Case Studies:
Medications and Human Breastmilk: Obesity, Diabetes, Heart Disease

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Objectives: Medications and Human Breastmilk: Obesity, Diabetes, Heart Disease

1. To review the treatment of Preeclampsia and Essential Hypertension along with the transfer/safety of medications in breastfeeding dyad
2. To review the treatment of Postpartum Cardiomyopathy along with the transfer/safety of medication in breastfeeding dyad
3. To review the treatment of Pregestational and Gestational Diabetes along with the transfer/safety of medications in breastfeeding dyad
4. To review the weight loss medications and safety in breastfeeding dyad

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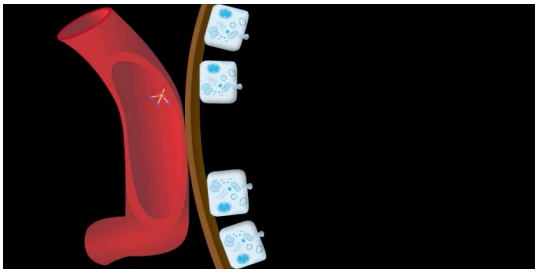
Colostral Phase (Day 1-2)



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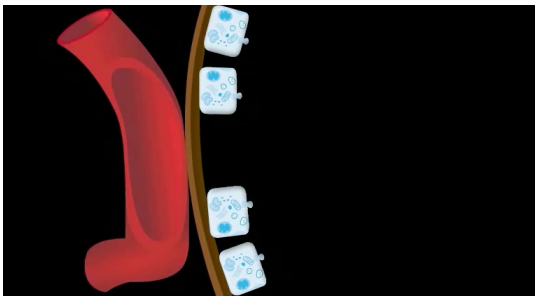
From Day 3 to Day 4 Postpartum



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Risk to Infant

- Depends on 3 major factors
  - Choice of Drug (penicillin vs anticancer drugs)
  - Age of the infant
    - Premature…some risk
    - Older infant…minimal risk
  - Volume of milk
    - Colostrum….minimal risk
    - Full breastfeeding… some risk
    - Late stage lactation…minimal risk
  - Exposure in utero?
  - Prior Dependence or Tolerance

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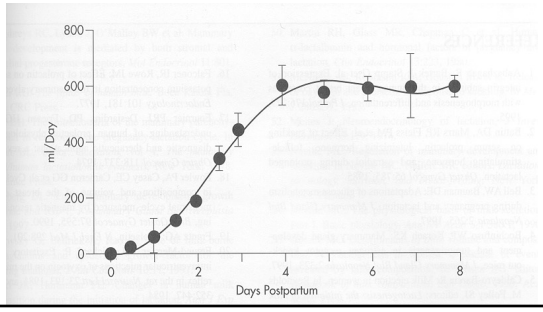
Milk Volumes during first week postpartum



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Pharmacokinetics and Drug Levels in Milk

- Molecular weight of drug really matters
- Drugs > 800 daltons enter milk poorly
  - Drugs < 300 daltons may enter milk easily
- Protein Binding:
  - Higher the binding the poorer the levels in milk
- pKa
  - Higher the pKa the more drug is trapped in milk.
    - "Ion trapping"
- Vd
  - Higher the Vd, the lower the levels in milk
  - They're all in the periphery, not in plasma

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Pharmacokinetics and Drug Levels in Milk

- Lipid Solubility
  - More lipid soluble, the higher drug levels in milk
- Plasma levels
  - The Higher, the more drug enters milk
  - The Lower, the less enters milk (fluticasone)
- Transport processes are poorly understood
  - At least 5 drugs are thought to be transported but 4 do not attain clinical levels
  - Ranitidine, Cimetidine, Iodine, Nitrofurantoin, Acyclovir

