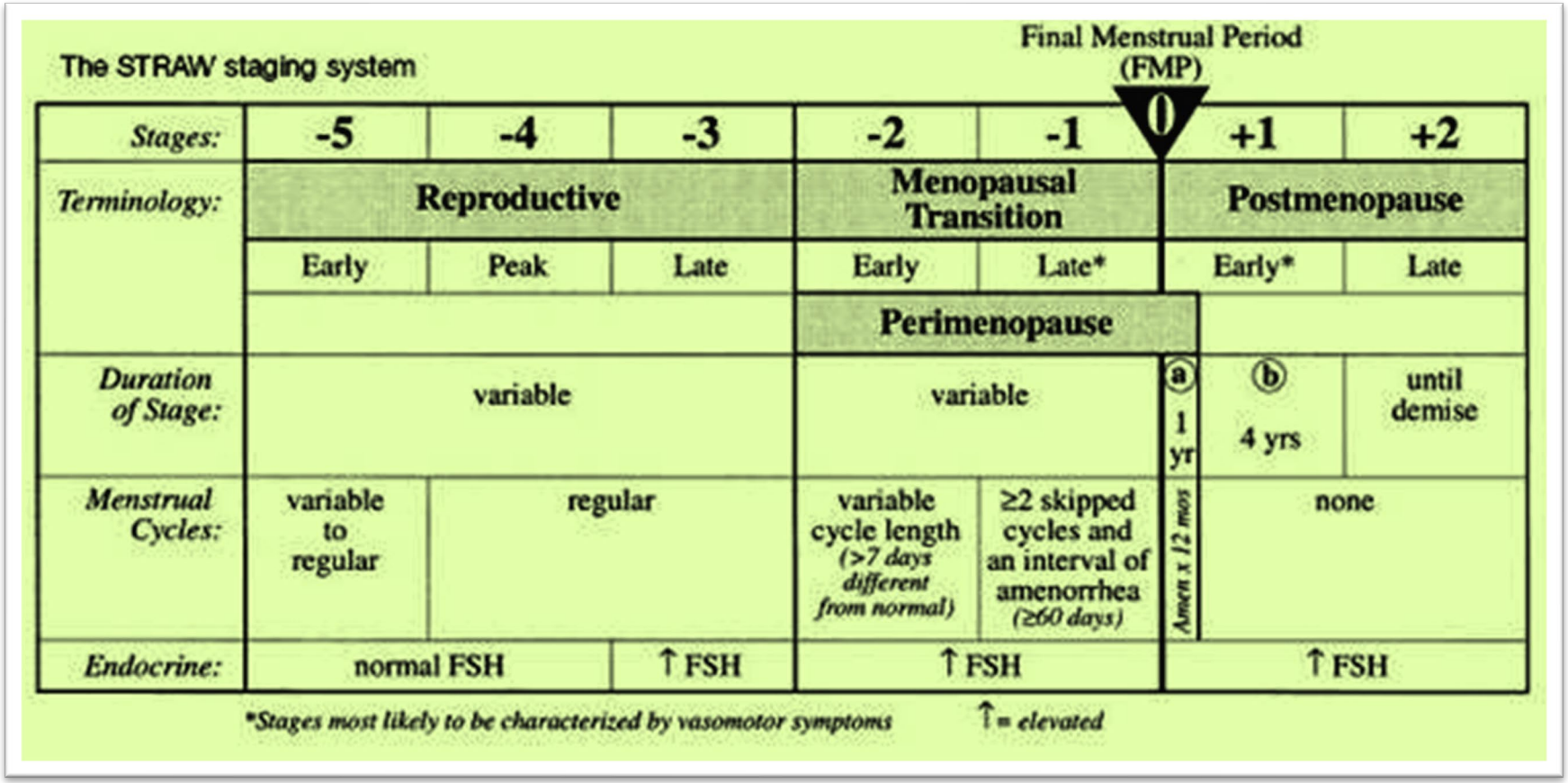
Effectiveness when used Perimenopause

Problem

- Not a lot known about the use of NFP/FABM during the peri-menopause transition.
- During this transition the menstrual cycle length shortens but becomes more variable as menopause approaches.
- It is like the reverse of the menstrual cycle variability with adolescents (Brown, 2011).

STRAW Model I



The STRAW staging system

Final Menstrual Period (FMP)

Stages:	-5	-4	-3	-2	-1	0	+1	+2
Terminology:	**Reproductive**			**Menopausal Transition**			**Postmenopause**	
	Early	Peak	Late	Early	Late*		Early*	Late
				Perimenopause				
Duration of Stage:	variable			variable		ⓐ 1 yr	ⓑ 4 yrs	until demise
Menstrual Cycles:	variable to regular	regular		variable cycle length *(>7 days different from normal)*	≥2 skipped cycles and an interval of amenorrhea *(≥60 days)*	*Amen x 12 mos*	none	
Endocrine:	normal FSH		↑ FSH	↑ FSH			↑ FSH	

**Stages most likely to be characterized by vasomotor symptoms*

↑ = *elevated*

Parameters of the Menstrual Cycle by Age Group

GROUP 1) age **18-25** (**N428 with =392 cycles of data**), **GROUP 2)** age **26-34** (**N=1,118, with 945 cycles of data**), and **GROUP 3)** age **35-52** (**N= 587 with 545 cycles of data)**

