



Restorative Reproductive Medicine

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Restorative reproductive medicine



- Infertility is a chronic health condition.
- Restorative reproductive medicine (RRM) seeks to diagnose underlying conditions.
- Creighton Model fertility charting is a valuable health indicator for prevention and treatment.
- NaProTechnology has the healthiest outcomes for mothers and babies.
- NaProTechnology is the key to current treatment and future research in RRM.

Restorative reproductive medicine



- is medical evaluation, techniques and interventions that seek to cooperate with or restore the normal physiology and anatomy of the human reproductive system.

Restorative reproductive medicine

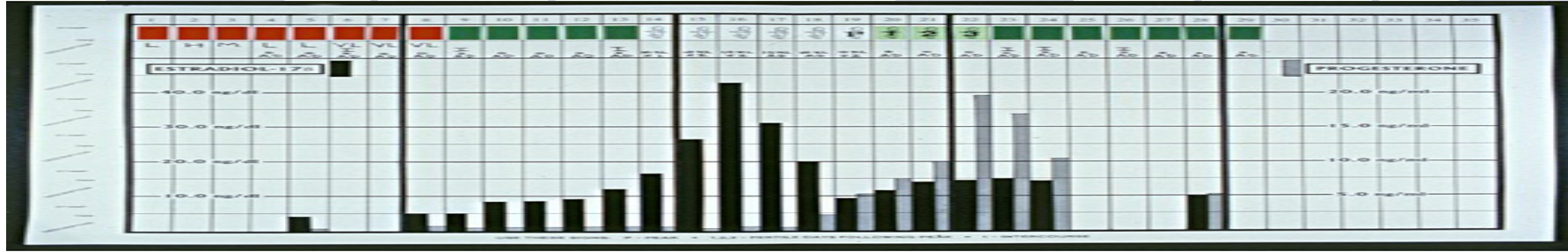


- does not employ methods that are inherently suppressive, circumventive or destructive.
- supports patients' right to understand and cooperatively manage their own fertility, with appropriate medical assistance.

Creighton Model Fertility*Care* charting

- Highly standardized system of fertility tracking
 - Vaginal discharge recording system
 - Standardized observation protocol
 - Standardized teaching system
- Teaching tailored to woman's individual reproductive and gynecologic situation

Creighton Model FertilityCare charting



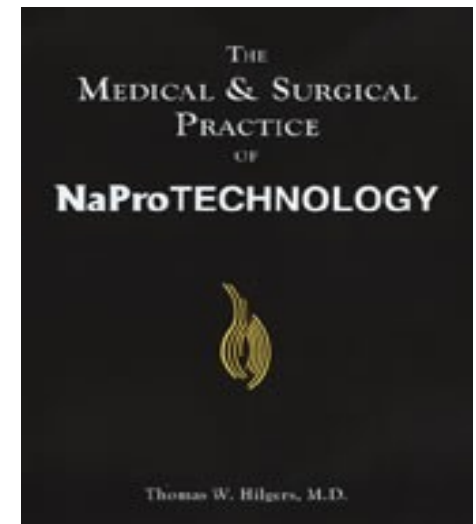


Creighton Model Fertility*Care* charting

- Biomarkers of vaginal bleeding and cervical mucus
 - Ovulation
 - Fertile days
 - Gynecologic and reproductive function

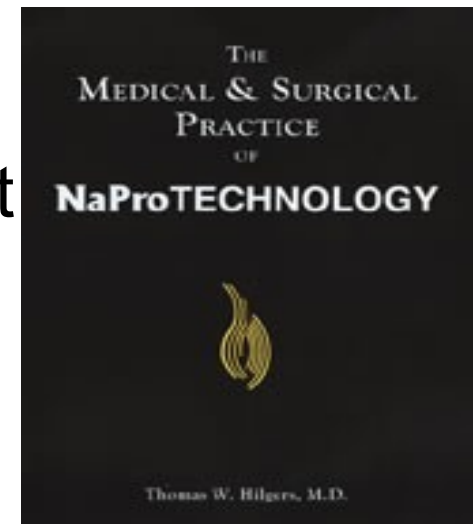
Natural Procreative Technology (NaProTechnology)

