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Date Feb 10, 1995
Updated Sept 9, 1997; May 1, 2000; Aug 1, 2002

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Subject Policy on Performing PET Studies on Females of Child-Bearing Potential

To PET Investigators

As noted on the prescription form for PET radiopharmaceuticals, if a female of child-bearing potential is to receive a research PET scan, the physician-investigator is responsible for determining pregnancy status. This is especially important, as these are research studies and many subjects are normal volunteers. Investigators must not only obtain a pregnancy test but also interview the subject because of the possibility of a negative test early in a pregnancy, i.e., during the first two weeks (approximately) after fertilization. Subjects should not only be asked if they think they could be pregnant; a history should be obtained to determine the possibility of pregnancy. The following documentation must be provided before the dose can be approved:

1. The report of a negative pregnancy test from the CC or another accredited lab, performed the day of the scan or the day before. If the MIS system is down and you obtain a verbal report, write a note with this information and the name of the person providing the report. The subject should be instructed beforehand on the timing of urine collection to avoid the problem of dilute urine invalidating the test results. If the test is unsatisfactory, it may be possible to proceed if an adequate history is obtained to exclude pregnancy; this information must be provided in a detailed note.
2. A signed statement from the subject concerning pregnancy and breast feeding. There are cards ("blue cards") available for this purpose.
3. A signed, dated note on the back of the blue card documenting your interview. This should state that you have interviewed the patient on (provide the date) and that on the basis of the interview and pregnancy test, you do not think that the patient is pregnant. The interview must be on the day of the scan. You should obtain enough information to support your decision, e.g., date of the LMP, whether it was normal, whether the subject has had sexual intercourse since the LMP, and what method of contraception was used. You must also determine whether the contraception method has been used long enough to establish its effectiveness. Minors should be interviewed alone. You should also document this interview in the chart.

We use the same upper age range for these procedures, 55 years, that is used for clinical nuclear medicine scans in DNM. In the case of subjects who are pre-menarche or who are surgically sterile (e.g., hysterectomy, oophorectomy), this should be recorded in a note and a pregnancy test need not be done. Subjects who are surgically sterile should still sign the blue card.

Wording must be included in consent forms to indicate that PET scans should not be performed if pregnancy is possible, that the subject should tell the investigator if she thinks she might be pregnant, and that a pregnancy test will be performed. The issues involved should be discussed with prospective scan subjects before the day of the scan to avoid last minute surprises. Note that the chance of pregnancy will be substantially decreased if it is possible to schedule the scan during the first part of the menstrual cycle.

If it is not possible to document non-pregnancy, the scan cannot be performed.

The above procedures are reviewed in a short training session given by the PET Department. Physicians must attend one of these sessions to be able to order scans in women of child bearing potential

The Medical Letter

On Drugs and Therapeutics

Published by The Medical Letter, Inc. • 1000 Main Street, New Rochelle, N.Y. 10801 • A Nonprofit Publication

Vol. 37 (Issue 941)
February 3, 1995

CHOICE OF CONTRACEPTIVES

New information about contraceptives continues to become available. The commonly used methods of reversible contraception are listed below.

Method	Mechanism of action	Failure rate* Typical Use	Failure rate* Perfect Use	Some adverse effects or disadvantages	Some advantages
No method		85%			
Periodic abstinence	Avoidance of coitus during presumed fertile days	20%			
Spermicide alone	Inactivation of sperm	21%	6%	Vaginal irritation	May protect against some sexually transmitted diseases (STDs)
Cervical cap with spermicide	Mechanical barrier; inactivation of sperm	18%	11.5%	Cervical irritation, may be difficult to fit, Pap smear abnormalities	Protection against STDs
Diaphragm with spermicide	Mechanical barrier; inactivation of sperm	18%	6%	Cervical irritation, increased risk of urinary tract infection	Protection against STDs
Condom	Mechanical barrier				
	male	12%	3%	Allergic reactions	Protection against STDs
	female	21%	5%	Difficult to insert, poor acceptability	Protection against STDs, including external genitalia
Oral contraceptives		3%			
Combined	Suppression of ovulation, changes in cervical mucus and endometrium		0.1%	Rare thromboembolism and stroke, myocardial infarction in older smokers, nausea, headache, depression	Protection against ovarian and endometrial cancer, pelvic inflammatory disease, fibrocystic breast disease, ovarian cysts, iron-deficiency anemia and dysmenorrhea
Progestin only	Changes in cervical mucus and endometrium, possibly suppression of ovulation		0.5%	Irregular, unpredictable bleeding in some	Protection against pelvic inflammatory disease, iron-deficiency anemia and dysmenorrhea
Intrauterine devices	Inhibition of sperm migration, fertilization and ovum transport			Increased ectopic pregnancy with progesterone device, rare uterine perforation, increase in menstrual blood loss with copper device	Decrease in menstrual blood loss and dysmenorrhea with progesterone device
Progesterone T *(Progestasert)*		2%	1.5%		
Copper T 380A *(ParaGard)*		0.8%	0.6%		Copper device can be left in place for 10 years
Medroxyprogesterone acetate *(Depo-Provera)*	Suppression of ovulation, changes in cervical mucus and endometrium	0.3%	0.3%	Menstrual irregularities, headache, weight gain, acne	Effective for 3 months
Levonorgestrel subdermal implants *(Norplant)*	Similar to progestin only	0.09%	0.09%	Menstrual irregularities, headache, weight gain, acne, removal problems	Ease of use, reversibility, effective for 5 years

* Percent accidental pregnancy during first year of use, modified from RA Hatcher et al, *Contraceptive Technology*, 16th ed., New York:Irvington, 1994, page 113.

EVENT	WEEKS POST-LMP	hCG LEVELS (mIU/ml)
Last Menstrual Period	0	0
↓ 14-18 Days		
Ovulation	2	0
↓ 1-20 Hours		
Conception	2	0
↓ 6-8 Days		
Implantation	3	0-20
↓ 3-6 Days		
Missed Period	4	4-430 (mean = 37)
Ultrasound Visualization		
Intrauterine gestational sac	5-6	373-7,800 (mean values)
Fetal heart movement	7-8	31,800-72,800 (mean values)

Figure 16. Time frame of early pregnancy. The hCG values are from Table 22 and Fig. 14 (*upper curve*).

In a study of 121 women in an *in vitro* fertilization and embryo transfer program, Lopata and associates (702) reported blastocyst implantation in 17 women. Based on urinary hCG levels measured by RIA and corrected for interference by hLH and other immunoreactive substances, implantation was detectable 8 to 9 days after fertilization in 20% of conception cycles, in 80% by days 12–13, in 93% by days 14–15, and in 100% by days 16–17. Hay et al. (473) monitored both serum and urine levels of hCG in *in vitro* fertilization and embryo transfer patients, and found that serum assay was the more sensitive indicator of pregnancy. Although the urine values generally paralleled the serum values, rises in urinary hCG levels occurred approximately 1 day later. In some cases where the serum levels of hCG were just detectable, no hCG was detected in the urine.

For Radiation Safety purposes, please answer the following questions:

Age:_____

Are you:

Pregnant	☐ Yes	☐ No
Breast Feeding?	☐ Yes	☐ No

I have had the opportunity to discuss any questions or concerns I have with a staff physician in Nuclear Medicine.

_____ _____

Patient's Signature Date