# GENERAL FERTILITY -PATIENT EDUCATION DOCUMENT Version I, 2022

New Leaders In Fertility & Endocrinology "NewLIFE"

FELLOWSHIP-TRAINED & BOARD CERTIFIED REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY SPECIALISTS

## New Leaders In Fertility & Endocrinology, LLC "New LIFE"

Dear NewLIFE Patient:

On behalf of our entire staff we would like to welcome you to our care. We love what we do, and we sincerely wish to assist in all ways possible on your journey to parenthood.

The following information is provided for you as a general introduction to the NewLIFE ways for common testing and fertility treatments. We ask that you READ CAREFULLY and completely.

While the booklets will answer the most common questions patients have about fertility testing and treatment, make notes or write questions in the margins and bring this booklet to your subsequent visits as a reminder.

Sometimes you may feel a bit overwhelmed by the paperwork, but this is an important step to make your office visits to be as productive as possible.

Studies in the United States have shown that of the 2.4+ million infertile people each year (that is about 10-15% of all reproductive age couples), only half will seek a physician's evaluation and of those some never receive the care from a true FERTILITY SPECIALIST. More notably, those same studies suggest that for people who seek and receive care, the majority <u>will</u> achieve a successful pregnancy. With this first step you have joined that "take charge" group....and soon to be successful majority!

We truly appreciate your efforts and hope you will continue on this road to success. Be assured that our entire staff is able and available to help you along your journey.

Warmly,

The NewLIFE Staff

## New Leaders In Fertility & Endocrinology MISSION STATEMENT

Our goal is to provide infertile patients with progress toward a successful and healthy pregnancy, as promptly, gently and as cost effectively as possible.

## GENERAL OFFICE ISSUES (PLEASE READ CAREFULLY)

The following describes many important topics and common patient concerns. Please read carefully and adhere to the recommendations provided.

1) Office Visits: That you are reading these Patient Education Booklets (documents) probably means that your initial consultation is being arranged. During the next few weeks before and after your first visit, additional information will be gathered about you. Once completed, a visit for treatment planning will be scheduled. Test results will be reviewed and if needed additional tests can be arranged. These visits are the best times to bring up questions that arise from reading these booklets.

2) Patient Responsibilities: A physician's expertise alone is rarely successful, and patients' efforts are needed for healing. Nowhere is this more evident than in the treatment of infertility. Physicians and nurses will provide the necessary information, training, counseling and guidance but partner with patients committed to educate themselves and become knowledgeable about fertility treatment. Thus, various online educational videos, patient information booklets and American Society of Reproductive Medicine pamphlets will be provided, as needed. It remains a patient's responsibility to read and understand these materials, asking questions when needed to achieve compliance. Because of time limitations and volume of patients, these written materials should be your <u>FIRST</u> reference for questions and bring others to subsequent visits. It is difficult, if not dangerous, to offer complex treatment or information to patients by means other than face-to-face visits where there can be dialogue. Telephone calls, faxing, portal posts and electronic or recorded messages are standby forms of communication.

3) Communication with the office: During treatment it is vitally important that the office have reliable and effective ways to provide updates and instructions to you. An active telephone number and one backup number that have private answering devices (home, work, mobile phone, voicemail) are required. Patient are responsible to access vital instructions in a timely fashion. Please provide written request if certain telephone numbers should not be used. Today, most information can be sent through a private and secure "Patient Portal." Patients should check their Portal BEFORE calling the office. Please notify the office during regular business hours of the onset of menstrual periods, ovulation surges and other important developments. Please keep numbers handy for our offices: Pensacola, Panama City, Destin, and Tallahassee, Florida, and Mobile and Dothan Alabama, and Biloxi Mississippi.

**TEST RESULTS** from fertility evaluation are not routinely reported until all testing is completed to avoid misinterpretation or incomplete results that may mislead patients. Lab results can be difficult when given by telephone and cannot be interpreted by non-medical office personnel. More productively, we attempt to present and discuss all findings together within a single visit, allowing patients to us all findings to make treatment decisions.

For **ROUTINE MATTERS**, please call your **LOCAL** office during regular business hours and, if needed, leave a <u>DETAILED</u> message with your full name and date of birth. Voice messages will be assessed and answered within 2 business days, in an order based on the information that you provide. Without this detail, your care may be delayed.

For **URGENT MATTERS** after office hours (e.g. medication reactions or timing) call the **Doctor's Directory at 850-444-5507** and a message will be sent to on-call medical personnel at your LOCAL office. **NOTE:** <u>non-urgent calls</u> made after-hours may generate a professional fee, or be deferred until regular office hours.

For true **EMERGENCIES**, call 911, and do not call an office, as this would delay getting help.

4) **Insurance**: Despite diligent efforts to assess your insurance coverage, neither you as a consumer, nor our medical office can be assured of reimbursement for infertility services, and some expenses may not be covered by insurance (see insurance section). This is an unfortunate consequence of the current philosophy of the insurance industry and its attitude towards fertility care.

5) Stress and Anxiety: The entire NewLIFE Team makes efforts to avoid or reduce common frustrations. Regardless of one's emotional strength, the "fertility journey" may become a significant stressor. It is common for patients to need extra support during this time. Access to professional counselors is encouraged, frequently recommended and occasionally required for some treatments. Referral to these helpful resources is often received with a sigh of welcome relief, as many couples are reluctant to talk about it. Stress management may have more than mental benefits, as some published reports suggest pregnancy may be more likely with counseling!

6) **Primary Care Physicians and Referring Ob/Gyns**: When referred for infertility sub-specialty care, we act as a fertility consultant only. Thus, you should keep routine check ups and visits with your Ob/Gyn or primary care physician, particularly for common gynecologic conditions: vaginal infections, PAP smears, mammograms, etc. Your care will return to your Ob/Gyn during the first trimester after conception is confirmed with a reassuring ultrasound.

## **INFERTILITY and YOUR INSURANCE COMPANY**

Insurance benefits are often difficult to define and interpret. Our experienced office staff will attempt to contact your insurance company, but if you are inclined, here are some IMPORTANT QUESTIONS to ask your insurance representative:

- 1. Is there a <u>specific</u> person that handles questions regarding infertility coverage? Request your insurance company policies regarding infertility, in writing. These may be found in the "exclusions" paragraphs located in your Benefits Booklet.
- 2. Is a referral required to see a fertility specialist?
- 3. What percent (aka "Co-Insurance") of fertility medicines, office visits and procedure expenses are covered?
- 4. Is there a different fee for office visits (aka "co-payment") for infertility services? For medications?
- 5. What is the annual deductible per person? Per family?
- 6. Is there a maximum out-of-pocket expense you can incur in a single year?
- 7. Is pre-authorization required for any particular service or procedures?
- 8. What **specific** procedures, if any, should be followed when filing a claim?
- 9. Is there a particular pharmacy to be used for medications? Where is it located? Are injectable drugs obtained differently? Is there a separate limit for the costs of prescription drugs?
- 10. Is there a particular laboratory to be used for blood tests? This lab affiliation must be ignored for some testing.
- 11. Are counseling services covered? What is the coverage and guidelines to be followed?
- 12. Is there a limitation on pre-existing conditions?
- 13. Is there a limited length of time, or age, that you can be treated for infertility?
- 14. Are the following basic tests covered for the "diagnosis of infertility"? Hormone tests, Genetic disease screening, Hysterosalpingogram (HSG), Semen analysis, and Ultrasound, etc.
- 15. Are the following therapies covered for the "treatment of infertility"? Meds (oral, gonadotropins), Ultrasounds, Blood & Lab Tests, Intrauterine insemination (IUI), In Vitro Fertilization
- 16. Is NewLIFE in your insurance network? If not, does your policy provide "out-of-network" benefits? If your plan has no infertility benefits, being "non-participating" "non-contracted" or "out-of-network" doesn't matter. If your plan covers fertility care, but not for out-of-network, you may want to ask for an exception (a "GAP letter") allowing care with a specialist that your insurance company doesn't have available.

