Progesterone in Pregnancy

We suggested you have your progesterone level checked because you have a history that is suggestive of low progesterone and/or there is something about your current pregnancy indicating a possible progesterone deficiency. The lab result have returned and we've suggested progesterone therapy, which has understandably created some questions on your part. This document is intended to help you understand the biology and the philosophy behind our recommendation for progesterone supplementation therapy. It is no substitute for a face-to-face conversation with us, but it is intended to expedite the process and get you started on the therapy we believe you and your baby need as quickly as practical. As with every aspect of your care, the decision of what is best for you and your baby is yours to make. We are recommending that you begin progesterone supplementation therapy, but if after reviewing this material you are not comfortable initiating therapy and/or you would prefer waiting until you can discuss it with one of the providers by phone or in person, we will respect your decision accordingly.

We've known for decades that progesterone plays a vital role in the maintenance of a healthy pregnancy and as part of our physicians' training as Creighton Model FertilityCare™/NaproTECHNOLOGY certified Medical Consultants they believe in closely following progesterone levels in all pregnancies known to be at risk for complication. This is a markedly different approach from that of most obstetricians and fertility specialists in the area.

Progesterone Studies

The National Hormone Laboratory at the Pope Paul, VI Institute for the Study of Human Reproduction in Omaha, Nebraska (www.popepaulvi.com) where our physicians' received their fertility certification has decades of data that depict women's progesterone levels throughout the course of a normal pregnancy. By analyzing this data, we are able to understand the progesterone level in a healthy pregnancy at every point that pregnancy. By contrast, we are also able to look at pregnancies with common complications and understand what the progesterone levels are in those pregnancies at various points along the developmental path.

As one might expect, in the abnormal pregnancies with complications such as preterm rupture of membranes, early miscarriage, preterm birth, and placental abruption, the progesterone levels are low at almost every point throughout the pregnancy. The simple fact is, progesterone is critical to developing and maintaining a normal, healthy pregnancy. Of course, it is not alone in this role, but it is nonetheless, a key component and without it, serious complications occur. Most important, when we correct a low progesterone level; that is, when we bring the progesterone level up to the normal level, we dramatically reduce the number of complications. This fact has been supported by numerous published research studies throughout the scientific literature in recent years.

Supplementing Progesterone

How we go about supplementing progesterone varies. There are some who suggest taking oral progesterone. Others suggest taking vaginal suppositories, and still others suggest creams and/or injections. The Creighton Model Fertility*Care*™ protocol prescribes a dose and route of progesterone therapy based on the level of progesterone detected in blood tests. As the pregnancy progresses and (hopefully) the progesterone level rises, it is often possible to decrease the dose and frequency of the progesterone therapy and, in many cases stop supplementation altogether.

We're often asked, why we use injectable progesterone instead of oral forms of the hormone? Progesterone has what in pharmacology is known as a high, "First pass effect." That is, when taken orally, it enters the intestinal tract and then the bloodstream, and then goes to the liver—this is the normal pathway for most medications and nutrients. The vast majority of progesterone is metabolized by the liver as it passes through the first time from the intestinal tract and this is known as the, "First pass effect." As a result, there is very little of the progesterone left to exert its effect on the target organ (in this case, the uterus) once it passes through the liver. By contrast when progesterone tablets are placed in the vagina, they are slowly absorbed through the walls of the vagina into the bloodstream and circulate in and around the blood vessels of the uterus before eventually making it to the liver. When progesterone is injected into the muscle in an oil base, it is even more slowly absorbed into the bloodstream, circulating around the body and exerting its effect before making it to the liver where it is metabolized. So our strongest progesterone delivery tool is injectable; our next best tool is a vaginal tablet, and our least effective tool is the oral tablet.

Bio-Identical Progesterone

We only prescribe what is known as, "Bio-identical" natural progesterone. That is, the progesterone is in every way—biochemically, biologically, pharmacologically, and structurally—identical to the progesterone produced by the human body. Some bottles of progesterone (Prometrium, for example) may have package inserts warning of the possibility of birth defects with the use of this medication. This warning refers to artificial progesterone substitutes (typically called progestins, a common ingredient in oral contraceptives) and not the pure, bio-identical progesterone that we prescribe. The Pope Paul, VI Institute has decades of experience using bio-identical progesterone in pregnancy and has no reported problems resulting from its use. We feel completely comfortable prescribing its use during pregnancy.

