

CURRENT MEDICAL RESEARCH

SUPPLEMENT

Hanna Klaus, M.D.

DIOCESAN ACTIVITY REPORT

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NFP Related Research

Indian Council of Medical Research Task Force on Natural Family Planning. **Field Trial of Billings Ovulation Method of Natural Family Planning.** *Contraception*, 53 (Feb. 1996): 69-74.

The long-awaited publication of the field trial of the Billings Method by the Indian Council of Medical Research conducted in Patna, Jaipur, Bangalore, Dindigul, and Kanpur reports 2,059 women who were followed for an average of 21 months or a total of 32,957 women/months of use. Most women were 26 years of age at the time of entry into the trial; one-third were illiterate; one-fourth had been in school up to standard VIII; one-third were standard IX or above; 88% were housewives; half lived in nuclear, half in joint families. Eighty-eight percent (88%) were Hindu, 9.6% Muslim, 1.8% Christian, 0.8% Sikh or other. Most had had two children. Method-related (perfect use) pregnancy rates were 1.1 at 12 months, 1.5 at 21 months; imperfect use (user-related) pregnancy rates: 10.5 at 12 months; 15.9 at 21 months. Continuation rate: 76% at 12 months, 52% at 21 months. At 21 months, urban continuation rate was 59.5 and rural, 41.1. This may be accounted for by a much higher loss to follow-up rate (23.5%) in the rural population than in the urban - (12%). Most of the discontinuations were due to pregnancy (16%) and switching to another method (20%). The authors

find that the method efficacy rate is very high and the cumulative user related pregnancy rate not at all disturbing in line of findings with other methods. Method switching is a normal practice among spacers and those who wish to avoid pregnancies but do not want a permanent method. Thus the inclusion of the Billings Method is a feasible and acceptable option for the Indian Family Planning Program especially in the light of "unmet need for contraception" of 17% of the Indian population. The authors acknowledge with thanks the assistance of Dr. Sr. Catherine Bernard, Executive Director of SERFAC, Madras, who had assisted in drafting the protocol for trial, trained the project staff and principal investigators, and provided background material free of charge. [*Congratulations Catherine! Ed.*]

Wilcox, A.J., et al. **Timing of Sexual Intercourse in Relation to Ovulation.** *New England Journal of Medicine*, 333 (Dec. 7, 1995): 1517-1521.

This article was picked up by the lay print and visual media and publicized highly. The team studied 221 women who had discontinued the birth control pill in order to try to become pregnant. The usual hormonal parameters: estradiol, pregnanediol, hCG, and LH were monitored and the window of fertility rediscovered to be no more than

six days up to ovulation. [*This study did not deal with isolated intercourse; hence, its conclusion that the timing of intercourse does not affect the sex of the baby, is not persuasive to this reviewer. In view of the enormous publicity which this article received, we append Jeff Spieler's letter which was published in The Washington Post. Ed.*]



Letter to the Editor

The Washington Post, Dec. 8, 1995,

[NB: The published version deleted the bracketed text in para. 2.]

The article "Fertility Ebbs at Ovulation" (*Washington Post*, Dec 7) surprised me for several reasons. For almost 25 years researchers (and, I thought, practicing physicians, especially gynecologists dealing with fertility) have known that within 24 hours after ovulation a woman is no longer fertile, and that sperm deposited in the female reproductive tract several days before ovulation are capable of fertilizing an ovum. While I was working for the WHO Human Reproduction Programme in the 1970s the Task Force on Methods for the Determination of the Fertile Period supported several research projects and publications that showed peak fertility occurring just prior to and on the day of ovulation, with a steep decline in pregnancy immediately after ovulation. A major methodological problem has been the accurate determination of the day of ovulation. This is why some studies have shown a small probability of

fertilization one or two days after ovulation. Direct visualization of ovulation or ultrasound determination of the day before and after maximum follicular diameter, are the best ways of pinpointing when ovulation actually occurs. Chemical tests of hormone levels have a margin of error of about 24 hours and, by definition, "to estimate the exact day of ovulation" is close to a contradiction in terms.