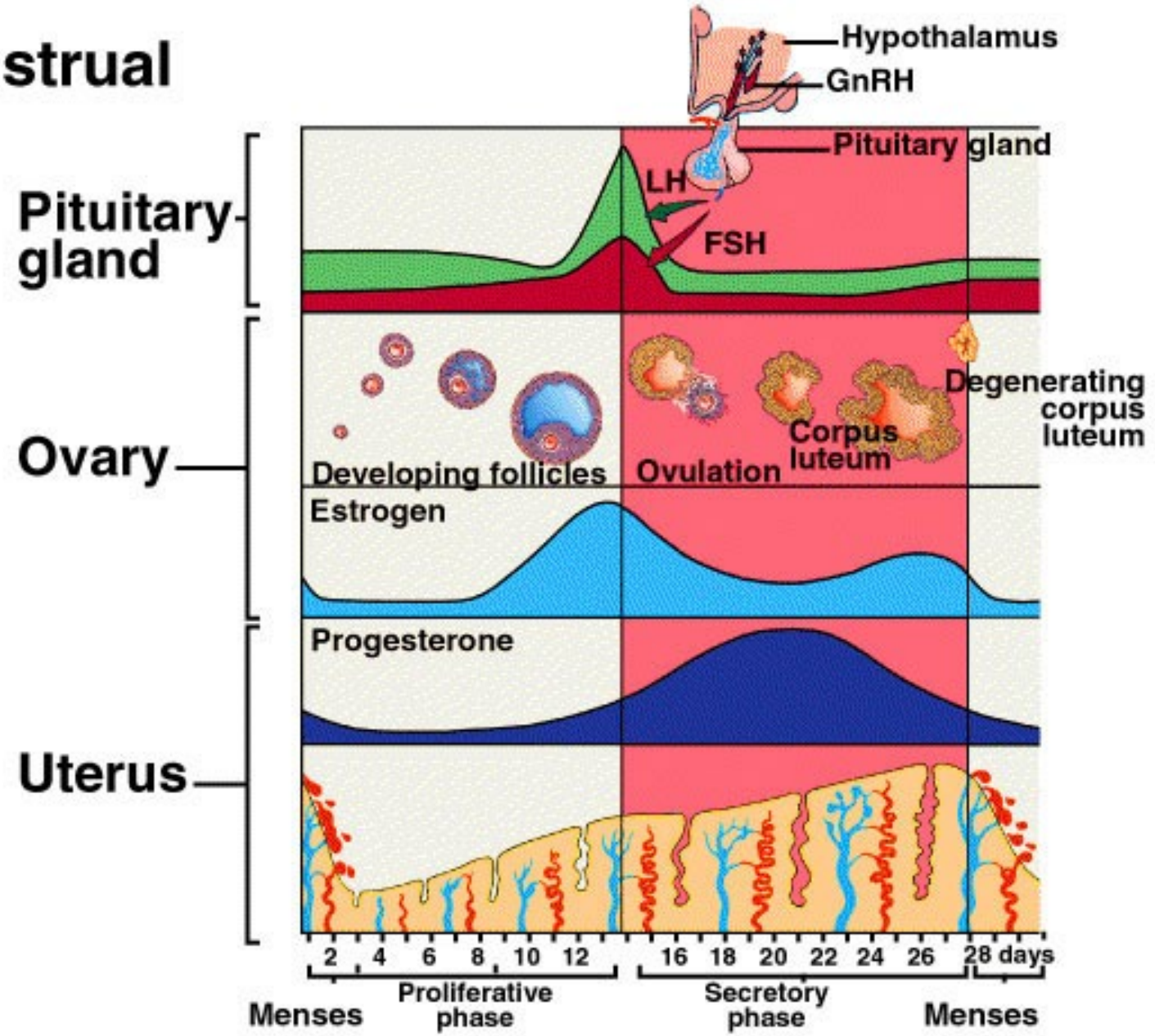
Parameter	Group 1 Mean/SD	Group 2 Mean/SD	Group 3 Mean/SD	P level
Total length	29.5/4.00	29.5/3.61	**28.3/3.15**	< .001
Follicular phase	16.1/3.64	16.6/3.49	**15.2/3.10**	< .001
Luteal phase	13.1/2.37	12.8/1.92	13.0/1.87	< .001
Menses	5.3/1.66	5.3/1.26	**5.0/1.43**	< .001

PRINCIPAL CRITERIA									
Menstrual Cycle	Variable to regular	Regular	Regular	Subtle changes in Flow/ Length	*Variable Length* Persistent ≥7- day difference in length of consecutive cycles	Interval of amenorrhea of >=60 days			

Physiological Reasons for the Peri-Menopause Transition

- Depletion of follicles and eggs
- Increased levels of FSH
- Lower levels of AMH
- Eggs **(and sperm)** are older with shortened and frayed chromosomes
- The estrogen LOOP phenomenon

The Menstrual Cycle



Background Studies

- Israeli study with orthodox women found **.2% pregnancy rate** (Laufer, et al. Fertility & Sterility, 2004;81:1328-1332)
- Flynn study (1991) **33% of women** (between 45 and 53) were potentially fertile, **61%** of the 177 menstrual cycles charted were potentially fertile (AJ of Ob/Gyn. 165(1991)1987-1989.
- Metcalf (1979) – **50% of menstrual cycles** are potentially ovulatory (JBiosocial Sc. 11:39-48).

