Uniformed Services University of the Health Sciences
CONSENT TO PARTICIPATE IN RESEARCH

Title: *Patient-Applied Pretreatment Analgesia for Intrauterine Device Placement (PAP AID)*
Principal Investigator: *Michael J. Arnold, MD, CAPT, USN*

You are being invited to take part in a research study. This form gives you important information about the study.

Please take time to carefully review this information. You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or personal physician) about participating in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without affecting this procedure or any other care you receive.

1. KEY INFORMATION:

This study is looking at an intervention to reduce the discomfort associated with Intrauterine Device (IUD) insertion. Our study is investigating whether a topical numbing medicine applied to the cervix with a tampon reduces the discomfort and improves the ease of the procedure. Studies suggest that applying the medication to the cervix during the procedure reduces discomfort, but only if there is a significant time between the application and the procedure.

This intervention appears to be beneficial in a small group of patients, but we need to perform a trial to see if it is truly helpful. Because of this, you may be placing topical lidocaine or an inactive substance. Neither you nor your provider will know.

If you participate, you will go to the clinic prior to the procedure to pick up the study materials and instructions. Since you have to come in prior to the procedure for pregnancy testing, this will just add a step. About an hour prior to the appointment time, you will open the tampon provided, dip the deep end in the material provided and place the tampon according to instructions provided. You will remove the tampon while changing for the procedure.

After the procedure, you will be asked two questions about your experience.

Potential benefits to you in this study are primarily the possibility of reduced discomfort, although the benefit is unproven and you may have the placebo. Potential risks to participating include discomfort from the tampon placement, discomfort from the gel against the vagina and cervix and more serious reactions including allergic reactions and a rare condition called methemoglobinemia that can cause shortness of breath, fatigue and lightheaded. Mothers who are breastfeeding may want to avoid this study because it is not known if lidocaine enters breastmilk. The alternative to participating in this research study is to simply decline to

participate. Participation in this study is entirely voluntary. Your decision will not affect your care at your local military treatment facility or within the Military Health System. If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

The purpose of this research study is to determine whether patient applied topical lidocaine (a numbing medication) reduces discomfort or improves the time and/or ease of performing an IUD insertion. We are also verifying that medication placement with a tampon is something patients are willing to do.

It is expected that 120 people who desire an IUD for contraception or control of their menstrual cycle will be enrolled for this study.

3. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

You have already spoken to our research coordinator, who will explain the study and answer any questions. The research coordinator will arrange for you to pick up the study materials prior to the procedure.

After picking up the study materials, you will be asked to apply the medication using a tampon per the instructions provided. The instructions should be clear enough, but please feel free to contact the research coordinator if you have questions.

Your provider may recommend that you take a medication prior to the procedure to reduce pain. Taking these medications will not interfere with this study.

The research materials you are given will include a research form that will have your research number but not your name, and you will give this form to the medical assistant who checks you in for the appointment. Your pain and procedural difficulty, the procedure time, and the provider assessment will be recorded on this sheet under your study number only. Your provider will return this form to the study team.

After you complete the procedure and provide your assessment, the study is done. The research coordinator may contact you for more opinions and suggestions surrounding the procedure.

4. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, there is a risk of:

Tampon Placement. You may experience some discomfort during the tampon placement, and

possibly a burning feeling after placement from the medication or placebo. This is generally a mild discomfort. Other risks include:
• Abrasion (injury to the skin)
• Bruising
• Pain
• Discomfort or pain with intercourse (dyspareunia)

Lidocaine Topical solution from the tampon

Side effects from lidocaine are similar to those observed with other local anesthetic or numbing agents. Most side effects occur either from a high dose or an allergic reaction , with the following most commonly reported:

1. Allergic reactions – These include skin lesions, hives, swelling or more serious reactions. People with a history of allergy to local anesthetic medications should not participate in this trial. Also, people with cuts or injuries in and around the vagina should not participate because this would increase the dose that gets into the bloodstream.

2. Methemoglobinemia – Methemoglobinemia is a rare but serious condition that can be caused by many medications, including local anesthetics. Methemogobinemia affects your body's ability to move oxygen and can result in: pale, gray, or blue colored skin (cyanosis); headache; rapid heart rate; shortness of breath; lightheadedness; or fatigue. With any of these symptoms, immediately remove the tampon and contact your doctor.

Nursing Mothers – Like many medications, it is not known whether lidocaine is excreted in human milk. Caution is recommended in breastfeeding. Both topical and subcutaneous lidocaine are commonly used for pain control in breastfeeding women for procedural analgesia.

Tampon Removal. Some people have mild discomfort with tampon removal.

IUD Placement. The IUD placement procedure has its own risks, which your provider has discussed with you. The medication placement should not affect these risks.

Confidentiality. Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your research study records or other information researchers have stored about you. As described in the "Who Will See My Information (Privacy) And How Will It Be Protected (Confidentiality)?" section below, every effort will be made to protect your privacy and confidentiality.