I am hoping that Ronald Jacobs of Obstetrics and Gynecology Associates was misquoted when the *Post* reported his saying "that the [peak fertility period] extended five days to a week after ovulation." [Likewise, The Washington Post figure "conception misconception" (page A27) is confusing because it mixes the concepts of the fertile period for maximizing the probability of conception with the fertile period for preventing unplanned pregnancy. Very simply stated and as the figure shows, the rhythm or calendar method of family planning is based on the notion that if one abstains between days 9 and 19 or days 10 and days 20 of a 28-day menstrual cycle, pregnancy cannot occur. This wide span is needed because of the imprecision of determining the actual fertile period based solely on the lengths of the shortest and longest previous 6-12 menstrual cycles. The actual "fertile span" is correctly shown in the figure for a 28 day cycle. However, research has shown that in a 28 day cycle ovulation can occur as early as day 12 and as late as day 18.]

Teachers and users of so-called natural family planning, mentioned by Professor Joe Leigh Simpson of Baylor College of Medicine, [in an accompanying editorial] like the Billings (ovulation) method, the basal body temperature (BBT) method and the sympto-thermal method have known, literally for decades, that after ovulation women are no longer fertile. These methods use physiological signs and symptoms of ovulation such as changes in cervical mucus and BBT to determine the start and end of the fertile period. I am pleased that the results of Dr. Wilcox's study have been published and that *The Wash-*

ington Post found this type of important information worthy of publication - Wilcox's data add to the world literature and confirm what many scientists, practicing physicians, and lay people already knew. However, I am surprised that *The Washington Post*, other newspapers and television shows are acting as if this is a front-page revelation. It is a shame that it takes so long for scientific knowledge to become general knowledge.

Jeff Spieler
Bethesda, MD

Hilgers, Thomas W., M.D. *The Scientific Foundations of the Ovulation Method*. Omaha: Pope Paul VI Institute Press, 1995 (pp. 81).

This nicely bound spiral notebook reflects the personal contribution to research and service delivery of the Ovulation Method which Thomas Hilgers' has modified into the Creighton Model. Understandably, a great deal of commonly known background research is abbreviated. The following is a brief review of this text.

Chapter one shows several figures of charts with very little explanation. Hilgers, Prebil, Daly, and Bailey embarked on a research project to monitor the Ovulation Method according to the vulvar sensation, crystalline patterns of dried cervical mucus, BBT, pain, and hormonal assays. This resulted in five publications which Hilgers details in Chapter 2. Chapter 3 relates Erik Odeblad's 30 years of research on cervical mucus in 18 pages, followed by a 2-page section on sperm penetration (Chapter 4). Chapter 5 focuses on hormone assessment and correlation. Chapter 6—"Correlation through Ultrasound"—contains thought provoking data: by correlating the peak day with ultrasound parameters in 33 women Hilgers reports finding that the follicle had

ruptured relative to peak day: P-2 = 6, 1%, P-1 = 15.2%, P = 33.3%, P+1 = 27.3%, P+2 = 9.1%, P+3 = 9.1%. Since rupture, however, had occurred within 24 hours of the exam on the previous day, this may not alter our understanding significantly. Hilgers also reports 47 previously infertile women followed for almost 2,000 cycles, whose conceptions occurred between P-2 and P+3 as gauged by the same criteria. Chapter 7 succinctly presents Ruth Taylor's work in which she correlated the karyopyknotic index of vaginal cells with mucus, and [not cited in this book], patterns which involved various infections particularly bacterial vaginosis. Chapter 8 looks at continuous mucus and the Basic Infertile Pattern (BIP) as recorded by the Creighton Standard Observational Method.

Chapter 9—"The Effectiveness of the Method"—is perhaps the most controversial since Hilgers has a different view on method effectiveness and use effectiveness. While all natural family planning providers agree that the method can be used to achieve or to avoid pregnancy, Hilgers in his earlier publications, to which he refers in this booklet, defines any pregnancy as "planned" if the client has been trained for 12 weeks or more. Thus in his article with Joanne Dowd, published in the *International Review of Family Planning* in 1985, half of 25% pregnancies were surprises. Nonetheless, Hilgers now considers only method effectiveness under pregnancy avoidance while he retitles informed choice pregnancies, "teaching-related" and unresolved pregnancies from Klaus' 1979 and Mascarenhas' 1978 studies as estimated demographic effectiveness. Demographic effectiveness is defined by Hilgers as the total pregnancy rate, a combination of use effectiveness to avoid pregnancy

and to achieve pregnancy. Not everyone supports this line of thinking. When Richard Fehring published the series of use effectiveness of the Creighton Model cited in Table 13, he published data from the previous study in the *Journal of Obstetric Gynecologic and Neonatal Nursing*, [see Current Medical Research, Winter 1995] the editors required that the life table use effectiveness of 12.8 be cited. The article abstract stated a 4% unplanned pregnancy rate. Hilgers' Table 13 includes Dowd's previously published study, which reported that half of the 25% conceptions were surprises. Clearly, unplanned pregnancies do not equal unwanted pregnancies, but the distinctions should be maintained to gauge the effectiveness of any family planning method.