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Other Kinetic Factors

- Bioavailability
  - How much is absorbed and ends up in Plasma.
- Oral, IM, Rectal bioavailability are often different
  - Drug exposure via milk depends on the oral absorption of the drug in the infant.
    - Monoclonal Antibodies (minimal to nil)
    - Morphine (26%)
    - Large proteins unabsorbed (heparin, etanercept, etc)
    - Sumatriptan (14%)
    - Domperidone (13%)
    - Tetracyclines (most poorly absorbed in milk)
- Stability in GI tract of infant is important
  - Proton pump inhibitors are unstable at low pH.
  - Monoclonal antibodies are unstable due to proteases in GI tract

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Some Suggestions

- Always evaluate stage of lactation.
  - Premature…higher risk
  - First 4 days, low milk volume…..low risk
  - Late stage… low milk volume….low risk
- Calculate and use the Relative Infant Dose. If less than 10% then it is probably safe.

$$\text{RID} = \frac{\text{Infant dose (milk) (mg/kg/day)}}{\text{Maternal dose (mg/kg/day)}}$$

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Case Number 1: **Severe Preeclampsia**

45 yo G5P4 presents to L&D at 38 weeks

- Severe Preeclampsia (BP 220/110; 3+ proteinuria; Platelet count 10 K)
- Magnesium for seizure prophylaxis
- Began induction
- She had one seizure during induction
- Labetalol IV prn to control BP
- Vaginal delivery 1 hour ago
- BP remains elevated – requiring transfer to ICU for BP management

She would like to nurse her infant. Is it safe?

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Magnesium

- Used for seizure prophylaxis in mother (4gram IV load ; then 1-2 gram q hour continuous infusion)
- Cruikshank (1982)
  - Average milk Magnesium concentration in those treated with IV Magnesium 6.4mg/dl vs controls 4.77 md/dL. On Day 2 treatment group 3.83 mg/dL vs control 3.19 mg/dL. On Day 3 treatment and control group identical (3.54 vs 3.52 mg/dL) Serum Magnesium Day 1 3.55 vs 1.82 mg/dL.
- Morris (1987)
  - Oral Magnesium poorly absorbed, averaging 4%
  - Infants would received about 1.5 mg of oral magnesium more than control
- Remains Controversial
- RID 0.2%

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Nicardipine IV

- Calcium Channel Blocker
- Bartels (2007)
  - 7 mothers (1-6.5 mg/hr)
  - 82% of 34 milk samples had undetectable levels
  - Six samples contained between 5.1-18.5 micrograms/L
  - Maximum infant exposure less than 300ng/day (level much lower than typically used in neonates)
- Jarreau (2000)
  - 11 mothers (20-120 mg nicardipine daily)
  - RID 0.07%
  - Infant monitoring (drowsiness, lethargy, poor feeding)

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Hydralazine

- Leidholm (1982)
  - 1 mother 50 mg three times daily
  - Concentration in breastmilk at 0.5 hour after administration (762 nmol/L)
  - Concentration in breastmilk at 2 hours after adminimatration (792 nmol/L)
- Pediatric dose 0.75-1mg/kg/day
- RID 1.2%
- Published pediatric dose 1mg/kg/day

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Beta Blockers

- Labetalol
  - Lunell (1985)
    - 3 women 600-1200 mg/day
    - Breastmilk peak concentrations 129, 223, 662 µg/L.
    - One infant measurable plasma levels (18µg/L) following 600mg dose
    - RID 0.2-0.6%
- Metoprolol
  - Liedholm
    - 3 women 100mg twice daily
    - Peak concentration levels 0.38-2.58 µmol/L; Infant would ingest approximately 0.05 mg at first feeding and considerably less at subsequent feeding.
  - Sandstrom
    - 9 women 50-100 mg twice daily
    - Average milk concentration throughout day 280 µg/L of milk (20-40 times less than typical clinical dose)
- Propranolol
  - Smith (1983)
    - Infant received <0.1 % of maternal dose
  - Lewis (1981)
    - 20 mg every 8 hours
    - 0-0.5 µg/L

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Beta Blockers

- Atenolol
  - 1 report of infant with bradycardia, cyanosis and low body temperature
  - Atenolol may be secreted variably but may be as high as 10 times greater than that of Propranolol
- Carvedilol
  - No data on transfer into human milk
  - Highly lipid soluble

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Case 2: **Essential Hypertension/Postpartum Cardiomyopathy**

- 30 yo G2P2 presents postpartum with essential hypertension
- She was managed throughout pregnancy with oral Labetalol
- She was delivered vaginally at 38 weeks without any difficulty.

