# Low Dose Naltrexone

Novel uses for a licenced medication

Dr. Phil Boyle, Dublin, Ireland, May 2014

## Disclosure

#### Doctor Phil Boyle, MICGP, MRCGP

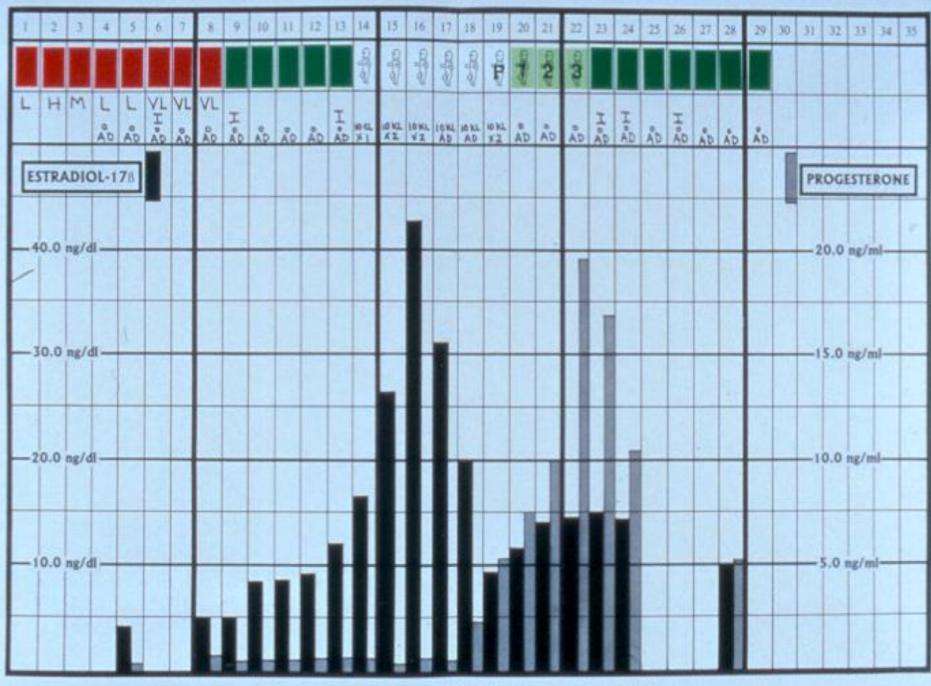
No financial interest or arrangement that would be considered a conflict of interest.

# Qualifications

- Family Physician –General Practice since 1997
- MICGP and MRCGP
  - Focus on Restorative Fertility Treatment since 1998
- Not an expert neurologist, rheumatologist, gastroenterologist
- Not an expert researcher

# Qualifications

- I am a clinician working in clinical practice
- Process of trial and error
- Frequently try new treatments
  - infertility and miscarriage
- I am trained to keep asking questions......