#### **IMPORTANT NOTICES:**

Despite answers to these questions provided during a telephone conversation, reimbursement from your insurance company CANNOT be guaranteed.

Your insurance company may deem certain services as "unnecessary" or denied for coverage AFTER a claim is submitted.

By law, insurance companies cannot practice medicine or recommend care, yet they do by default, by controlling payment.

Ultimately, decisions for such services remain with you and your physician.

When services (diagnostic and therapeutic) are considered effective and necessary for successful pregnancy with your physician, but are denied for payment by an insurance company, these expenses become a patient's responsibility.

## **GENERAL INFORMATION ABOUT FERTILITY**

#### What is infertility?

A couple with "average fertility" has a 15-20% chance of becoming pregnant during a single menstrual cycle. Eighty to ninety percent of these couples should become pregnant during one full year. Infertility is common, with one in six couples having trouble conceiving and/or inability to carry a pregnancy to delivery. **Infertility is defined as the failure to become pregnant after one year of unprotected sexual intercourse.** This definition or failure to conceive in 6 months for women over 35, and 2 consecutive miscarriages are reasons to seek evaluation. Infertility affects more than 2.5 million people each year in the United States which means you are NOT alone!

#### What causes infertility?

Pregnancy will follow a series of steps, each being required for a natural conception. Ovulation is complex and dependent on the action of hormones released by the ovary, the pituitary gland and a part of the brain called the hypothalamus. Ovulation usually occurs about fourteen days <u>before</u> the next menstrual period. When released from the ovary, an egg is swept into a fallopian tube where fertilization may occur, if healthy sperm are available. Just a few of the total number of sperm released into the vagina actually survive to arrive in the fallopian tube. Five to seven days after ovulation, a fertilized egg (embryo) implants in the lining of the uterus where nourishment can maintain its continued development.

Studies have found that about 60% of infertility is caused by female factors, 40% by male factors, and 20% by a combination. Defects in almost every step have been reported and any one defect may result in decreased fertility. Common causes of infertility include hormone dysfunction, blocked or damaged fallopian tubes, pelvic adhesions, endometriosis, and abnormal or decreased numbers of sperm and poor cervical mucus. Thus, a very thorough approach must be taken to accurately diagnose the cause(s) of infertility.

#### How is infertility evaluated?

To determine causes of infertility, we use your medical history, physical findings and results of diagnostic testing. This is called an **infertility work-up or evaluation**. Specific diagnostic tests are selected based on this information and on previous testing and/or treatment. These might include blood testing of hormones and others factors, vaginal ultrasounds, hysterosalpingogram (HSG), diagnostic laparoscopy and/or hysteroscopy, endometrial sampling, semen analysis and other tests. For some, the findings of these initial tests will warrant additional tests to find specific causes.

#### What is the next step?

After your infertility work-up, all results of your tests will be reviewed with you during a return office visit and various options for treatment will be offered. We do not usually discuss an individual test result until all of the others are available, as one may mislead a true interpretation. When available, your physician will meet to present everything found and pertinent to your care. This important visit is called "Treatment Planning" or a "Treatment Plan".

Your input, perspectives, concerns, feelings and understanding are very important in making a decision about treatment. We encourage you to visit as a couple whenever possible and to ask questions, keep notes and follow directions. We provide Patient Education Documents (such as this one) to help patients to understand and prepare for this decision making visit.

It is vital that you keep us informed of your status and changes, and ultimately, infertility care is PATIENT INITIATED.

## NORMAL OVULATION & CONCEPTION

#### The Process

The ovaries are two small glands, each about one-and-one half to two inches long and three-fourths to one inch wide, located in a woman's pelvic cavity (Figure 1). They are attached to the uterus (womb), one on each side, near the fimbria (fingerlike) openings of the fallopian tubes. About once a month, a mature egg is released by one of the ovaries. The fimbriae of the fallopian tubes sweep over the ovary and pick up the egg after it has been released from the follicle (the fluid-filled ovarian cyst containing the egg). Fertilization usually occurs in the tube, and the resulting embryo (fertilized egg) continues to mature and increase its number of cells as it travels to the uterus and implants in the endometrium (uterine lining). The embryo's full journey through the tube takes four to five days.

#### Hormone Production during the Menstrual Cycle

In addition to producing eggs, the ovaries also secrete hormones. Hormones are substances secreted from organs of the body, such as the pituitary gland, adrenal gland, or ovaries, which are carried by a bodily fluid such as blood to other organs or tissues where the substances exert a specific action. The cycle of ovarian hormone production has two main "phases". During the first, the follicular phase, an egg matures inside the ovary. The egg is surrounded by fluid and hormone-producing cells. The maturing egg, the surrounding cells, and the fluid are collectively known as a "follicle" which grows into a "cyst" about an inch diameter on the surface of the ovary, before the fluid and the egg are released at ovulation.

In natural cycles, an ovary contains several developing follicles, but usually only one follicle reaches maturity each month and releases an egg. This follicle, known as the dominant follicle, secretes a generous amount of the female hormone estradiol (estrogen) into the bloodstream during the first phase of the cycle. The estrogen circulates to the uterus where it stimulates the endometrial cells to reproduce rapidly and repeatedly, causing the uterine lining to thicken as ovulation approaches. The physician can usually see this thickening on an ultrasound exam.

The second phase of ovarian hormone production begins with ovulation. The dominant follicle ruptures, usually around day 14 in a 28-day cycle, and releases a mature egg onto the surface of the ovary near the fallopian tube. The empty follicle collapses and the remaining follicle cells develop a yellow color. Collectively these cells are known as the corpus luteum, literally a "yellow body." The corpus luteum secretes estrogen and large quantities of progesterone throughout the second half of the cycle, known as the "luteal phase", which lasts approximately two weeks. This combination of progesterone and estrogen causes the uterine lining to further mature, become receptive to and nourish an embryo. About a week after ovulation, the endometrium is in prime condition for an embryo to implant. A sample of this endometrium can tell approximately how many days have passed since ovulation and whether the hormones have been effective. If no embryo implants, the secretion of estrogen and progesterone declines about two weeks after ovulation and, as a result, the endometrium is shed. This shedding of the endometrium is called menstruation.