Chapter 9 touches on Hilgers' NaProTechnology (natural procreative education). He lists how the various aspects of his teaching methodology are applied to understanding the variations in cycle patterns. Throughout this text, it is necessary to try to follow Hilgers' thinking in order to understand his definitions, which are somewhat different from the rest of NFP providers as well as other family planners and demographers.



Contraceptive Technology and Use

Rosenzweig, B.A., et al. **Observations of Scanning Electron Microscopy Detected Abnormalities of Non-lubricated Latex Condoms.** *Contraception*, 53 (Jan. 1996): 49-53.

Condoms have been studied for integrity by testing mechanically and also with spectrofluorometry, DNA molecular hybridization, and scanning electron microscopy. The present paper reports scanning

electron microscopy studies of 15 Trojan condoms less than 6 months from date of manufacture. Samples were viewed under low and high power light microscopy as well as electron microscopy. While 60% appeared normal under low power, only 30% were normal under scanning microscopy which revealed either melting or a combination of ridging and cracking or other surface modalities. [While the clinical significance of the surface abnormalities has not been fully defined and the limitations of the technique of scanning electron microscopy must be factored into the equation, this study should cause everyone to pause before considering condoms an effective barrier to viral transmission. Ed.]

Anderson, J.E., et al. **Condom Use for Disease Prevention Among Unmarried U.S. Women.** *Family Planning Perspectives*, 28 (Jan./Feb. 1996): 25-28.

Another analysis of a 1988 National Survey of Family Growth sought to identify reasons for condom use. Sexually experienced unmarried women aged 17-44 used condoms for protection against STDs 41% of the time. Thirty percent (30%) said they used them every time or most times; 67% of these cited disease prevention as their primary motivation and 4% said contraception; 29% had both reasons for using condoms. Highest level of condom use for disease prevention was found among young women, never married women, those with highest incomes, women at the early stage of their reproductive career, women who had not been surgically sterilized and were not using oral contraceptives, women who believed in the effectiveness of condoms and who had infrequent intercourse. Black women and those who believed

condoms and spermicides to be effective in protecting against disease were twice as likely to use condoms as their counterparts at every act of intercourse, or nearly every act; women who had intercourse two or more times per week, who used the pill, or who were pregnant were about half as likely to do so.

Graham, CA et al. **The Effects of Steroidal Contraceptives on the Well-being and Sexuality of Women: A Double-blind, Placebo-controlled, Two-centre Study of Combined and Progestogen-only Methods.** *Contraception*, 52 (Dec. 1995): 363-369.

A placebo-controlled, double-blind study was conducted to ascertain the direct hormonal effects of combined and progesterone only oral contraceptives on the well-being and sexuality of women in Manila, Philippines, and Edinburgh, Scotland. One hundred fifty (150) women who had either been sterilized or whose partners had been vasectomized were recruited and studied prior to treatment, and over the next four months, women were randomly assigned to either OC's, progesterone-only, or placebo. There was no crossover component. Effects were gauged by daily ratings, questionnaires, and interviews. Half the women in Edinburgh found their interest in sex was reduced. The effects of the combined pill on the mood were modest but negative, more noticeable in the Scottish than the Filipino women. Progesterone-only pills did not affect sexuality and led to some improved sense of well-being in both centers. While sexual interest reduced markedly in the Scottish women, sexual enjoyment did not. In Manila, there were no treatment effects on sexual activity but a significant reduction in frequency in

the combined oral contraceptive group in the first month which continued but less so during the last three months. Combined oral contraceptives showed significantly more premenstrual depression as gauged by the Beck Depression Inventory, while the Manila subjects were more irritable regardless of treatment group. Scottish women were less cheerful with combined oral contraceptives, more cheerful with progesterone-only in the first month of treatment. There was no change in anger or tension. By the end of the fourth month, oral contraceptive users in both centers reported worsening of the mood. The Manila women reported significant increase in nausea, especially in the first treatment month while on placebo, while women on hormones did not report effects of period-time pain, bloating, breast tenderness, energy, or headache. However, by the third treatment month, both centers reported an increase in nausea with both treatment groups while fatigue was reduced during the bleeding phase. With progesterone-only, there was more spotting and fewer bleeding free days in the treatment groups.

