Which Breast Pump for Which Mother: An Evidenced-Based Approach to Individualizing Breast Pump Technology

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Abstract

The majority of new mothers in the United States use breast pumps in the first four months post-birth in order to achieve their personal human milk feeding goals. Although these mothers seek guidance from health care professionals with respect to the type and use of breast pumps, there are few evidence-based guidelines to guide this professional advice. This paper reviews the evidence to facilitate professional individualization of breast pump recommendations using three categories of literature: the infant as the gold standard to which the pump is compared; the degree of maternal breast pump dependency (e.g., the extent to which the breast pump replaces the infant for milk removal and mammary gland stimulation); and the stage of lactation for which the pump replaces the infant. This review can also serve to inform public and private payers with respect to individualizing breast pump type to mother-dyad characteristics.

Keywords

Milk Expression; Breast Pump; Breast Pump Dependency; Stages of Lactation; Lactation Initiation

In the United States (US), approximately 85% of mothers with healthy newborn infants express milk within the first four months post-birth, and the majority do so using a breast pump.1 This figure does not include mothers of premature or sick infants or mothers with personal health conditions that necessitate breast pump use.2 These mothers seek guidance from physicians and nurses about the appropriate type and use of breast pumps to help them achieve their personal human milk (HM) feeding goals. Although mothers use breast pumps for different reasons, times and durations after birth, they often receive a “one size fits all” recommendation that reflects the health care provider’s personal breast pump experiences or industry marketing claims, rather than current research in this field.
The most recent Cochrane review on HM expression (defined as any non-infant method for removing HM, including both breast pump use and hand expression) included only 10 studies that enrolled a total of 632 mothers for data analysis. These studies included mothers from both industrialized and developing countries (US, UK, Malaysia, Brazil, Egypt, Kenya and Nigeria) whose reasons for HM expression varied from one-time participation as a research subject to exclusive use of HM expression due to a prematurely-born infant. The major conclusion from this Cochrane review was that the “most suitable method” for HM expression may depend on individual circumstances that were not addressed in the actual report. A more recent review on the feeding of expressed HM reached a similar conclusion, and highlighted the need to tailor the method of HM removal to the mother's purpose for not feeding directly from the breast. Thus, the health care provider is left with the recommendation to individualize the type of breast pump, but has few evidence-based guidelines to do so.

This paper addresses this gap in the literature by providing an evidence-based approach to help clinicians individualize breast pump technology to a mother's specific needs and HM feeding goals. Because the breast pump replaces the infant for purposes of HM removal and mammary gland stimulation, the breast pump should mimic the infant's sucking rate, rhythm and pressures to the greatest possible extent. Thus, the science of infant feeding is reviewed as a foundation for understanding the role of the breast pump. Second, the extent to which the breast pump replaces the infant for HM removal can serve as an organizing framework for classifying pumping mothers into three categories: minimally, partially or completely breast pump dependent. Finally, the endocrine and autocrine mechanisms that regulate lactation differ by lactation stage (initiation, coming to volume, and maintenance of established lactation) and are affected directly by the infant's sucking and HM removal patterns. Thus, the physiologic mechanisms underlying these lactation stages are summarized and implications for appropriate breast pump types and usage for different categories of breast pump dependency during these stages are detailed.

**The Pump Replaces the Infant during Breastfeeding**

A fundamental principle of breast pump use is that the pump replaces the infant for purposes of HM removal and species-specific stimulation of the mammary gland, whether breast pump use is minimal (e.g., brief separations) or complete (infant does not feed at breast). Thus, understanding the infant's role in HM removal and mammary gland stimulation is essential. There is remarkable synchrony between effective mammary gland stimulation at different stages of lactation and the sucking and feeding patterns used by healthy infants to extract HM. This synchronization provides the infant with adequate nourishment and the mammary gland with adequate stimulation. Additionally, the infant's ability to adapt the sucking rate, rhythm and suction pressure to the variable rates of HM flow during individual feedings at breast is a uniquely human feeding pattern that has not been observed in other mammals. This sophisticated plasticity of sucking and feeding patterns is more than simple HM removal, a fact that underscores the importance of adapting the breast pump and its use to the specific situation.
Infants use a combination of suction (e.g., vacuum, negative pressure that occurs with lowering of the mandible) and expression (positive pressure that occurs with closure of the mandible) when feeding from the breast.\textsuperscript{13-19} During suction, the infant uses negative pressure to create the elongated nipple shape and transfer HM from the breast.\textsuperscript{16,18} In contrast, during expression, the infant compresses the ducts in the mammary gland, \textit{which stops or slows HM transfer}, and allows the infant to safely swallow the bolus of HM and reopen the airway to breathe.\textsuperscript{16-18,20} as opposed to previously-held theories that infants transfer HM during expression.\textsuperscript{16,18,21,22}

