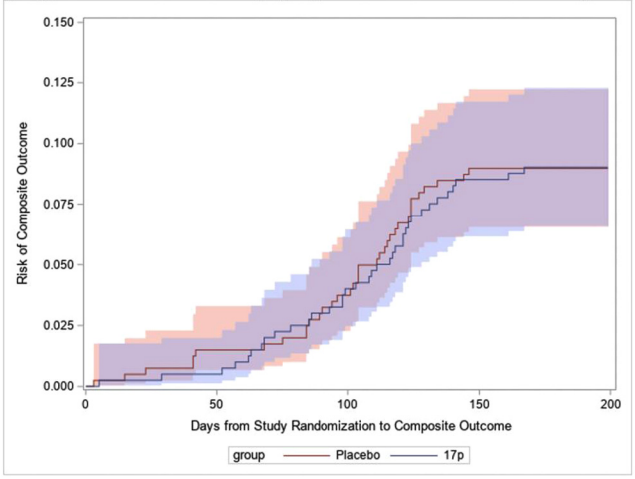
CONCLUSION: In this trial with complete ascertainment of outcomes and very high adherence to study drug, weekly antenatal 17P injections did not reduce the composite risk of preterm delivery or stillbirth among women with HIV in Zambia.

Table 1. Outcomes by treatment assignment in the IPOP trial, February 2018 – August 2020, Lusaka, Zambia

	17P n = 399		Placebo n = 401		Risk Difference (%) (95% CI)	Risk Ratio (95% CI)
	n	%	n	%		
Primary composite outcome						
Delivery < 37 weeks and/or stillbirth[a]	36	9.02	36	8.98	0.05 (-3.92, 4.01)	1.01 (0.65, 1.56)
Livebirth < 37 weeks	26	6.52	25	6.23	0.28 (-3.10, 3.67)	1.05 (0.61, 1.78)
Stillbirth at any gestational age	10	2.51	11	2.74	-0.24 (-2.45, 1.98)	0.91 (0.39, 2.13)
Secondary outcomes						
Delivery < 37 weeks	31	7.77	35	8.73	-0.96 (-4.77, 2.85)	0.89 (0.56, 1.41)
Spontaneous delivery < 37 weeks[b]	25	6.36	26	6.63	-0.27 (-3.72, 3.18)	0.96 (0.56, 1.63)
Provider-initiated delivery < 37 weeks[c]	6	1.60	9	2.40	-0.80 (-2.80, 1.21)	0.67 (0.24, 1.86)
Delivery < 34 weeks	14	3.51	16	3.99	-0.48 (-3.11, 2.15)	0.88 (0.44, 1.78)
Delivery < 28 weeks	3	0.75	5	1.25	-0.50 (-1.87, 0.88)	0.60 (0.15, 2.51)

Abbreviations: CI, confidence interval
[a] Chi-square test for difference in proportions $p = 0.98$
[b] Excludes 15 provider-initiated preterm births
[c] Excludes 51 spontaneous preterm births

Figure 1. Cumulative-incidence curves for risk of composite outcome (i.e., preterm birth or stillbirth) by days from randomization and study arm

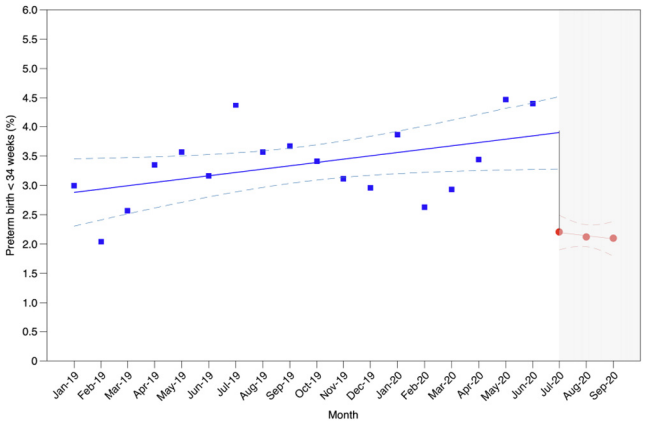


OBJECTIVE: It has been suggested that lockdown during the COVID-19 pandemic decreased prematurity rates. We investigated the impact of lockdown on obstetric outcomes.

STUDY DESIGN: We performed a cohort study on women who gave birth at three maternity hospitals in metropolitan Melbourne, Australia, between Jan 1st, 2019 and Sept 16th, 2020. Data were extracted from the common birth registry of the three maternities. The second lockdown started July 8th, 2020 and required people to stay at home, with limited exemptions. We performed interrupted time-series analysis to compare the monthly rates of preterm birth before 34 weeks prior to and after July 2020. We also compared the group of women who delivered between July and September 2020 to the group of women who delivered during the same period in 2019.