- Creighton Model Fertility*Care* charting
- Medical protocols guided by the woman's chart
- Medical and surgical components
- Empowers women or couple in partnership with physician for health



Natural Procreative Technology (NaProTechnology)

- Scientifically developed system for restorative reproductive medicine
- Practice-based research to develop and improve protocols for evaluation and intervention
 - international NaProTechnology and Surveillance of Treatment





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Health conditions



- Acute
- Sudden onset
- Shorter duration
- Tend to have single or few causes
- May be cured by single intervention or
- May resolve spontaneously

- Chronic
- Gradual onset
- Longer duration
- Usually have multiple causes
- Outcomes improved with multiple sustained interventions
- Rarely resolve spontaneously

Health conditions- examples

The title is centered at the top of the slide. It is flanked by five circles of varying shades of light purple. From left to right: a solid purple circle, an outlined purple circle, a solid purple circle, an outlined purple circle, and a solid purple circle.

- Acute
- Appendicitis
- Respiratory viral infection
- Fractured bone
- Chronic
- Asthma
- Diabetes
- Degenerative arthritis

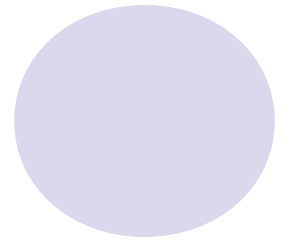
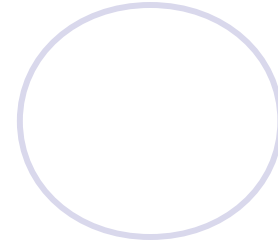
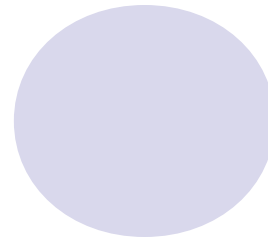
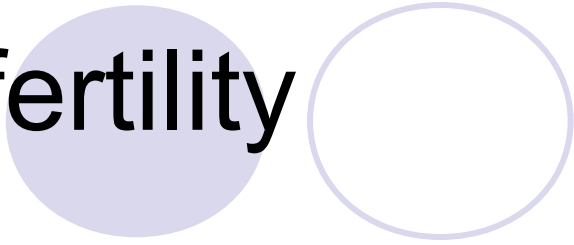
Infertility

- Gradual, unknown, or early onset
- Ongoing issues
- Potential for recurrence
- Syndrome, not diagnosis
- Many possible etiologies

Infertility

- Rarely fully “cured” by single intervention.
- Spontaneous or treatment pregnancy may occur without altering underlying conditions.

Infertility



- Couple's syndrome
 - Inability to get pregnant

Infertility

- Couple's syndrome
 - Inability to get pregnant
 - Health of the baby
 - Health of the mother in pregnancy
 - Long-term health of the mother
 - Long-term health of the father
 - Long-term health of the child



Restorative reproductive medicine

- Infertility is a chronic health condition.
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Infertility



- RRM
- Infertility indicates the presence of disease with the challenge to diagnose and treat for optimum health for all persons involved.

- ART
- Infertility presents a technical challenge to bypass the dysfunctional process.

Appropriate Diagnosis



- RRM
- Seeks to diagnose all identifiable and potential underlying causes.
- Seeks to identify all identifiable exacerbating and mitigating factors.