\textbf{Hand Expression versus Breast Pump Use: The Human Infant as a Model}

The distinction between the infant’s use of suction and expression has implications for the two broad categories of HM expression techniques. Breast pumps remove HM by use of suction, as does the infant.\textsuperscript{4,23} In contrast, hand expression removes HM by compression of HM ducts in the absence of suction.\textsuperscript{3,24,25} Although hand expression is often recommended as an alternative to pumping, the few randomized trials comparing these methods have consistently demonstrated the superiority of electric breast pumps over hand expression for purposes of effective and efficient HM removal.\textsuperscript{24-29} In one randomized cross-over study, HM output, serum prolactin and serum oxytocin were compared for 23 mothers of healthy term infants who used 5 different techniques to remove HM between 28 and 42 days post-birth.\textsuperscript{24} Of the 5 methods evaluated, hand expression resulted in the least HM output, and significantly lower prolactin and oxytocin responses than the breast pumps.\textsuperscript{24}

Two randomized studies have compared hand expression with electric breast pump use. One study conducted with mothers of “sleepy term infants” who latched and sucked poorly concluded that hand expression is superior to breast pump use during the initiation of lactation, as measured by the fact that more mothers in the hand expression group (96.1\%) than in the breast pump group (72.7\%) were still likely to be “breast feeding” (by self-report) at two months.\textsuperscript{30} Of note, all mothers in this study used either hand expression or the breast pump to augment rather than replace the infant, and no measures of HM output were compared. Only one randomized study compared HM output in mothers of very low birth weight (VLBW; ≤1500 grams birth weight) infants who used exclusive hand expression (n = 12) versus a hospital-grade electric breast pump (n = 14) during the first seven days post-birth.\textsuperscript{25} Cumulative HM output for the first seven days in hand expression mothers was significantly less than for electric breast pump mothers (456 mL versus 1,317 mL). Hand expression mothers demonstrated lower median HM output throughout the following 8-28 days post-birth, despite changing from hand expression to electric breast pump during this time.

One observational study\textsuperscript{31} and one randomized clinical trial\textsuperscript{27} have suggested that the \textit{combination} of simultaneous pumping (e.g., both breasts at the same time) with an electric breast pump and breast massage, either with\textsuperscript{31} or without\textsuperscript{27} hand expression, increases HM output during pumping. However, neither of these studies tested only hand expression in the absence of simultaneous electric breast pump use. Thus, hand expression alone should not be used routinely, especially for mothers of VLBW infants who use a breast pump to replace--not to supplement--the breastfeeding infant.
Evaluating Breast Pumps: The Breastfeeding Infant as the Gold Standard

Whereas earlier breast pump evaluations primarily compared pumped HM volume and mothers’ preferences in observational or randomized designs, the early 2000’s ushered in new state-of-the-art technologies that redefined these simplistic measures. These technologies included ultrasound imaging of the term infant during breastfeeding, computerized tomography of breast fullness, and the use of accurate weighing scales to depict and measure HM ejection and flow rates. These technologies moved the research question from “Does the mother like the breast pump?” to “How does the breast pump compare to the healthy term infant during breastfeeding?”

Subsequent studies have evaluated the effectiveness, efficiency, comfort and convenience of breast pumps and breast pump suction patterns (BPSPs; computer programs embedded in the pump that integrate changes in sucking rates, rhythms and pressures), using the infant as the “gold standard” to which the pump technologies are compared. Additionally, researchers have begun to control for extraneous factors that directly impact outcome variables, but were unappreciated in earlier studies. These factors include the sizing and temperature of breast shields (the part of the collection kit that fits over the breast, which varies from a 24mm to 40 mm tunnel), vacuum pressure, and the interval since the last pumping or breastfeeding.

