

PRIMO-LACTO: A CLOSED SYSTEM FOR COLOSTRUM COLLECTION

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BACKGROUND

- Colostrum is a viscous, antibody and nutrient rich milk produced during the first few days after birth.
- Colostrum is filled with antibodies and immunoglobulins, which protects newborns from bacteria and viruses, and also has a laxative effect that helps them expel the first stools called meconium. When a baby is fed their mother's colostrum, it is as if that baby is getting their first vaccination.
- Only a few milliliters of colostrum are produced each hour.
- Every year, approximately 1 million US newborns cannot nurse during the colostrum period due to prematurity, lack of sucking reflex, ankyloglossia or other health issue.
- Current practice is to collect colostrum in plastic spoons, cups and bottles. Transfer to a feeding syringe causes significant colostrum loss, and potential for contamination and infection.

HYPOTHESIS

The Primo-Lacto system will improve colostrum collection by preventing colostrum loss, setting appropriate volume expectations for mom and improving nurse work-flow.

METHODS

Inclusion Criteria:

- Mothers who deliver premature infants below 34 weeks gestation will be approached one to three days after delivery, when they normally would be expected to have started pumping their breasts (assuming that they plan on providing breast milk to their infant). In addition, mothers of non-latching infants or infants with other health conditions that prevent breastfeeding will be approached.

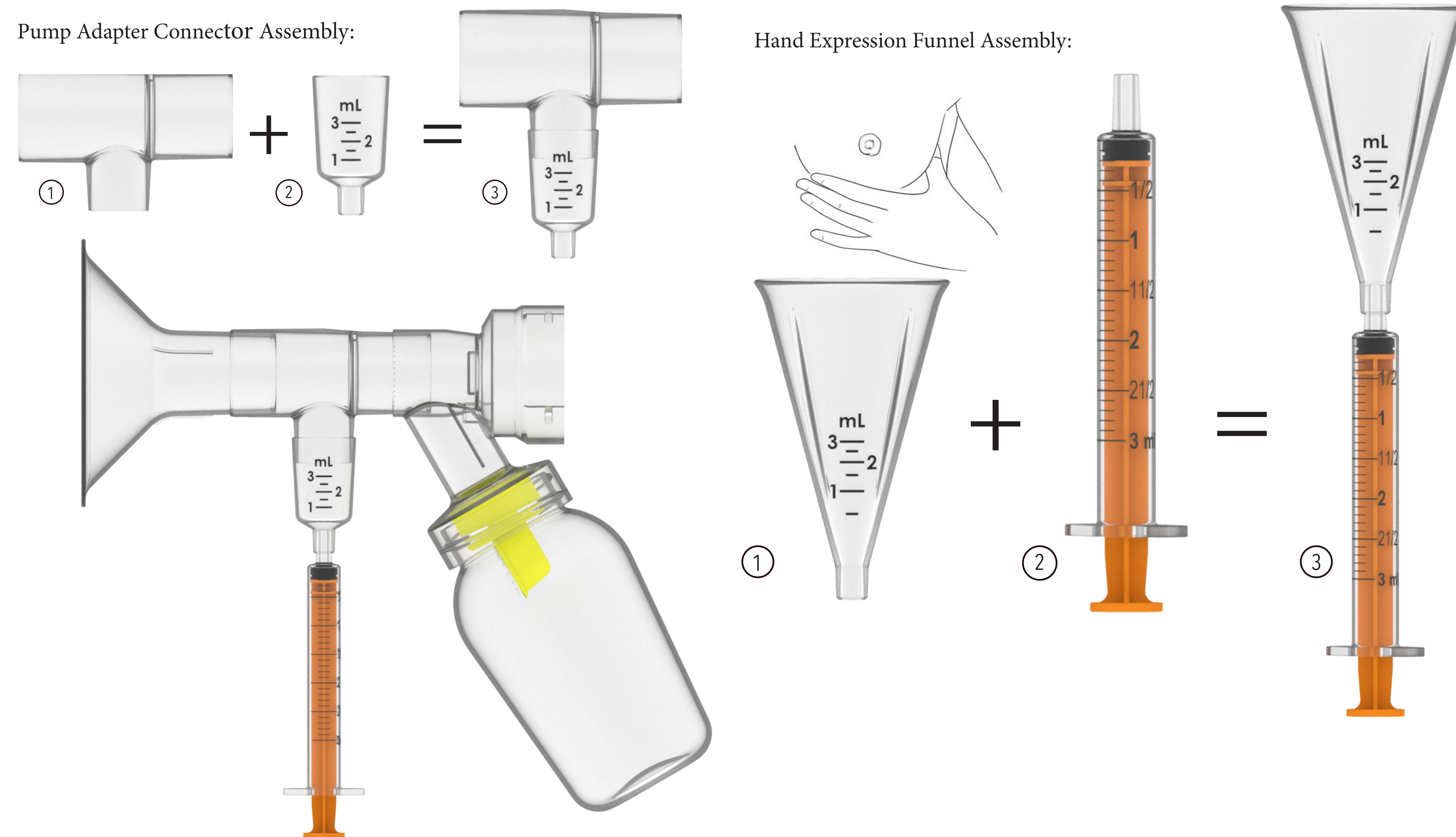
Study Design:

- Prospective, with each mother serving as her own control. The sequence of the four lactation procedures is the same for all mothers. The study uses scaled data from participants' (mothers and nurses) responses to questions comparing both Primo-Lacto and traditional collection procedures.
- Open-ended responses from participants have been reviewed in a qualitative manner. At this point in the study, there were 30 enrolled mothers from two different hospitals.

STANDARD PRACTICE



PRIMO-LACTO SYSTEM



This study is continuing through summer 2016. The goal is to have 120 mothers tested at three hospitals: Sharp Mary Birch in San Diego, CA, Memorial Hospital of South Bend, IN and John Muir Hospital in Walnut Creek, CA.

CLINICAL PILOT STUDY

Instructions for Nurse or Lactation Consultant:

Suggest alternate method with each session. Standard practice pumping and hand expression, and then Primo-Lacto method (repeat)

Record:

- EGA - estimated gestational age (at birth)
- Birth weight
- Gravida, Para
- 1.) Have mother hand express using standard method. (15 min.)
- 2.) Have mother pump express (5 min.) using the standard method.
- NEXT SESSION:
- 3.) Have mother pump express using the Primo-Lacto System (15min)
- 4.) Have mother hand express using the Primo-Lacto System (5 min)

*Primo-Lacto parts are packed sterile and were hand-washed between sessions.

INTERIM STUDY DATA: 30 PATIENTS

Table 1: Summary of Patient Perspective

METHOD	Pump	Pump & Adapter/Syringe	Hand	Hand & Funnel/Syringe
Ease	3.35	4.14	2.68	3.59
Satisfaction	3.06	4.02	2.59	3.57
Confidence	3.83	4.28	3.04	3.88

Table 2: Summary of Nurse Perspective

METHOD	Pump	Pump & Adapter/Syringe	Hand	Hand & Funnel/Syringe
Ease	3.10	4.28	3.00	3.97
% Colostrum Lost	15.25	6.41	11.39	6.49
Time To Collect	7.71	6.72	4.06	4.59

EASE	SATISFACTION	CONFIDENCE
5= Very Easy	5= Very Satisfied	5= Completely Confident
4= Somewhat Easy	4= Somewhat Satisfied	4= Somewhat Confident
3= Neutral	3= Neutral	3= Neutral
2= Somewhat Difficult	2= Somewhat Dissatisfied	2= Not very confident
1= Very Difficult	1= Very Dissatisfied	1= Not confident at all

From Memorial Hospital in South Bend, Indiana:

"I loved how it was easy to transfer my colostrum from the collector into syringe." -mom of premature infant

From Sharp Mary Birch Hospital in San Diego, California:

"I love this adapter. Using this new device, I was able to collect a small amount of colostrum that would have been lost using the regular pump equipment. Having a preemie in the NICU makes it that much more important to collect even small drops, and with this new device I was able to do so. -mom of premature infant

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