She would like to breastfeed. What is the best option for her and her infant?

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Nifedipine

- Calcium Channel Blocker
- Ehrenkranz (1989)
  - Maternal dose varied from 10-30 mg three times daily
  - Highest concentration 53.35 micrograms/L was measured at 1 hour after 30 mg dose
  - 16.25 micrograms/L 60 minutes after 20 mg dose
  - 12.89 micrograms/L 30 minutes after 10mg dose
  - Milk levels fell linearly
  - Authors conclusion: highest concentration found in daily intake of 150mL /kg of milk = 8microgram/kg/day (less than 1.8% of therapeutic pediatric dose)
- Manninen (1991)
  - 11 patients
  - Nonsignificant levels in human milk

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ACE Inhibitors

- Lisinopril
  - No breastfeeding data exists
  - Theoretic risk in premature infants due to renal toxicity
- Enalopril
  - Redman (1990)
    - 5 women 20mg dose; infant would ingest less than 2 µ/day
    - RID 0.07-0.2%
- Captopril
  - Devlin (1980)
    - 12 women
    - 100mg three times daily
    - Maternal serum level 713 µ/L breastmilk levels 4.7 µ/L at 3.8 hours after dose
    - Infant would ingest 0.002% of captopril consumed by its mother

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Diuretics

- Furosemide
  - Potent loop diuretic
  - Pediatric use is common
  - Oral bioavailability very poor in newborns (may need 1-4 mg/kg twice daily to see an effect)
  - RID unknown
  - Idea that decreased blood volume leads to decrease breastmilk theoretical
- Hydrochlorothiazide
  - Thiazide diuretic
  - RID unknown
  - Considered safe at low doses

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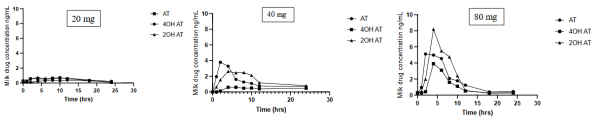
Minimal transfer of atorvastatin and its metabolites in human milk: a case series



Concentration profile of atorvastatin and active metabolites (2OH AT and 4OH AT) in human milk at 20 mg, 40 mg and 80 mg dosages.

Campbell L, et al. *Breastfeed Med*. 2024 Nov;19(11):889-894.

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Parameter (units)	Atorvastatin			Ortho-hydroxy Atorvastatin (2-OH)			Para-hydroxy Atorvastatin (4-OH)		
Dose (mg)	20	40	80	20	40	80	20	40	80
AUC (ng.hr/mL)	10.6	31.48	44.29	11.7	35.25	49.82	6.6	10.2	25.17
$C_{ss,ave}$ (ng/mL)	0.441	1.31	1.84	0.488	1.46	2.07	0.275	0.425	1.05
C_{max} (ng/mL)	0.703	3.78	5.11	0.383	2.62	8.2	0.772	0.60	3.9
T_{max} (hour)	10	2	2	4	4	4	12	4	4
Maternal Dose (mg/kg/day)	0.347	0.62	1.26	0.347	0.62	1.26	0.347	0.62	1.26
Infant Dose (mg/kg/day)	0.000066	0.00019	0.00027	0.000072	0.00022	0.00031	0.00004	0.00022	0.00015
Relative Infant Dose (%)	0.019	0.03	0.02	0.02	0.03	0.02	0.011	0.03	0.012

- Pharmacokinetic data of atorvastatin and its metabolites in human milk
- Atorvastatin and its metabolites were quantifiable in all the milk samples collected at different dosages.
- Very low amounts were observed with relative infant dose to all below 0.05%.

