

Title: Immediate postpartum contraceptive implant placement and breastfeeding success in women at risk for low milk supply: a randomized non-inferiority trial

Principal Investigator:

Antoinette A. Danvers,

MD MBA MSCR MS

Department of OBGYN & Women's Health

1695 Eastchester Rd. Suite 306, Bronx, NY 10461

Email: adanvers@montefiore.org

Co-Investigators:

Molly Findley, DO, MPH

Phone: 718-405-8200; Fax: (718) 405-8016

Email: mfindley@montefiore.org

Jessica Atrio

Phone: 718-405-8200; Fax: (718) 405-8016

Email: jatrio@montefiore.org

Abstract:

Immediate postpartum initiation of the etonogestrel contraceptive implant has been proven to decrease rates of rapid, repeat pregnancies. Evidence supports that in healthy women with term infants initiation of the contraceptive implant 1-3 days postpartum does not appear to have any adverse effects on lactogenesis or breastfeeding continuation. However, no high quality study to date has examined the effects of progestin-only contraception in women known to be at risk for low milk supply, including women with a premature delivery, obesity, polycystic ovarian syndrome, diabetes, or a prior history of low milk supply.

Our goal is to measure the impact of timing of postpartum contraceptive implant insertion on breastfeeding success and duration. This will be a three-armed randomized non-inferiority study of women who plan to breastfeed, have known risk factors for low milk supply, and who intend to use the contraceptive implant postpartum. Women will be randomized to one of three groups for the timing of contraceptive implant placement: within 30 minutes of placental delivery, 24-72 hours postpartum, or 6 or more weeks postpartum. Women will be assessed at 6 weeks, 3 months and 6 months postpartum. Outcomes will include time to lactogenesis II, duration and exclusivity of breastfeeding, continuation of and satisfaction with the contraceptive implant, and side effects, including bleeding patterns, associated with the implant.

Findings from this trial will be used by clinicians, hospital systems, and policy makers working to expand access to immediate postpartum implants while supporting women in meeting their breastfeeding goals.

Specific Aims

Our goal is to measure the impact of timing of postpartum contraceptive implant insertion on breastfeeding success and duration and to explore women's experiences with and attitudes towards contraceptive and breastfeeding counseling in the peripartum time period.

Specific Aim 1: To compare time to lactogenesis stage II among women randomized to receive the contraceptive implant within 30 minutes postpartum, 1-3 days postpartum and 6 or more weeks postpartum, utilizing a validated measure

Specific Aim 2: To assess rates of breastfeeding continuation, exclusivity, and satisfaction as well as device continuation and method satisfaction at 6 months postpartum among women who were randomized to receive the contraceptive implant within 30 minutes postpartum, 1-3 days postpartum and 6 or more weeks postpartum, utilizing a validated measure

Rationale

Immediate postpartum initiation of the etonogestrel contraceptive implant has been proven to decrease rates of rapid, repeat pregnancies¹. Evidence supports that in healthy women with term infants initiation of the contraceptive implant 1-3 days postpartum does not appear to have any adverse effects on lactogenesis or breastfeeding continuation². However, no high quality study to date has examined the effects of progestin-only contraception in women known to be at risk for low milk supply, including women with a premature delivery, obesity, polycystic ovarian syndrome, diabetes, or a prior history of low milk supply^{3,4}. Preventing unintended pregnancy in this population of women is particularly important, as many of the conditions that put women at risk for difficulty with breastfeeding also increase the likelihood of a medically complex pregnancy with poorer outcomes for both women and infants. Clinicians, hospital systems, and policy makers working to expand access to immediate postpartum implants and desiring to support women in meeting their breastfeeding goals need quality evidence to guide them when offering immediate postpartum implants to some of their most medically complex patients⁵.

It is unclear if the specific timing of immediate postpartum implant initiation may have an effect on breastfeeding success. Theoretically, exposure to progesterone prior to the establishment of lactogenesis may interfere with the successful establishment of a milk supply⁶. In creating work flows to increase access to postpartum implants, placing an implant within 30 minutes of delivery may be the most efficient and streamlined option for many settings. However, no data exists on the effect of initiating a contraceptive implant prior to 1-3 days postpartum on the timing of lactogenesis or breastfeeding duration.

