

## High Hopes *versus* Harsh Realities

### The Population Impact of ECPs

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## The Hope

Widespread use of ECPs could prevent **HALF** of all unintended pregnancies and abortions in the US each year

—Trussell, Stewart *et al.* 1992

*Trussell et al. Fam Plann Perspect 1992*

## The Reality – 20 Years Later

Fifteen studies have examined the impact of increased access to ECPs on pregnancy and abortion rates

Only one has shown any benefit

*Raymond et al. Obstet Gynecol 2007;*  
*Polis et al. Cochrane Rev 2010;*  
*Shaaban et al. Contraception 2013*

The great tragedy of science—  
the slaying of a beautiful  
hypothesis by an ugly fact

TH Huxley, *Collected Essays, 1894*

## Agenda Today

- Review these studies
- Discuss possible explanations for disappointing findings
- Consider the role of ECPs in the contraceptive method mix

## The Fifteen Studies

- Conducted 1998-2011
- 14 randomized trials, 1 cohort study
  - Total of 12,804 women enrolled
- 1 demonstration project
  - >17,831 women given ECPs
- Followed women up to one year
- Compared increased access to standard access

## Common Study Design

- Women assigned to one of two groups:
  - Advance Provision (intervention): given a supply of ECPs for later use should the need arise
  - Standard Provision (control): obtain ECPs from a clinic in the regular way

## Selected Studies

	N	Regimen	% Pregnant	
			Intervention	Control
Glasier	1083	Yuzpe	5%	6%
Lo	1030	LNg	1%	2%
Hu	2000	mife	4%	3%
Raine	1228	LNg	8%	9%
Raymond	1490	LNg	9%	10%
Shaaban	1158	LNg	0.8%	5%

## The Single Exception

- Women using LAM in Egypt
- Lower pregnancy rate appears to be due to better uptake of regular contraception
- Authors argue that women used EC to buy time to get to a family planning clinic

*Shaaban et al. Contraception 2013*

## Explanations for Negative Results

1. Flaws in studies

## Problems with the Studies

- Small sample size (50-2868 women)
- Huge loss to follow-up (1-62%)
- Weak intervention
- Good access in comparison group
- Low baseline risk of pregnancy – little room for improvement with EC
- Not randomized

## However...

None of the 14 studies had all of these problems —

Indeed, some were very good!

Consistency of findings hard to ignore

## Explanations

1. Flaws in studies
2. Increased risk taking

## ECPs and Risk Taking

- No evidence of increase in unprotected sex or decrease in use of regular contraception with enhanced ECP access
- Some suggest “improved” behavior (but most data self-reported)
- 4 studies showed no effect on STIs

Polis *et al.* *Cochrane Rev* 2010

## However...

- Reanalysis of one of the randomized trials suggests that easier access to ECPs
  - may have increased the frequency of coital acts with the potential to lead to pregnancy
  - led to greater substitution of ECPs for condoms or another contraceptive
  - increased repeat use greatest among those with lowest baseline risk of pregnancy

Raymond and Weaver. *Contraception* 2008  
Weaver *et al.* *Obstet Gynecol* 2009  
Baecher *et al.* *Human Reprod* 2009

## Explanations

1. Flaws in studies
2. Increased risk taking
3. Low ECP efficacy

## Current Estimates

- ECP efficacy conveys the **reduction** in pregnancy risk after a **single** coital act
- Plan B package (LNg regimen): 7/8=88%
- Published literature:
  - LNg regimen: 52% - 100%
  - UPA regimen: 62% - 85%

## Methodology

In a group of ECP users, compare:

- **observed** number of pregnancies
- **expected** number of pregnancies (number that would have occurred without ECPs)

Calculate the reduction due to the ECPs

## Example

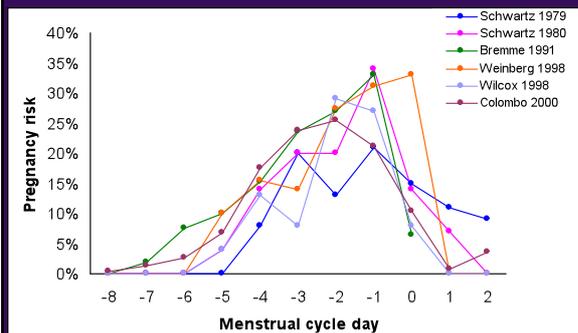
### WHO 1998 trial of LNG vs. Yuzpe regimen

- 1001 women using LNG regimen
- Pregnancies observed: 11
- Pregnancies expected without EC: 75.3
- Pregnancies prevented:  $75.3 - 11 = 64.3$
- Efficacy:  $\frac{64.3}{75.3} = 85\%$

## Expected Pregnancies

- Determine the day of the menstrual cycle when the coital act occurred
- Estimate that day relative to day of ovulation
- Use published probabilities of pregnancy by cycle day to estimate expected pregnancies

## Pregnancy Risk by Cycle Day



## Do Any of the Charts Apply?

Women in the charts wanted to be pregnant

ECP users wanted **NOT** to be pregnant.