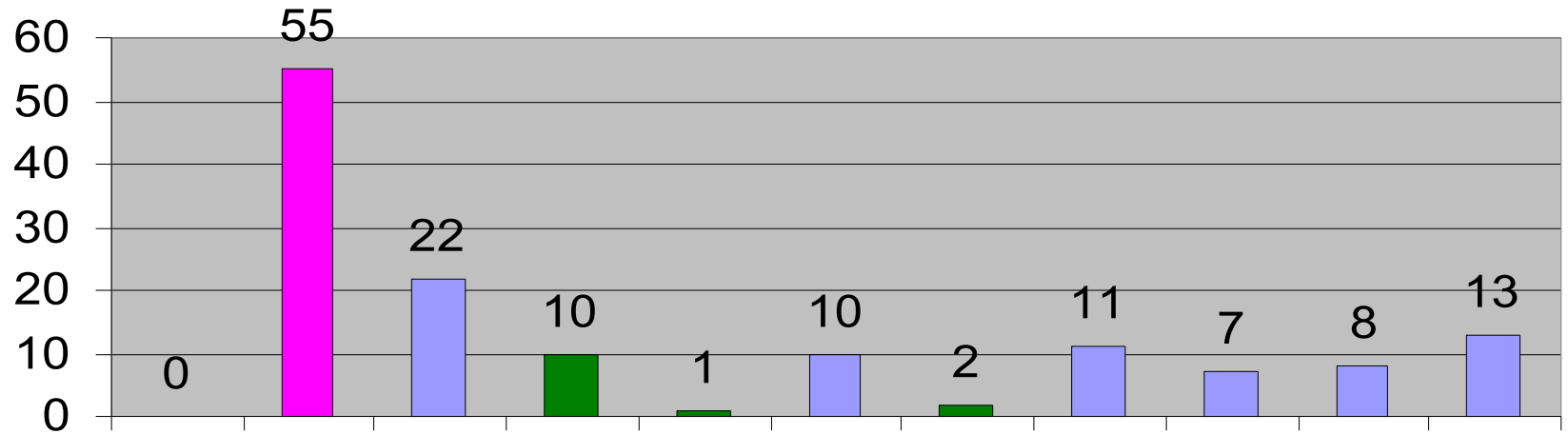
- ART
- Ignores diagnosis and contributing factors, except for factors that may impact effectiveness of IVF treatment.

Infertility

- Many possible etiologies
- Usually, *multiple* etiologies are found with a NaProTechnology evaluation

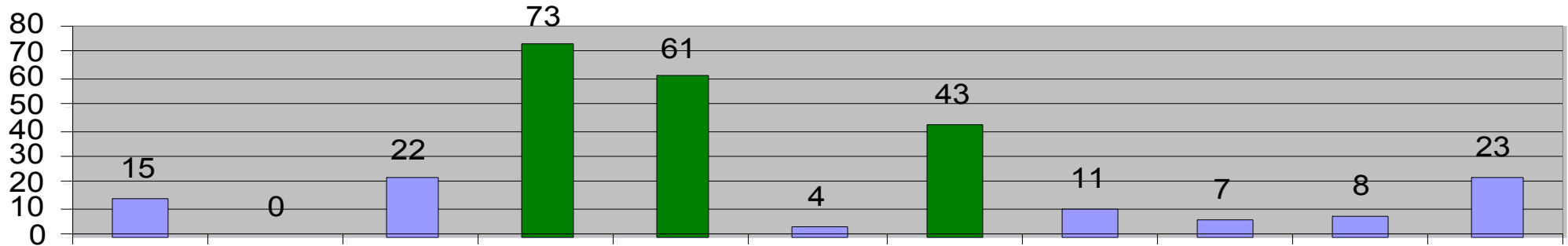
Infertility- prior diagnoses

95 Couples ART Diagnosis



Infertility- NaPro diagnoses

95 Couples NPT Diagnosis





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Creighton Model Fertility*Care* charting

- Vaginal discharge recording system

Postovulatory hormone testing

STAMP	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35				
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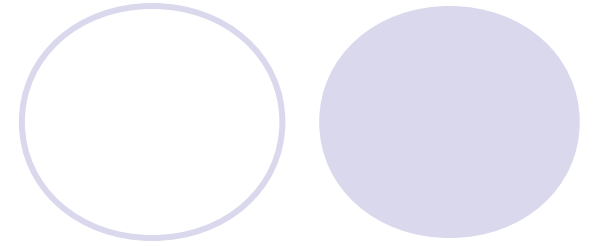
REMINDER: ORDER NEW CHART, STAMPS AND MAKE APPOINTMENT FOR FOLLOW-UP.