Research Design and Methods

Research Design and Study Subjects

This will be a three-armed randomized non-inferiority study of women delivering at the Weiler Hospital of the Albert Einstein College of Medicine who plan to breastfeed, have known risk factors for low milk supply, and who intend to use the contraceptive implant postpartum. Women will be randomized to one of three groups: device placed within 30 minutes of placental delivery, 24-72 hours postpartum, or 6 or more weeks postpartum. All study activities will adhere to the CONSORT guidelines for reporting randomized trials.⁷ Women will be assessed at enrollment, 1-5 days postpartum, 6 weeks, 3 months and 6 months postpartum.

Eligibility Criteria will include:

- 1) Live pregnancy of at least 24 weeks gestation
- 2) Intention to use a contraceptive implant postpartum
- 3) Intention to use a non-hormonal bridging method of contraception until a contraceptive implant can be placed
- 4) 18 years of age or older
- 5) English or Spanish speaking
- 6) Women will be enrolled either during prenatal care or upon admission to Labor and Delivery.
- 7) Absence of pain. Among women who are being enrolled on Labor and Delivery MUST fall into one of the three following categories:
 - Women presenting for induction of labor. Women will be approached and enrolled prior to the onset of labor.
 - Women presenting for a planned cesarean delivery. Women will be approached and enrolled prior to entry into the operating room.

- Women who have an Epidural in place for management of pain. Prior to engaging in a discussion regarding the study protocol, women will be asked if they are experiencing any pain, and if the answer is yes, they will not be eligible for entry into the study.

7) Presence of at least one of the following conditions known to be a risk factor for low milk supply:

- Expected delivery prior to 37 weeks
- Obesity (pre-pregnancy BMI >35)
- Polycystic Ovarian Syndrome
- Diabetes (gestational or pre-gestational)
- Self-reported difficulty with low milk supply in past

Setting and Population

Efforts will be made to identify and recruit eligible women during their prenatal at outpatient Montefiore Health Centers affiliated with the Weiler Hospital of the Albert Einstein College of Medicine in the Bronx, NY. The Bronx is home to the poorest congressional district in the country, and the worst healthcare outcomes in New York State⁸. One in three adults in the Bronx is obese⁹, and in the poorer neighborhoods a full 61% are either obese, diabetic, or both¹⁰. In 2013, there were 4023 deliveries at Weiler Hospital, most to poor women of color (Table 1).

Table 1: Demographics of women delivering at Weiler Hospital in 2013

| Age | | Race | | Ethnicity | | Insurance Type | |
|-------|-------|---------------------------|-------|------------------------|-------|-----------------------------|-------|
| <20 | 7.1% | Black or African American | 31.3% | Hispanic or Latina | 48.9% | Medicaid and Self-Pay | 64.7% |
| 20-30 | 57.7% | White | 11.0% | Non-Hispanic or Latina | 45.9% | Private Insurance | 35.3% |
| >30 | 35.2% | Asian | 3.4% | Declined | 5.2% | Socioeconomic Status | |
| | | Multiracial | 41.5% | | | Below NYS Average | 91.2% |
| | | Declined | 12.8% | | | Above NYS Average | 8.8% |

Since July of 2014 immediate postpartum initiation of LARC devices has been available to all medically eligible women at Weiler Hospital. Currently we place approximately 100

devices, including 60 implants each month. As the tertiary referral center in a vulnerable and high-risk community, it is reasonable to estimate that at least 50% of the women who deliver at Weiler Hospital have at least one risk factor for low milk supply.

Recruitment

For women who receive prenatal care within the Montefiore system, the recruitment process will start during their prenatal visits. It is a routine part of prenatal care for women to get contraceptive counseling and education about the benefits of breastfeeding. Flyers and brochures advertising the study will be made available to all clinical sites providing prenatal care and to all prenatal care providers. Women will have the opportunity to review these materials, contact the research team with any questions, and review the consent form prior to admission to labor and delivery if they desire. Women who are interested in enrolling in the study will be identified by prenatal care providers and research study staff will call the women and provide information about the study. Women will have the opportunity to consent for participation into the study over the phone. In these cases, a pop-up message will be created in EPIC to alert the study team when this patient present for admission to Labor and Delivery. Once these women present to Labor and Delivery they will also be asked to sign a study consent form and reaffirm their desire to participate in the study. They will be randomized into the trial only once they present to Labor and Delivery and reaffirm their desire to participate in the trial.