WHO Review

- 50% of women over 40 are potentially fertile;
- Risk of pregnancy for women 40-44 is about 10%, 2% for women 45-49, and not zero for women over the age of 50.
- “Irregular menses and amenorrhea make the **use of (FABM) impractical**.”

WHO Scientific Group on Research on the Menopause in the 1990s (Geneva. Switzerland 1994)

Purpose

- In reviewing the literature, however, **there are no studies** on the efficacy of NFP/FABM among peri-menopausal women.
- Therefore, the **purpose** of this study was to determine the efficacy of using **NFP/FABM** to avoid pregnancy among women 40 to 55 years of age.

Methods

- Retrospective analysis of existing data
- All women sought and taught NFP/FABM at Marquette University
- Older FAB method and new MM
- 150 women 40 yrs or older with ovulatory cycles
- 12 month unintended pregnancy rate
- Use of survival analysis- Kaplan-Meier

Results – Demographics (N = 150)

- **Age**: Mean = 41.7, SD = 2.5
  Range = 40-54
- **Years Married**: Mean = 13.6, SD = 6.9
  Range = 1 – 32
- **Children**: Mean = 4.3, SD = 1.9
  Range = 1 – 9
- 73% Catholic; 54% White/24% Hispanic

Results: Pregnancy Rates

- **Total Pregnancies = 4.**
- **Correct Use Pregnancies = 1**; 98% survival at 12 months of use.
- **Typical Survival rate = .94 or 6 pregnancies per 100 users over 12 months of use.**
- The one unintended pregnancy was 40 year old women with first post partum cycle.

Conclusion

- NFP/FABM use among older women can be very effective.
- The high efficacy could be a reflection of **diminished fertility** among older women.
- High efficacy could also be a reflection of **higher motivation** to avoid pregnancy.
- Need more participants 40 and older.

Evidence Grades for NFP

	Grades	
	MDM	RJF
Preventing pregnancy in premenopausal women	B	C

Effectiveness in atypical situations

Can I use NFP after stopping the pill?

Menstrual Cycle Characteristics after Discontinuation of Oral Contraceptives

- Retrospective analysis of 70 women stopping OC's vs. 70 age matched no-OC users
- All new to Creighton model

Nassaralla et al. (2011) *J. Women Health* 20(2):169

Menstrual Cycle Characteristics after Discontinuation of Oral Contraceptives

Recent OC users had:

- Sig. lower mucus quality scores, 1st 2 cycles
- Later EDO
- Lighter menses, 1st 4 cycles
- "Menstrual cycle biomarkers significantly different 1st 6 cycles combined"
- Confidence & Satisfaction with CrMs no different for women or men.

Nassaralla et al. (2011)

Use of STM- post hormonal contraceptives

- 175 women discontinuing OC's (3048 cycles)
  - Prior OC use mean= 3.5yrs (range 1-13yrs)
  - Mean age 26.2 yrs.
  - OC formulations used
    - 74% fixed combo EE= 30-37 µg
    - 6% fixed combo EE= 20 µg
    - 2% fixed combo EE=50 µg
    - 18% other combos & POP
- 284 matched women using STM (6251 cycles)

Gnoth et al *Gynecol Endo.* 2002; 16:307

Characteristics of post-pill cycles

- First post-pill cycle:
  - 51% normal
  - 49% had major disturbance
    - 32% short luteal phase (<10day)
    - 10% no temp shift
    - 7% long cycle w/ normal luteal phase
- Compared to STM cohort, post-pill cycles:
  - Significantly longer for 9 cycles
  - Sig. more anovulatory cycles for 3 cycles
  - Delayed mucus Peak Day for 6-7 cycles
  - Delayed first day of temp rise for 6-7 cycles

Women can use STM Immediately after Discontinuing OC's

	Post pill	Control
ID mucus peak -cycle #1	84%	90%
ID mucus peak -cycle #3	95%	96%
Unintended pregnancy rate	1.63	1.70

Gnoth et al *Gynecol Endo.* 2002; 16:307

Evidence Grades for NFP

	Grades	
	MDM	RJF
Preventing pregnancy in women immediately after stopping hormonal contraceptives	B+	B+