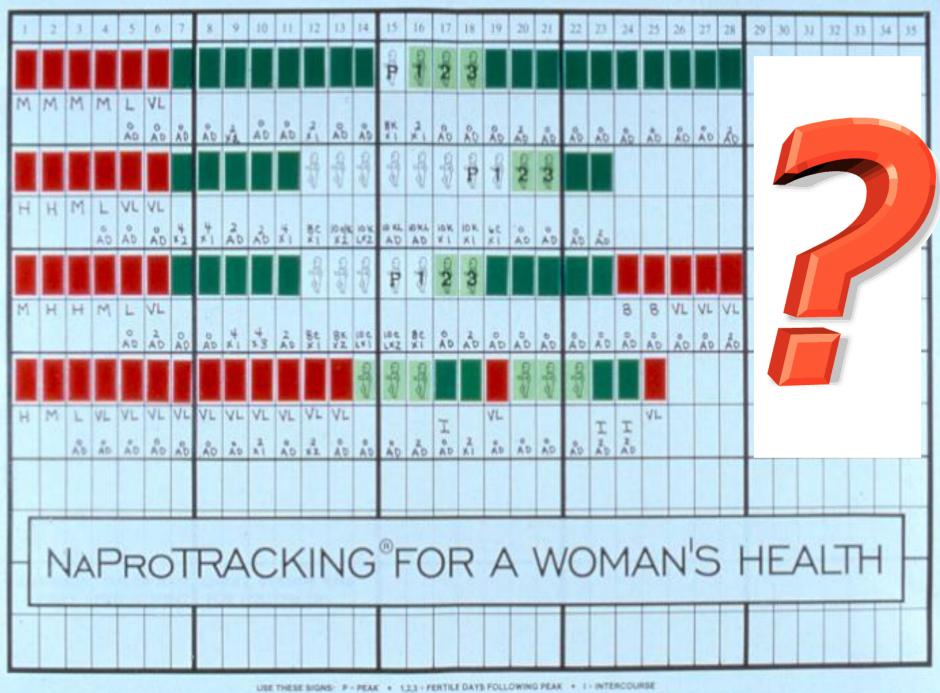


USE THESE BIGNS: # - PEAK + 1.1.3 - PERTILE DAYS FOLLOWING PEAK + 1 - INTERCOURSE

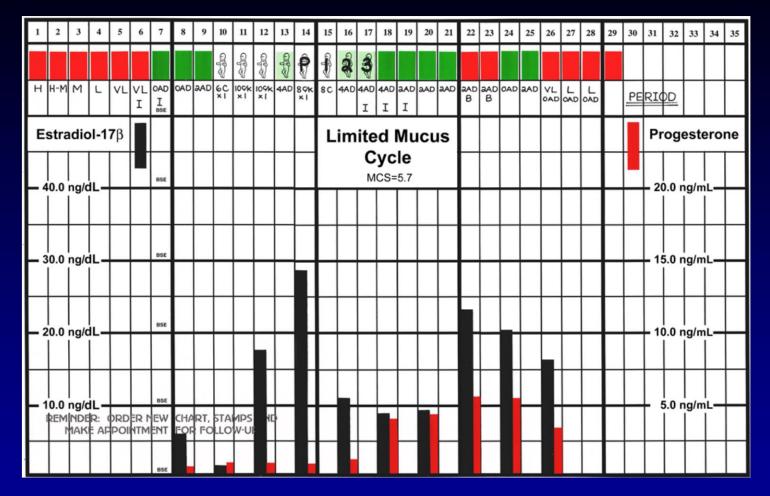
# CREIGHTON MODEL Method and Use Effectivenessto Avoid Pregnancy—By CenterJ. Repro Med5-Study Composite and Ordinal Month of UseJune 1998

<ol> <li>Through 12 ordinal months</li> <li>Through 18 ordinal months</li> <li>To avoid pregnancy</li> <li>n/a = Not applicable</li> </ol>	Creighton University Omaha	St. John's Mercy Hospital St. Louis	St. Francis University Omaha	St. Joseph Hospital St. Louis	Marquette <sub>Nursing Center</sub> Omaha	5-Study Composite
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1	8 n/a	n/a	n/a	97.1	n/a	96.4

Hilgers TW: The Medical & Surgical Practice of NaProTechnology. Pope Paul VI Institute Press, Omaha, NE, 2004.



# Could the FertilityCare Charts be telling us <u>something more</u>?



A woman with premenstrual spotting, a history of four consecutive miscarriages and a clearly suboptimal luteal phase hormone profile (From: Pope Paul VI Institute research, 2004).

# The FertilityCare Physician

Can predict which couples are at increased risk of ...