In particular, a new metric, the percent of available milk removed (PAMR), provided a much-improved measure for the effectiveness of HM removal, as it standardized the volume of HM removed by the breast pump to the baseline HM volume in the breast prior to pumping. Expressed as a percentage or proportion, the PAMR controls for the fact that there is substantial within- and between- mother variability in baseline HM at any single time point, and a PAMR = 80% might be 150 mLs for one mother and 50 mLs for another (or the same mother at a different time). However, the measurement of PAMR requires additional subject procedures, researcher time and research equipment (e.g., collection of pre-and post- pumping HM samples, creatatocrit measures and use of the PAMR algorithm) than measurement of absolute pumped HM volume. Thus, while it is the gold standard measure of the effectiveness of HM removal, the PAMR has not been routinely incorporated into current breast pump evaluation studies.

The efficiency of HM removal is measured by mL of HM removed per unit of time spent pumping, and has been reported in numerous breast pump studies. A healthy breastfeeding infant removes approximately 80% of the total ingested HM volume in 5 minutes and an efficient breast pump removes 85% of the available HM in the breast in 15 minutes. Although the efficiency of HM removal is not routinely evaluated in breast pump studies, it is an important consideration for mothers, especially those who must pump HM during time-restricted work breaks or several times daily for a NICU infant. In addition to breast pump type, simultaneous versus serial pumping, BPSPs that mimic the human infant during breastfeeding, and warmed breast shields improve the efficiency of HM removal during pumping.

Several studies have compared the comfort and convenience of breast pumps and BPSPs in randomized and non-randomized designs. Mothers commonly prefer one breast
pump or BPSP type over another, despite the fact that the same maximum absolute negative pressure (e.g., suction) is achieved by both. Although often minimized in marketing claims, this is a real perception and is a function of the shape and timing of the suction curve during each cycling of the breast pump. These curves determine how quickly the maximum absolute negative pressure is reached, how long it is held, and how quickly it returns to baseline during each cycle. These differences impact not only comfort but also the effectiveness and efficiency of HM removal. Finally, mothers also value highly individual features in a breast pump such as portability, quietness, ease of use, and discreet carrying cases, which allow them to fit HM removal into their daily activities. Although there is a variety of brands and models of breast pumps, they can be categorized into three primary types: manual, battery-operated and mini-electric; double electric; hospital grade electric. Table 1 summarizes the primary characteristics and highlights the differences among these breast pump types.

**Minimal, Partial and Complete Breast Pump Dependency**

The extent to which the breast pump replaces the infant for feedings is a major consideration in the selection of a breast pump because either the infant or the pump must serve as the primary regulator of lactation. Thus, a first step for the health care provider is to ascertain whether the infant or the pump is primarily responsible for HM removal and mammary gland stimulation over the course of a day. For mothers who feed healthy term infants directly from the breast, a breast pump is needed for occasional or routine brief separations from the infant, potentially including the mother's return to the workplace based on the duration of the workday. In these instances, the breast pump replaces the infant for fewer than half of daily feedings, and the infant removes HM effectively and efficiently during the remaining daily breast feedings. These mothers are minimally breast pump dependent and the breastfeeding infant remains the regulator of lactation.

In contrast, completely and partially breast pump dependent mothers rely upon the breast pump to regulate lactation either temporarily or long-term due to a variety of reasons: the inability of the infant to remove HM effectively and efficiently, lengthy separation from the infant, and maternal health problems or preferences for feeding some or all pumped HM by bottle. Mothers who are partially breast pump dependent include those with late preterm, early term and discharged NICU infants who consume small volumes of HM at the breast, slip off of the nipple frequently, fall asleep quickly after the feeding starts, and do not awaken to feed at regular intervals. If these mothers did not use a breast pump to complement HM removal and mammary gland stimulation, HM synthesis would be impaired. Thus, the pump preserves and regulates lactation so that the infant continues to consume partial and eventually complete feedings at the breast. Other mothers are partially breast pump dependent due to their own health issues. For mothers who are completely breast pump dependent, such as mothers of extremely premature infants, the pump replaces the infant as the primary regulator of HM removal and mammary gland stimulation, and often does so for weeks or months after birth. Mothers whose term infants are unable to breastfeed (e.g., craniofacial anomalies, hypotonia) or choose to provide exclusive HM by bottle are also completely breast pump dependent.
Mothers can move among the categories of breast pump dependency, so the type of breast pump they need may change. For example, a completely breast pump dependent mother with a 1000 gram infant typically progresses from complete to partial breast pump dependency during and immediately following the NICU hospitalization. However, she can progress to exclusive breastfeeding and/or minimal breast pump dependency after effective and efficient feeding at the breast has been established. Conversely, a minimally-breast pump dependent mother with a healthy breastfeeding infant can move from minimally to completely breast pump dependent if she or her infant is hospitalized or the mother-infant dyad is otherwise separated later in lactation.