The first day of full flow is called "cycle day one." The length of the menstrual cycle is determined by counting the number of days from cycle day one until the start of the next menstrual period. Since ovulation usually precedes menstruation by two weeks, a woman with a 28-day menstrual cycle is most likely to ovulate on day 14. Similarly, a woman with a 32-day cycle is most likely ovulate on day 18.



Menstrual Cycle Events

## FINDING A CAUSE OF INFERTILITY: DIAGNOSTIC TESTS

Following your first consultation, it is likely that you will be instructed to begin or complete your fertility evaluation. Testing may include some or all of the following tests to determine a cause or causes of your infertility.

#### ✤ DIAGNOSTIC CYCLE MONITORING

The "Diagnostic Cycle" process is performed to evaluate the components of your entire menstrual cycle and quality of ovulation. If you do not regularly ovulate, you may be given an oral medication to induce ovulation. A numbered Step-by-Step DIAGNOSTIC INSTRUCTION SHEET will be provided to you and the nursing staff to help with scheduling tests, some of which must be performed on specific days of the cycle. The illustration above, "Menstrual Cycle Events" is a useful aid, showing the normal rise and fall of hormones during a menstrual cycle and changes that take place in the ovaries and uterus during the menstrual cycle.

### **\*** TREATMENT CYCLE MONITORING: BASIC INFORMATION

Cycle monitoring involves tracking the growth of ovarian follicles through blood hormone testing and ultrasound studies. It is necessary to follow the ovary's response to fertility pills and injectable medications. Monitoring allows adjustments in medication dosage and may help to avoid hyper-stimulation or multiple pregnancies.

Monitoring usually begins within the FIRST few days after starting your menstrual flow and typically begins with a "baseline" vaginal ultrasound and blood tests. Monitoring during the rest of your cycle will depend on your individual mode of treatment and your response to treatment. Blood tests and ultrasounds are routinely scheduled in the morning between 8:00 AM and 12:00 noon to allow time for results to be obtained within the workday. Monitoring is vital and mandatory for safe and effective fertility treatment. Monitoring days are usually predetermined and set in advance, but we try to be flexible regarding appointment times. Please let the clinical coordinators know what time of morning is best. If needed, please make arrangements with your employer. The staff reviews blood results and ultrasounds daily, essential to the proper management of your cycle. Provide the office with home, work, voicemail and mobile phone numbers and which is the best method for contact, phone number or where to leave a message.

IMPORTANT: Updated instructions may not be available or provided to you until after 5:30 p.m. Many days, there is no need for new instructions, and you will hear, "continue the same dose unless we instruct otherwise." If you are expecting instructions on a monitoring day, calling the office may interrupt and delay the staff's efforts. Results and instructions may be delivered via a Patient Portal, and you should have established (registered) an account. If you were expecting, but have not received a call by 7:00 PM, please call and ask for your LOCAL coordinator through the Doctor's Directory. And if no further changes are given, no calls are made, "continue the same dose unless we instruct otherwise."

#### ✤ OVARIAN RESERVE TESTING

There is a profound and progressive impact of maternal age on the quantity and quality of human eggs. There are differences between women of the same age, as well. While "egg quality" cannot be reliably measured by blood tests, the relative number of eggs or follicles can be assessed in many ways that help your physician counsel you on your prognosis and possible recommendations for conservative or aggressive treatments. Ovarian reserve testing generally relies on biochemical tests (hormone levels), biometric tests (ovarian size, number of small follicles), and clinical response to ovarian stimulation. The best time to assess the first two is early in the menstrual cycle, often called "Baseline" or "Cycle Day 3 lab" when ultrasound and hormone levels are performed. While these tests are helpful and quite predictive, attempting to stimulate extra follicles may be used to further assess ovarian reserve.

#### ✤ GENERAL HEALTH and PRE-CONCEPTION SCREENING

Achieving a pregnancy may seem to be the primary goal, but a **healthy** pregnancy and baby are ultimately the true desire. Maternal health plays a significant role in conception, successful pregnancy, and health babies. Therefore, conditions that may affect pregnancy are routinely assessed prior to starting treatment and are completed during the initial testing. Examples include, blood pressure, height, weight, thyroid screen, immunity for transmissible viruses, blood type. Before treatment with IVF/ART, the FDA requires screening for infections and infectious diseases. Other tests may be recommended for specific symptoms or findings.

#### ✤ GENETIC CARRIER SCREENING

Recessive genetic diseases are not common but can be severe or lethal to a newborn. These are NOT similar to Down Syndrome or other "chromosomal" genetic conditions. Being a carrier of a recessive gene causes no symptoms and genes pass silently through generations, so that not having a "family history" does not exclude the possibility of being a carrier. In the past, without detailed screening, these diseases would occasionally appear in families that had previously unaffected children. Couples can be "carriers" even if they have had no affected children. When BOTH parents are carriers, then 1 in 4 of their children will be affected, and possibly suffer severe health issues. The American College of Obstetricians & Gynecologists (ACOG) recommends education about these conditions and consideration for testing by couples planning to conceive. Consultation with a Certified Genetics Counselor (CGC) is helpful and is initiated automatically when testing is positive. Most people are NOT carriers. In fact, only 5-10% will have a positive screen, and therefore the chance that both male and female are carriers is extremely low. Many conditions can be avoided in offspring with testing and intervention.

#### ✤ DIAGNOSTIC HYSTEROSCOPY IN THE OFFICE

A diagnostic hysteroscopy is a procedure that allows your doctor to examine the inside of the uterus with a small, lighted scope inserted through the cervix. Saline (salt water) is instilled to allow visualization of the uterine cavity. Abnormal conditions of the uterus, such as internal fibroids, scarring, congenital malformations, tumors, polyps and internal tubal obstruction may be viewed, giving your physician valuable insight on further diagnosis and treatment.

Diagnostic hysteroscopy may be completed in the office and is usually scheduled a few days after menstrual bleeding has stopped, when the uterine lining is thin and is less likely to cover up an abnormality. This procedure is short, and usually takes less than 10 minutes. Most patient find this test fascinating and without discomfort. It is recommended at least annually.



#### Patient Instructions BEFORE Office Hysteroscopy

- 1) Contact the office on day 1 or 2 of menstrual bleeding to schedule your hysteroscopy. You may be asked to use oral contraceptives, and this makes scheduling more flexible. If menses occur on a weekend/holiday, call next business day.
- 2) If you commonly experience severe menstrual cramps, please take ibuprofen (600 mg) or naproxen (275 mg) with a light meal about 1 hour before the hysteroscopy.

#### Patient Instructions AFTER Office Hysteroscopy

- 1. You may experience light to moderate vaginal bleeding for 2 to 6 days. Refrain from intercourse for 2-3 days after the office procedure.
- 2. If you experience cramps or discomfort persists, you may take Tylenol, ibuprofen (600 mg) or naproxen (275 mg) with a light meal
- 3. Call the office immediately if you have any of the following symptoms:
  - ◊ Bleeding as heavy as the heaviest flow during your menstrual
  - ◊ Severe pain that is not improving with time or medication
  - ◊ A temperature of 100.4°F or above.
  - ◊ Difficulty urinating.