- Infertility
- Miscarriage
- Abnormal pregnancy outcome



### The FertilityCare chart can let us know if the treatment plan is effective

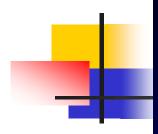
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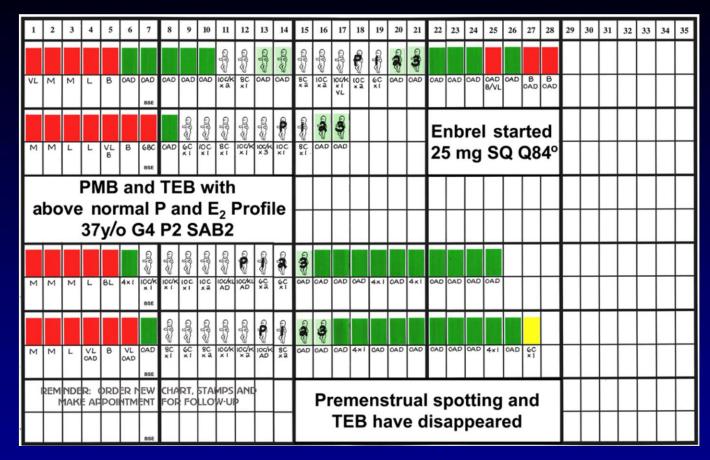
This patient had premenstrual spotting associated with decreased progesterone levels. Following that, she was treated with post-Peak HCG, 2000 units IM on Peak +3, 5, 7 and 9. This is shown in the last three cycles of this figure. This corrected her bleeding abnormality

Hilgers TW: The Medical & Surgical Practice of NaProTechnology. Pope Paul VI Institute Press, Omaha, NE, 2004.



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In this chart, this woman with a longstanding infertility problem was treated with luteal phase support without benefit (first 3 cycles). Then, she was treated empirically with metronidazole 500 mg by mouth two times a day (PO BID) for 10 days and the bleeding stopped (From: Pope Paul VI Institute research, 2004).



This is the same patient as in Figure 32-21. The premenstrual spotting is shown in the first cycle of charting. She was treated by a reproductive immunologist with Enbrel 25 mg SQ every 84 hours. On treatment with Enbrel, her premenstrual spotting and tail-end brown bleeding disappeared

# Clinical experience with LDN

• Started to prescribe it in 2004

# Low Dose Naltrexone



# LDN – plays an important part



# Low Dose Naltrexone

Clinical Experience since 2004

- LDN is used to treat Clinical Endorphin Deficiency
- About 50% of fertility patients
- Safe to continue during pregnancy and breastfeeding

# Clinical Endorphin Deficiency

- 1. PMS
- 2. Polycystic ovaries or Endometriosis
- 3. TEBB
- 4. Fatigue 2 or more of these
- 5. Low Mood
- 6. Anxiety
- 7. Sleep
- 8. Family History of Autoimmunity

# Clinical Endorphin Deficiency

- Available from brochure
  - <u>http://fertilitycare.net/documents/LDNInfoAug13aa.pdf</u>

# Side Effects

- 1. Vivid Dreams
- 2. Sleep Disturbance
- 3. Nausea for about 2 weeks
- 4. Headache
- 5. Dry Mouth over 95% acceptable

# Drug Interactions

- 1. Morphine
- 2. Codeine
- 3. Alcohol

- Safe to combine with steroids
- Discontinue 2 days before surgery and resume after stopping pain relief

# No longer an Experimental Treatment

- It is a licensed drug but at a much higher dose (50mg) for a different indication drug addiction
- A growing number publications at LDN Website
  - MS, Crohn's and fibromyalgia
- A <u>proven potent immune modifying treatment</u> through a double blinded randomized placebo controlled trial 2011

# Low Dose Naltrexone

#### Dosage

• 3mg nightly

or

• 4.5mg nightly

# Low Dose Naltrexone

- Needs to be specially compounded as
- Fast release preparation
  - Not lactose or calcium carbonate filler
  - Preferably microcrystalline filler (avicel)
- Suppliers listed
  - <u>www.lowdosenaltrexone.org</u>

### Infertile 36y female with R.Arth. 2004

- Diagnosis of PCOD and 10 years of Infertility, previous success in our programme
- **First episode of Acute onset of R. Arth.** 
  - When trying to conceive for the second time
- Diagnosed by Rheumatologist
- Resistant to NSAIDS
- Advised Methotrexate (then cannot conceive!)