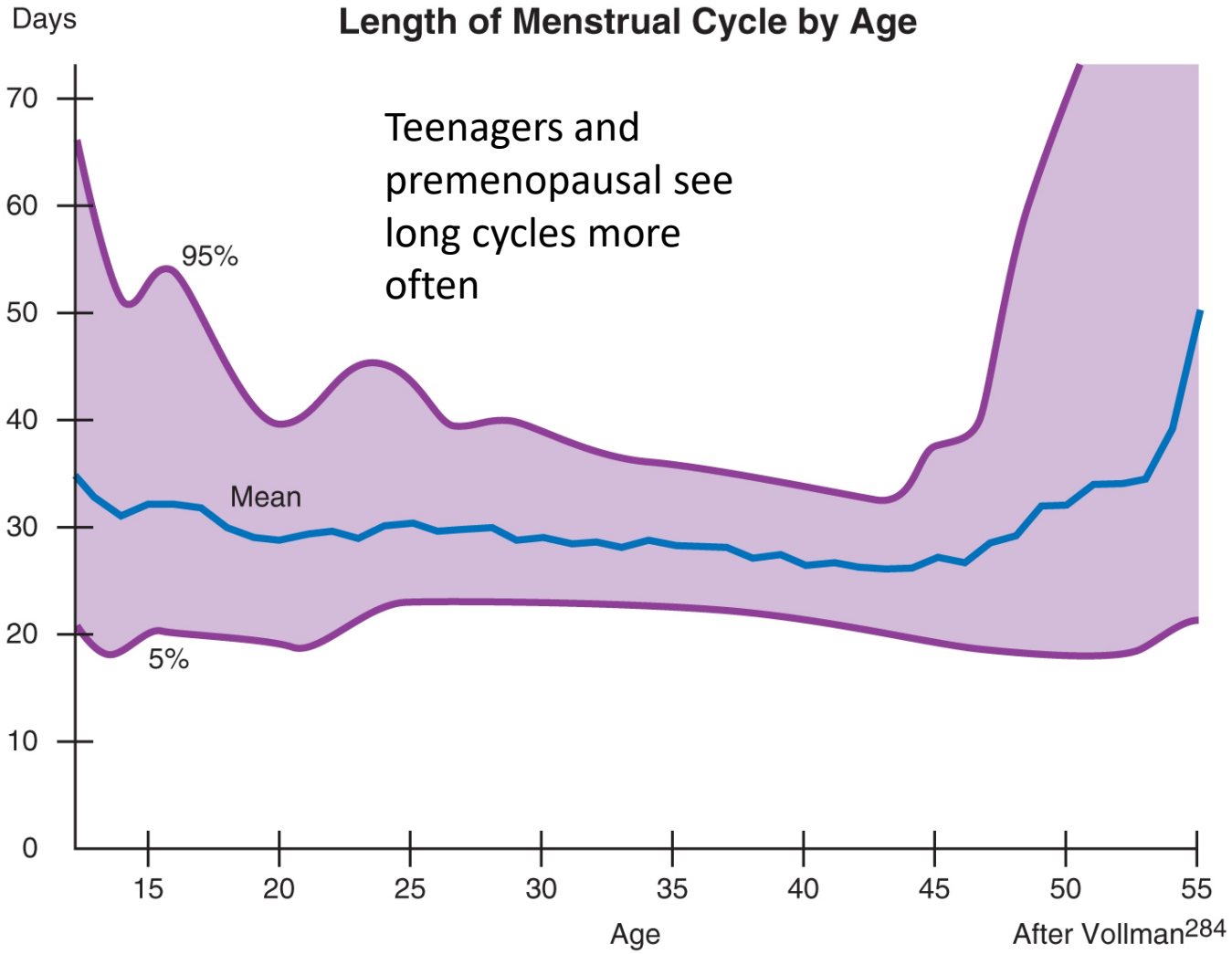
Effectiveness in atypical situations

How effective is NFP with short or long cycles?

Use of NFP in Short / Long Cycles

- Major efficacy trials excluded women with consistently short/long cycles
- How many women fall outside the typical range?

Cycle Variability by Age



Teenagers and premenopausal see long cycles more often

Very few with short cycles

From: Fritz & Speroff *Clin. Gynecol. Endo. and Infertility 8th ed.* (2011) p.241

Cycle variability- Danish population

Consistently short or long cycles very rare:

- 0.5% - usual cycles lengths <21days
- 0.9% - usual cycle lengths >35days

But an occasional odd cycle is common

- 19% of women -at least 1 cycle <21days
- 29% of all women -at least 1 cycle >35 days

Munster, Br J Ob Gyn 99(5):422 (1992)

Cycle Variability- US sample

- 95% of cycles between 22-36 days long
- 95% of cycles- 6 day fertile window between days 4-23
  - 25% of cycles with all 6 days between 10-17
- Intracycle variability >7days in 42% of women

Fehring, Schneider, Raviele JOGNN 2006

NFP in variable cycles

- Little hard evidence of effectiveness
- Long cycles more likely than a very short one

- Underlying Biology suggests:
  - Daily observation methods should effectively cope
  - Calendar based methods may be challenged

Evidence Grades for NFP

	Grades	
	MDM	RJF
1. Preventing pregnancy in women with consistently short cycles (<21days)	F	F
2. Preventing pregnancy in women with consistently long cycles (>35days)	F	C
3. Preventing pregnancy in women with the occasional long/ short cycle	C	C

Differences between Contraception and NFP

Satisfaction with Current Use of NFP In Comparison with Current Users of Contraception and Sterilization (In Percentages) Oddens, B.J., *Contraception*, 59 (1999): 277-286.

	PILL (N=522)	STERIL (N=136)	NFP (N=76)
Concern preg	**2.7**	**1.9**	**13.6**
Concern health Risks	**71.3**	**7.2**	**0.0***
Easy to use	**91.9**	**86.9**	**38.3**
Satisfied	**82.9**	**92.1**	**71.6**
More Tense	**5.5**	**6.5**	**21.5**
More Irritable	**13.0**	**7.2**	**5.1***
More Anxious	**1.9**	**1.4**	**19.0**
More Depressed	**10.3**	**5.0**	**3.8***
Freq of Intercourse	**23.3**	**28.1**	**7.6**
More Spontaneity	**38.8**	**37.4**	**11.4**
More Pleasure	**25.0**	**28.8**	**27.8***
Sex Drive Increased	**8.4**	**19.0**	**21.5***

Comparison Studies of NFP and Contraception

- Fehring, R., & Lawrence, D. (1994). Spiritual well-being, self-esteem and intimacy among couples using natural family planning. *The Linacre Quarterly,* 61(3), 18-29.
- Fehring, R., Lawrence, D., & Sauvage, C. (1989). A comparison of self-esteem, spiritual well-being, and intimacy in couples using natural family planning with couples using oral contraceptives. *International Review of Natural Family Planning*, 13(3&4), 227-236.

