



# Obesity & Contraceptive Dosing

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# Disclosures

## Royalties

Up to Date, Inc. Author

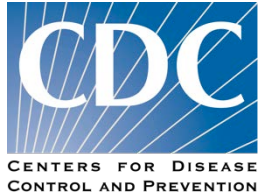
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## Institutional Grant Funding



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## Expert Working Groups







OHSU

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The Sopranos: Our Sneak Preview ■ Iraq and al-Qaeda

# TIME

## WHAT REALLY MAKES YOU FAT?



The latest science on how your body handles CARBS vs. FATS

### Body Weight and Risk of Oral Contraceptive Failure

Victoria L. Holt, PhD, MPH, Kara L. Cushing-Haugen, MS, and Janet R. Daling, PhD

**OBJECTIVE:** To examine the hypothesis that higher body weight increases the risk of oral contraceptive (OC) failure.

**METHODS:** We conducted a retrospective cohort analysis of data from 755 randomly selected female enrollees of Group Health Cooperative of Puget Sound who completed an in-person interview and dietary questionnaire between 1990 and 1994 as control subjects for a case-control study of ovarian cysts. Among the 618 women who were OC ever-users, we used Cox proportional hazards regression models to estimate the relative risk (RR) of pregnancy while using OCs associated with body weight quartile.

**RESULTS:** During 2822 person-years of OC use, 106 confirmed pregnancies occurred (3.8 per 100 person-years of exposure). After controlling for parity, women in the highest body weight quartile (70.5 kg or more) had a significantly increased risk of OC failure (RR 1.6, 95% confidence

In a 1980 letter to the *Medical Journal of Australia*, Boden reported a cluster of low-dose OC failures among relatively heavy women (Boden DC. Unplanned pregnancies and the pill [letter]. *Med J Aust* 1980;1:391). Also in 1980, a small study by Stadel et al of ethinyl estradiol (EE) blood levels in OC users found that women in the lowest serum EE quartile had a nonsignificantly higher mean weight than those in the highest quartile (142.2 versus 133.5 lb), indicating that OC metabolism may be enhanced among heavy women.<sup>5</sup> No more recent research on this topic is evident, although the lower-dose OCs currently marketed may have a greater impact on failure likelihood among heavy women. We conducted this analysis to investigate the relationship between a woman's weight and her risk of pregnancy while using

2002 Holt VL, et al. *Obstet Gynecol*

# What determines contraceptive effectiveness?

Drug efficacy x adherence x continuation  
Fecundability x coital frequency

# HOW WELL DOES BIRTH CONTROL WORK?

What is your chance of getting pregnant?



Really, really well



The Implant



IUDs



Copper IUD



Sterilization

Works, hassle-free...

Up to 5 years

Up to 7 years

Up to 12 years

Forever



Less than 1 in 100



Pretty well



The Pill



The Patch



The Ring



The Shot

For it to work best, use it... Every. Single. Day.

Every week

Every month

Every 3 months



6-9 in 100, depending on method



Not as well



Pulling Out



Fertility Awareness



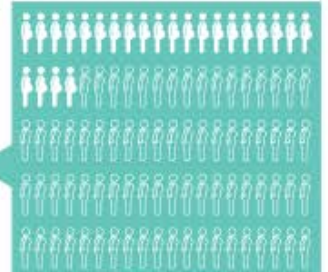
Internal Condom



Condom

For each of these methods to work, you or your partner have to use it every single time you have sex.