NAPROTRACKING® THE PROCREATIVE CYCLE

USE THESE SIGNS: P - PEAK • 1,2,3 - FERTILE DAYS FOLLOWING PEAK • I - INTERCOURSE

Duration of follicular phase

limited to cycles of length 21 to 42 days



Creighton Model charting in infertility



Figure 4: Charting examples observed in infertility.

Creighton Model charting biomarkers

- Duration of preovulatory (prepeak) and postovulatory (postpeak) phases
- Mucus cycle score
- Premenstrual or postmenstrual spotting
- Intermenstrual spotting or bleeding

Premenstrual spotting in a randomized trial of CrM instruction

CrM Group

- N=71
- Mean age 28.1 years
- 12% women recorded premenstrual spotting (1-2 days)
- 20% cycles

Control Group

- N=70
- Mean age 28.2 yrs
- 4% women recorded premenstrual spotting (1-2 days)
- 8% of cycles

CrM group: cycles to conceive

	Premenstrual spotting <u>absent</u>	Premenstrual spotting <u>present</u>
Conception	49 (34%)	7 (17%)
No conception	95	34
Total	144	41

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Chronic disease perspective



- NaProTechnology
 - Chronic health condition management
 - Addresses all underlying disease and factors to the extent possible
 - Seeks to optimize health of baby, mother, father
- ART
 - Acute approach- do something to get pregnant as quickly as possible, almost at any cost

Appropriate evidence



- “Chronic” approach
- Cumulative outcomes over time
- Cohort analysis
- Full picture

- “Acute” approach
- Short-term outcomes only
- No context for cumulative outcomes over time
- Misleading

Appropriate evidence- example



- Diet and weight loss
 - Acute: weight loss at 1 month
 - Chronic: weight loss at 6 months, 1 year

National registries for ART



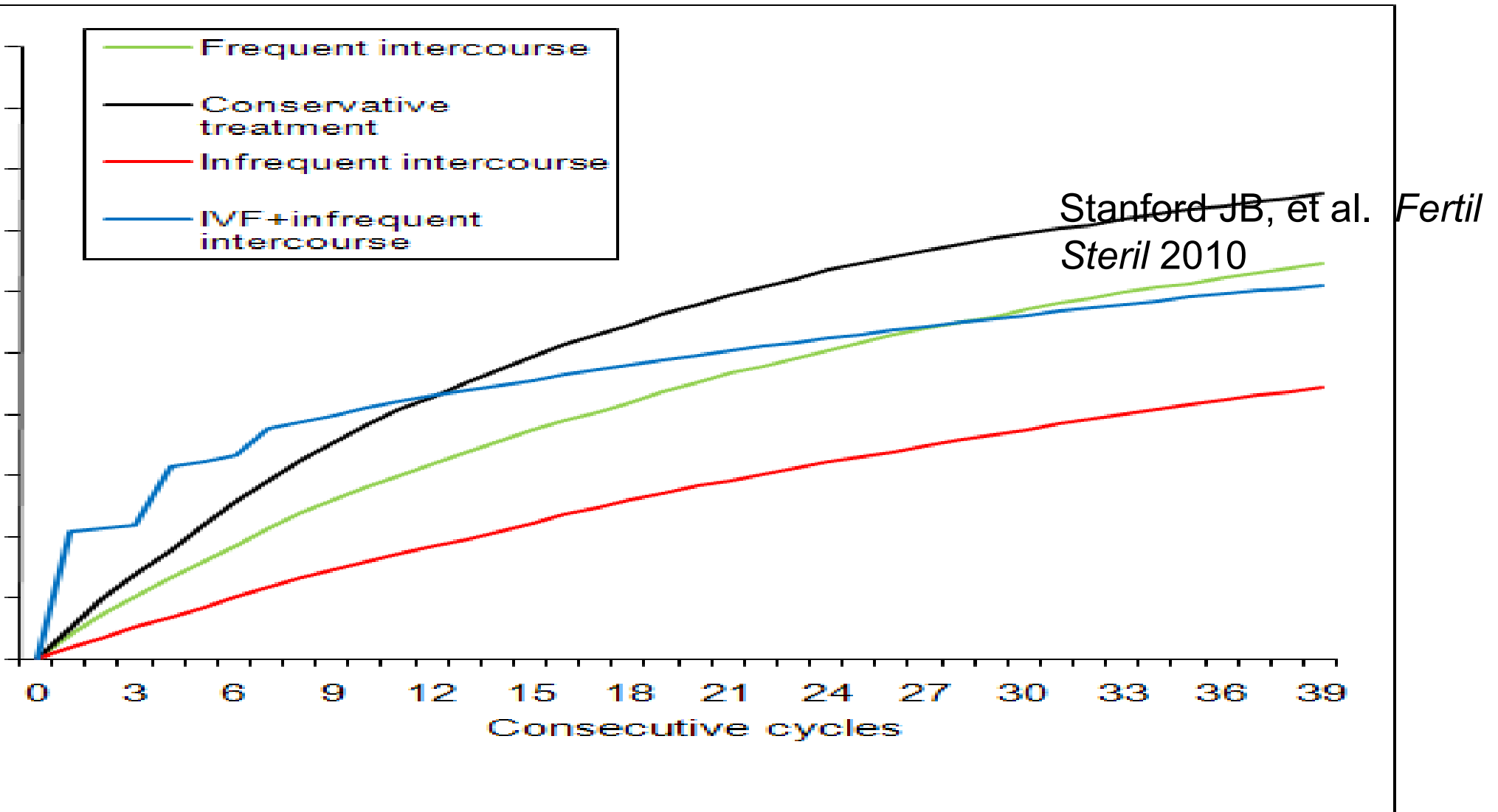
- USA- SART and CDC
- Europe- ESHRE
- UK- HFEA
- All have data in terms of treatment *cycles*
 - Unknown number of women
 - Unknown cycles per woman