In general, the more intensive and longer the breast pump dependency, the more important is the pump's effectiveness, efficiency, comfort and convenience. Hospital grade electric pumps that accommodate different sizes of breast shields, the ability to warm breast shields and the use of simultaneous versus sequential pumping meet these criteria. In contrast, personal use electric, battery and manual operated pumps, especially those restricted to sequential versus simultaneous pumping and only one breast shield size, do not meet these same criteria. Additionally, personal use pumps are not designed to be sufficiently durable for partially and completely breast pump dependent women.

**Stages of Lactation: Regulatory Mechanisms and Implications for Breast Pump Use**

The processes that regulate HM synthesis and secretion vary over the course of lactation, and these variations have important implications for breast pump use in addition to type. These phases of lactation include initiation, coming to volume and the maintenance of established lactation. The early post-birth phases of initiation and coming to volume, while time-limited, are especially important because their achievement is critical to the maintenance of established lactation and eventual exclusive HM feeding. Table 2 (supplementary) integrates degree of breast pump dependency and stage of lactation, and provides clinical examples of mother-infant dyads in each category.

**Initiation Stage**

The initiation stage, otherwise known as the transition from lactogenesis I (secretory differentiation) to lactogenesis II (secretory activation; the milk coming in; the onset of copious HM production), is an extraordinarily complex series of hormonal, anatomical and HM compositional changes that occur in the first days post-birth. Hormonally, the initiation of lactation in all mammals is triggered by the rapid decline in serum progesterone that accompanies the birth of the placenta, freeing prolactin, inhibited pre-birth by progesterone, to begin the regulation of HM synthesis. Prolactin, in combination with infant suckling, catalyzes the closure of paracellular pathways between mammary epithelial cells, with resulting retention of HM lactose in the gland. The rapid increase in HM lactose draws water into the lactocytes and corresponds with mothers' perceptions of the HM coming in. This extraordinary series of events occurs within 72 hours post-birth in healthy mothers with breastfeeding infants and is a one-time event that is critical to continued HM synthesis.
Human Infants Use Different Sucking Patterns During the Initiation of Lactation

During the initiation stage, the infant feeds at the breast using a different sucking pattern than during the coming to volume and maintenance of lactation phases. Studies of healthy term infants who served as their own controls for breastfeeding and bottle feeding of expressed HM during the first four days post-birth demonstrated that infants sucked “differently” during breastfeeding (rapid sucks with intermittent, lengthy pauses between sucking bursts) than bottle feeding, attributed to the small volume of HM available to the infant during the initiation phase. Using accurate test-weighing to measure HM intake during the first 24 hours of life in exclusively breastfed healthy infant, researchers recently confirmed that infants consumed an average of 15 mL of HM during the entire first 24 hours of life, feeding 10.2 times and transferring only 1.5 mL per breastfeed. During the next 2-3 days, the maternal HM volume increases, but the overall flow of HM remains less rapid and less consistent than during established lactation and the term infant responds by sucking faster, using stronger pressures and more pauses than when HM flow is more regular and rapid, as during bottle feeding or established breastfeeding. There is some evidence that this human-specific sucking pattern has a programming impact on the mammary gland during the initiation phase, and may be important to recreate in BPSPs.

Integrating the Initiation Stage and Breast Pump Dependency Categories

The majority of mothers who use a breast pump during the initiation phase are either partially or completely breast pump dependent, and often have health problems that increase the risk for delayed and/or failed lactogenesis II. During delayed lactogenesis II, the paracellular pathways do not close in a timely manner, so HM lactose is not retained in the mammary gland resulting in minimal HM output. Although, by definition delayed lactogenesis II is temporary, mothers who are partially or completely breast pump dependent require effective and efficient mammary gland stimulation during this time so that delayed lactogenesis II does not segue into irreversible low HM volume. A hospital grade electric breast offers effectiveness, efficiency, comfort and convenience to these mothers.