Depending on the specifics of your clinical circumstance you may already be taking vaginal progesterone or you may be just starting it for the first time after reading this document. More than likely, it is being recommended that you begin twice weekly injection therapy, possibly in addition to daily vaginal therapy, while we await the lab results.

Bio-identical progesterone is generally very well tolerated with few side effects. It is common to experience soreness at the site of an injection. Using the technique described in the teaching materials is essential to minimizing discomfort at the injection site. Applying vitamin E oil can often relieve itching at the injection site.

<u>Frequently asked questions with Progesterone Teaching</u>

How long will I have to use the progesterone?

Length of use depends on the body's response to the medication. Some will use it through the first trimester, some will use it throughout the entire pregnancy. That is why we do regular blood draws to monitor levels and adjust the dose as necessary.

What will happen if the medication is injected into the wrong spot?

There can be additional pain, swelling, and possibly numbness and tingling in the legs. Even if the injection is in the wrong spot, massage and heat can help.

Is there anything I can eat or do to help my progesterone levels?

Maintain a healthy diet, take your vitamins, manage stress, and avoid exposure to polish, paints, non-organic meat, pesticides, herbicides, as well as emulsifiers found in cosmetics and soaps.

What are the side effects of using this progesterone?

Pain/swelling at injection site, breast tenderness, headache, weight gain/loss, acne, nausea, increased body/facial hair, loss of scalp hair, drowsiness, or dizziness may occur. Please call the office if any of your side effects are bothersome.

Can I come into the office for an injection if my partner is not available?

You can definitely schedule an injection with the nurse.

Fertility & Midwifery Care Center

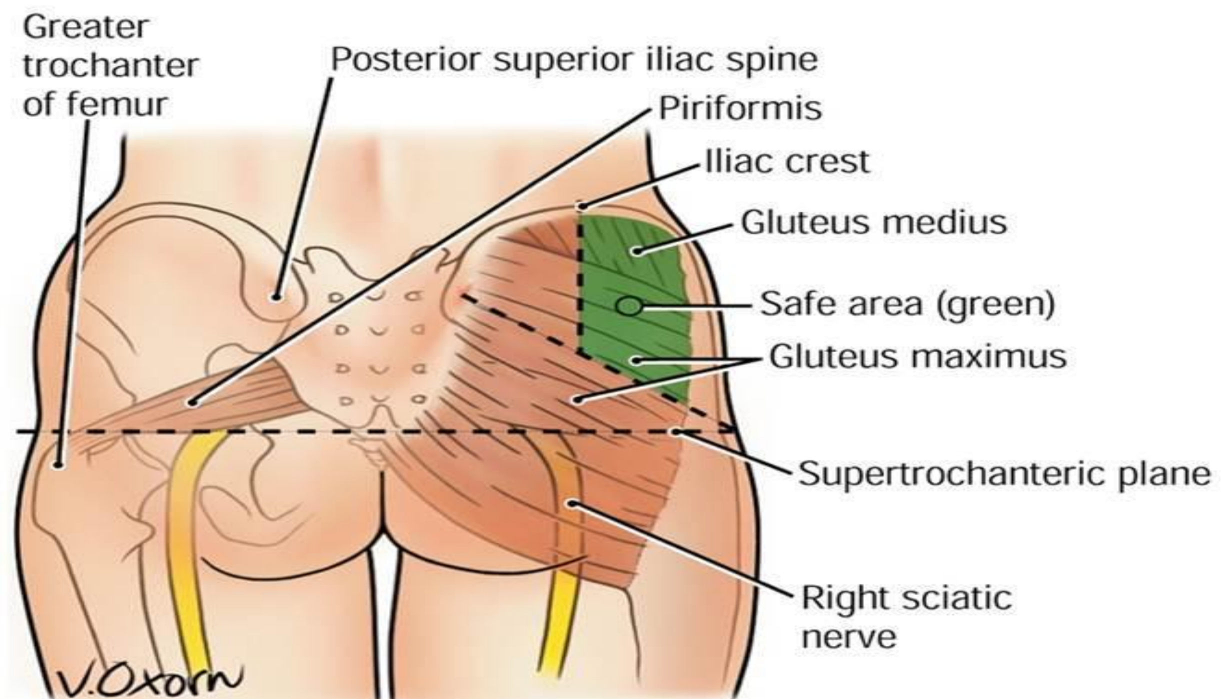
IM Progesterone Injection Administration Instructions