Cochrane evaluation of IVF



- Outcomes should be reported as a pregnancy rates per woman or couple, because repeat cycle data are not statistically independent and are less relevant to the patient.

Cumulative pregnancy rates



Cochrane evaluation of IVF



- “The effectiveness of IVF relative to other treatment options for unexplained infertility remains unproven. Adverse events and the costs associated with the interventions compared have not been adequately assessed.”

Cumulative live birth rates



- Per couple, not per cycle
- Adjusted live birth rates
 - Couples who drop-out of treatment are no longer counted after they drop out
- Crude live birth rates
 - Include all couples who start treatment, whether or not they continue (intention to treat)

Cumulative live birth rates- example



- 100 couples
 - 50 drop out after 3 months
 - 50 get pregnant after 9 months
 - Crude live birth rate: 50%
 - Adjusted live birth rate: 100%
 - “True” value somewhere in between

Chronic disease evidence



- Accounts for population characteristics that impact the prognosis

Population characteristics- example



- Study A, treatment A
 - 80% adjusted live birth rate
 - women's average age= 23 years, had been trying to get pregnant for an average of 1.5 years.
 - all women previously had a live birth
- Study B, treatment B
 - 20% adjusted live birth rate
 - women's average age= 43 years, had been trying to get pregnant for an average of 10 years.
 - none of the women previously had a live birth

Comparing cohorts- NPT and ART

- Ireland NPT
- N=1072
- Mean female age=35.8
- Duration infertility=5.6 yrs
- Prior ART=33%
- Prior pregnancy=47%
- **2 years**
JABFM 2008
 - Adjusted=52.8% *BIRTH*

- Netherlands ART
- N=1351
- Mean female age=32.8
- Duration infertility=3.6 yrs
- Prior ART=0%
- Prior pregnancy=47%
- **1 year**
Hum Reprod 2007
 - Adjusted=64.7% *pregnancy*

Comparing cohorts- NPT and ART

- Ireland NPT
- Twins 4.5%
- Birth < 2500 grams
 - 4.5%
- Netherlands ART
- Twins 22%
- Birth < 2500 grams
 - Not reported

Infertility

- Couple's syndrome
 - Inability to get pregnant
 - Health of the baby
 - Health of the mother in pregnancy
 - Long-term health of the mother
 - Long-term health of the father
 - Long-term health of the child