It is standard practice at Montefiore to counsel all women on admission to Labor and Delivery about their contraceptive options, including immediate postpartum IUDs and implants upon admission. This counseling is provided by the admitting resident, PA or faculty on Labor and Delivery. The admitting team routinely reviews and documents a contraceptive plan and breastfeeding intentions for each woman admitted to labor and delivery. The study's research coordinators will review the patients admitted to Labor and Delivery regularly (1-3 times daily) in order to identify women eligible for participation in this trial. Only those women who have a documented intention to use a contraceptive implant postpartum will be approached by the study team for possible enrollment into the trial.

Women will be enrolled, consented and randomized on Labor and Delivery, prior to delivery. The study brochure will be included in the standard educational materials provided to all women on admission to Labor and Delivery. All enrollment and screening will be done in private labor and delivery rooms and all measures will be taken to ensure patient privacy. Women will be explicitly told that their participation in this trial is voluntary and that they have the option of receiving a contraceptive implant at any of the time points included in this study if they decline participation in this trial. Only co-investigators who have completed CITI training and who are intimately familiar with the study protocol will be approaching or enrolling patients into the trial.

During the informed consent process, women will receive standardized contraceptive counseling, including information about the contraceptive implant and its potential effects on breastfeeding. Women who are eligible for the trial and interested in participating will be enrolled and randomized in a 1:1:1 ratio to one of the three groups to determine their timing of contraceptive implant placement. Participants will be assigned using computer-generated random numbers in blocks of varying sizes with strict allocation concealment using sequentially numbered opaque envelopes. Women will be informed of their randomization group at the time of enrollment into the trial.

Women randomized to receive the implant within 30 minutes of delivery will have the implant placed in the delivery room or operating room within 30 minutes of placental delivery. Placement of the implant will not interfere with any skin-to-skin interactions that are currently routinely encouraged for the mother and infant after every delivery. Women randomized to receive the implant within 1-3 days of delivery will have their implant placed on the postpartum unit more than 24 hours after delivery, but prior to discharge from the hospital. Women randomized to receive the implant at 6 or more weeks postpartum will be scheduled for an outpatient visit with the family planning clinic at 6-8 weeks postpartum for implant placement.

Study Procedures

Follow-up and data collection for participants in all three groups will be identical. In order to achieve specific aim 1, time to lactogenesis stage II will be measured based on maternal perception based on measures described and validated by Chapman et al¹² and utilized in a similar study by Gurtcheff et al.² Beginning on the first postpartum day,

subjects will be contacted daily. Subjects will be asked, “Has your milk come in? Some women experience this as a prickly feeling or tingling in the breast, dripping from the other nipple when nursing, milk running from the baby’s mouth, or gulping by the baby. ” If the response is positive, women will then be asked, “When did your milk come in?” and the response recorded to the nearest hour. If lactogenesis has not occurred prior to hospital discharge, the patient will be contacted at least daily by their preferred method (phone, text or email) from study personnel until lactogenesis can be confirmed and recorded.

To achieve specific aim 2, women will complete study follow-up questionnaires at 6 weeks, 3 months and 6 months postpartum either by phone interview or by electronic web-survey, depending on the participant’s preference. These questionnaires will assess breastfeeding status, exclusivity and satisfaction as well as contraceptive method continuation, satisfaction, and side effects, including bleeding. Women will be asked to contact the study coordinators when they stop breastfeeding or if they discontinue the contraceptive implant.

Recruitment, Follow-up and Retention.