Comparison of Psychological/Spiritual Variables Between NFP Couples (N=44 Couples & 88 Individuals) and Contraceptive Couples (N=44 Couples & 88 Individuals)

	NFP M/SD	CONTRA M/SD	T-TEST
Spiritual Well-Being	108.7/10.3	96.4/15.0	6.36***
Religious Well-Being	55.3/6.5	46.7/10.4	6.98***
Existential Well-Being	53.4/5.3	49.7/ 7.7	3.73**
Self-Esteem	84.2/12.0	78.1/17.3	2.70**
Sexual Intimacy	78.2/13.4	72.8/16.0	2.43**
Intellectual Intimacy	77.7/14.2	71.7/17.0	2.57**
Recreational Intimacy	72.8/13.5	68.3/15.0	2.09*

*** $p <= 0.001$; ** $p <= 0.01$; * $p <= 0.05$

Physical/Biological differences

Contraception

- Fertility
  - Medical problem
  - Needs to be controlled
  - Is suppressed
- Medical Side effects
- Can mask medical problems
- Easy to use

NFP

- Fertility
  - A natural process
  - Needs to be lived with
  - Is monitored
- No medical side effects
- Helps identify medical problems
- At times challenging to use

Fehring & Kurz (2002)

Psychological Differences

Contraception

- No need to understand
- Communication- *are you using?*
- Woman is the object
- Role model: sterility

NFP

- Understand fertility
- Communication- *are we fertile?*
- Woman is respected
- Role model: fertility

Spiritual Differences

Contraception

- Act is conditional
- God's gift of fertility is to be controlled
- God not invited
- Separates what God has put together
- Fosters a *Culture of Death*

NFP

- Act is mutual self-gift
- Fertility is a gift from God
- Couples become co-creators with God
- Maintains what God has put together
- Fosters a *Culture of Life*

NFP and Divorce

M. Wilson

- **Hypothesis**: the divorce rate will be less likely among couples who used NFP
- Catholic Women (21-44) in Wilson Survey (N = 505) and in the 1995 (NSFG) 21-44 (N- 10,471).
- **3%** in the Wilson Survey were divorced and **15%** of the NSFG Catholic women.
- Comparison is like comparing apples and oranges! One group population based, the other not., self-selected.

2010 NSFG (1,502 Catholic Women) (N = 105 ever use of NFP & Divorce)

Method	Odds Ratio	95% CI	Significance
Pill (OC)	**1.05**	**0.76 – 1.45**	**< .742**
Sterilized	**2.41**	**1.82 -- 3.20**	**< .001**
Rhythm	**0.76**	**0.54 – 1.06**	**< .109**
NFP	**0.47**	**0.24 – 0.91**	**< .023**
Church Attend	**0.66**	**0.49 – 0.89**	**< .007**

Ever use of NFP 9.5% Divorced; Never use 18.3% Divorced.

Influence of NFP

- Logistic regression: predictor variables 1) **sterilized** 2) abortion 3) multiple sex partners, 4) cohabitated, 5) **NFP use**, 6) importance of religion, and 7) **church attendance**.
- Dependent variable: **divorce or not**
- R = 45% (R square = 2%)
- NFP, Church Attendance, and Steril – were significant.

Evidence Grades for NFP

	Grades	
	MDM	RJF
NFP users divorce less frequently than couples using contraception	F	F

Which Method should I Recommend?

Creighton Model

Two-Day Method

Standard Days Method

Marquette Model

Billings Ovulation Method

Sympto-Thermal Method

Lactational Amenorrhea Method

Is There A Best Method?

- The best method is..

  "The method that ***works best*** for the couple"

- How to choose?
- Consider:
  - Couple's needs
  - Characteristics of the different methods

Couple's Needs

- Availability of qualified instructor?
- Comfort with On-line learning?
- Time/ "ability" to learn?
- Comfort with "medical vs. non-medical" approach?
- Offers a double check?
- Affordability (initial & ongoing)?
- Special circumstances?
  - Postpartum
  - Premenopausal
  - breastfeeding
- Irregular sleep schedules?
- Irregular Cycles?
- History of infertility?

Characteristics of Methods

- **Calendar based**
  - Standard Days (Cycle Beads)
- **Mucus-only methods**
  - Billings
  - Creighton Model
  - Two Day Method
- **Sympto-Thermal**
  - CCL (Couple to Couple)
  - Northwest Family Services
  - Serena
  - Various diocesan-based programs
  - TCOYF (Toni Weschler) and others
- **Sympto-Hormonal**
  - Marquette
- **Hormonal**
  - Marquette

Fertility Signs Employed

- **Good clinical evidence**
  - External cervical mucus (numerous grading scales)
  - Basal body temp
  - Calendar based rules
  - Urinary hormonal metabolites
  - Lactational amenorrhea

- **Poor/ missing clinical evidence**
  - Internal mucus observations
  - Cervix
  - Salivary electrolytes
  - Ferning patterns

NFP is too Complicated to Use

NFP too complicated?