Campbell L, et al. *Breastfeed Med*. 2024 Nov;19(11):889-894.

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Case 2 Represents with Postpartum Cardiomyopathy

- Postpartum 7 days represents to ER with Shortness of Breath, Chest pressure, Lower extremity edema
- O2Sat 80% RA
- Pulse 110
- BP 130/80

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Shortness of Breath, oxygen desaturation postpartum differential

- Pulmonary Emboli
- Pulmonary Edema
- Myocardial Infarction
- Acute or Chronic Kidney Disease
- Postpartum Cardiomyopathy

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Enoxaparin

- Low molecular weight fraction of heparin
- One study with 12 women 20-40mg SQ 5 days post partum (n=4) or cesarean section (n=8) no change in anti-Xa activity noted in the 12 breastfed infants
- Large molecular weight (2000-8000 Daltons)
- Minimal oral bioavailability

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Warfarin

- Oral anticoagulant
- Highly protein bound in maternal circulation
- One study (2) patients anticoagulated with warfarin, no warfarin detected in infant's serum nor changes is coagulation detectable. (McKenna et al)
- Another study, 13 mothers, less than 0.08Uumol/L was detected in milk and no warfarin detected in infant plasma. (Orme ML et al)

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Apixaban

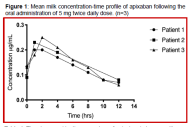

Figure 1. Mean milk concentration-time profile of apixaban following the oral administration of 5 mg twice daily dose. (n=3)

Table 1. The pharmacokinetic parameters of apixaban in human milk.

Parameter	Patient 1	Patient 2	Patient 3
Dose	5 mg twice daily	5 mg twice daily	5 mg twice daily
AUC (μg·h/mL)	1.637	1.915	1.84
C_{avg} (μg/mL)	0.134	0.16	0.15
C_{max} (μg/mL)	0.2	0.29	0.25
T_{max} (hr)	2	1	2
Infant dose (mg/kg/12 hr)	0.01	0.01	0.01
Relative Infant Dose (%)	14	21	20

Due to this medications:
Small volume of distribution
High pKa
Significant entry into milk
We do not recommend use during breastfeeding

Datta P, Bramnik A, Rewers-Felkins K, Krutsch K, Baker T, Hale TW. Transfer of Apixaban into Human Milk. Obstet Gynecol. 2021 Jun 1;137(6):1080-1082. doi: 10.1097/AOG.0000000000004388. PMID: 33957661.

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Rivaroxaban transfer into Breastmilk

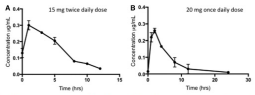

FIG. 1. Mean milk concentration–time profile of rivaroxaban in human milk in two mothers ($n = 2$) after oral administration of (**A**) 15 mg twice daily and (**B**) 20 mg daily.

TABLE 1. PHARMACOKINETIC PARAMETERS OF RIVAROXABAN AFTER TAKING 15 AND 20 MG DOSAGES

Parameter	*Value (±SD), n = 2*	*Value (±SD), n = 2*
Dose	15 mg twice daily	20 mg daily
AUC (μg · hour/mL)	1.9 (±0.005)	1.7 (±0.37)
C_{avg} (μg/mL)	0.16 (±0.0004)	0.07 (±0.02)
C_{max} (μg/mL)	0.3 (±0.02)	0.26 (±0.01)
T_{max} (hours)	1	2
Infant dose	0.01 mg/kg per 12 hours	0.01 mg/kg per day
RID (%)	5	4

RID is low due to high plasma protein binding of rivaroxaban and subequent poor penetration into human milk.
More studies needed
Doses from breastmilk are over 100 times lower than doses given directly to pediatric patients.