The following steps have been shown to reduce the likelihood and intensity of reactions, such as pain, irritation, bruising, and itching, to the progesterone injection:

1. Draw up oil into syringe with large bore needle (usually 18 gauge).
2. Replace needle with 21 gauge needle for administration.
3. Insert needle into the upper outer quadrant side of the gluteal (buttocks) region; rotating left and right sides with each injection.
4. Inject medication **extremely slow,** over the course of **at least** 2-3 minutes (no matter the amount of medication you're injecting).
5. Massage the area for at least 1 minute.

*We encourage you to massage the site and to use a heating pad as needed to relieve any discomfort.

*If pain at the injection site, consider preheating area in addition to the above instructions.



B. Posterior View, Intragluteal Injection

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Updated: 10.10 .18

Progesterone Injections

Progesterone is one of the reproductive hormones, normally produced by the ovary after ovulation. It is needed to prepare the endometrium for implantation of an embryo and is used as part of an assisted reproductive technology (ART), ovulation induction or sometimes to induce a period in a woman who hasn't ovulated. **Here are step-by-step instructions for administering Progesterone Injection injections:**

1. Wash your hands thoroughly and make sure that the surface you work on is clean.

2. Use an alcohol swab to cleanse the rubber stopper of the progesterone medication.

3. Using the 3cc syringe with a 1.5 inch needle, pull back on the plunger to the 1cc mark.

4. Pierce the rubber stopper of the progesterone vial. Inject 1cc of air into the vial.

5. Turn the vial upside down; making sure the tip of the needle is below the fluid level. Withdraw the dosage ordered. Progesterone is oil, so it will pull into the syringe more slowly. Pull the needle out of the vial and then pull back on the plunger to clear the needle of any medication. **(If you are given 2 different size needles, at this is time you'd recap the 18GA needle & remove it. You then replace it with the 21 or 22GA needle).**

6. With the needle pointing toward the ceiling, flick the side of the syringe to disperse the air bubbles and the air pocket at the top of the syringe,

7. Then gently push the plunger to eliminate any air until you expel one or two drops of liquid from the tip of the needle.

You are now ready to administer the progesterone by intramuscular injection.

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Administering a intramuscular injection

Lying down, or standing with your weight off of the side to be injected, locate the upper outer quadrant of your buttock. The injection is given here.

1. Wipe the site with alcohol. Then let dry.

2. Insert the needle at a 90 degree angle with a smooth dart-like motion. The needle needs to be inserted all the way leaving none of the needle visible.

3. Draw back on the plunger. If you are accidentally in a blood vessel, blood will appear in the syringe. If so, **DO NOT INJECT**. Pull the needle out, dispose of everything, and start the entire process again.
If no blood appears, slowly push the plunger all the way to inject the medication, and pull the needle straight out.