Successful recruitment, follow-up and retention represents the most significant challenge to the completion of this project. The population of women we intend to enroll is socioeconomically disadvantaged and has high rates of non-adherence to postpartum care. Only 43% of women who deliver at Weiler attend a postpartum visit within 12 weeks of delivery. While this is a difficult to study population, they are also the women who may benefit the most from access to immediate postpartum contraception as attendance at a postpartum visit clearly represents a significant barrier to care for most of these women. Dr. Bonuck has a proven track record of successfully following women in this specific community in the immediate postpartum period. She served as the principal investigator on a set of trials examining the effects of a primary care intervention on breastfeeding outcomes¹³. During these trials she successfully recruited and followed a cohort of postpartum women from our institution and has developed a set of proven strategies for ensuring high levels of retention among a population of women with historically high attrition rates¹⁴. We intend to use the following specific strategies:

- 1) Strong Rapport with the Participants

- a) Research Coordinators (RC) will visit the women enrolled in to the study at least twice during their postpartum admission to encourage rapport building
 - b) RCs will maintain regular contact with participants throughout the follow up period via text and email. Reminders will be emailed and texted in the weeks prior to any scheduled follow-up.
 - c) RCs will send birthday ECards for all the study participants.
 - d) Participants will be provided with business cards and other items (pens, magnets) containing the RC cell phone number and study contact information.
- 2) Convenience for the Participants
- a) Brief- Upon final pilot testing the follow-up questionnaires will take < 15 minutes to complete.
 - b) Flexible methods- Participants will have the option of completing the follow-up questionnaires via phone or web survey.
 - c) Flexible hours- Women will indicate their preferred times to be called, including nights and weekends
 - d) Bilingual- All written study materials will be available in both English and Spanish. The RCs will be bilingual.
- 3) Educational and Appropriate Materials and Questionnaires
- a) The interview scripts and questionnaires will be developed to utilize non-judgmental language. The scripts and questionnaires will be piloted for content, clarity, and appropriateness prior to beginning enrollment.
 - b) Educational materials regarding contraceptive options and breastfeeding support will be made available to all women participating in the cohort. Study personnel will be available to answers women's questions regarding their breastfeeding and contraceptive options.
- 4) Strategies for Maximizing Retention
- a) Multiple Contacts- Upon enrollment, we will obtain all potential contact options for the woman that she is willing to share (cell and home phone numbers, home address, and email), as well as contact information for at least three other people.
 - b) Research Coordinators will send out texts, emails and postcards to alert participants if they were unable to be reached for an interview.
- 5) Patient Incentives

- a) Women will be given \$50 at enrollment and \$30 for completion of each subsequent follow-up questionnaire. Incentives will be disbursed using debit cards that allow money to be transferred electronically, allowing the women to have access to the money within 24 hours of survey completion. This dollar amount is in line with other projects that have had >90% retention over one year in our Bronx population.

Sample Size

To achieve specific aim 1, we chose a non-inferiority margin of an additional 8 hours to achieve lactogenesis II, as this would be clinically relevant. In order to achieve 80% power, using a one-sided Type 1 error of 5%, and with a standard deviation in time to lactogenesis of up to 18 hours^{15,16}, 63 women would be needed in each group, for a total of 189 women.

To achieve specific aim 2, larger sample size will be required. Prior studies in our population have found that breastfeeding continuation rates at 6 months postpartum are 27%¹³. Assuming a non-inferiority margin of 15%, to achieve 80% power using a one-sided Type 1 error of 5%, we would need to enroll 109 women per group, for a total of 327 women total. Assuming a 15% loss to follow up rate, we will enroll 375 women total, 125 in each group. This recruitment goal will be met over an 18 month time period and is attainable based on the approximately 60 implants placed each month on the Labor and Delivery and Postpartum units.

Risks and Benefits

Answering Questions during Enrollment or at Follow-up: Women may feel uncomfortable answering questions about breastfeeding and birth control. Women can choose not to answer questions that make them feel uncomfortable. All interviews that are done in the hospital setting will be done in a private room (all patient rooms on Labor and Delivery or on Postpartum are private), with the door closed. For follow-up, women will be able to choose if they complete the questionnaire over the phone, at a time convenient for them, or via a web-based HIPPA secure survey generated through REDCaps.

Insertion of the Implant: Choosing to enroll in this study means that women will be assigned to one of three time points for contraceptive implant initiation after delivery, as opposed to receiving it at a time of their own choosing. Currently all women delivering at Weiler are routinely offered immediate postpartum initiation of the contraceptive implant at all the time points being studied as a part of this protocol. Insertion of the implant is a very safe procedure with risks comparable to a blood draw or IV placement. Having the implant placed as part of this study does not confer any additional or different risk associated with the insertion procedure than if the implant was placed at any other time.