RESULTS: A total 15,394 women gave birth. Interrupted time-series analysis demonstrated a significantly lower monthly rate of deliveries before 34 weeks of gestational age after July 2020 (Figure 1; p = 0.001). There were 2,207 deliveries between July to Sept. 2019 and 1,870 deliveries between July to Sept. 2020. Baseline characteristics were comparable, except for a significantly difference in twins (1.5% in 2020 versus 2.6% in 2019, p = 0.012). After excluding women with pregnancies complicated by major fetal abnormalities or stillbirth, the risk of preterm delivery before 34 weeks was much lower in patients who delivered between July and September 2020 (2.1% versus 3.3%, RR 0.64, 95% CI 0.44 to 0.94, p = 0.022) (Table 1). Similar patterns were observed for iatrogenic and spontaneous preterm birth at different gestational ages. The effect persisted after logistic regression adjustment for multiple pregnancies (adjusted OR 0.65, 95% CI 0.46 to 0.96, p = 0.028). The decrease in prematurity was not at the cost of an increase in stillbirth or undetected small for gestational age neonates.

CONCLUSION: Strict lockdown has a strong impact on iatrogenic and spontaneous prematurity rates. While returning to normal, which aspects of lockdown contributed to this unprecedented effect should be evaluated.



11 Impact of the coronavirus pandemic lockdown on obstetric outcomes

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Table 1. Pregnancy and neonatal outcomes of women who delivered between July and September 2020 and those who delivered between July and September 2019.

	Delivery Jul-Sep 2020 n = 1,899	Delivery Jul-Sep 2019 n = 2,268	Mean difference or Risk ratio (95% CI)
Number of neonates, *n*	1,928	2,329	-
Major fetal abnormality, *n (%)*	23 (1.2)	60 (2.6)	0.46 (0.29 – 0.75)
Stillbirth of structurally normal fetus, *n (%)*	12 / 1,905 (0.6)	26 / 2,269 (1.1)	0.55 (0.28 – 1.09)
Live born neonates without major abnormalities, *n (%)*	1,893 (98.2)	2,243 (96.3)	1.02 (1.01 – 1.03)
Gestational age at birth (weeks), *mean ± SD*	38.9 ± 2.0	38.7 ± 2.2	0.18 (0.05 – 0.31)
Preterm birth < 37 weeks, *n (%)**	135 / 1,866 (7.2)	204 /2,190 (9.3)	0.79 (0.63 – 0.96)
Spontaneous, *n (%)**	74 (4.0)	100 (4.6)	0.87 (0.65 – 1.17)
Medically indicated, *n (%)**	61 (3.2)	104 (4.7)	0.69 (0.50 – 0.94)
Preterm birth < 34 weeks, n (%)*	40 / 1,866 (2.1)	73 / 2,190 (3.3)	0.64 (0.44 – 0.94)
Spontaneous, *n (%)**	23 (1.2)	38 (1.7)	0.71 (0.42 – 1.19)
Medically indicated, *n (%)**	17 (0.9)	35 (1.6)	0.57 (0.32 – 1.01)
Preterm birth < 28 weeks, *n (%)*	8 / 1,866 (0.4)	18 / 2,190 (0.8)	0.52 (0.23 – 1.20)
Spontaneous, *n (%)**	6 (0.3)	12 (0.5)	0.58 (0.22 – 1.56)
Medically indicated, *n (%)**	2 (3.2)	6 (4.7)	0.39 (0.08 – 1.93)
Birthweight (grams), *mean ± SD***	3,286.8 ± 14.0	3,219.4 ± 13.3	67.4 (29.5 – 105.3)
Birthweight percentile, *mean ± SD***	47.9 ± 0.7	47.0 ± 0.6	0.92 (-0.81 – 2.68)
Birthweight < 10th percentile, *n (%)***	205 / 1,915 (10.7)	232 / 2,294 (10.1)	1.05 (0.89 – 1.26)
Birthweight < 3rd percentile, *n (%)***	51 / 1,915 (2.7)	47 / 2,294 (2.0)	1.30 (0.88 – 1.92)
Admission to NICU or SCN**, *n (%)*	296 / 1,915 (15.5)	409 / 2,294 (17.8)	0.87 (0.76 – 0.99)

Note: Pregnancies of fetuses with major abnormalities or that resulted in stillbirths excluded from analysis of the other neonatal outcomes. SD: Standard deviation. IQR: Interquartile Range. BMI: Body Mass Index. * Denominator is the number of pregnancies that resulted in at least one live birth without major congenital abnormalities (1,866 in the second epoch and 2,190 in the first epoch). ** Denominator is the number of neonates born alive (1,915 in the second epoch and 2,294 in the first epoch.