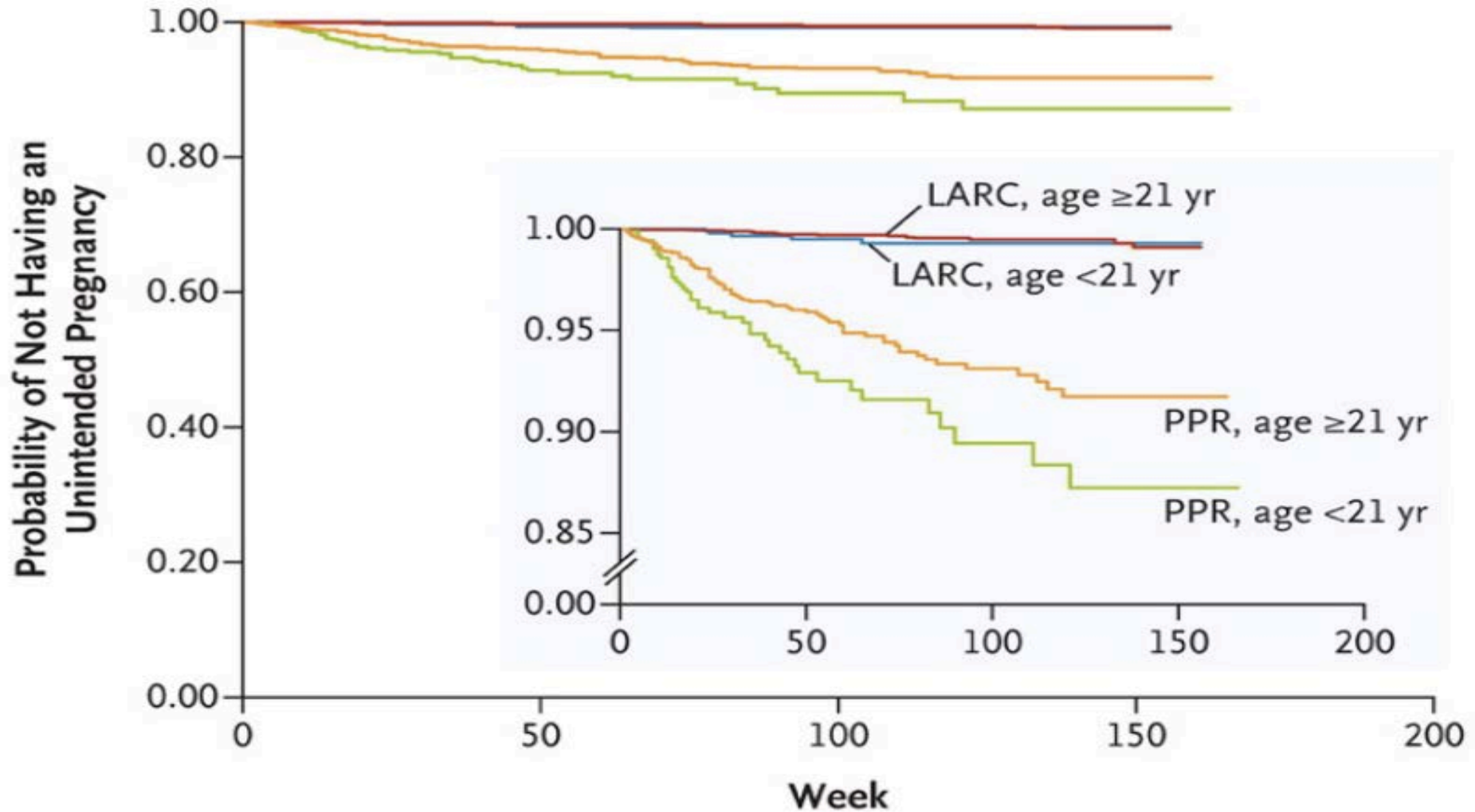
Use a condom with any other method for protection from STDs.