Integrating Guidelines for Breast Pump Use with Breast Pump Type in Completely Breast Pump Dependent Mothers

The timing of first breast pump use in mothers of VLBW infants has been studied in recent randomized and non-randomized studies. In a randomized study, mothers who used a hospital-grade electric breast pump within the first hour post-birth produced significantly greater cumulative HM output at Day 7 and Week 3 compared to mothers who used the same breast pump after the first hour post-birth. Recently, Parker again found that breast pump use in the first hour post-birth explained the greater HM output in breast pump-dependent mothers of VLBW infants whose first breast pump use was ≤6 versus >6 hours post-birth. An experimental initiation BPSP, created to mimic the sucking pattern of the healthy term infant during the initiation of lactation, was used only until the onset of lactogenesis II (mean = 3.1
days) in the experimental group while the control mothers used the standard BPSP that was
designed to maintain established lactation. All mothers used the standard BPSP after
lactogenesis II. Over the first 14 days post-birth, experimental BPSP mothers produced 7000
mL of HM versus 4000 mL for control mothers. Thus, interventions during the initiation
phase of lactation appear to have a long-lasting programming impact on subsequent HM
output in vulnerable breast pump dependent mothers.

Coming to Volume Stage

*Coming to volume* is the period between the onset of lactogenesis II and the achievement of
a threshold HM volume of 500-600 mL/day, typically between 4-7 days post-birth in
healthy populations of mothers and infants who breastfeed exclusively. Coming to
volume is the stage associated with the greatest risk of suboptimal breastfeeding and early,
unplanned weaning in otherwise healthy populations, and is fraught with
problems for partially and completely breast pump dependent mothers with lactation risk
factors. These adverse outcomes are understandable given that the mechanisms
regulating lactation change completely during this time.

Coming to volume ushers in a remarkable transition from the endocrine to the autocrine
control of lactation, meaning that HM must be removed effectively from the breasts in order
to be replaced. Two primary mechanisms regulate coming to volume and its
segue into the maintenance of lactation: the suckling-induced prolactin surge and the
feedback inhibitor of lactation (FIL). The suckling induced prolactin surge, wherein
the anterior pituitary secretes prolactin in concentrations up to 3-fold over baseline values
within 30-45 minutes after the beginning of feeding or pumping, is triggered only in
response to suckling and HM removal. FIL is a HM protein-mediated mechanism that
functions to down-regulate sensitivity of the alveolar membrane to prolactin when HM
remains in the breasts after feeding or pumping. FIL functions at the level of the
individual breast, meaning that HM not removed from the same breast over time reduces
HM synthesis in the individual breast, but not necessarily the other breast.

For unseparated healthy mothers with exclusively breastfed infants, the suckling-induced
prolactin surge and the FIL begin to tailor maternal HM output to the individual infant’s HM
intake during coming to volume. In contrast, mothers who are partially or completely breast
pump dependent are at risk during coming to volume. These women need a hospital-
grade electric breast pump that removes HM effectively and efficiently during this important
phase, even if the mother and infant are not separated. Among the women most frequently
overlooked for breast pump use during coming to volume are mothers of late preterm and
early term infants who are not separated in the maternity unit and are discharged home
within 2-3 days post-birth. The literature is replete with studies demonstrating that these
infants are at risk for inadequate HM intake during breastfeeding, compromising both the
suckling-induced prolactin surge and FIL and predisposing to permanent inadequate HM
output.

Similarly, completely breast pump dependent NICU mothers are at risk during coming to
volume, but for different reasons. The stress, fatigue, pain and serious maternal
illness and medications that accompany preterm/high risk birth can inhibit prolactin, and

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these mothers are especially vulnerable to non-evidence based practices (e.g., use of hand expression, setting an alarm clock to pump HM during the night) that further exacerbate this critical lactation transition. An ineffective breast pump, improperly fitted breast shields, insufficient time spent pumping, and improper suction pressures are common problems that compromise coming to volume. Use of the coming to volume assessment tool can prevent and/or identify these common problems in breast pump dependent mothers.