Overall Problem

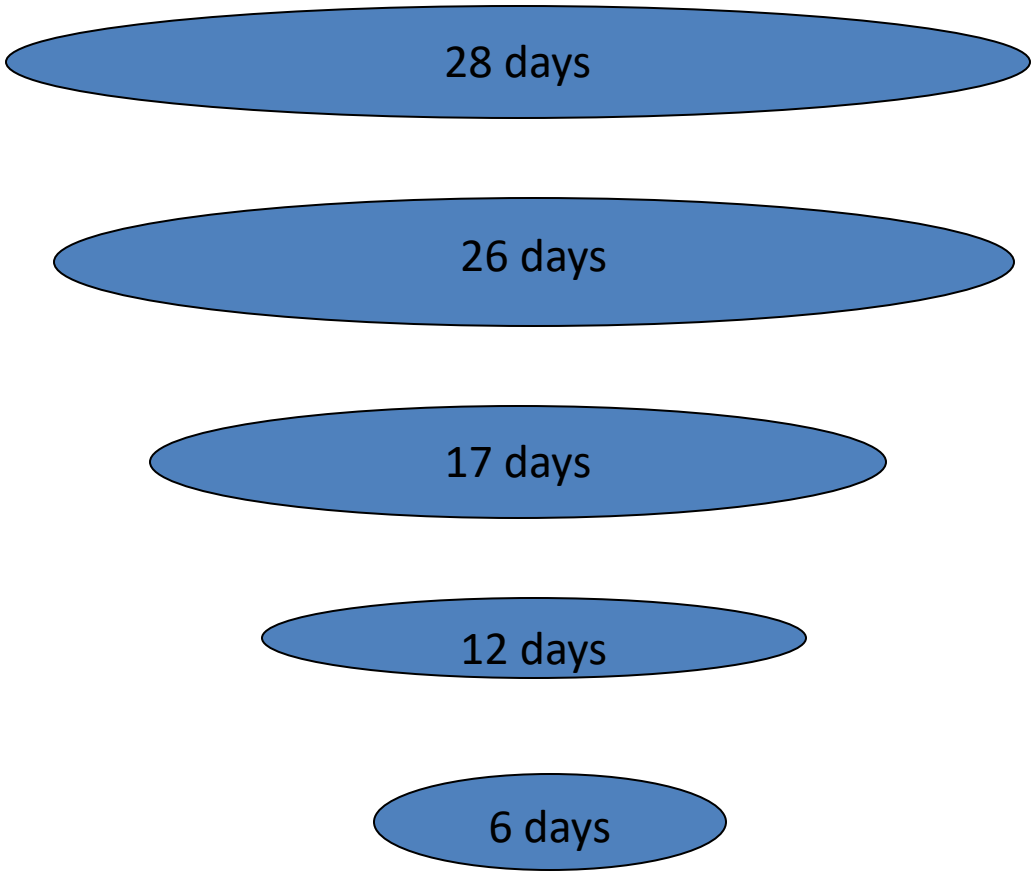
- Only 0.1% of US women use modern methods of natural family planning.
- Women (and men) want safe, effective, easy to use, and convenient methods of family planning.
- Although NFP methods are free of side effects, they are often ineffective and complex to learn and use.

Thesis

- One reason that NFP methods are not used more – are that they are not that effective – i.e., 20-25 pregnancies per 100 women (Trussell, 2011).

- Another reason is that they are not easy to use or to provide.

Comparison of fertile phase



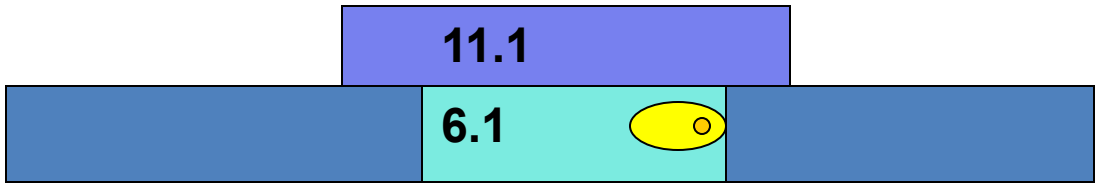
Cervical Mucus - Columbo

- Colombo – 1999, 2003
- Average cervical mucus days = **17 days**
- Missed mucus peak **17%**
- Master NFP teacher correlation = **60%**

Length of Fertility (N=1149)

- CPEFM was **6.1 days** (SD = 2.6)
- Mucus was **11.1 days** (SD = **5.8**)

- ($t = 28.33$, $p < 0.000$)
- ($r = 0.18$, $p < 0.000$)



Efficient Use & Provision

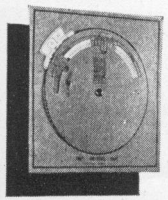
- Leo Latz, MD: 12 minute NFP method – calendar rhythm
- Georgetown: Standard Days method – fixed calendar system
- Georgetown: TwoDay mucus only method
- Marquette Lite:12 minute NFP – CEFM plus formula

Efforts of Loyola, Georgetown, Heidelberg and Marquette University Researchers to Simplify NFP

Latz's Three Minute "Rhythm"

- Shortest cycle minus 19 days
- Subtract shortest from longest and add "8" days to that number
- Example: 26 shortest and 30 longest
- Rhythm is: 26 –19 = **7** and 4 + 8 = **19**
- Fertile window is from day 8 through day 19 = 12 days.