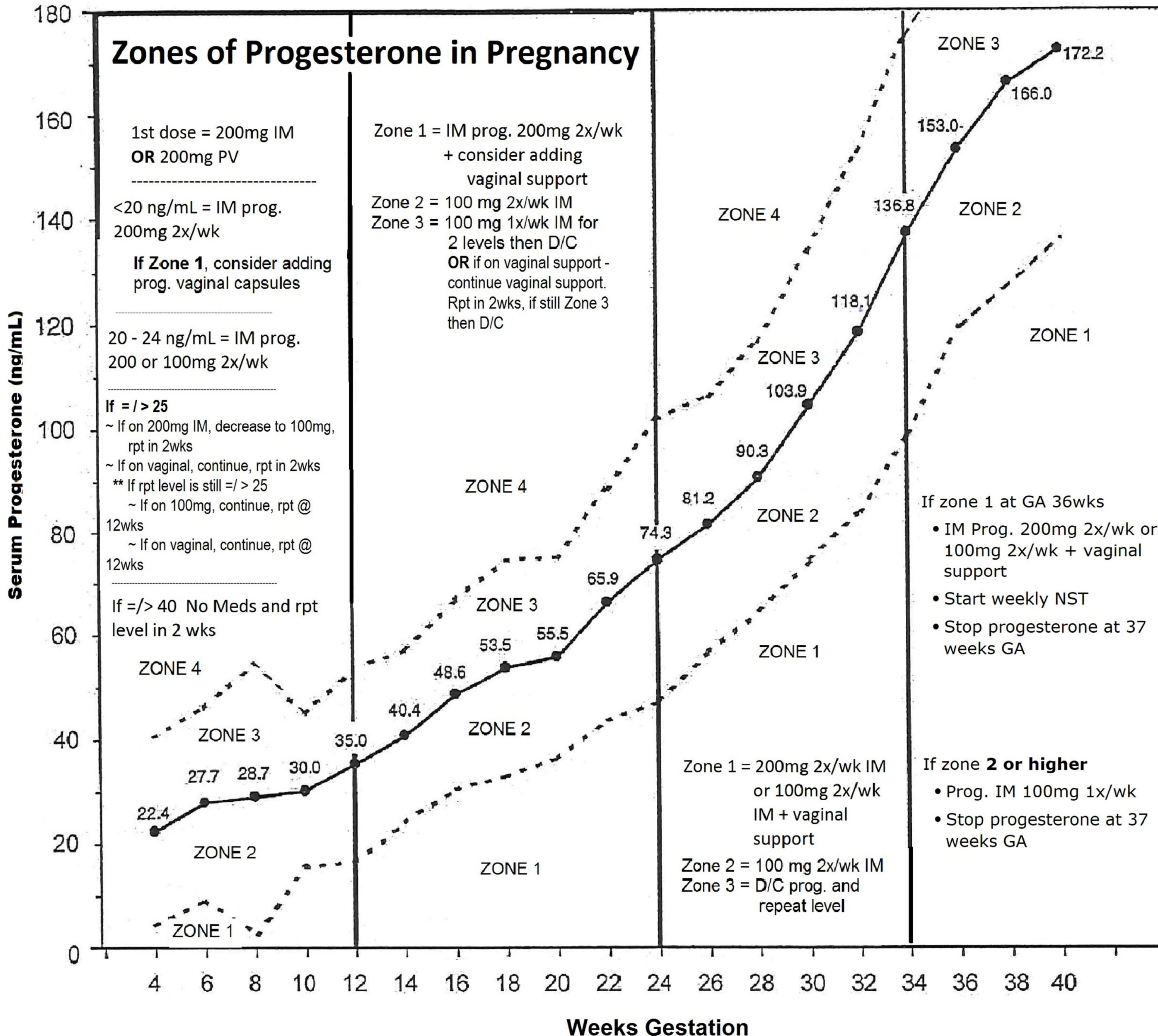
4. Alternate sides, left or right, each time injections are given.
Apply pressure and massage the injection site gently for thirty seconds. Apply band-aid to injection site
Never reuse needles and syringes.

5. Dispose of the syringe in a biohazard container such as a Sharps container - or in an unbreakable plastic container such as a laundry detergent bottle that you can seal.

Please be aware that some of these instructions may vary slightly based upon your particular situation or preference.

Modified Progesterone Support Protocol

Pope Paul VI Institute



Indications for Progesterone monitoring & supplementation:

1. Previous SAB
2. Previous infertility
3. Previous stillbirth
4. Previous prematurity (</= 37 weeks)
5. Previous PROM (</= 37 weeks)
6. Previous gestational hypertension, Pre-eclampsia, HELLP syndrome
7. Previous abruption
8. Congenital uterine anomaly
9. Patient with cerclage
10. Low Progesterone
11. Endometriosis
12. PCOS

Progesterone Follow up

Zone 1:
- < 32 weeks, re check every 4 weeks
- >32 weeks, recheck every 2 weeks

Zone 2:
- <14 wks recheck every 2 weeks
- > 14 wks, recheck every 4 weeks

Zone 3:
- always recheck every 2 weeks

*****If off protocol, recheck level at GA 34 weeks*****

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