**Maintenance of Established Lactation Stage**

The autocrine mechanisms that control HM secretion become more mother-infant specific and efficient as lactation progresses. In particular, HM storage capacity, the ability of the mammary gland to store synthesized HM without triggering the FIL, becomes highly individualized. This individuality explains why some mothers can feed or pump significantly less frequently than others and still maintain an adequate HM output over time. Similarly, although daily HM intake (mean = 808 mL) remains relatively stable in the individual breastfed infant between 1-6 months of age, the between-infant variability is striking (463 mL-1370 mL). Furthermore, during this time, exclusively breastfed infants consume markedly different volumes of HM during individual feeds over the course of a day (0-240 mL), with most mothers having a “more productive and a less productive breast”. If a mother is not made aware of these normal fluctuations in pumped HM, it limits her ability to evaluate the suitability of a breast pump for her personal situation. This situation is especially common for minimally breast pump dependent mothers who have had limited opportunities to visualize pumped HM volume prior their return to employment outside the home.

For minimally breast pump dependent mothers, the efficiency and convenience of the breast pump often takes priority over its effectiveness and comfort, especially if the pump is chosen for employment outside the home. For most mothers, the mini-electric or double electric breast pump fulfills these criteria because the breastfeeding infant regulates lactation processes, compensating for unremoved HM by feeding effectively and efficiently during remaining daily breastfeeds. The clinician should be aware that some portable, battery operated breast pumps incorporate a double collection kit (e.g., breast shields and containers for the two breasts), but in fact operate sequentially rather than simultaneously, by alternating suction between the breasts.

Partially breast pump dependent mothers must be reminded that the pump—not the infant—provides effective and efficient HM removal and regulates lactation processes until the infant is capable of doing so. For late preterm, early term, and discharged NICU infants, this transition can occur as late as 44 weeks, corrected age. Thus, these mothers should continue the use of a hospital grade electric breast pump because of its effectiveness, efficiency and comfort to complement feedings at breast until infants consume adequate volumes of HM from the breast routinely and demonstrate adequate weight gain without additional daily bottle feeds of expressed HM. Completely breast pump dependent women are typically those with a NICU or other special needs infant or those who have decided to feed expressed HM exclusively by bottle. These mothers require the maximum...
effectiveness, efficiency, comfort and convenience provided by a hospital grade electric breast pump, especially if their individual HM feeding goal is to provide HM via pumping for several months.

Summary

Given the prevalence of breast pump use in the United States, it is important that perinatal health care providers are able to provide evidence-based recommendations about breast pump types in order to help mothers meet their individual HM feeding goals. This advice should integrate the three abovementioned categories: the ability of the pump to mimic the human infant during breastfeeding, the degree of maternal breast pump dependency and the stage of lactation for which the pump replaces the infant. This review provides extensive evidence for each of these categories and can serve as a reference for individualizing the breast pump type and use to the specific mother-infant dyad. This information can also serve as an evidence-based guide for public and private payers to insure that mothers receive a breast pump that is individualized to their specific HM expression needs.

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Table 1
Characteristics of Commonly-Used Breast Pumps

| Characteristic                        | Manual, Battery-Operated, Mini-Electric | Double Electric (Includes Personal Use Pumps) | Hospital Grade Electric |
|---------------------------------------|-----------------------------------------|-----------------------------------------------|-------------------------|
| Usage                                 | Single-User                             | Single-User                                   | Multi-User              |
| Availability                          | Purchase                                | Purchase                                      | Rental (can be purchased) |
| Collection Kit                        | Single (Sequential milk removal)        | Double (Caution: Some models feature Sequential rather than Simultaneous milk removal even with double collection kit) Limited number of breast shield sizes may be available | Double (Simultaneous milk removal) Different breast shield sizes available |
| Breast Pump Suction Pattern (BPSP) Options | Limited or no options                   | Most have adjustable suction pressures Some have adjustable rate and rhythm Some have limited embedded BPSPs that mimic the breastfeeding infant | Adjustable rate, rhythm and suction strength are standard Some have embedded BPSPs that mimic the breastfeeding infant |
| Primary Advantage                     | Convenience                             | Convenience Greater effectiveness, efficiency, and comfort than manual, battery-operated and mini-electric models | Maximum effectiveness, efficiency and comfort, but Not as portable as smaller and lighter pumps in other categories |
| Intended Use                          | Brief separations from an otherwise healthy, breastfeeding infant | Return to full-time employment outside the home Brief (1-2 days) travel separations during established lactation | Partially and completely breast pump dependent mothers during any stage of lactation Other mothers who value effectiveness, efficiency and comfort over portability |
| Not Intended For                      | Partially or completely breast pump dependent mothers at any stage of lactation | Partially or completely breast pump dependent mothers at any stage of lactation | No exclusions--can be used by any category of mother at any stage of lactation |