## \* RADIOLOGIC HYSTEROSALPINGOGRAM (HSG) TESTING FOR "OPEN TUBES"

Hystero-Salpingo-Gram (HSG) commonly called the "dye test" is used to discover if there is blockage of the fallopian tubes or abnormalities of the uterus and cervix. A dye visible to X-ray is injected through the cervix into the uterus and fallopian tubes and this procedure is provided by a radiology service outside the office. HSG may cause cramping and pre-medication is recommended and the procedure takes half an hour. HSG is scheduled between day 7 - 11 of your menstrual cycle, after menstrual flow ceases and before ovulation. If your menstrual flow is prolonged, the procedure may be postponed to the next month. If you are on birth control pills, it may be scheduled more readily in same month. The HSG test is known to be BOTH "false positive" (findings not true) and "false negative" (missed true findings) but it remains an important test.

#### **Risks to Patients**

In addition to discomfort and bleeding, HSG may rarely result in reactions, puncture of the uterus or infection. Infection occurs in less than 1% of patients but can require hospitalization and intravenous antibiotics. Patients are asked to monitor themselves after the test for any symptoms suggesting complications such as infection, fever, pain, bleeding. Technologies advance providing alternatives to the HSG, see laparoscopy and hysteroscopic Tubal Perfusion Test (hs-TPT).

#### **Patient Instructions**

1. Contact the office during the FIRST 3 days of your menstrual period. If this occurs on a weekend or holiday, please call the next business day.

2. Call the office to reschedule your HSG appointment if you have not stopped bleeding on the day it is scheduled. The test cannot be performed while you are actively bleeding. Let the office know if you're taking oral contraceptive pills.

3. Take Advil® or Anaprox® (Naprosyn) with food or liquids at 1-2 hours before the procedure to minimize uterine cramping. Antibiotics may sometimes be ordered for the morning of and evening after the procedure.

4. After the test you may experience cramping and spotting. If you develop a fever, or bleeding becomes heavier than a menstrual period, **call the office immediately.** After office hours, or on weekends or holidays, call the Doctors Directory.

#### **Special Situations**

\*\*\* If you have allergy to iodine, shellfish or radiology contrast/dye, you may need pre-medication or the HSG may need to be declined for alternative tests.



Hysterosalpingogram ("HSG" or the "dye test")

#### \* HYSTEROSCOPIC TESTING FOR OPEN TUBES (Tubal Perfusion Hysteroscopy)

Hysteroscopic Tubal Perfusion Test ("hs-TPT") also known as "Parryscope" is a newer technique for the fallopian tubes that does not use radiation or dye and is usually completed with great ease in the office. It is similar to a diagnostic hysteroscopy, and is an easy, short procedure completed with saline (salt water) and small air bubbles. Images are displayed, allowing patients to watch. No special preparation is needed, but unlike the Diagnostic Hysteroscopy, the hs-TPT may be scheduled closer to the time of ovulation when menstrual debris/blood is less likely to interfere. It looks for flow of saline and air bubbles to suggest open fallopian tubes. Failure of flow into the tubes suggests obstruction, and an ultrasound should immediately follow to determine if fluid is collecting at the end of a tube, called "hydrosalpinx." Sometimes a radiologic HSG is necessary following this procedure, or ordered instead of the hs-TPT, if a patient has prior pelvic/tubal surgery, certain risk factors. Reliability of TPT findings is similar to the HSG, with some false and missed findings.

#### **Risks to Patients**

hs-TPT has similar risks as hysteroscopy described above. Infection occurs in less than 1% of patients but can require hospitalization and intravenous antibiotics. Patients are thus asked to monitor themselves after the test for any symptoms suggesting complications such as infection, fever, pain, bleeding. In general, compared to radiology HSG, office hysteroscopy is more convenient, more comfortable, less expensive and does not expose patients to radiation.

## ULTRASOUND

This painless procedure allows your physician to take pictures of your ovaries and uterus using supersonic sound waves. A small probe is placed in the vagina and images are displayed on a video screen during the exam and may be recorded on film. This test may also determine the thickness of the lining of the uterus, development of eggs in the ovary and identify uterine fibroids or other uterine abnormalities.

There are no known risks to the use of ultrasound and the vaginal approach has made holding a full bladder unnecessary. It is likely that ultrasound will be used many times during the fertility evaluation and is a vital tool for successful fertility treatment.

#### **\*** OVULATION DETECTION

In most ovulating women, the length of each menstrual cycle will range from 25 to 32 days. Ovulation occurs approximately 13-15 days before the <u>next</u> menstrual period. Keeping track of the length of menstrual cycles helps to determine the approximate time of ovulation. Ovulation predictor kits, which are available at most drug stores, are also helpful in determining the approximate time of ovulation. These kits detect Luteinizing Hormone ("the LH surge") that is found in urine 12 to 40 hours before ovulation.

You will be instructed on when to begin testing, based on your cycle length and other factors and should continue if ovulation is expected. One brand or type of ovulation test kit has not been proven superior to another. In general, us a kit that is easy for you to read. Test kits typically contain 5 or 6 tests that are to be used on consecutive days until a positive test occurs.

#### **Other Guidelines:**

- 1. Use urine from the first time you go after getting out of bed in the morning (it's the most concentrated).
- 2. Read package directions carefully to be sure of accurate interpretation of test results.
- 3. Notify office when there is a positive test. It should be negative the FIRST day that you test.
- 4. If you are not having insemination, have intercourse the night of a positive LH and the following night.
- 5. When purchasing ovulation detection kits, the <u>one-step</u> kits that give results in 5 minutes are recommended for ease of use.

#### **Other Methods of Ovulation Detection**

Basal Body Temperature Charting (BBT) - helpful only if cycles are consistently regular and chart shows consistent biphasic (elevated temperature after the first half of the cycle).

Serial use of ultrasound can reveal follicle growth to maturity, and its collapse with release of an egg.

Endometrial biopsy - confirms adequate ovulation within the uterine lining but is not practical for use on a monthly basis.

Serum Progesterone Level - a single sample is helpful if within normal range and drawn on the correct day of the cycle. Serial sampling (3 samples at 5-9 days after LH surge) is sometimes requested to diagnose subtle ovulation problems.

Positive Pregnancy Test - If this test is positive, you don't need ovulation kits. Ovulation has definitely occurred!

#### ✤ ENDOMETRIAL SAMPLE

An endometrial sample or biopsy is used to evaluate the quality of ovulation by assessing the progesterone-induced changes inside the uterus and/or to exclude microscopic infection or inflammation, excessive growth (hyperplasia) or cancer in some women and confirm uterine receptivity. It may performed in the office 10-12 days after a positive LH surge or hCG injection and after a negative pregnancy test. The procedure requires just a few minutes with speculum and the passage of a thin catheter through the cervix to obtain a small piece of tissue from the uterine lining. You may experience some menstrual-like cramping and discomfort during and after the procedure. It is recommended that you take ibuprofen or naproxen with a meal at least 60 minutes prior. You may have some light spotting after the procedure. Notify the nurse if bleeding becomes heavier than a menstrual period.