Breastfeeding: Currently all available data regarding breastfeeding and the implant demonstrate that immediate postpartum initiation of the implant does not have any effect on breastfeeding establishment, success, or duration. Prior studies have not specifically looked at women who have risk factors for low milk supply, however, the CDC, ACOG, and institutional guidelines do support the use of the implants in the immediate postpartum period for this population. Currently the routine practice at Montefiore is that all women are offered immediate postpartum placement of a contraceptive implant. All women are counseled that current evidence does not demonstrate that the implant would have any effect on breastfeeding, but that data is limited, especially for women with risk factors for low milk supply. This study does not confer any additional risk to breastfeeding women over our current routine practice but will allow those women who are enrolled into the trial to have more ready access to providers and community resources for breastfeeding support.

Analysis Plan

The following outcomes will be evaluated using T-tests and include: exclusive breastfeeding continuation, any breastfeeding continuation, implant continuation. Additional secondary outcomes include side effects and tolerability of the implant, vaginal bleeding patterns, and contraceptive use. To evaluate these secondary outcomes between the two groups we will use the T-test, Wilcoxon Rank Sum test, Chi-squared test, or Fisher's exact test as appropriate.

Data and Safety Monitoring

Patient safety will be monitored continuously by the research team. Given that each of the study interventions is currently considered standard of care at Montefiore, a Data

Safety Monitoring Board is not needed for this trial. The principal investigator and research team will actively review all outcomes for the patients throughout the course of the study, and identify potential adverse events experienced by study participants and report them to the IRB as required by local standards. The PI will be responsible for reviewing these reports and making the final determination of relatedness, reporting to the IRB, and taking relevant actions as needed.

Adverse Event

An **adverse event** (AE) is any symptom, sign, illness or experience that develops or worsens in severity during the course of the study.

A number of adverse events are expected in the course of the management of labor and postpartum including: pain, bleeding, fevers, chills, nausea, vomiting, diarrhea, dizziness, and endometritis. The only non-serious events that will be specifically collected by the research-team and classified as AEs for this study are those that are both unexpected and considered to be related to study procedures or study drug. All adverse events will be collected, recorded, and assessed locally by the PI or research-team. Events that are determined to be both unexpected and related to the study will be reported and reviewed.

Serious Adverse Event

Adverse events are classified as serious or non-serious. A **serious adverse event** is any AE that is:

- fatal
- life-threatening
- requires or prolongs hospital stay
- results in persistent or significant disability or incapacity
- a congenital anomaly or birth defect
- an important medical event

Important medical events are those that may not be immediately life threatening, but are clearly of major clinical significance. They may jeopardize the subject, and may require intervention to prevent one of the other serious outcomes noted above.

All serious adverse events will be reported to the principal investigator.

Adverse Event Reporting Instructions

Any serious adverse event whether or not it is considered related to the study, will be reported by telephone, email or fax within 24 hours of awareness to principal investigator:

Antoinette A. Danvers Email: adanvers@montefiore.org

The investigator will compile a serious adverse event form and the case will be discussed within 48 hours with the study team. A SAE form will be completed for any SAE that is experienced after the subject has signed the Informed Consent Form.

The Principal Investigator will submit updated SAE. The Principal Investigator will evaluate women who experience a SAE as necessary until the event is resolved.

The principal investigator will report adverse events for review by the IRB per local reporting requirements.

Adverse Event Reporting Period

The study period during which adverse events must be reported is normally defined as the period from the initiation of any study procedures to the end of the study treatment follow-up. For this study, the study treatment follow-up is defined as 6 months postpartum.

Post-study Adverse Event

All unresolved adverse events should be followed by the investigator until the events are resolved, the subject is lost to follow-up, or the adverse event is otherwise explained. Before discharge, the investigator should instruct each subject to report any subsequent event(s) that the subject, or the subject's personal physician, believes might reasonably be related to participation in this study.

Study Stopping Rules

If more than 30% of women in any study group have primary lactation failure and are unable to achieve lactogenesis the study will be temporarily stopped and the data reviewed to determine if it reasonable to continue the study.