In trying to explain the effect on moods, the authors suggest that it has long been believed that progestogens have a negative effect on sexual interest, but this study showed no such effect in the progesterone-only group. However, the higher level of Levonorgestrel in the oral contraceptive group may have caused the adverse effect. They also suggest that oral contraceptives affect sexual interest by reducing free testosterone. Free testosterone has been found to relate positively with sexual interest in women who are in satisfactory and enjoyable sexual relationships. This effect was not so high when relationships were less satisfactory. [This paper failed to note

two important aspects: 1) It did not distinguish between women who had been sterilized themselves and women whose partners were sterilized and 2) It did not address the frequently encountered denial of the effect of sterilization. Very often this denial does not become evident until such women require a hysterectomy and then realize that their child-bearing days are indeed over. Ed.]

Mauldon, J., and Luker, K. **The Effects of Contraceptive Education on Method Use at First Intercourse.** *Family Planning Perspectives*, 28 (Jan./Feb. 1996): 19-24.

A multi-variate analysis of data from the 1988 National Survey of Family Growth finds that formal contraceptive educational programs increase the likelihood that a teenage woman will use a contraceptive method at first intercourse. The odds that she will use a condom increased by about one-third following instruction about birth control. The likelihood of pill use is not significant unless the contraceptive education occurs in the same year that a teenager becomes sexually active, in which case, the odds that any method including condom use increased to 70-80% and the odds of pill use more than doubled. The authors suggest that with increased educational efforts, the proportion of teenagers who use condoms at first intercourse would increase from 52-59% while the proportion of those using no method may decrease from 41-33%. [The authors suggest that the education in itself may lead to sexual behavior. Since this report only analyzes 1988 data, it is not surprising to find no reference to non-contraceptive sexual education except in the bibliography which acknowledges the work of Kirby and Howard. Ed.]

Mol, B.W.J., et al. **Contraception and the Risk of Ectopic Pregnancy: A Meta-Analysis.** *Contraception*, 5 (Dec. 1995): 337-341.

Twelve case control and one cohort study were sufficiently well documented to permit meta-analysis for the risk of ectopic pregnancy after contraception. Current users of oral contraceptives or barriers are at decreased risk for ectopic pregnancy. Women who were sterilized have a very low risk of pregnancy but if they do become pregnant, the risk of ectopic pregnancy is 9.3. The risk for ectopic pregnancy after IUD use is 1.6, and for past use of OCs is 1.2, (N.S).

Rosenthal, S.L., et al. **Experience with Side Effects and Health Risks Associated with Norplant Implant Use in Adolescents.** *Contraception*, 52 (Nov. 1995): 283-285.

Seventy-two (72) young women mean age 15.5 years, were implanted with Norplant as part of their ordinary medical care in the Pediatric Department at the University of Cincinnati. Sixty-eight percent (68%) were Afro-American, 29% Caucasian, 87% receive Medicaid funding, 61% had never been pregnant, 11 had prior abortions - 3 spontaneous, 8 induced. The other 24% had given birth. At review at least one year after implantation, 48 young women still had their implants in place for a median length of 18 months - range of 12-29 months. Twenty-four (24) adolescents had had their implants removed 8-34 months after insertion. Continuation rates -97% at 12 months; 86% at 24 months. Median weight gain was 5.8 lbs at 12 months; the increase was gradual. There were exceptions - one young woman had gained 67 lbs. within a year and some had lost as much as 31 lbs. Eighty-three percent (83%) had regular menses prior

to insertion. At 12 months, 18% still had regular menses, 16% were amenorrheic, the rest had irregular bleeding. There was no association between body mass index and menstrual irregularities. Condom use definitely decreased despite counseling. Fifty-four percent (54%) had at least one episode of PID before insertion, 33% after. The difference was not statistically significant.



Fertility/Infertility

Gardner, D.K., et al. **Environment of the preimplantation human embryo in vivo: metabolite analysis of oviduct and uterine fluids and metabolism of cumulus cells.** *Fertility & Sterility*, 65 (Feb. 1996): 349-353.