### Infertile 36y female with R.Arth.

#### **LDN**

Rapid 80% improvement in symptoms
No Side effects
Conceived after 2 cycles of LDN and other fertility treatment

Successful pregnancy

### Low Dose Naltrexone - LDN

### Surprise!!



Huge resistance among many doctors to even try it out!

### **Doctor Resistance**

Unlicensed for Auto-immune disorders
Experimental treatment
Not "evidence based" medicine
Doctors not covered by medical insurance

#### **Too Risky!**

# Up the Creek with a Paddle

Beat MS and Many Autoimmune Disorders with Low Dose Naltrexone (LDN)

#### Mary Anne Boyle Bradley

# Clinical Experience

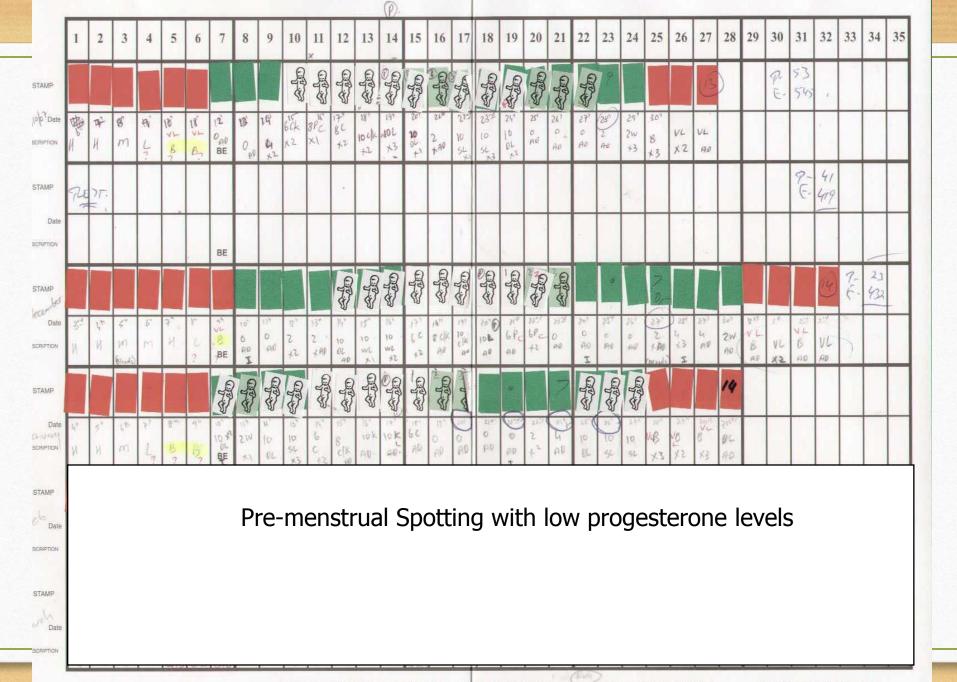
- 1. Case C 3 previous failed IVF cycles
- 2. Six recurrent miscarriages

# Case C

- Gravida 1 (with IVF), Para 0, 5 Years of primary infertility
- Female age 38, Male age 38
- Mild Endometriosis
- 12 previous cycles of clomid
- 3 attempts at IUI
- 3 previous failed IVF

## Case C – NPT Diagnoses

- Endometriosis
- Oligoasthenozoospermia Male Factor
- Clinical endorphin deficiency
- Low progesterone and oestradiol combined poor follicle function and corpus luteum insufficiency Obvious from Chart
- Food Intolerance to eggs