Ad in June, 1935 – The Linacre Quarterly



SAFE PERIOD CHART
Makes Rhythm Method Accurate

More and more the Catholic doctor is being called upon for advice on the subject of periodic abstinence. The clergy in making recommendations depends on the physician to present the physiological aspect. This can best be accomplished with the aid of the TIMELY ABSTINENCE CHART. Scientifically designed, this chart is adjustable for regular as well as irregular cycles and has a range of 21 to 34 days. It completely interprets the Ogino Knaus Law.

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$1.00 POSTPAID
(Orders for six or more 20% discount)

We maintain a special service for the Catholic doctor. Write for complete information.

National Chart Company
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Standard Days Method (SDM)

- **Days 8 – 19 fertile**
- **Cycle length 26 – 32**
- **95% Correct Use**
- **88% Typical Use**

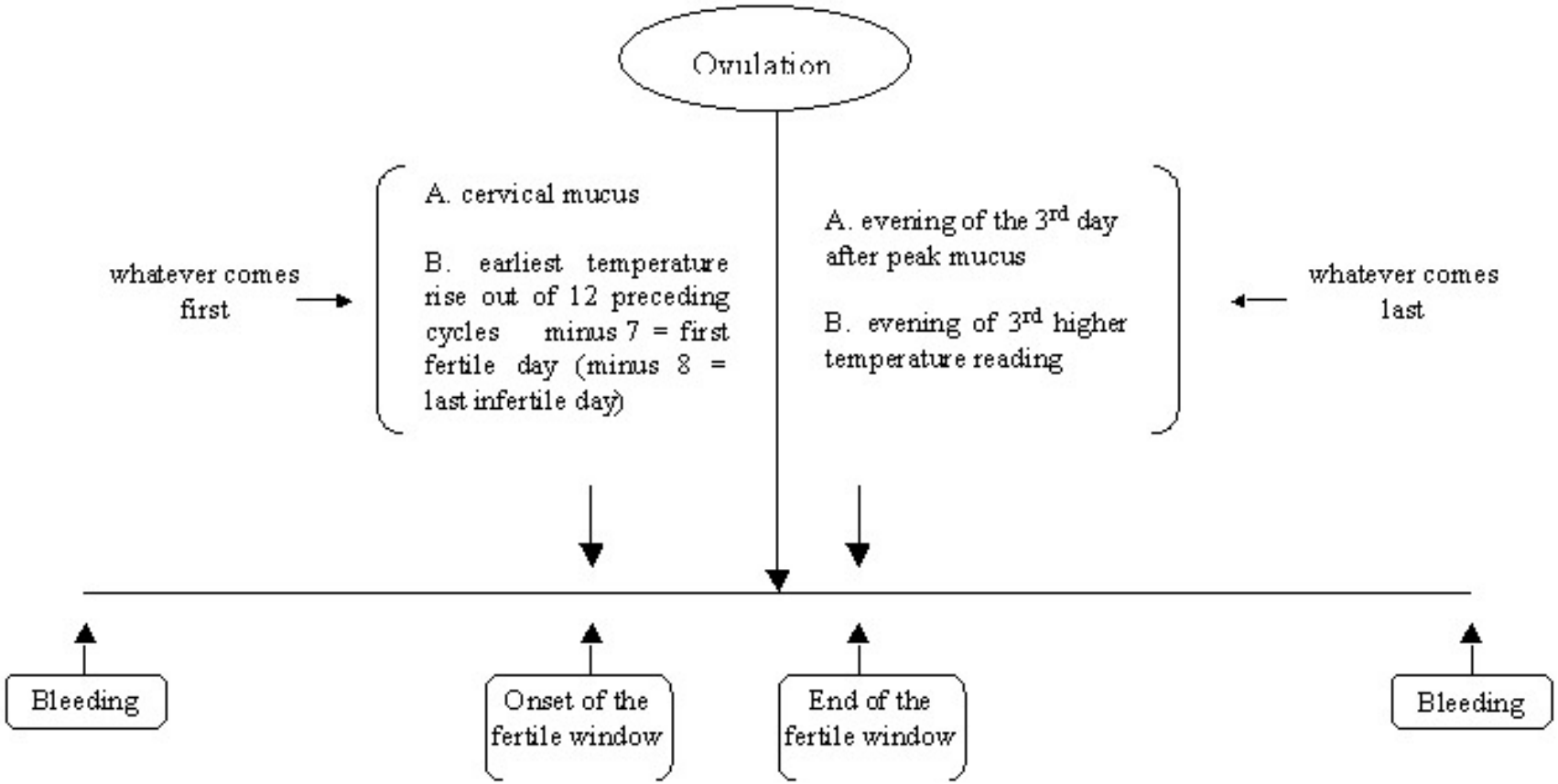
Arevalo M, Jenning V, Sinai I. **Efficacy of a new method of family planning the Standard Days Method.** Contraception 2002;65:333-338.

Efficacy of the TwoDay Method

- Did I note any secretions today?
- Did I note any secretions yesterday?
- Correct use = **96.5%**
- Typical = **86.3%**

Arevalo, Jennings, et al., **Efficacy of a new method of family planning**. Fertil Steril, 2004: October Issue.