When embryos are conceived in vitro, the culture medium generally bears little resemblance to physiological conditions, which may help explain low success. The composition of tubal and endometrial fluid was studied in women who were cycling normally but had other causes for infertility with the exception of endometriosis. It was found that Pyruvate in the oviduct did not vary with the day of the cycle, while lactate increased from 4.87 mM in the follicular phase to 10.50 mM at the time of ovulation while glucose decreased from 3.11 mM in the follicular phase to 0.5 mM mid-cycle and subsequently rose to 2.32 mM in the luteal phase. In the uterine fluid, concentrations of pyruvate, lactate, and glucose remained constant throughout the cycle. Metabolite concentrations in the uterine fluid differed significantly from those in the oviduct in mid-cycle. Cumulus cells readily consume glucose in vitro producing lactate. Thus the early embryo is exposed to different metabolite concentrations as it passes along the tract.

Wilcox, L.S., et al. **Assisted reproductive technologies: estimates of their contribution to multiple births and newborn hospital days in the United States.** *Fertility & Sterility*, 65 (Feb. 1996): 361-366.

Compared to 1972-74 rates, the rate of triplet and higher order multiple gestations/100,000 white live births increased by 191% in 1990-1991. Thirty-eight (38%) were due to assisted reproduction technologies (ART) and 30% to increased childbearing among older women. Overall, ART contributed 22% of US triplet and higher order multiple birth during 1990 and 1991. Since infants of multiple gestations are far more likely to be premature and have low birth weight, their stay in hospital is much longer than that of term birth infants with considerably higher morbidity and perinatal mortality rates. [The article does not attempt to estimate economic costs. Ed.]

Taymor, M.L. **The regulation of follicle growth: some clinical implications in reproductive endocrinology.** *Fertility & Sterility*, 65 (Feb. 1996): 235-247.

An extensive review of the regulation of follicular growth is presented and should be read in its entirety. Taymor describes the model for unifollicular development and the agents which cause it. In the human and primate menstrual cycle, one follicle is selected because it has adequate FSH receptors when plasma FSH levels are high. The follicle becomes dominant in spite of falling FSH levels because intraovarian growth regulators increase its sensitivity to FSH. This insight is important for the treatment of amenorrhea, anovulation, polycystic ovary disease, as well as in producing controlled ovarian hyperstimulation as part of assisted reproductive technology.

Melis, G.B., et al. **Ovulation induction with gonadotropins as sole treatment in infertile couples with open tubes; a randomized prospective comparison between intrauterine insemination and timed vaginal intercourse.** *Fertility & Sterility*, 64 (Dec. 1995): 1088-1093.

Two hundred couples (200) couples who had unexplained or mild male factor related infertility were randomized into two treatment groups: one group was treated for three consecutive cycles with ovulation induction with gonadotropins followed by timed vaginal intercourse. The second group was treated similarly but received intrauterine insemination. Pregnancy rates by cycle three were no different between the two treatment protocols, 28 and 27% respectively in the mild male factor group and 44 and 43% in the unexplained group. Multiple pregnancies and spontaneous abortions were comparable in all groups. There were no ectopic pregnancies. [Clearly in these patients, IUI offered no advantage. Ed.]



Menstrual Cycle

Rosenberg, M.J., et al. **The Effect of Desogestrel, Gestodene, and Other Factors on Spotting and Bleeding.** *Contraception*, 53 (Feb. 1996): 85-90.

Data from two comparative multi-center clinical trials of preparations containing respectively 75_g gestodene + 30_g ethinyl estradiol (EE) with 150_g desogestrel + 30_g EE, the other compared the same gestodene preparation with 150_g desogestrel + 20_g EE. Both found a higher risk of spotting or bleeding in all cycles among desogestrel users ranging from 20-70% higher in the first study and 40-140% in the second. The differences were statistically significant in four of six cycles

in each study and persisted even after controlling for consistency and recency of OC use as well as smoking. When data were pooled and controlled for estrogen dose, the desorgestrel containing preparation was significantly associated with more frequent spotting or bleeding in five of six cycles and independent of smoking, consistency and recency of OC use. [Combined with the recent three British studies which attribute increased thromboembolic episodes to gestodene, it appears that the promise of no side effects may not be borne out by experience. Ed.]