Data Quality

Personnel Selection and Training

The primary investigator and the research team will be responsible to complete the monitoring process as these individuals have experience in the conduct of clinical research and familiarity with research regulations. Furthermore, they are well aware of safety and adverse event review and reporting, the study protocol, the study database, the informed consent forms and processes and this monitoring plan.

Frequency

Enrollment will be complete when 375 subjects are enrolled into the trial. Approximately 25 subjects will be enrolled per month. The research team will review the study database and cross check to the medical record for accuracy. Quality assurance will be conducted periodically throughout the study as described below:

- The first time-point of review will occur after the first 5 subjects have been enrolled.
- If no issues of concern are noted, subsequent quality monitoring will occur at least every 6 months by 2 persons on the research team. All findings will be discussed with primary investigator and any concerns will be shared with members of the safety monitoring board.
- The final point of review will be conducted when 100% of the subjects have been enrolled and completed the study.

Additional quality data check may occur on an as-needed basis as determined by the principal investigator.

Data Quality Checks

All database entries for all the subjects at each site will be source data verified. Special attention will be given to the following variables and will be 100% source data verified for *all* subjects enrolled in the study.

- Informed Consent
- Inclusion/Exclusion Criteria
- Serious Adverse Events
- Primary Outcomes/Endpoint Data Verification

Data Management

REDCap (Research Electronic Data Capture) is a secure web application for building and managing online surveys and databases. We will use REDCap software to create data collection forms, generate HIPPA secure web links to the follow-up questionnaire, complete double data entry and manage all data from the study. Only the research coordinators and investigators will have access to the study charts and to the REDCaps database.

Study Close Out

The principal investigator and research team will conduct the study close out at the time of the final within 3 months after the last patient has completed the study.

The following activities will be completed by the PI to close out the study:

- Ensure all data has been reviewed and collected;
- Ensure all outstanding queries are answered;
- Confirm all Serious Adverse Events, if applicable, have been reported to the IRB(s) and the FDA;
- Ensure all protocol violations were submitted to the IRB per local requirements;
- Ensure that all continuing review reports were submitted to the IRB.

Links with Other Projects

Montefiore is part of the New York City Department of Health and Mental Hygiene's consortium for Quality Improvement Network for Contraceptive Access¹⁷. Participation in this consortium is an opportunity for hospitals to get support and technical assistance to increase their access to contraception and LARC. Montefiore is a leader in the region, and through this consortium our policies and procedures have been made available to other hospitals seeking to increase contraceptive access. The results of our proposed

study will inform local hospital policies and city initiatives that support breastfeeding while increasing LARC access postpartum.

Expected Outcomes

The findings from this study will inform clinical practice, national guidelines and policies regarding postpartum use of the etonogestrel contraceptive implant and breastfeeding safety for women at risk for low milk supply.

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Project Timeline

YEAR 1: 2016-2017

| | Jul | Aug | Sep | Oct | Nov | Dec | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep |
|-----------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| IRB submission and approval | X | X | X | | | | | | | | | | | | |
| Pilot Data Collection Forms | | X | X | | | | | | | | | | | | |
| Database Development | X | X | X | | | | | | | | | | | | |
| Recruitment and Enrollment | | | | X | X | X | X | X | X | X | X | X | X | X | X |
| 6 week follow up | | | | | X | X | X | X | X | X | X | X | X | X | X |
| 3 month follow-up | | | | | | | X | X | X | X | X | X | X | X | X |
| 6 month follow-up | | | | | | | | | | X | X | X | X | X | X |
| Data Entry | | | | X | X | X | X | X | X | X | X | X | X | X | X |

YEAR 2: 2017-2018

| | Oct | Nov | Dec | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec |
|----------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Recruitment and Enrollment | X | X | X | X | X | X | | | | | | | | | |
| 6 week follow-up | X | X | X | X | X | X | X | X | | | | | | | |
| 3 month follow-up | X | X | X | X | X | X | X | X | X | | | | | | |
| 6 month follow-up | X | X | X | X | X | X | X | X | X | X | X | X | | | |
| Data Entry | X | X | X | X | X | X | X | X | X | X | X | X | | | |
| Data Cleaning and Analysis | | | | | | | | | | | | | X | X | |
| Manuscript Writing | | | | | | | | | | | | | X | X | X |
| Grant Preparation | | | | | | | | | | | | | X | X | X |