#### **Risks to Patients**

In addition to discomfort and bleeding, endometrial biopsy may rarely result in perforation of the uterus. Patients are asked to monitor themselves after the test for any symptoms suggesting complications such as infection, fever, pain, bleeding.

#### **Patient Instructions**

- 1. Notify the office of a positive LH surge to schedule the biopsy.
- 2. Take ibuprofen or naproxen with food one hour before the procedure.
- 3. Please call the office with the date of <u>next</u> menstrual period (normal flow).
- 4. Call the office or Doctors Directory (after hours) if you experience any severe cramping, fever and/or heavy bleeding.

#### ✤ SEMEN ANALYSIS

The **semen analysis** is the most important single test in the evaluation of the male, reporting among other parameters, the number of sperm, the percent of moving sperm ("motility"), their structure and shape ("morphology"), and the volume of the semen sample.

As semen analyses are performed on <u>SPECIFIC DAYS</u> in each office appointment times must be scheduled.

Written "Patient Instructions" and a collection container will be provided to you when the test is requested, but general considerations are:

1. A semen specimen should be obtained following a two- to four- day period of sexual abstinence.

2. Avoid soaps, detergents, creams or lubricants to aid specimen collection. These agents may interfere with sperm motility. Assistance from the female partner is encouraged and may improve the quality of the sample.

3. Collect the ENTIRE specimen in the sterile container. The volume should be a little more than one-half teaspoon. Please let the lab know if any spillage occurred during specimen collection. **This is very important!** 

4. The semen is ROUTINELY collected at home and should be delivered to the office/lab within as soon as possible after ejaculation. Keep the specimen at room temperature during transportation. **Do not put it near a heater!** Time is not as important as temperature when transporting semen samples, therefore, drive carefully.

6. <u>Always</u> label the specimen cup with NAME, DATE and TIME of collection and number of days since last ejaculation. According to laboratory policy, specimens received without this information may be refused and may not be processed.

7. Be prepared to provide photo identification when the specimen is delivered to the office/lab.

#### ✤ ADDITIONAL MALE TESTS

Male infertility accounts for approximately 40% of cases, and technology is advancing to identify more causes. When a semen analysis remains abnormal on TWO samples, further testing is usually needed in an attempt to find a cause. These tests typically include pituitary and testicular hormone levels, genetic screening, and ultrasound of the testicles and specialized testing of sperm cells.

From the male's test results, various treatments and procedures may be selected to regain normal sperm production, or enough sperm for assisted reproduction. Some tests will be ordered on a male when a couple is experiencing recurrent pregnancy losses. Consultation with urology may be necessary, as well.

## ♦ LAPAROSCOPY FOR FERTILITY EVALUATION & TREATMENT

Laparoscopy is a valuable tool to identify and often treat many fertility problems, particularly diseases that affect the fallopian tubes or ovaries. Like the hs-TPT or HSG "dye test," laparoscopy may also be used to test for open fallopian tubes.

Unlike the imaging (radiology or ultrasound), laparoscopic surgery can reliably identify adhesions or endometriosis around the ovaries or tubes. Both of these conditions can impair fertility. Thus, laparoscopy remains an essential part of the fertility evaluation. Unless there are concerns from the information you provide, laparoscopy is usually held as one of the final procedures and may be recommended after completion of other basic tests.

Scientific and technical advances now allow specially trained fertility surgeons to correct many conditions with laparoscopy, without making a large incision (laparotomy) and this shortens the recovery time to just a few days.

Laparoscopy is a safe and effective way to identify endometriosis and adhesions. Studies now show improved pregnancy rates after corrective laparoscopic surgery. Further, this treatment is usually provided during the <u>same</u> surgery.

In general, when laparoscopy is recommended for infertility or preservation of fertility, a reproductive specialist is the preferred surgeon, as they are adept at correcting and restoring function of fallopian tubes. This is particularly the case with tubes are noted to be "blocked" or be a "hydro" or "hydrosalpinx", as the first attempt to repair a tube has the best chance of success. General ObGyn surgeons will often decline an attempt to repair a blocked tube, and instead, refer the patient to a Reproductive Endocrinologist.



#### **Risks to Patients**

Laparoscopy is a surgical procedure with the inherent risks of surgical complications that are generally uncommon in health patients. The categories of complications include:

Anesthesia - reactions to medications, breathing and circulation problems;

Infection - bacteria on the skin may enter an incision or abdomen, sometimes requiring treatment.

Bleeding - excess blood loss and transfusion are uncommon with laparoscopic surgery.

Injury - when anatomy is distorted, or repair or removal of disease is necessary, other organs may be at risk.

If laparoscopy is recommended, you will be given pre-operative instructions to help prepare and prevent complications. Please read and heed them completely.

#### Scheduling

Surgery is scheduled in advance unless an emergency. For diagnostic laparoscopy, the preferred timing is after menstruation has stopped but before ovulation occurs. Additionally, surgeons have specific "blocked times" that are reserved. For convenience, some patients will want to "reset" their period with contraceptive pills to align a preferred surgery date.

## FERTILITY MEDICATIONS AND TREATMENTS

#### ♦ USE of ORAL CONTRACEPTIVE PILLS (OCP's)

At first consideration, use of a birth control pill may seem contradictory to achieving pregnancy, but the issue is a bit more intricate. Several situations require alteration of the menstrual cycle to enhance the timing or effectiveness of fertility treatment. OCP's contain a synthetic estrogen and progesterone that temporarily suppress normal ovarian and pituitary hormone production, improving some conditions, such as PCOS and endometriosis. Within the uterus these pills can prevent an abnormal endometrial lining that is out of phase, overgrown or unreceptive to an embryo. When OCP's are stopped, it results in light bleeding, and some women will have no bleeding. Though not a concern for treatment, women COMMONLY have spotting while taking OCP's and this is usually NORMAL! OCP's are <u>always</u> stopped before ovulation drugs are started.

#### Indications and Benefits:

**Polycystic Ovary Syndrome** (PCOS) - With this condition the ovaries produce abnormal amounts of male hormones and ovulation is often difficult to stimulate. While drugs such as clomiphene and fertility injections sometime induce ovulation, many people are resistant. OCP's improve the PCOS prior to attempting to make the woman ovulate, thus reducing the dose of medicine required.

**Persistent Ovarian Cysts** - Occasionally a cyst will remain or arise after a natural or stimulated cycle. This would be detected on a "baseline" ultrasound scan and if it is producing hormones, could negatively affect the next cycle. To suppress these types of cysts, OCP's allow time for the cyst to resolve and prevent new ones from developing. Use of OCP's reduces the chance of having to cancel/postpone treatment.

**Cycle regulation** - Many couples have busy schedules and timing of intercourse is difficult, if not impossible, with their normal menstrual cycle. In such cases, the cycle start may be changed by OCP's, allowing ovulation to fall near a particular date.

**Low-responders** - Some women produce few follicles and will respond better if given a combination of OCP's and Lupron injections before starting fertility medicines. This appears beneficial to women in their late 30's or 40's.