Muysson M, Marshall K, Datta P, Rewers-Felkins K, Baker T, Hale TW. Rivaroxaban Treatment in Two Breastfeeding Mothers: A Case Series. Breastfeed Med. 2020 Jan;15(1):41-43. doi: 10.1089/bfm.2019.0124. Epub 2019 Sep 18. PMID: 31532233.
Saito J, Kaneko K, Yakuwa N, Kawasaki H, Yamatani A, Murashima A. Rivaroxaban Concentration in Breast Milk During Breastfeeding: A Case Study. Breastfeed Med. 2019 Dec;14(10):748-751. doi: 10.1089/bfm.2019.0230. Epub 2019 Nov 20. PMID: 31746638.

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Aspirin

Table 1. Pharmacokinetic Parameters of Salicylic Acid After 81 mg Aspirin.

Parameter (units)	Value (range)
AUC (ng.hr/ml)	576.4 (98.75–967.6)
C_{avg} (ng/ml)	24 (4.1–40.3)
C_{max} (ng/ml)	114.9 (27.1–165.4)
T_{max} (hr)	4 (2–4)
Infant dose (μg/kg/day)	3.6 (0.6–6)
RID (%)	0.4 (0.09–0.55)

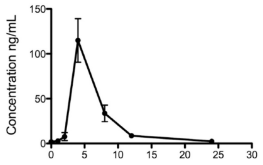

Figure 1. Mean milk concentration-time profile of salicylic acid in human milk following the oral administration of 81-mg aspirin tablets to breastfeeding mothers (n = 6).

Datta P, Rewers-Felkins K, Kallem RR, Baker T, Hale TW. Transfer of Low Dose Aspirin Into Human Milk. J Hum Lact. 2017 May;33(2):296-299. doi: 10.1177/0890334417695207. Epub 2017 Mar 20. PMID: 28418802.

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Digoxin

- Positive ionotropic medication (increases contractility)
- Typical dose 0.25 mg / day
- (5) women
  - Average breast milk concentration 0.64 μg/L
  - Breastfeeding infant receives less that 1 μg/day of digoxin
  - Monitor for drowsiness, lethargy, cardiac arrythmias, poor feeding

Levy, M, Granit L, Laufer N. Excretion of drugs in human milk. N Engl J Med. 1977 Oct;297(14)789.

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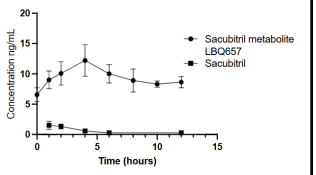
The Concentration of Maternal Sacubitril/Valsartan (Entresto) Transferred into Human Milk is Negligible

Parameters (units) (n=5)	Value (Sacubitril)	Value (LBQ 657)	Valsartan
Calculated Milk Parameters			
AUC (ng.hr/mL)	5.96	114.9	ND
C_{avg} (ng/mL)	0.4966	9.5	ND
C_{max} (ng/mL)	1.52	12.2	ND
T_{max} (hr)	1	4	ND
Infant dose (mg/kg/12 hrs)	0.00049	0.00071	--
RID (%)	0.01	0.22	--

Pharmacokinetic parameters of Sacubitril, its active metabolite LBQ 657, and Valsartan



Drug concentrations in timed human milk samples (n=5) characterizes the maternal transfer of drug residues into milk for sacubitril and its active metabolite LBQ657.

Valsartan was not quantified in any milk samples at a detection level of 0.19 ng/mL.

Falconi S et al. *Front Public Health*. 2024 May 22;12

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Gestational Diabetes/Type 2 diabetes mellitus

- 30 yo G2P1 at 28 weeks presents with Gestational Diabetes.
- BMI 39
- Plans to nurse infant but had difficulty nursing first baby

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Metformin

- Used to treat Non-insulin dependent diabetics/PCOS
- Oral bioavailability 50%
- 7 women taking metformin (1500 mg/d) RID 0.28% No health problems in six infants. (Hale et al)
- 5 subjects with no detectable levels in nursing infants (Gardiner et al)
- 5 women taking 500mg bid RID 0.65% (Briggs et al)