### Case C – NPT Treatments

- Clinical endorphin deficiency significant
  - Naltrexone 4.5mg nightly

- Food Intolerance to eggs
  - Change in diet

## Case C – NPT Treatments

- Endometriosis
  - Laparoscopy and diathermy June 2008
- Oligoasthenozoospermia
  - CoEnzyme Q10 200mg daily
  - Tamoxifen 20mg daily
  - FertilityPlus for men
  - Lifestyle (cigarettes, alcohol, caffeine, stress)

## Case C – NPT Treatments

- Low progesterone and oestradiol combined poor follicle function and corpus luteum insufficiency
  - Clomiphene 150mg daily x 3 days, starting on day 3 of the cycle with HCG 5000 iu mid cycle to facilitate follicle rupture and HCG 2,500 iu on days 3, 5 and 7 after ovulation

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USE THESE SIGNS: P = PEAK • 1.2.3 = FERTILE DAYS FOLLOWING PEAK • I = INTERCOURSE BE = E

BE = BREAST SELF-EXAM

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I = INTERCOURSE BE = BREAST SELF-EXAM

## Case C – NPT Pregnancy Treatments

- Positive pregnancy test in September 2008
- Cyclogest 400mg pv nocte until 14 weeks
- Naltrexone 4.5mg nocte until 38 weeks



## Case C – NPT Pregnancy outcome

• They had a healthy baby boy by normal vaginal delivery weighing 3.400kg in June 2009, when mum was 40 years old.

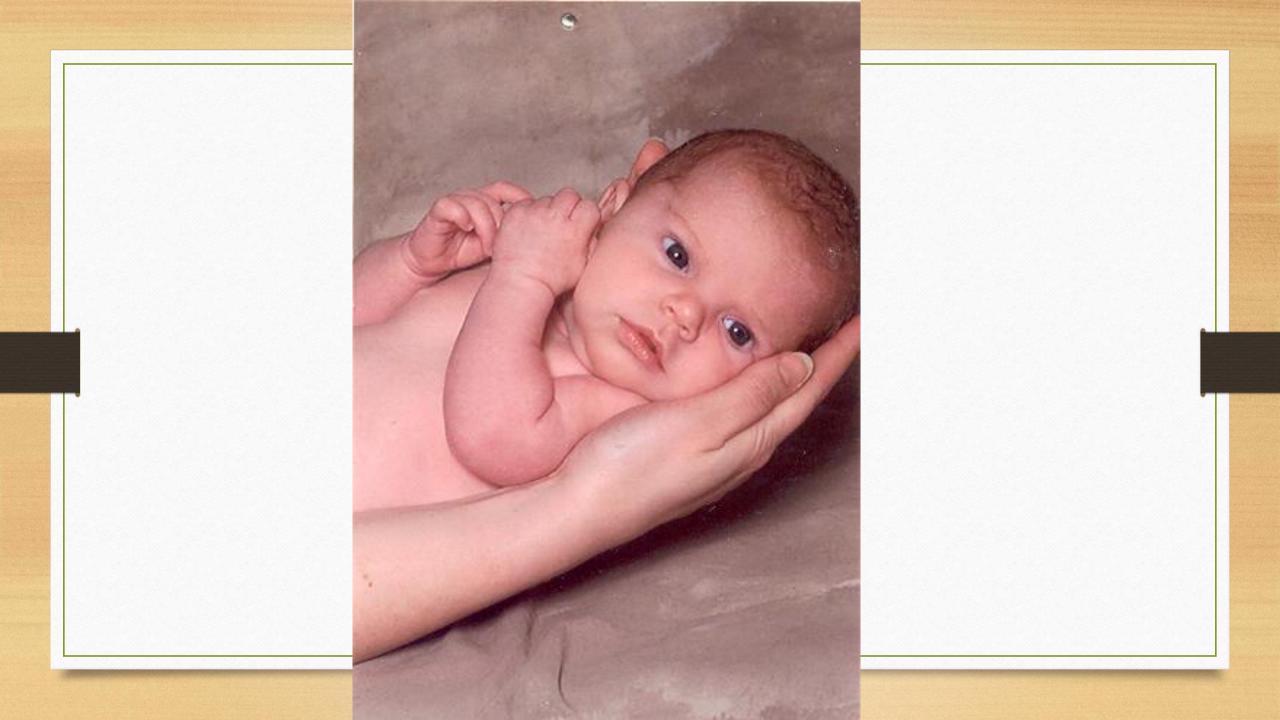
### Case C – Comments

- We continued Naltrexone throughout pregnancy in this case because the patient felt dramatically better preconception with treatment.
- It appears she had significant endorphin deficiency which needed ongoing treatment
- Over 200 pregnancies with naltrexone