#### **PATIENT INSTRUCTIONS:**

Once you start taking OCP's you should continue the ACTIVE PILLS until instructed to stop. Please call before stopping the active pills, as this might cause a menstrual period and delay your treatment.

#### SIDE EFFECTS AND RISKS:

- Headache, nausea and bloating are uncommon and usually require no change in medication.
- **Break-through Bleeding** Light spotting or bleeding can be an annoying consequence. This may occur at any time and is unpredictable. However, there is no effect on the ovaries and does not usually require any alteration. Call if bleeding exceeds your normal menstrual flow.
- Blood Clots With extended OCP use (months), the chance of blood clots in leg veins is slightly increased, but remains much lower than the risk of clots associated with pregnancy. If you experience swelling, pain in the legs or shortness of breath, call immediately.

## ✤ ORAL MEDICATIONS for OVULATION INDUCTION

**Clomiphene citrate** (Clomid®) and Letrozole (Femara®) are oral medication used to stimulate ovulation in non-ovulating women. It is also used to enhance the quality of ovulation, to correct luteal phase defects and to ensure the proper timing of artificial inseminations. Clomiphene acts to block estrogen, "tricking" the pituitary gland to produce more hormone to stimulate the ovaries. With clomiphene ovulation, an injection of hCG (Ovidrel®, Pregnyl®, etc) may also be used.

**Dosage /Timing** The lowest effective dose is desired to avoid side effects. Thickened cervical mucous may occur at higher dosages. Thus, treatment begins with one or two pills a day and is increased as needed. Your physician will determine the dose and the number of days to take clomiphene. Ovulation should occur 5 to 8 days after you take the last tablet. Intercourse or insemination should take place around the time of ovulation. Notify the office when you have a positive LH surge test so that inseminations may be scheduled.

**Side Effects** (See Risks & Complications section) Common side effects include hot flashes, headaches, breast tenderness, nausea, nervousness, visual disturbances, vaginal dryness and ovarian cysts. Thickened cervical mucous may also occur at higher dosages. Fertility pill treatment increases the rate of multiple pregnancy to 5 - 10%. (Also, see multiple pregnancies)

## **♦** FERTILITY INJECTIONS

Fertility injections are protein hormones, also called "gonadotropins", Follicle Stimulating Hormone (FSH) and Luteinizing Hormone (LH) that are purified from urine of menopausal women or generated in a laboratory. These are administered by intramuscular or sub-cutaneous injection. **Gonal-F®** and **Follistim®** are synthetic FSH made by recombinant DNA technology and are given as sub-cutaneous injections. Bravelle® and Menopur® contain FSH and LH. Gonal-F and Follistim contain only FSH. With injectable fertility medications, ovulation is always triggered by an injection of hCG (Pregnyl®, Ovidrel®) that initiates the release of eggs from the follicle.

Side Effects (See Risks & Complications section)

Mood swings and pelvic discomfort may be seen with these medications.

Multiple pregnancy occurs in 20-30% of these cycles when injections are used alone, most are twins.

**Ovarian Hyperstimulation Syndrome** occurs in less than 1% of cycles. The ovaries may become enlarged and patients can gain five to ten pounds rapidly with severe pelvic pain.

**Call the office immediately if you experience any of these symptoms.** After office hours, or on weekends or holidays, call the Doctors' Directory.

#### **♦** INTRAUTERINE INSEMINATION (IUI)

**Intrauterine insemination (IUI)** is a procedure in which sperm are "washed" (concentrated) and placed into the uterus through a catheter. A sperm wash takes about 30 minutes in the Andrology Lab and involves separating the sperm cells from the fluid, white blood cells, prostaglandin's (which can cause uterine cramping) and "debris." With natural intercourse this "washing" is accomplished by sperm swimming through cervical mucus. To place the washed sperm inside the uterus, a speculum is inserted into the vagina and a small catheter and syringe containing the sperm is inserted through the cervix into the uterus. The specimen is injected and the catheter and the speculum are removed (see FIGURE below). The procedure is usually painless and takes only a few minutes. Afterward you should remain reclining for a few minutes.



#### **Patient Instructions**

- 1. A semen specimen for intrauterine insemination should be produced following a two to three day period of sexual abstinence, unless otherwise instructed.
- 2. Obtain a sterile container from the office to collect the specimen AT HOME !
- 3. Avoid soaps, detergents, creams or lubricants to aid specimen collection. These agents may interfere with sperm motility. Assistance from the female partner is encouraged and may improve semen quality.
- 4. Collect the entire specimen in the sterile container. The volume should be between one half and one teaspoon. If there is any spillage, let the lab know.
- 5. If the specimen is obtained at a location other than the office, it must be delivered to the office/lab as soon as possible (ASAP) after collection. Keep the specimen close to body or room temperature during transportation. **Do not put it near heat or direct sunlight!** Time is not as important as temperature when transporting semen samples, therefore, drive carefully.
- 6. <u>Always</u> label the specimen cup with your NAME, DATE and TIME of collection and number of days since last ejaculation. According to lab policy, specimens received without this information may be refused and not be processed.
- 7. Inseminations are scheduled 12-48 hours after urine +LH surge, or 24-36 hours after administration of hCG.

#### Side Effects & Risks

**Bleeding** - You may have some spotting. The cervix is fragile, and insertion of the catheter may cause the tissue to bleed. **Cramping** - You may also experience uterine cramping for a short time after IUI and you may take acetominophen or ibuprofen.

**Infection** - Bacteria in the semen or in the vagina may be passed into the uterus with insemination. The chance of infection is believed to be very small but would probably require antibiotics. Although unlikely, a severe infection may require hospitalization and intravenous antibiotics.

#### Call the local office immediately if you experience any of the following symptoms:

Cramping that persists or becomes severe.

Bleeding as heavy as the heaviest flow during your menstrual period.

A temperature of 100.4°F or above.

After office hours, or on weekends or holidays, call the Doctors' Directory.

#### \* THERAPEUTIC DONOR INSEMINATION (TDI) or use of DONOR SPERM

Despite great advances in treatment of male factor infertility, there is occasionally a need for donated semen. Use of donor sperm may be indicated when there is absence of sperm or the available sperm cannot fertilize eggs. The success of insemination with frozen/thawed, donor sperm appears to be somewhat lower than the chance of conceiving with fresh sperm.

Several national sperm banks recruit and screen donors according to standards established by the American Society for Reproductive Medicine (formerly called American Fertility Society) and the American Association of Tissue Banks. The genetic and medical histories of each donor, as reported by the donor, are reviewed and traced back two generations. The donor and his sperm are screened for some, but not all genetic diseases such as sickle cell anemia, Tay-Sachs disease, thalassemia, and for various sexually transmitted diseases, including but not limited to hepatitis, human immunodeficiency virus (HIV), cytomegalovirus, gonorrhea, chlamydia, trichomonas, monilia, gardnerella and syphilis. These standards have been established to reduce the risk of transmission of genetic and infectious diseases. However, in spite of these precautions, it is possible for donated sperm to harbor unidentified genetic abnormalities or undetected infections which may be passed on to the resulting child(ren). Infected sperm may also pass on a disease to the woman attempting pregnancy.