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Type 1 diabetes

- Goal is to achieve euglycemia before/during embryogenesis
- Glucose transfers across placenta but insulin does not
- Transition at time of birth can be challenging
- Increased risks of IUFD
- Increased risk of Preeclampsia

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Insulin

- Large peptide 5808 Daltons
- Whitmore et al did small pilot study: insulin is transported into breastmilk; however no difference in insulin breastmilk levels in found in non-diabetics, Type2 diabetics not on insulin and Type 1 diabetics on insulin therapy.
- No evidence that insulin therapy leads to hypoglycemia in infant.

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Insulin Glargine

- Recombinant human insulin (acts up to 24 hours)
- Large peptide that forms crystals when administered subcutaneously that absorb slowly producing sustained release

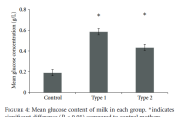

FIGURE 4: Mean glucose content of milk in each group. *indicates significant difference ($P < 0.05$) compared to control mothers.

Whitmore TJ, Trengove NJ, Graham DF, Hartmann PE. Analysis of insulin in human breast milk in mothers with type 1 and type 2 diabetes mellitus. Int J Endocrinol. 2012;2012:296368. doi: 10.1155/2012/296368. Epub 2012 Mar 5. PMID: 22500167; PMCID: PMC3303574.

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Obesity

- 30 yo presents for evaluation – she desires pregnancy but her menses are very irregular. BMI 40
- She reports she has tried "every diet there is" and exercises infrequently. She is tearful and frustrated.
- She is considering trying compounded GLP1 agonists

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Determination of Semaglutide (Ozempic) in Human Milk Following Subcutaneous Dosing

- Pregnancy is involved with significant weight gain, which may have potential negative impact on both physical and mental well-being.
- Semaglutide/Ozempic approved in 2017 has shown to have 94% similarity with GLP-1 hormone.
- Has long half life and has demonstrated effective weight loss in diabetic patients.
- Lactating mothers have expressed overwhelming interest in taking semaglutide during breastfeeding.
- Samples collected from **eight** women were released from the InfantRisk Center Human Milk Biorepository at 0, 12, and 24 hours post semaglutide administration.
- **No semaglutide was detected in any of the milk samples at any time**.

Maternal and Infant information:

- Most of these women were in later stages of postpartum.
- All of the infants were exposed to semaglutide through breastmilk, but none reported any adverse effects. Mothers reported that all infants were meeting or surpassing expected milestones at the time of the survey

Observations:

- Semaglutide may accelerate weight loss more quickly than typical postpartum weight loss. Result from **early satiety** and **reduced caloric intake**, potentially lowering milk production and altering milk nutrient composition.
- Poor maternal nutrition may affect breast milk quality, potentially impacting infant development. Breastfeeding mothers taking semaglutide should be monitored to ensure daily nutrient requirements are met.

A summary of the table of results is presented on the next slide.

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Determination of Semaglutide (Ozempic) in Human Milk Following Subcutaneous Dosing

Summary of milk analysis results.

Participant	SubQ Dose (mg/Week)	Semaglutide (0 h)	Semaglutide (12 h)	Semaglutide (24 h)
1	0.5	n.d.	n.d.	n.d.
2	0.5	n.d.	n.d.	n.d.
3	0.25	n.d.	n.d.	n.d.
4	0.5	n.d.	n.d.	n.d.
5	0.25	n.d.	n.d.	n.d.
6	1	n.d.	n.d.	n.d.
7	0.5	n.d.	n.d.	n.d.
8 *	1	n.d.	n.d.	n.d.

* The participant reported using a semaglutide product from a compounding pharmacy rather than a product prepared by the manufacturer; n.d. means not detected at lower limit of detection (LLOD) of 1.7 ng/mL.

Diab M, et al. Nutrients. 2024 Aug 28;16(17):2886.

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References for Obesity/DM/Cardiovascular disease

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