12-24 in 100, depending on method

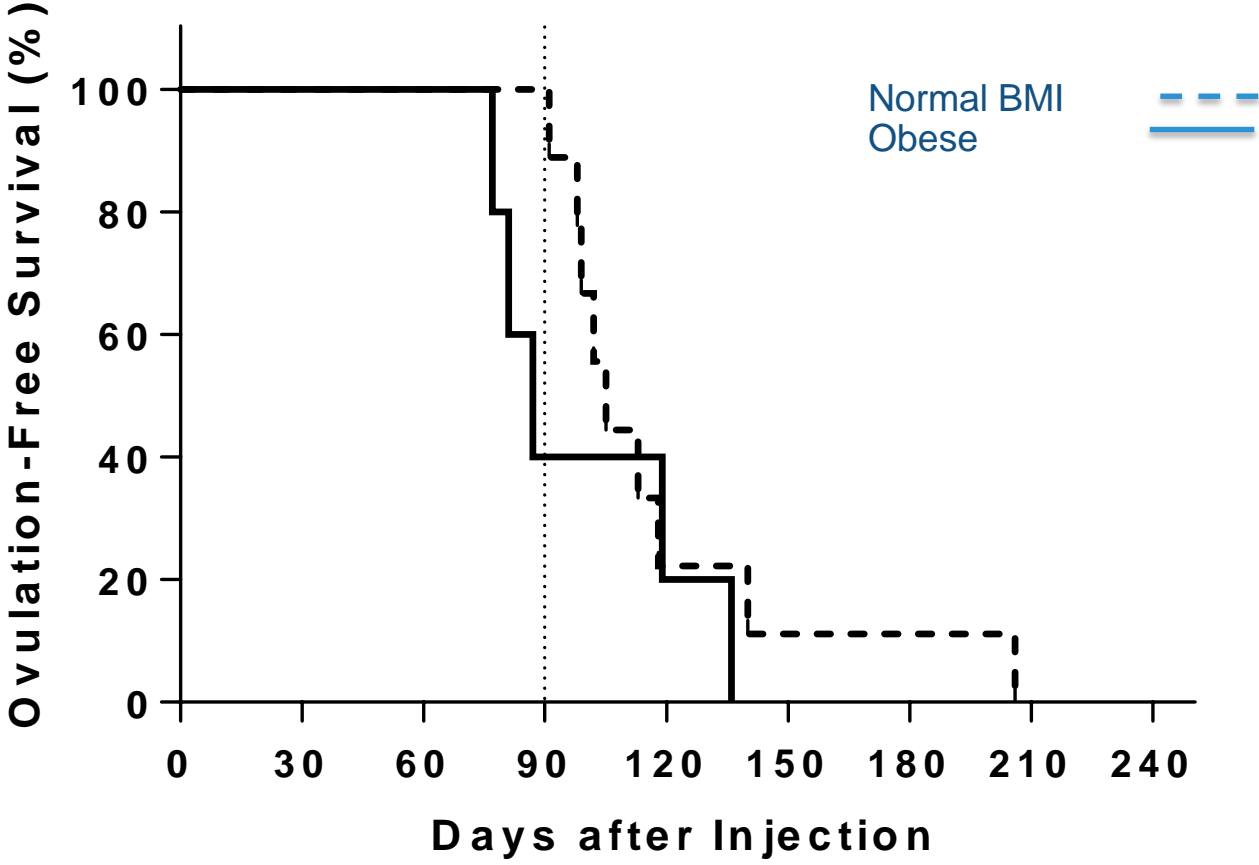
FYI, without birth control, over 90 in 100 young people get pregnant in a year.