European Double Check



High Tech – 3 Minute Rhythm

- **TO AVOID PREGNANCY: Do not have intercourse during fertility**
- **1. Fertility BEGINS on day 6 during the first 6 cycles; After 6 cycles of charting then,**
- **2. Fertility BEGINS on the earliest day of PEAK during the last 6 cycles minus 6 days**
- **3. Fertility ENDS on the last PEAK day plus THREE full days; After 6 cycles**
- **4. Fertility ENDS on the last PEAK day of the last 6 cycles plus THREE full days**

Rebecca Peck MD

- 12 Minute office session to teach NFP.

- http://www.youtube.com/watch?v=qj5k90OnbFg

Medical Applications

- Menstrual Cycle as a Vital sign
- Use of NFP with sub-fertility
- Use of NFP with dysfunctional bleeding
- Use of NFP to monitor Tx of PCOS
- Use of NFP to time medications and tests.

NaProTechnology

J.B. Stanford, T.A. Parnell, and P.C. Boyle, “Outcomes from treatment of infertility with natural procreative technology in an Irish general practice,” *Journal of the American Board of Family Medicine* 2008;21:375-384.

Retrospective cohort study (N=1,234) infertility patients from one family medical practice in Ireland during the years 1999-2006. The gross live birth rate at twelve months of treatment was 27.6% and at twenty-four months 33.9%.

E. Tham, K. Schliep, and J. Stanford, “Natural procreative technology for infertility and recurrent miscarriage. Outcomes in a Canadian family practice,” *Canadian Family Physician* 58 (2012): e267-74.

Retrospective cohort of 99 couples with infertility and another 9 couples with recurrent miscarriage. Live births, the adjusted proportion at 12 months was 44.5 per 100 couples and at 24 months was 66.0 per 100 couples

RCT Study

S. Bhattacharya, K harrild, J Mollison, et al., “Clomifene citrate or unstimulated intrauterine insemination compared with expectant management for unexplained infertility: pragmatic randomized controlled trial,” *British Medical Journal* 2008;337:a716.

The scientists found that the live birth rates for the clomefine group (N=194) was 26/192 (14%), for the intrauterine insemination group (N=193) it was 43/191 (23%), and for the expectant management group (N=93) 32/193 (17%). There were no statistical differences among the three pregnancy rates of these three treatment groups.

Backup /Extras

Can I require NFP as part of Marriage Prep?

Common Concerns

- No one will be happy
- Not enough teachers
- Too expensive/burdensome for the couples
- The bishop will never mandate it
- We won’t be able to teach everybody
- Even if we teach them, they won’t use it

Required Dioceses

- Dioceses requiring full NFP course:

Denver	Colorado Springs
Fargo	Cheyenne
Phoenix	St. Augustine
Lexington	Covington
Richmond	Little Rock

- Compliance with diocesan policy: Poor to Good

Required NFP Classes- Couples Feedback

Covington Experience 2009-present:

- 45% admit having a negative attitude before class
- 95% state they have a better understanding of their fertility
- > 90% found taking the class beneficial
- 83% would recommend classes to a friend
  - 74% with a negative attitude would recommend

Common Concerns

- ***No one will be happy***
  - experience shows otherwise
- ***Not enough teachers***
  - True, but mandated policy brings more
  - Alternative learning vehicles (Home course, online)
- ***Too expensive for the couples***
  - $150-200 for lifetime skills vs. wedding costs
  - Surprisingly few requests for financial aid

Common Concerns

- ***The bishop won't mandate it***
  - Arlington experience
  - Focus on those who are interested
- ***We won't be able to teach everybody***
  - Focus on what you can do
- ***Even if we teach them they won't use it***

How effective is an introduction to NFP?

- Peoria- experience over 12+ yrs.
- Full day (5.5hr) Christian Sexuality Workshop
- 7-10% of couples skip CSW go to Full NFP
- CSW brings 3-8% more to full NFP class
  - Even when diocese paid NFP instruction costs
- Logistical/ resource effort for the diocese?

LAM- WHO trial

- 4118 breastfeeding women, 7 countries
- 3443 completed study
- 85 total pregnancies
  - 46 in B.F women not using contraception

	Full Breast.		Partial B.F.		Weaned	
Contraceptive use	No	Yes	No	Yes	No	Yes
# pregnant	14*	2	32	16	12	9

*13 from China center

Cycle Lengths in 'Postponing' Studies

Method	Study	Included cycle lengths, age
Billings	WHO multi country (1980)	23-35 days
	Indian Task force (1996)	26-31 ±5, 15-35yrs.
Standard Days	Arevalo (2002)	"most cycles 26-32 days" 18-39yrs.
STM	Frank Herman (2007)	22-35days (20% deviation), 19-45yrs.
	Frank Herman (1997)	No specific length, 19-45yr
Creighton	Hilgers (1998)	43% -21-38 days, 5% -cycles usually>38days, 3%-over 40yrs
	Howard & Stanford (1999)	46% -21-38 days, 5% -cycles usually>38days, <2%-over 40yrs
Marquette	Fehring (2007)	21-42 days
	Fehring (2012)	21-42 days 18-42 yrs.
Two Day	Arevalo (2004)	No specific length, 18-39 yrs.