12 Observations from an inner city hospital during COVID-19: preterm birth rate and mode of delivery

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OBJECTIVE: COVID-19 is causing an evolving global pandemic and to date the effects on both maternal and fetal outcomes as well as obstetric practice are unclear. Recently, hospitals worldwide have reported a higher rate of cesarean delivery among infected individuals, and a trend in the reduction of preterm births prior to 28 weeks. We aim to investigate the effects of COVID-19 on the rate of preterm birth and the mode of delivery at our institution in the height of the pandemic and unknown risks of this virus.

STUDY DESIGN: Retrospective review of all pregnant women who delivered live singleton pregnancies at Mount Sinai West between March through May 2020 (pandemic period) compared with March through May 2019 (prepandemic period). Demographic data and outcomes were collected. Student t-test, Chi-square or Fisher exact tests, logistic and linear regression were used as appropriate.

RESULTS: A total of 2,436 women were included: 1,306 patients in 2019, 1,135 patients in 2020. There was a 14% decline in overall births at Mount Sinai West during the pandemic period compared with the prepandemic period. There was a statistically significant decline in the rate of operative vaginal delivery during the pandemic period (5% vs 7%, p=0.03), but cesarean delivery rates remained unchanged. There was no difference in PTB <28 weeks gestation in 2019 compared with 2020 (0.6% vs 0.3%, p=0.21). There was a trend showing lower rates of very low birth weight babies in 2020 compared to 2019, however this was not statistically significant (0.6% vs 1.2%, p=0.06).

CONCLUSION: Our study shows no difference in preterm birth during the height of the pandemic, however there was a trend in lower rates of very low birth weight babies. Interestingly, not addressed in the literature before, at our institution there was a 38% decline in operative vaginal delivery rate without a change in cesarean section rate during the pandemic. Perhaps this is suggestive of a more hands off approach by physicians during the height of the unknown risk. Larger numbers will be needed for further evaluation of these trends.

Table 1. Maternal and Pregnancy Characteristics

Maternal Characteristics	Prepandemic period n=1,306 (%)	Pandemic period n=1,135 (%)	P-value
Age	32.9	33.2	0.109
BMI	33.5	29.6	0.323
Nulliparity	182	135	0.13
Race/ethnicity			0.806
White	579 (44.3)	554 (48.8)	
Black	144 (11)	167 (14.7)	
Asian	172 (13.2)	188 (16.6)	
American Indian/Alaska Native	0 (0)	1 (0.1)	
Native Hawaiian or other	0 (0)	1 (0.1)	
Unknown/not reported	411 (31.5)	224 (19.7)	

Table 2. Study Outcomes

Outcomes	Prepandemic period n=1,306 (%)	Pandemic period n=1,135 (%)	P-value
Preterm Birth			
Prior to 37 weeks	95 (7)	79 (7)	0.76
Prior to 28 weeks	8 (0.6)	3 (0.3)	0.21
Mode of delivery			
Cesarean delivery	368 (28)	329 (29)	0.66
Vaginal delivery	844 (65)	748 (66)	0.51
Operative vaginal delivery	93 (7)	57 (5)	**0.03**
Birth weight			
Low birth weight (<2500g)	83 (6)	65 (6)	0.52
Very low birth weight (<1500g)	16 (1.2)	7 (0.6)	0.06

13 Development of an Ascending Model of Infection and Preterm Birth

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OBJECTIVE: Microbial invasion of the intraamniotic cavity (MIAC) and intraamniotic inflammation (IAI) are factors associated with spontaneous preterm birth (PTB). Understanding the route of infection, site of colonization and mechanisms of host inflammatory response is critical to reduce PTB risk. Although multiple models have been reported, reproducible evidences are lacking to determine route of MIAC and kinetics of ascension. This study developed an ascending model of infection and PTB with live bacteria (E. coli) in pregnant mice.

STUDY DESIGN: Two independent experiments were conducted: 1. To determine E. coli induced PTB, CD-1 mouse were injected with three different doses of E. coli (103, 106, and 1010 colony forming units[CFU]) 25 μl of either E. coli in liquid broth (LB; control) or LB alone (control) was administrated into the vagina on embryonic day (E)15 using a 200-F06DL pipette tip. PTB (defined as delivery before E18.5) was monitored using live video, and 2) To determine the kinetics and colonization, 1010 CFU/ml (colony forming unit/ml) E. coli labeled with 10 μM carboxyfluorescein succinimidyl ester (CSFE) was vaginally administered. Mice were sacrificed at 6h, 24h and 48h and various tissues were collected. 10 μm frozen section were counter-stained with DAPI and microscopically analyzed to check E. coli trafficking in uterine tissues.