## Case C – repeat attempt

- Second attempt in February 2010
- Same treatment approach successfully conceived by September 2010.

- Delivered a second healthy boy at term 19th May 2011
  - Mum 42 years old.



# Endometriosis- 27 year old female

- Dx Age 18
  - 5 laparoscopies
  - Oral Contraceptive Pill
  - Zoladex x 3 years made pain bearable
- Deferred University studies

- Depression
- Profound fatigue
- Underactive thyroid
- Anxiety
- Joint pain

 Severe PMS 7 days each cycle & brown menstrual bleeding
 Hospitalised repeatedly for investigation and treatment of pain

- **2007**
- LDN 4.5mg nightly
- Diet based on IgG antibody testing

- It has completely changed my life
- For the first time in a long time, I can say I have a life

- Depression gone
- Profound fatigue gone
- Underactive thyroid on a lower dose of medication
- Anxiety gone
- Joint pain gone
- Severe PMS 7 days each cycle now 2 days and mild
- brown menstrual bleeding gone
- Pain -

- A complete transformation has occurred physically, mentally and emotionally
- For the first time in my life I feel like a complete human being and not a multitude of symptoms
- I was helpless and a hopeless case before this treatment

## Bipolar Disorder - 28 year old female

• On Lithium for 10 years

- Previously hospitalised
- Trying to conceive and wean off lithium
- Part of treatment included LDN

Delivered 4 years ago 2010 – Never had a relapse
Maintained on LDN

## Publications

- PubMed search <u>"Low Dose Naltrexone"</u> 83 results May 2014
  - Pain Relief
  - Opioid, Alcohol and smoking cessation
  - Fibromyalgia
  - Crohn's Adults and children
  - Systemic Sclerosis
  - Cancer Treatment
  - Multiple sclerosis

# Endorphin Stimulation

- Immune modifying effect
  - Local effects Reduces pro-inflammatory cytokines

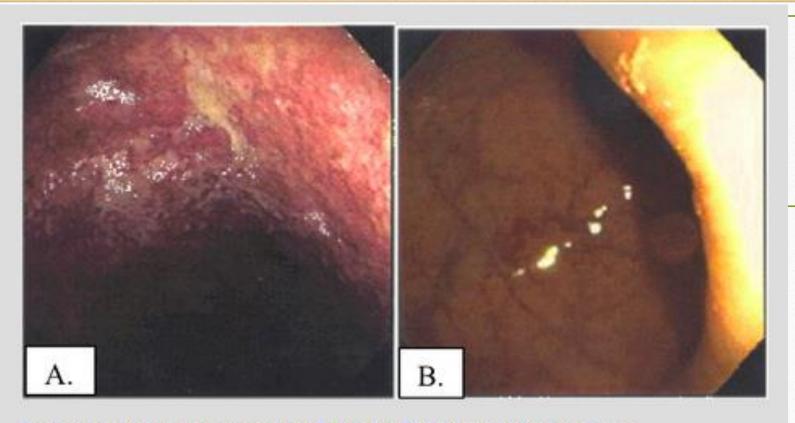
Interleukin (2,6,12), TNF (Tumor Necrosis Factor) alpha, Gamma Interferon