Health of the baby



- NaProTechnology
- Expected lower miscarriage rates
- Low birth weight rates under 5%
- Expected lower rates of prematurity, perinatal mortality

J Amer Board Fam Med, 2008

- ART
- High miscarriage rates
- Low birth weight rates 30%+
- Also higher rates of prematurity (2.0x), perinatal mortality (2.2x), and birth defects (2.0x)

*Obstet Gynecol 2004
NEJM 2002*

Health of the mother in pregnancy

- Higher risk in infertility for
 - Miscarriage
 - Preeclampsia
 - Other pregnancy complications
- NaProTechnology should reduce these risks

Long-term health issues



- Woman
 - Diabetes, cardiovascular (PCOS)
 - Pelvic pain and GI problems (endometriosis)
 - Endometrial, ovarian, breast cancer (hormonal)
 - Risks should be reduced with NaPro treatment
- Man
 - To be identified
- Child
 - Neurodevelopment issues, others?

Ethical dimensions



- NaProTechnology
- Partnership between CFCP, CFCMC, couple
- Acknowledges God inherently
- Goal is healthy baby, mother, father

- ART
- Technological accomplishment of the physician
- Promotes mastery of man
- Goal is a baby, quickly, at almost any cost

Ethical dimensions



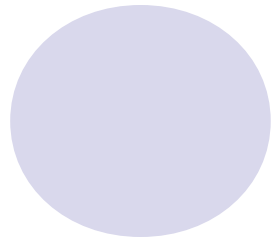
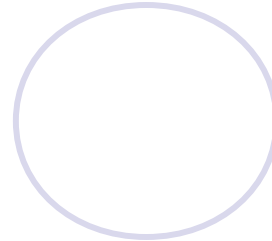
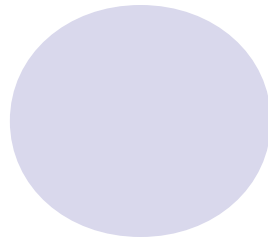
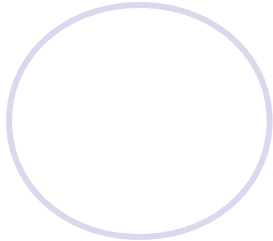
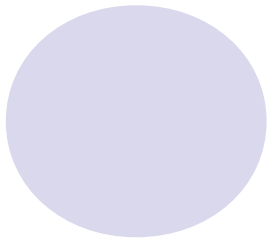
- NaProTechnology
- Profound respect for human life from its earliest stages of development

- ART
- Embryonic stages of life are treated instrumentally as a means to an end

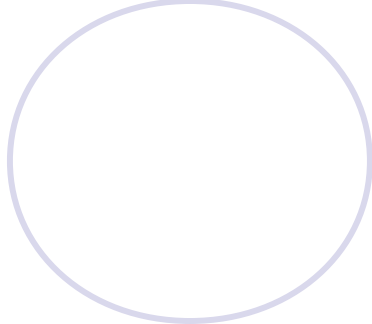
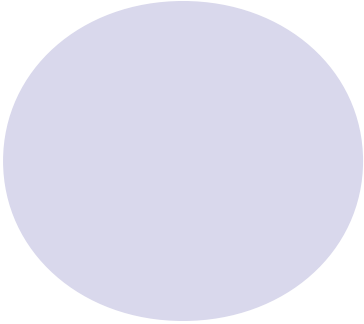
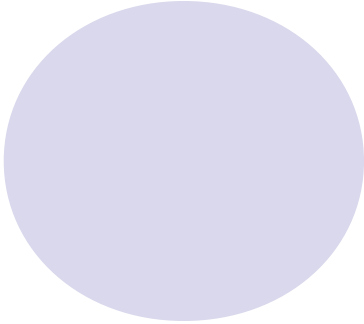
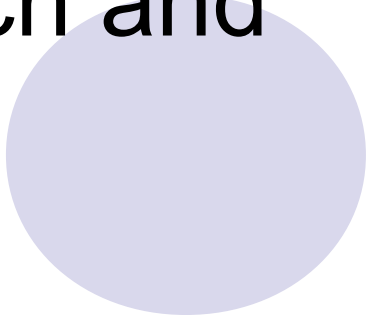
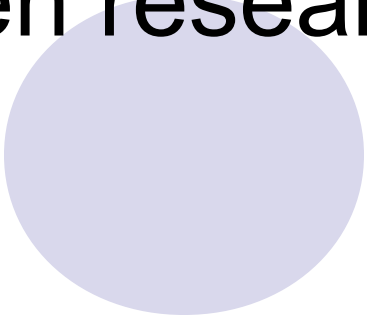
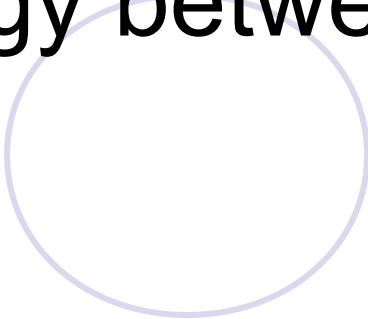