The risk of major birth defects following use of donor sperm appears to be the same as in the general population. Similarly, there is no apparent increase in the risk of pregnancy complication following donor sperm insemination.

Before starting a treatment cycle, the woman/couple may be provided with a list of several sperm banks and information on how to inquire about donor sperm. It is the responsibility of the woman/couple to select and contact the sperm bank, select the donor and order the sperm of their choice, and ensure its timely delivery to this facility for analysis and preparation for insemination.

When use of donor sperm is indicated, it is strongly recommended that the couple participate in at least one counseling session with a local psychologist or licensed counselor. This may be waived if the couple acknowledges the concerns and declines this request. NewLIFE does not participate in inseminations from a "known" sperm donor, relative or friend.

If elected, both female recipient and partner/spouse (if applicable) will be asked to provide consent on a separate form for use of sperm from a donor bank. You will be authorizing this practice to use sperm from a single donor as the sole source of sperm in a treatment cycle(s) and that, from the moment of insemination, you accept any child(ren) resulting from the procedure of donor sperm insemination as your own. The child(ren) produced as a result of donor sperm insemination is/are considered, in all respects, the child(ren) of the woman/couple. Financial responsibility for the pregnancy, any pregnancy complications and the child(ren) resulting from donor sperm insemination, is the responsibility of the woman/couple.

## SIDE EFFECTS, RISKS AND COMPLICATIONS OF FERTILITY TREATMENT

#### **\*** OVULATION INDUCTION MEDICATIONS

Overall, side effects directly due to fertility medications are uncommon and mild. For patient education purposes some of these are described in this section of the booklet.

The most frequent adverse reactions to clomiphene include ovarian enlargement, transient hot flushes (which may be unpleasant but are not dangerous) and abdominal discomfort. Women who do not ovulate normally on their own, may notice new symptoms usually associated with ovulation, e.g. mid cycle ovulation pain, premenstrual symptoms (abdominal discomfort, breast tenderness, etc.) and menstrual cramps.

If you experience persistent or progressive pelvic pain, you should report it to your physician. Other side effects, occurring in a very small percentage of women, include nausea, vomiting, nervousness, insomnia, visual symptoms, headache, dizziness and light-headedness.

Fertility injections are protein hormones similar to, and with some, identical to those made in the body. Thus, side effects are uncommon. The chance of multiple pregnancy (e.g. twins, triplets, etc.) with injections is significantly increased (See Multiple Pregnancy page that follows). Most of the side effects of these drugs are minor, involving discomfort, but not usually requiring ongoing or unusual medical intervention. The manufacturers advise that rare but serious pulmonary conditions and thromboembolic (blood clot) events have been reported in conjunction with the use of ovarian stimulation medication and some patients might have a hypersensitivity (allergy) to such drugs. Symptoms of generalized rash, swelling or difficulty breathing should be reported immediately to your doctor.

These drugs may occasionally cause the development of ovarian cysts (non-cancerous, fluid-filled structures in the ovaries); in rare instances these may need to be removed surgically, in which case hospitalization may be required. It is also possible for ovarian cysts to rupture, causing an episode of pain. Under rare circumstances, the rupture of an ovarian cyst may be associated with sudden bleeding and require surgery and/or blood transfusion(s). Such acute bleeding is very unusual. The removal of an ovarian cyst can result in the loss of an ovary, though this is uncommon.

Though it is recommended to avoid use of any medications during pregnancy, it is sometimes difficult to rule out the possibility of a pregnancy even when it seems that normal menstruation has occurred. For this reason, women may be asked to have a pregnancy test prior to starting treatment. Additionally, couples may be asked to refrain from intercourse, or use barrier protection at certain times of the woman's cycle.

## ✤ ECTOPIC PREGNANCY & WARNING SIGNS

An ectopic pregnancy is a pregnancy that implants somewhere outside of the uterus. It can occur in a fallopian tube, on an ovary, or in rare instances inside the cervix or in the abdomen. The pregnancy does not usually develop normally and may rupture, causing bleeding and damage to the tube or ovary. If not treated, an ectopic pregnancy can be life threatening.

Ectopic pregnancy occurs in less than 1% of pregnancies. Women with a history of prior ectopic pregnancy, chlamydia, pelvic inflammatory disease, gonorrhea, endometriosis and/or tubal adhesions are at higher risk. Diagnosis of an ectopic pregnancy is usually made with ultrasounds and blood hormone studies. In some instances the drug methotrexate can be used to treat the condition or surgery may be required to remove the pregnancy.

#### Symptoms of an ectopic pregnancy may include:

- \* Uterine cramping/bleeding
- \* Sharp lower abdominal pain on the right or left side.
- \* Light-headedness or fainting
- \* Cold sweats
- \* Shoulder pain

Infertility patients have an increased risk for an ectopic pregnancy. Therefore, your blood hormone levels will be monitored and an ultrasound scheduled early in pregnancy to rule out an ectopic pregnancy. **Call the office immediately if you experience any of the symptoms listed above.** After office hours, or on weekends or holidays, call the Doctors Directory.

### ✤ OVARIAN HYPER-STIMULATION SYNDROME

**Ovarian Hyperstimulation Syndrome (OHSS)** is a serious condition that results from an exaggerated response to fertility medications used for ovulation induction. It typically arises after ovulation (hCG injection) and is more likely if a pregnancy occurs. When it develops, ovaries may become too large and may leak fluid, bleed, twist or rupture. Fluid may collect in the abdomen and/or lungs and blood may become concentrated resulting in kidney damage or blood clots, if not treated. Severe ovarian hyperstimulation is rare (<1%) in patients closely monitored but women with polycystic ovary syndrome and those that conceive are at higher risk.

OHSS is best managed by <u>prevention</u> and close cycle monitoring with ultrasound and blood tests. Use of large volumes (2 liters/day) of electrolyte containing fluids (Gatorade®, Powerade®) may be advised in some cases, and if unable to tolerate oral fluids, intravenous replacement may be needed. If an exaggerated response occurs, the cycle may be canceled by withholding the hCG injection and avoiding intercourse. Birth control pills may also be used to reduce the cyst size.

Once OHSS develops it is most commonly improved by removal of excess fluid in the abdomen, but may also respond to or be managed with intravenous fluid therapy, salt restriction, albumin and avoidance of abdominal and pelvic exams and intercourse. These therapies will sometimes require hospitalization when potentially life-threatening conditions arise.

#### **Symptoms**

Persistent pelvic pain Abdominal fullness Difficulty breathing Decreased urination Rapid weight gain (2 lbs or more per day) Nausea/vomiting Diarrhea

If you develop any of these symptoms during the 1-4 weeks after the hCG injection, contact the office <u>immediately</u>. After hours or on holidays call the Doctors Directory.