• Cause inflammation from wbc and macrophages

Naltrexone influences mu, kappa and delta receptors locally

**Central effect** increases endogenous enkephalins (Metenkephalin) centrally to heal the bowel.

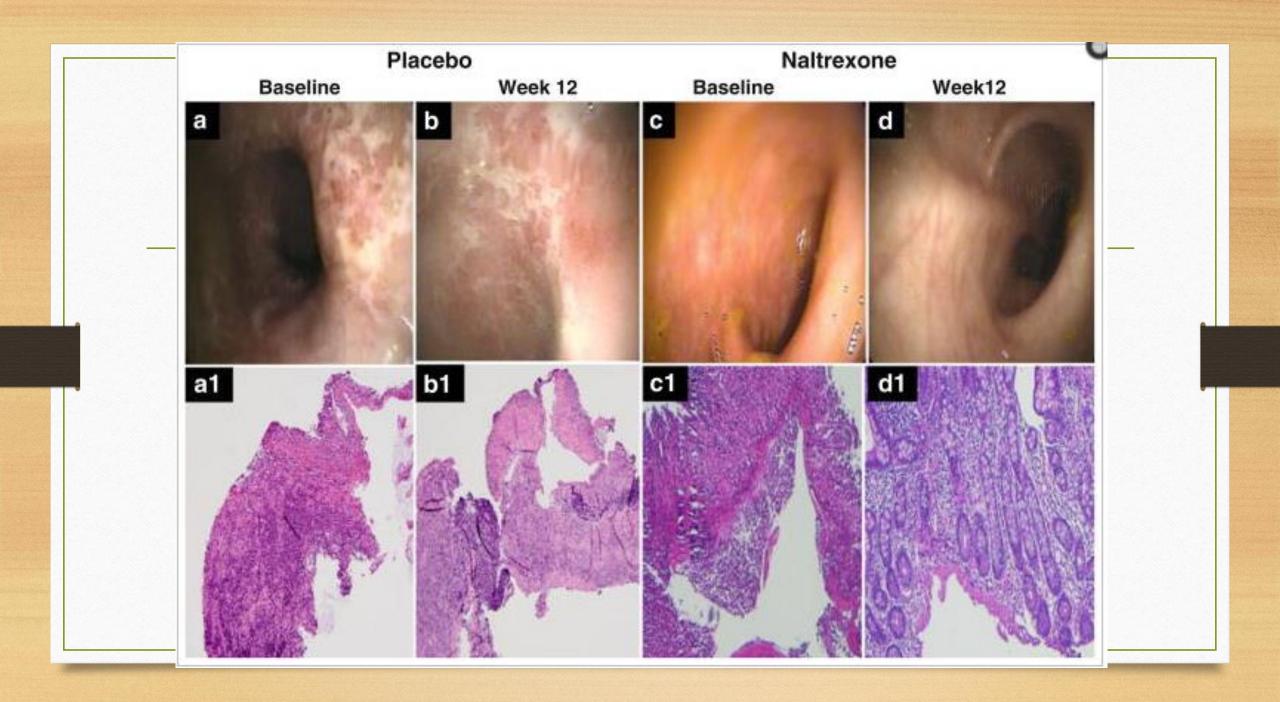
#### Professor Jill Smith - Am J. Gastro 2007.



Endoscopic Improvement in Crohn's Colitis with Naltrexone

Figure A: Shown is the rectum of a subject with active Crohn's Disease before starting therapy with naltrexone 4.5 mg/day. The mucosa is ulcerated, edematous, and inflamed.

Figure B: Shows the same area of the rectum in the same patient four weeks after naltrexone therapy. The lining is now healed, ulcers resolved, and the mucosa is healthy.



## Naltrexone promotes mucosal healing in active Crohn's disease: 2011

Randomized placebo-controlled trial.