Driver, H.S., et al. **Sleep and the Sleep Electroencephalogram across the Menstrual Cycle in Young Healthy Women.** *Journal of Clinical Endocrinology and Metabolism*, 81 (Feb. 1996): 728-735.

Sleep patterns and the sleep encephalogram were studied during 139 sleep episodes from nine young

women who had no pathology, particularly no pre-menstrual syndrome. Ovulation in menstrual cycle stage were confirmed by BBT, urinary LH, plasma levels of estrogen and progesterone in mid-luteal phase. No subjective difference in the rating of sleep quality or mood was noted nor was there any detectable change in total sleep time, sleep efficiency, sleep latency, rapid eye movement (REM), or slow wave sleep. A slight change in non-REM sleep - the upper range of the so-called sleep spindles - and electroencephalographic (EEG) finding showed large variations across the cycle with a maximum in the luteal phase. However, sleep spindle frequency in healthy young women varies parallel to core body temperature while homeostatic sleep regulatory mechanisms as induced by the time course of slow wave EEG activity were not substantially affected by the menstrual

cycle. [During menopause, many women have shown sleep disturbances in REM sleep which are relieved by hormonal replacement therapy, particularly estrogens. Whether estrogen is the cause or merely the concomitant is now under discussion. Ed.]



Menopause

Sener, A.B., et al. **The effects of hormone replacement therapy on uterine fibroids in postmenopausal women.** *Fertility & Sterility*, 65 (Feb. 1996): 354-357.

Forty (40) naturally post-menopausal women with uterine fibroids were randomized into two hormonal replacement therapy protocols. Group I (22) received 50 micrograms, transdermal E₂, plus 5 mg of oral medroxyprogesterone acetate mpa continuously, while Group II received 0.625 mg oral conjugated equine estrogen and 2.5 mg oral mpa continuously. The size of uterine

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fibroids was assessed by ultrasound. All women had at least one fibroid measuring 20 millimeters or more. Measurement repeated after one year HRT. Patients also had measurements of E₂, FSH and LH pre and post-treatment. Size of the fibroids increased significantly in the transdermal therapy group. Some women complained of spotting but none abandoned the study. Although one woman's fibroid increased from 20-60 millimeters, she had no symptoms, and the fibroid regressed at the conclusion of hormonal treatment. [Transdermal estrogen bypasses the portal-enteric circulation where much of estrogen is metabolized. The greater response of the fibroids is most likely due to this. Ed.]

Burger, H.G., et al. **The Endocrinology of the Menopausal Transition: A Cross-Sectional Study of a Population-Based Sample.** *Journal of Clinical Endocrinology and Metabolism*, 80 (Dec. 1995): 3537-3545.

While the endocrinology of the normal menstrual cycle and the postmenopausal period is well studied, the menopausal transition for the years when intervals can be short or long has been less well studied. Burger and group provide a population-based study of 380 well-nourished women, mean age 49.4 years, range 45.6-56.9 years who were studied with FSH, estradiol (E₂), immunoreactive inhibin (INH), testosterone (T), and sex hormone binding globulin (SHBG). Five groups of subjects presented: 1) 27% had regular menstrual cycles; 2) 23% a change in menstrual flow without a change in frequency; 3) 9% a change in frequency but no change in flow; 4) 28% changes in both frequency and flow; and 5) 13% had not had a period at least three months prior to the study. After adjusting for age and body mass

index, mean FSH increased across both menstrual groups and was 53% higher in group 4 than in group 1, and 253% higher in group 5. Mean E₂ and INH in group 5 were 54% and 53% lower than in group 1. Group 5 women had higher FSH and lower E₂ and INH levels than those who later on had at least one more period. While a serum increase in FSH and decrease in E₂ and INH are the major endocrine changes in the menopausal transition, finding an isolated elevated FSH is no assurance that subsequent ovulation may not occur. In fact, FSH levels rise progressively from age 27 onwards. This report confirms another report showing that INH levels decline steadily as a function of increasing age while E₂ levels begin to decline at age 38. The last finding is controversial. Some investigators find unchanged E₂ levels in women who continue to have regular menstrual cycles while others find the opposite. Future studies will attempt to relate these data to cardiovascular risk factors and bone mineral density.

Castracane, V.D., et al. **When Is It Safe to Switch from Oral Contraceptives to Hormonal Replacement Therapy?** *Contraception*, 52 (Dec. 1995): 371-376.