Reportable Events. All medical interventions can have unexpected impacts. Any events that have the possibility of negatively affecting you and might be related to this study will be reported to the study team and evaluated by a research monitor who is not a part of the study team.

You could feel like you have to take part in this study because you are in the military or because someone you know has endorsed it. Please don't join this study if you don't want to. This study is

entirely voluntary, so your choice to participate is entirely and only your decision.

There may also be other risks of taking part in this study that we do not yet know about.

5. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

The possible benefits to you as a research participant in this research study are reduced discomfort and a more rapid or easy procedure. However, there is no guarantee that you will benefit from being in this research. Others may benefit in the future from the information learned during this study.

6. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

Since this is an unproven intervention for IUD insertions, the alternative is to not use the tampon-applied medication.

Some providers recommend taking an over-the-counter pain medication such as ibuprofen or acetaminophen prior to the procedure to reduce discomfort. You can take these medications whether you take part in this medication or not.

Choosing not to take part in this research study is always an option.

7. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

No, there is no compensation provided.

8. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

9. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Michael J. Arnold, MD, CAPT, USN; (Tel) 301-295-3630

10. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

Uniformed Services University of the Health Sciences

As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

11. SOURCE OF FUNDING:

This study is being paid for by a grant from the American Academy of Family Physicians Family Medicine Discovers Rapid Cycle Scientific Discovery and Innovation (FMD RapSDI) program.

12. LOCATION OF THE RESEARCH:

This research is being conducted by Family Medicine faculty at the Uniformed Services University of the Health Sciences (Bethesda, MD), Walter Reed National Military Medical Center (WRNMMC) and Military Family Medicine clinics that work with the University.

13. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

The Uniformed Services University of the Health Sciences and their affiliated research team members do not have any financial or personal conflicts of interest to disclose.

14. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at:
https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf

The research team will keep your research records. These records may be looked at by staff from the Uniformed Services University (USU) Institutional Review Board (IRB) and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

This form, which has your name on it, and any contact information you provide will be stored separately from the research data collected during the procedure. All study data will be assigned a unique identification number and will not be identified by names or anything piece of information that people could use to identify you (e.g., your birthday). The research data will be available to the investigators and research team members participating in this study at the Uniformed Services University of the Health Sciences. Those listed will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

If applicable, a description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This web site will not include information that can identify you. At most, the Web site will include a summary of results. You can search this Web site at any time.

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

15. LONG TERM USE OF DATA

The investigator has requested to save selected data collected from your participation in this research study for possible use in future research. Data will have anything that might identify you removed; it will be de-identified—not personally identifiable. Information gained from your participation in this research study will be published in journals, discussed for educational purposes, and used generally to further science. Research that uses the information you provide may lead to the development of new inventions, products, or discoveries (some that might be patented and licensed); there are no plans to share any potential profits with you. You will not be personally identified; all information will always be presented as anonymous data. After all data has been collected from you, any documentation linking your identity to your data will be destroyed.

Data that we obtain from you for this study might be used for future studies, in the same area as the original study or it may be for a different kind of study. If we do so, data may then be used for future research studies or given to another investigator without getting additional permission from you. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

Any future research using your retained data will require a research protocol for the proposed study approved by an Institutional Review Board (IRB) (a committee responsible for protecting research participants) or other authorized official responsible for protecting human subjects of research. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

16. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

17. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you have numerous options:

1. Notify the research coordinator who performed virtual consent.
2. Notify the Primary Investigator.
3. Notify the Local Coordinator.

4. Don't pick up study materials prior to the IUD insertion.

5. Notify the provider or support staff that you don't want to participate when reporting for the procedure.

The principal investigator of this research study may terminate your participation in this research study at any time if he determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

18. CONTACT INFORMATION:

Principal Investigator (PI)
The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Michael Arnold
Phone: (301) 295-3630
Mailing Address: 4301 Jones Bridge Rd, Bethesda, MD 20814

USUHS Human Research Protection Program (HRPP) Office
The Human Research Protection Program Office Point of Contact and/or Human Protections Administrator (HPA) at USUHS will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Administrator: Petrice B. Longenecker, PhD, MA, CIP
Phone: (301) 295-3303

Institutional Review Board (IRB) Office
If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Office at:
(301) 295-3303, 4301 Jones Bridge Rd, Bethesda, MD 20814

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

SIGNATURE

Your signature documents your consent to participate in this research. I agree that I have been provided time to read the information describing the research study in the consent form and have done so. I have been provided with the opportunity to ask questions, and all of my questions have been answered to my satisfaction.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Research Subject

_____ _____
Signature of Research Subject Date

SIGNATURE OF RESEARCH COORDINATOR

_____
Printed Name of Research Coordinator

_____ _____
Signature of Research Coordinator Date