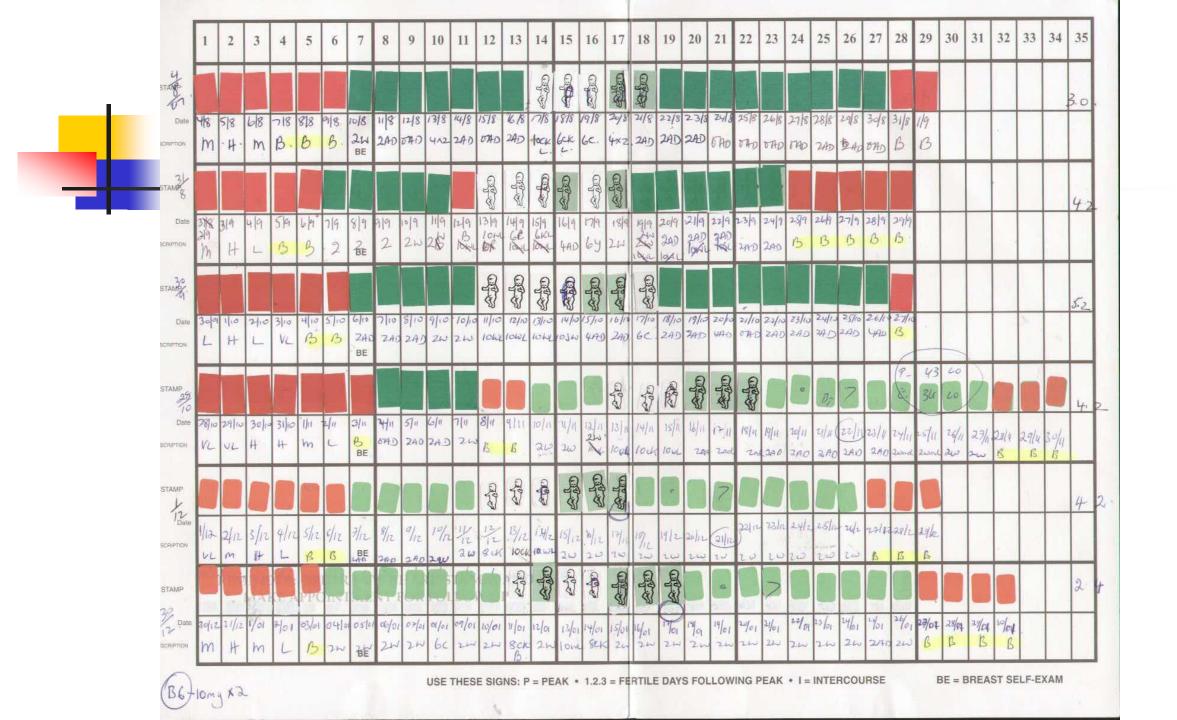
Digestive Diseases and sciences 2011Impact factor 20122.260American Journal of Gastroenterology - Impact factor 20127.553New England Journal of Medicine- Impact factor 201251.658

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3381945/

## **Case Presentation**

#### • The Future.....Pre-Treatment!

- 31yo G0 P0 1<sup>st</sup> Visit Feb 2008
- Engaged wedding July 2008
  - +++PMS, Fatigue,
  - +FH Sister PCOS
- Not Sexually Active
- Not trying to conceive ...yet!



- Peak +7
  - Low Progesterone
  - Low Oestradiol

Endorphin Deficiency



### Treatment

- Cyclogest Peak +3 for 10 nights
- Naltrexone 4.5mg

### Treatment

- Improved Progesterone
- PMS gone
- Energy and mood improved

### But....still abnormal bleeding...

Ultrasound May 08

- PCOS
- Endometrial Polyp
- Surgical referral
  - Hysteroscopy & Polypectomy July 08

Healthy and Happy

- PMS, Energy
- Normal Chart
  - Bleeding, Mucus
- Normal hormones
  - Progesterone, Oestradiol





Problem was <u>identified</u> and <u>solved</u> ....even before it officially existed!

What would have happened without LDN and NaProTechnology?

# The Future....for LDN

- It is safe....
- Doctors need to consider the mounting clinical and published evidence in favour of LDN!
- Proven Immune modifying treatment Placebo RCT.