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IIRRM: synergy between research and practice



Learning from each other



Care delivery is undergoing constant changes, many of which constitute natural experiments from which we could learn important lessons. These care changes, however, usually come up too quickly to allow the usual approach to development and funding of a research proposal that could evaluate their effects, and there are rarely research-practice connections that could coordinate the design and implementation of studies of these innovations.

Learning from each other



- [Primary care professions] must admit we have quality problems that require unified attention and action.
- [We should] convert the paradigm from “translate research into practice” to “optimize health and health care through research and quality improvement.”

Learning from each other



- [We should] develop and facilitate more partnerships among clinicians, researchers, and care delivery leaders for engaged scholarship in both research and quality improvement.



International NaProTechnology
Evaluation and Surveillance of
Treatment for subfertility and
miscarriage

iNEST

Reasons for iNEST



- Document outcomes for peer-reviewed medicine
- Project likely outcomes for patients, based on baseline characteristics
- Improve NaPro efficiency, quality, and outcomes
- *Outcomes = live birth, health pregnancies, healthy babies, healthy children*



iNEST design

- Prospective cohort of couples
- NPT practice-based initiation
- Follow all couples for 3 years *regardless of treatment continuation or discontinuation*
- Obtain treatment data from NPT physician



iNEST design

- Synergize study procedures with practice procedures
- Provide added value for both practices and patients
 - Study provides online clinical entrance questionnaire

Participating patients



- Written informed consent is obtained for 3-year follow-up with option for more.
- Initial clinical questionnaire facilitates the clinical evaluation.
- Follow-up questionnaires, *reimbursed*
 - Yearly
 - Pregnancy outcomes
 - Exit

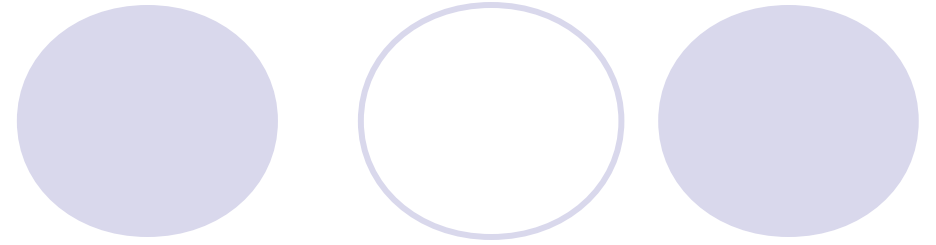
Main outcome



- Live birth up to 3 years after beginning NPT
- Examine in terms of baseline characteristics and treatment choices



Get involved!



- **Join the IIRRM!**
 - www.iirrm.org
- **Arrange to start with iNEST**
 - joseph.stanford@utah.edu

Getting started as an iNEST practice

- Identify responsible physician(s) *and staff*
- Integrate initial clinical questionnaire into practice
- Complete online research training
- Obtain local research ethics approval or waiver
- Phone conferences and site visit with study coordinators

Acknowledgments



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 - Woman's Reproductive Health Foundation
 - St. Augustine Foundation
 - University of Utah Health Studies Fund
 - University of Utah Primary Care Research Center
 - Atlas Foundation

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