#### ✤ MULTIPLE PREGNANCY

**Multiple pregnancy / multiple births:** As fertility medications may stimulate more than one egg (often that is a primary goal), pregnancy with two or more babies occurs more often than the 1% of spontaneously conceived pregnancies in the general population. Multiple pregnancies occur in about 7% of clomiphene-stimulated cycles and 20-30% if fertility injection cycles. The majority of pregnancies in both cases are twins.

Unfortunately, multiple pregnancies cannot be reliably predicted or prevented. Mothers carrying multiple pregnancies are at higher risk of anemia, pregnancy-induced hypertension (toxemia), liver dysfunction, bleeding, infection and early labor with ruptured membranes. Serious maternal complications increase, in general, with each additional gestation as shown in Table 1.

Number of	Preterm	Preterm	Gestational	Pre-eclampsia
Fetuses	Labor	Delivery	Diabetes	
1	15%	10%	3%	6%
2	40%	50%	5-8%	10-12%
3	75%	92%	7%	25-60%
4	>95%	>95%	>10%	>60%

Table 1. Rates of Major Maternal Complications by Fetal Number

Source: American Society for Reproductive Medicine. Practice Committee Report. Nov 2000

Most multiple pregnancies require C-section delivery. Medical conditions in the mother will further raise the risk for maternal complications. Babies from multiple pregnancies have a higher risk for miscarriage, abnormal growth, birth defects and genetic abnormalities and handicaps due to prematurity and early delivery. Premature delivery is common in twins and expected in pregnancies with three or more babies. The risk to premature infants increases the earlier they are born and the possibility for severe complications with potential life-long disabilities exist. Pediatric intensive care for multiple premature babies is very expensive and many couples express deep concern about caring and raising multiple children at the same age. When considering the possibility of these obstetrical and neonatal complications, couples may consider selective reduction to reduce risk.

## **♦ SELECTIVE REDUCTION FOR MULTIPLE PREGNANCY**

Pregnancy with more than a twin has become rare with contemporary fertility care. When it occurs, pregnancy is complicated ("high risk") with risks to mother and babies. Though a very difficult decision, and not an option for all couples, reducing a multiple pregnancy to a lower number, twins or triplets, is available at larger medical referral centers. The methods used are effective and safe. The chance of endangering the entire pregnancy is low (4-9%) but this risk is increased when larger numbers of pregnancies are reduced (i.e. quintuplets versus quadruplets).

Though pregnancies reduced to twins and triplets retain the possibility for pregnancy complications, reduced pregnancies will have significantly better outcomes than those not reduced as the length of pregnancy and birth weight of the babies are increased, reducing the chance of long term disabilities.

A couple's attitude toward this procedure should be considered and agreed by both partners <u>BEFORE</u> initiation of fertility treatment. A couple having serious emotional, ethical, or religious reservations regarding the selective reduction procedure may attempt to limit the risk in a number of ways. Options include: a) cancelling any stimulated cycle with more than 3 mature follicles; b) substitute sexual intercourse for insemination; c) convert the cycle to In Vitro Fertilization where the number of embryos placed into the uterus may be controlled. These options are not always absolutely secure or available.

Please discuss this with your partner first and then with your physician <u>BEFORE</u> providing consent to treatment and before treatment begins. To address this difficult situation, couples should discuss this issue and decide together what their choices would be in such cases. Their decision may be aided by consultation with clergy, a perinatologist (high-risk pregnancy specialist) and other counselors.

## ✤ PREGNANCY AND BIRTH FOLLOWING FERTILITY TREATMENT

The likelihood that infertility treatments will result in a pregnancy or live birth depends on many individual factors: primarily, the age of the woman, the quality of the sperm, the response of the woman's ovaries to stimulation with clomiphene or gonadotropins, the underlying cause(s) of infertility, and the condition of the uterus. Whatever the course of treatment, the response of any individual patient cannot be predicted with certainty. It is important to discuss your particular circumstances and history with your physician in order to arrive at a reasonable understanding of your chances of pregnancy or birth following on or more treatment cycles. However, there are no guarantees of successful outcome no matter how favorable the rate projected for a given couple.

After pregnancy is achieved, the following complications may occur:

- 1. The fetus may not develop normally and spontaneous miscarriage may occur.
- 2. Abnormalities in the fetus become suspected or detected through prenatal diagnostic procedures (e.g. "triple screen" blood testing, chorionic villus sampling, amniocentesis or ultrasound) and may lead the woman/couple to decide to terminate the pregnancy.

Even an apparently normal ongoing pregnancy presents risks to both the mother and the baby, and cannot guarantee a normal delivery at term of a healthy infant. In pregnancies occurring after infertility treatments, as in pregnancies resulting from intercourse, serious unforeseen obstetrical complications occur. Such complications may result in miscarriage, the loss of the child in advanced pregnancy (stillbirth) or delivery of a baby too premature to survive. A prematurely born infant may experience serious life threatening complications or permanent medical disability.

While the use of medications for ovulation induction involves increased risk of multiple pregnancy, other obstetrical complications (not related to multiple birth) seem to occur following infertility treatments at the same rate that they occur in pregnancies following spontaneous conception.

The rate of major birth defects in children born to mothers in the general population is about 3-4%. The risk that a child will be born with a major birth defect increases as its parents' ages increase. There is no evidence that genetic problems, which are responsible for half of birth defects, are increased by infertility treatments. But amniocentesis and/or chorionic villas sampling, each of which can aid the recognition of many of these defects early in pregnancy, should be discussed with your obstetrician. Ultrasound screening and other examinations may detect some but certainly not all defects. It is generally recommended that women who will be age 35 years or older by the date of expected delivery should consider prenatal diagnostic testing. This should be discussed with your obstetrician.

In rare instances, pregnancy may result in serious harm or even death to the mother due to occurrences such as pulmonary embolism (blood clot to the lung), stroke to hemorrhage after delivery. There is no known increased risk for these complications in pregnancies following infertility treatments.

The Reproductive Endocrinology and Infertility physicians do not function as obstetricians, but will work cooperatively with a woman's obstetrician in early pregnancy. Generally, the early care of pregnancy is provided by the fertility specialist, but the patient returns to her obstetrician for routine care after a healthy pregnancy has been established, usually around the 7-8th week. Details of her infertility treatment, the pregnancy hormonal testing and pregnancy ultrasound scans will be released to the obstetrician designated by the woman/couple and to the referring physician, unless specifically requested otherwise by the woman/couple.

#### **\* OVARIAN CANCER RISK**

The Society of Assisted Reproductive Technology (SART) and the American Society for Reproductive Medicine (formerly the American Fertility Society) attempt to address concerns that using fertility drugs can cause breast, ovarian, or uterine cancer. These cancers are more common in women with infertility, so it is difficult to know whether the infertility is the reason for the cancer or the use of the medications. In current studies that take into consideration the increased risk of cancer due to infertility, there does not seem to be an increased risk of cancer due to the fertility drugs alone. More studies need be done to confirm whether there is an association of cancer with use of fertility drugs.

If you are planning on or believe Assisted Reproductive Technologies (ART) aka "IVF" may be necessary, please continue reading the second Patient Education Document on ART.

NOTES (please make notes of any topics or concerns you may have, to be addressed at your next visit):