Possible differences in:

- Fecundity?
- Amount and type (broken condom, withdrawal?) of unprotected sex?
- Accuracy of data?

## Do Any of the Charts Apply?

- One study found that in 25 of 69 women seeking EC, no sperm were present in the vagina
- When sperm were present, the number was much lower than in women trying to conceive

Espinós-Gómez et al. *Eur J Obstet Gynecol Reprod Biol* 2007

## Do Any of the Charts Apply?

- Another study found that 99 women were between days -5 and +1 when the day of ovulation was estimated as usual cycle length minus 13
- Hormonal data indicated that only 51 of these 99 (56%) were in fact between days -5 and +1

Espinós et al. *Contraception* 1999

## Efficacy: Conclusion

Numbers of expected pregnancies reported by studies are probably too high

Most published efficacy figures are probably overestimates

## Don't Give Up...

### ECPs do work!

- Physiology studies show effects incompatible with pregnancy
- LNg regimen proven to be more effective than Yuzpe → it must be more effective than nothing
- UPA more effective than LNg

*Raymond et al. Contraception 2004;  
Glasier et al. Lancet 2010; 375:555-62*

## Explanations

1. Flaws in studies
2. Increased risk taking
3. Low ECP efficacy
4. Insufficient use

## Effects of Increased Access

- In nearly all studies increased access resulted in substantially increased use

### But...

- Repeated use was uncommon
- Many unprotected acts remained uncovered by ECPs

## Effect on Pregnancy

- Among the randomized trials, only three powered to detect a reduction in pregnancy rates
- In the community intervention study in Lothian, Scotland, about 1 in 5 women aged 16-29 got ECPs in advance to take home

## Why No Reduction in Trials?

- In San Francisco, 45% of the women in the advance provision (AP) group who had UPI did not use ECPs
- In Nevada/NC, 33% of women in the AP group had UPI at least once without using ECPs

*Raine et al. JAMA 2005;  
Raymond et al. Obstet Gynecol 2006*

## Why No Reduction in Abortion Rates in Lothian?

- Women most at risk probably did not get ECPs

Glasier *et al.* *Contraception* 2004

## Reasons for Non-Use

- Failure to perceive pregnancy risk
- Forgetting
- Lack of motivation to use EC
- Inconvenience

### Limits to ECP use in the real world

- Expensive
- Side effects

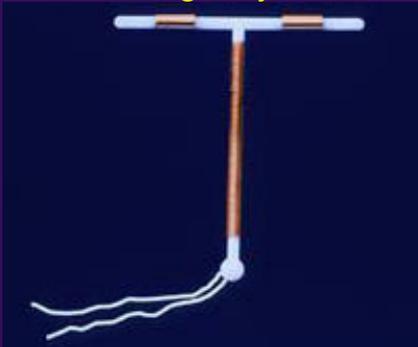
## Fourteen Studies, No Benefit

1. Flaws in studies - but consistency compelling
2. Increased risk taking - evidence mostly against
3. Low ECP efficacy - precise efficacy unknown
4. Insufficient use - definitely a problem

## What To Do Now?

- “be most slow to believe what we most wish should be true.” Letter from Samuel Pepys to Balthazar St Michael, 9 October 1679
- Do not promise public health impact: do not oversell by implying ECPs will reduce unintended pregnancy or abortion rates or be cost effective
- Stress efficacy for individuals: everyone deserves a second chance to prevent an unintended pregnancy

## The Best Emergency Contraceptive



## not-2-late.com

not-2-late.com

WELCOME. You've come to right place if you want to prevent pregnancy after sex.

- Get Emergency Contraception **NOW**
- INFO about Emergency Contraception
- Q&A about Emergency Contraception
- Info for **TEENS**

Find a Morning After Pill Provider Near You ZIP CODE

The Emergency Contraception Website  
Your website for the "Morning After"

This website is operated by the Office of Population Research at Princeton University and by the Association of Reproductive Health Professionals and has no connection with any pharmaceutical company or for-profit organization. This website is best viewed by a tablet or independent computer.

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