Lactation at Work: A Wearable Breast Pump (Willow) Device Study

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1.0 Background

The American Association of Pediatrics (AAP), Healthy People 2030 (HP2030) and World Health Organization (WHO) recommend six months exclusive breastfeeding and up to two years of breastfeeding with table food. These recommendations are based upon decades of research regarding health outcomes for both the lactating parent and infant. Research shows that for the infant, the short-term benefits of lactation (described as 3 to 6 months of exclusively consuming human milk) include building important immunities against common illness in the first year of life and reducing the risk of ear infections, stomach flu, Respiratory Syncytial Virus, Crohn's disease, eczema and childhood cancers. Short-term benefits for the lactating parent include quicker recovery from giving birth, increased bonding with the infant, and lower risk of postpartum depression. Long-term lactation provides lifetime health benefits for the infant including lower risk of asthma, diabetes and Sudden Infant Death Syndrome.

Even with this evidence and education during pre- and post-natal visits with the healthcare team, it can be difficult to balance lactation, returning to work, and creating a pumping schedule. With more women in the workplace than ever before, returning to work after a birth is extremely common and employers must work to create welcoming environments for new parents.

HP 2030 has set the goal that 42.4% of infants in the United States are provided human milk exclusively for the first six months, but as of 2020 only 25.4% of infants have reached this milestone. While many parents set a goal of six months, there is a wide range of individual goals that new mothers may set based on circumstances. One of the questions asked in this study is lactation duration goal versus actual duration as we know most mothers do not reach their initial lactation goals. Providing human milk exclusively while returning to work is a monumental task that requires resources, commitment, and support. Despite the expanded protections for nursing mothers in the Fair Labor Standards Act (FLSA) in 2010 and 2022, the top three reasons lactating mothers stop pumping at work include lack of space, support from co-workers, and a flexible work schedule.

Physicians in training (also known as "House Staff" or residents and fellows), face similar barriers to other working mothers (e.g., inadequate space, support, and time); however, there are unique challenges for this group. Residents have training limitations to length of parental leave outlined by their specialty boards and do not have as clearly defined and protected time for pumping breaks as they rely on a faculty supervisor to approve breaks based on a clinical/operating schedule. Residents who work on a clinical team are expected to work an average of 60 hours per week, this may be exceeded in some specialties. The new language in the PUMP Act specifies that the employer must provide "reasonable break time" for pumping with the expectation on the employee and their supervisor to determine what that means. This places the burden on the resident to communicate and justify their needs with their supervising faculty.

Our study will evaluate the role of a wearable, cordless breast pump in helping lactating House Staff reach their lactation goals.

2.0 Rationale and Specific Aims

Our study will evaluate the role of a wearable, cordless breast pump in helping lactating House Staff reach their lactation goals. Each lactating person who enrolls will be given a Willow 360 or Willow Go breast pump. Through monthly survey data as well as downloadable pumping frequency and duration data, we will be able to track a woman's breastfeeding journey, identifying the impact of the wearable breast pumps on women reaching their lactation goals.

3.0 Animal Studies and Previous Human Studies

No animal studies have been performed as these pumps are for human use only. There have been no published studies using exclusively Willow pumps. Previous studies evaluating impact of breast pumps has not been focused on the pump type itself.

4.0 Inclusion/Exclusion Criteria

List the criteria:

- Current Vanderbilt University Medical Center House Staff member with personal or GME-provided smart phone
- Currently pregnant or recently post-partum with plans to lactate and pump once they return to work

5.0 Enrollment/Randomization

Participation will be solicited through biannual emails sent from the Graduate Medical Education (GME) office at VUMC.

Additional advertisement for the study will be done through an automated email for any pregnant person seeking parental leave. A House Staff member can indicate interest by emailing the study PI (Kathryn Sunthankar). Once they self-identify, the PI will contact them for consent and other questions for the study.

6.0 Study Procedures

After a participant indicates interest in participating, they will be contacted by the study PI to introduce them to the study and obtain consent if they wish to enroll. At enrollment they will receive a pump of their choosing (Willow 360 or Willow Go) which will be shipped from Willow to VUMC GME during the participants 3rd trimester (i.e. before delivery so the pump is available to her immediately post-partum or whenever she decides to use the pump). Upon receipt of the pump, the participant will receive an intake survey (~15-20 minute completion time).

After the participant delivers, she will indicate to the study team the date of birth of her infant. At that time, surveys will be automatically scheduled to be delivered on a monthly basis. These brief (~2 minute) monthly surveys will collect information about how the infant is being fed and pump utilization (both study-provided pump and other participant-provided pumps) and nursing.

Throughout the duration of the study there will be two focus groups that are conducted through secure Microsoft Teams link. These will be conducted by key study personnel, including Dr. Jennifer Keeton from Kansas University Medical Center. These focus groups will use questions that have already been indicated in the survey and the responses will be transcribed anonymously (participants indicated by participant #1, etc.). The first focus group will occur within the first 3-6 months of enrollment. The second focus group will occur 18-24 months after enrollment.

When the participant decides to stop pumping or breastfeeding, she will email the study PI to conclude her participation in the study. At that time a follow up phone call or in person meeting (at choice of participant), will be scheduled as part of the exit visit to see if there are any modifications to study procedures that need to be made. She will then receive an exit survey.

7.0 Risks

There is minimal risk to participants other than normally occurring risks when pumping milk. These include engorgement, nipple pain, breast pain, perceived or actual low supply, infant lack of interest in breast milk (early weaning), physical incompatibility with wearing devices, infection, or stressors that can lead to individual's cessation of pumping. The study team will work to provide education on the device and access to lactation education to minimize risk.

8.0 Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others

If there are any adverse events or unanticipated problems, participants will reach out to the study PI (Kathryn Sunthankar) at katie.sunthankar@vumc.org. Adverse events (which may include breach of confidentiality) which are serious, unanticipated, and related to the research procedures require reporting to the IRB within 7 calendar days of the Investigator's knowledge of the event.

9.0 Study Withdrawal/Discontinuation

If a participant decides to withdrawal, they will reach out to the study PI (Kathryn Sunthankar) at katie.sunthankar@vumc.org. Indications for withdrawal include no longer interested in participating, completion of lactation or subsequent pregnancy.

10.0 Statistical Considerations

This study will be largely qualitative and descriptive in nature. There is no comparison group as all participants will be receiving a wearable pump.

11.0 Privacy/Confidentiality Issues

Participants will be identified in the survey using their wearable pump serial number as their participant ID. This will be tracked throughout the duration of the study. Only the site PI will have access to information linking participants name, infant date of birth and

pump serial number. Additionally, to protect anonymity, individual data for the post survey will be reviewed to ensure there are no serious triggers in the final comments that would indicate concerns with the program or identify the participant.

Individuals that reach out to participate will be provided information on pumping with the Willows and the informed consent form at the beginning. Biographic data will be collected through the RedCap survey and only collected at planned intervals (quarterly) to assess midpoint measurements as deidentified aggregate data.

12.0 Follow-up and Record Retention

The duration of an individual subject's participation in the study will be determined by the individual. During the intake survey they will provide their expected duration and will notify the team when they have finished pumping. The monthly survey will ask users to identify if they are complete with pumping, they will then be directed to the outtake survey. The duration anticipated at enrollment is six months and a maximum of two years.