

PRIMO-LACTO: A CLOSED SYSTEM FOR COLOSTRUM COLLECTION

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Testing Hospitals: Sharp Mary Birch in San Diego, CA, Memorial Hospital of South Bend, IN and John Muir Hospital in Walnut Creek, CA.

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.

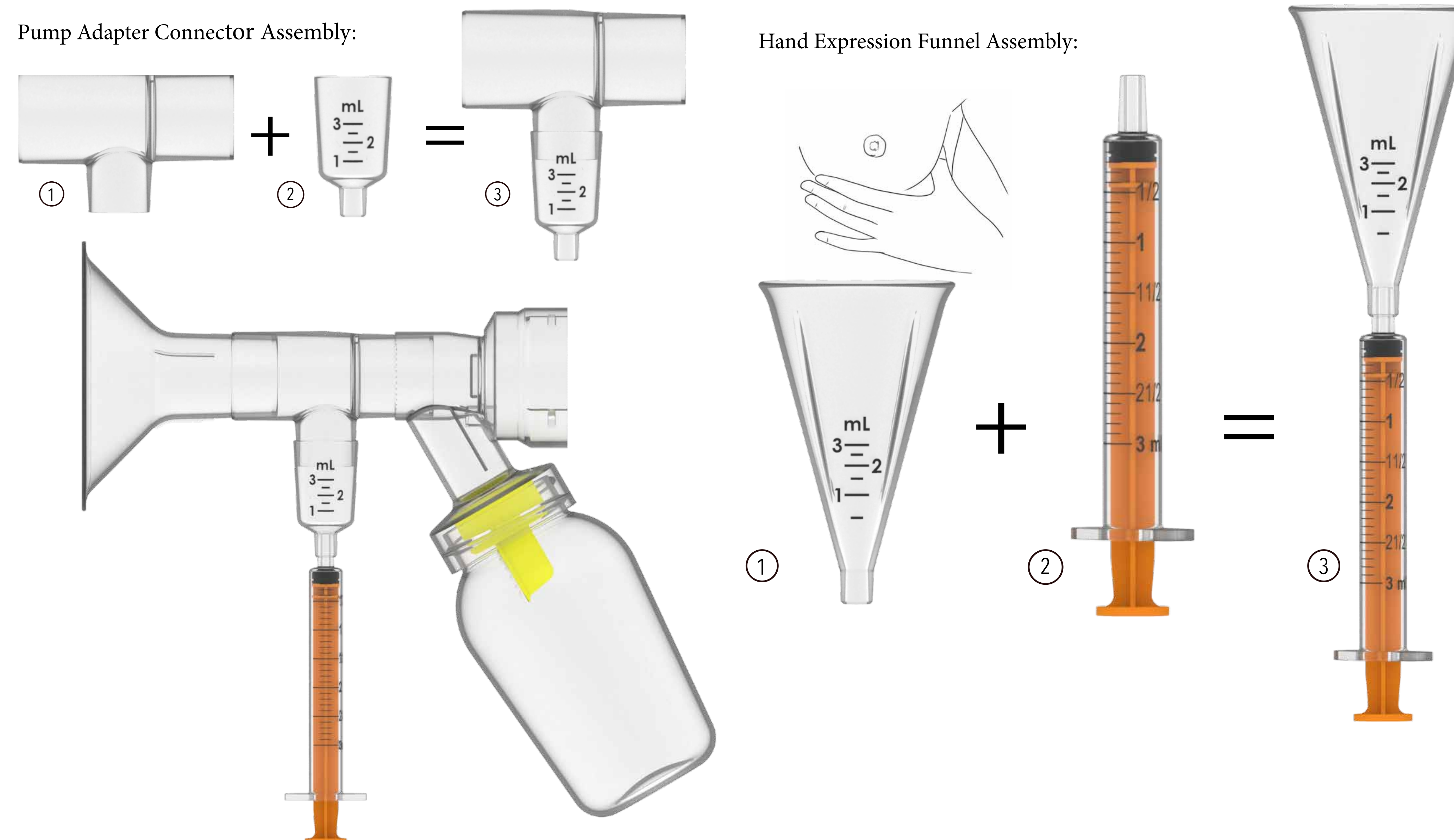
Study Design:

- 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



Across all methods, mothers found the combination of hand expression funnel and syringe (Primo-Lacto) the easiest to use ($F=8.68, p<.001$). The combination of pump, adapter and syringe (Primo-Lacto) was found to be the most satisfying ($F=9.16, p<.001$) and gave mothers the most confidence ($F=7.54, p<.001$). The adapter and syringe attachment with the breast pump (Primo-Lacto) improved ease of colostrum collection by 32% ($t=5.98, p<.001$). Nurses observed a 31% reduction in colostrum loss with the pump adapter. Nurses observed that mothers lost 43% less colostrum with the funnel compared to regular hand expression ($t=2.48, p=.007$).

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.

STUDY DATA: 30 PATIENTS

To analyze the results, I included data sets from 69 mothers from whom complete data was available. There were 91 nurses that completed full data sets. Mothers with no milk expression were excluded from analysis. The data analysis was completed by a third party with no prior knowledge or involvement in the study.

Table 1: Patient Perspective

Rated on 1-5 scale with 5 being the best rated.

	Ease	Satisfaction	Confidence
Hand Only Control	3.15	3.11	3.51
Hand & Funnel + Syringe (PL)	3.86	3.89	4.33
Pump Only Control	3.20	3.66	3.85
Pump & Adapter + Syringe (PL)	3.01	4.11	4.25

Table 2: Nurse Perspective

Ease of collection rated on 1-5 scale with 5 being the easiest, estimated colostrum loss, and collection time in minutes.

	Ease	% Lost	Collection Time (min)
Hand Only Control	3.12	12.77%	6.46
Hand & Funnel + Syringe (PL)	4.19	7.24%	6.08
Pump Only Control	3.13	13.51%	8.39
Pump & Adapter + Syringe (PL)	4.14	9.33%	7.70

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