Note: The information in this table reflects both cited evidence and marketing guidelines for product use.
Table 2
Examples of Mother-Infant Dyads with Differing Degrees of Breast Pump Dependency during the Three Stages of Lactation

| Phase of Lactation                  | Degree of Breast Pump Dependency                                                                 |
|------------------------------------|---------------------------------------------------------------------------------------------------|
|                                    | Minimal                                                                                           |
| Initiation                         | Healthy infant who feeds at breast effectively and efficiently at least 8-12 times daily          |
|                                    | Pacifiers and bottle feeds do not substitute or replace at-breast feedings                         |
|                                    | Pump Type: None                                                                                   |
|                                    | Partial                                                                                           |
|                                    | Late preterm/early term birth                                                                     |
|                                    | Otherwise healthy term infant who does not feed consistently and effectively at breast (e.g.,  |
|                                    | sleepy baby; unsustained latch)                                                                  |
|                                    | Mother of multiples with ≥ 1 infant who feeds effectively and efficiently and ≥ 1 who does not    |
|                                    | Pump Type: Hospital grade electric                                                                 |
|                                    | Complete                                                                                          |
|                                    | Premature and/or sick infant admitted to the NICU and unable to feed at breast                    |
|                                    | Maternal illness requiring separation from infant                                                  |
|                                    | Maternal HM feeding goal to provide pumped HM exclusively by bottle.                              |
|                                    | Pump Type: Hospital grade electric                                                                 |
| Coming to Volume                   | Healthy infant who feeds at breast effectively and efficiently at least 8-12 times daily         |
|                                    | Mother may express HM for engorgement or comfort                                                   |
|                                    | Pump Type: Manual or mini-electric (or personal use electric pump if mother already has one)     |
| Maintenance of Established Lactation| Late preterm, early term or term infant who does not feed consistently and effectively atbreast |
|                                    | at least 8-12 times daily (including ≥ 1 of multiples)                                            |
|                                    | Term NICU infant who feeds at breast effectively and efficiently part of the day                   |
|                                    | Pump Type: Hospital grade electric                                                                 |
|                                    | Premature and/or sick NICU who is unable to feed at breast                                       |
|                                    | Maternal illness requiring separation from infant                                                  |
|                                    | Maternal HM feeding goal to provide pumped HM exclusively by bottle.                              |
|                                    | Pump Type: Hospital grade electric                                                                 |
| Maintenance of Established Lactation| Late preterm, early term or term infant who does not feed consistently and effectively atbreast |
|                                    | as evidenced by inadequate HM transfer (e.g., test-weights) or weight gain, and/or ineffective     |
|                                    | feeding behaviors (slipping off the nipple, falling asleep early in the feeding, not waking to   |
|                                    | feed) Maternal illness requiring separation from infant                                            |
|                                    | Mothers of NICU infants who consume some but not enough HM during breast feeding during the late  |
|                                    | NICU hospitalization or early post-discharge period                                                |
|                                    | Pump Type: Hospital grade electric until infant consumes >80% of daily feeds at breast, then      |
|                                    | personal use pump MAY BE adequate                                                                  |
|                                    | Premature and/or sick infant admitted to the NICU and unable to feed at breast                    |
|                                    | Maternal illness requiring separation from infant                                                  |
|                                    | Maternal HM feeding goal to provide pumped HM exclusively by bottle.                              |
|                                    | Pump Type: Hospital grade electric; MAY BE ABLE TO substitute personal use pump for <50% of daily |
|                                    | pumpings for convenience, if returning to employment                                               |

Note: The information in this table is an integration of cited evidence and marketing guidelines for product use.