Women who have been on oral contraceptives into their menopausal years are often advised to switch to hormonal replacement therapy (HRT). Before making the change, it is necessary to evaluate ovarian status. Twelve (12) postmenopausal women who had been on OCs and 9 peri-menopausal women, age 36-47 were studied and compared with normal controls, aged 17-25 and 26-35 who were using low-dose OCs. In the young women, estradiol levels increase at one week off the pill, together with FSH and LH in follicular phase lev-

els. Women over 40 showed a marked rise in FSH while those 36-40 had a lower response. Estradiol levels were variable but tended to show some age grouping, while LH offered little diagnostic separation. Post-menopausal women did not always have an elevated FSH level one week off the pill, but uniformly, estradiol levels never increased above basal values in peri-menopausal women who were indeed post-menopausal. If a woman who has been off hormones for two weeks shows no increase in FSH and/or no change in basal estradiol levels, one may presume that the risk of fertility is no longer present.



Adolescent Sexuality

Mott, F.L., et al. **The Determinants of First Sex by Age 14 in a High-Risk Adolescent Population.** *Family Planning Perspectives*, 28 (Jan./Feb. 1996): 13-18.

Data from the National Longitudinal Survey of Youth contains demographics of over 12,000 males and females aged 14-21 in 1979 until 1992. Ten percent (10%) of the original sample was lost to attrition. Interview topics included employment, education, health, marital history, fertility, income, household composition, and geographic residence. This data set considered only adolescents 14 or older by 1992 whose mothers were also available for study. Eighty percent (80%) of these children were born to mothers younger than 20 whose family traits placed them in a high-risk population group; almost 90% of the mothers reported having had sexual intercourse before age 18. Half had not attained a high school diploma, and a large proportion were "well on their way to an above-average family size." The outcome measure for the women's adolescent children

was whether or not they had had sex by age 14. If a mother had had sex before the age of 14, the child was likely to have a similar pattern. If mother worked extensively outside the home, early sex by the children was twice as likely. It was eight times as likely among black boys as among non-Hispanic white boys. Girls who smoked and boys who used alcohol were twice as likely to have sex before the age of 14 as those who did not. Church attendance was an important determinant of delayed sexual activity if the children's friends attended the same church.

Lawrence, M.H. & Goldstein, M.A. **Hepatitis B Immunization in Adolescents.** *Journal of Adolescent Health*, 17 (Oct. 1995): 234-243.

Hepatitis B (HBV) is estimated to affect over 300 million people, more than 5% of the world's population; more than a quarter million people die annually of HBV-associated acute and chronic liver disease. The virus is a potent carcinogen and chronic carriers are at risk of developing cancer of the liver - the HBV virus is considered to be the cause of 75-90% of hepatocellular carcinomas. The virus is endemic in most of Africa, Pacific Islands, Southeast Asia, China, Middle East and the Amazon Basin where infection of-

ten begins from early childhood contact, perinatal transmission or close household contacts. While the US is not yet considered endemic, more than 5% of the population has been infected as shown by serological studies. One means of transmission is through sexual intercourse, as well as other body fluids. Three hundred thousand infections are estimated to occur annually leading to 20,000 chronic infections and over 4,000 deaths. A safe and effective vaccine has been licensed since 1982 in the US but has not been utilized. HBV has increased 37% in the interim. Because high risk groups have not responded to immunization campaigns, the Immunization Practices Advisory Committee of the Centers for Disease Control and the American Academy of Pediatrics now recommend routine vaccination of all adolescents because logistically it is easier to access students in middle schools. The current vaccination schedule is three injections, the first two given at four-week intervals, the next one six months after the second dose. Two vaccines—Recombivax HB and Engerix-B—are available, are equally immunogenic, are both produced by recombinant DNA technology and have had very few side effects, primarily soreness at the injection site. Because immunizing a previously exposed indi-

vidual apparently causes no side effects, prevaccination serologic testing is generally not cost effective. However, a chronic carrier is not cured by the vaccination, nor does the vaccine make high risk behavior any safer since the risks for acquiring all other STDs is not affected. Currently the three injection course costs \$150-\$200 for an adult, although the recently lower dosage recommendations for adolescents is expected to lower the price for the series. If/when a universal vaccination program for adolescents is implemented, a substantial reduction in the price is anticipated.

Questions?

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