# Short-acting methods = adherence challenges



# Confirmed Compliance

## Novel Levonorgestrel Injection

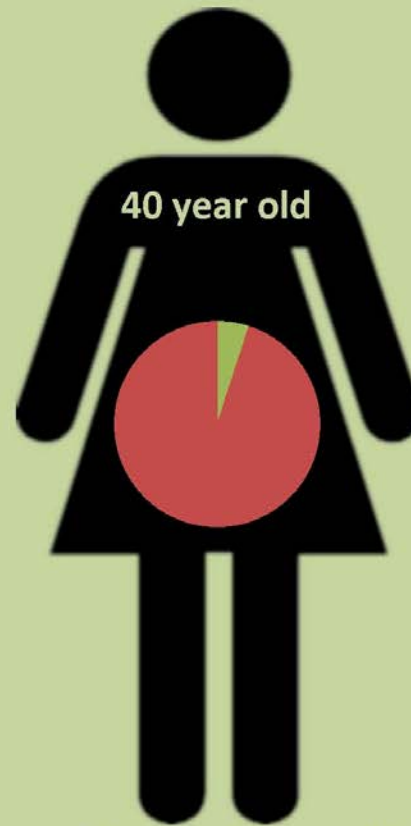




## Your chance of pregnancy each month declines with age

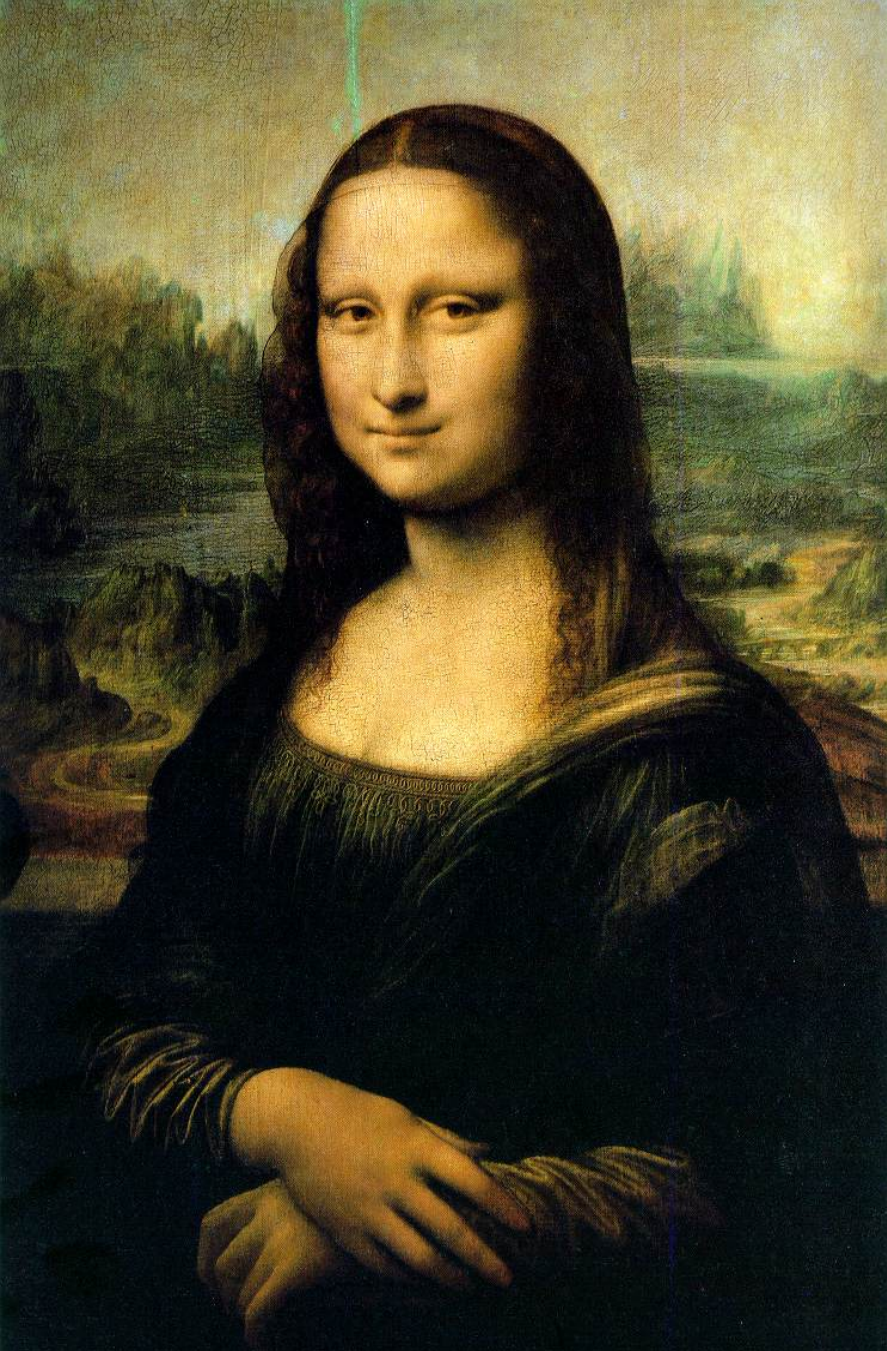


A healthy 30-year old woman has about a **20%** chance of getting pregnant each month.



A healthy 40-year old woman has about a **5%** chance of getting pregnant each month.



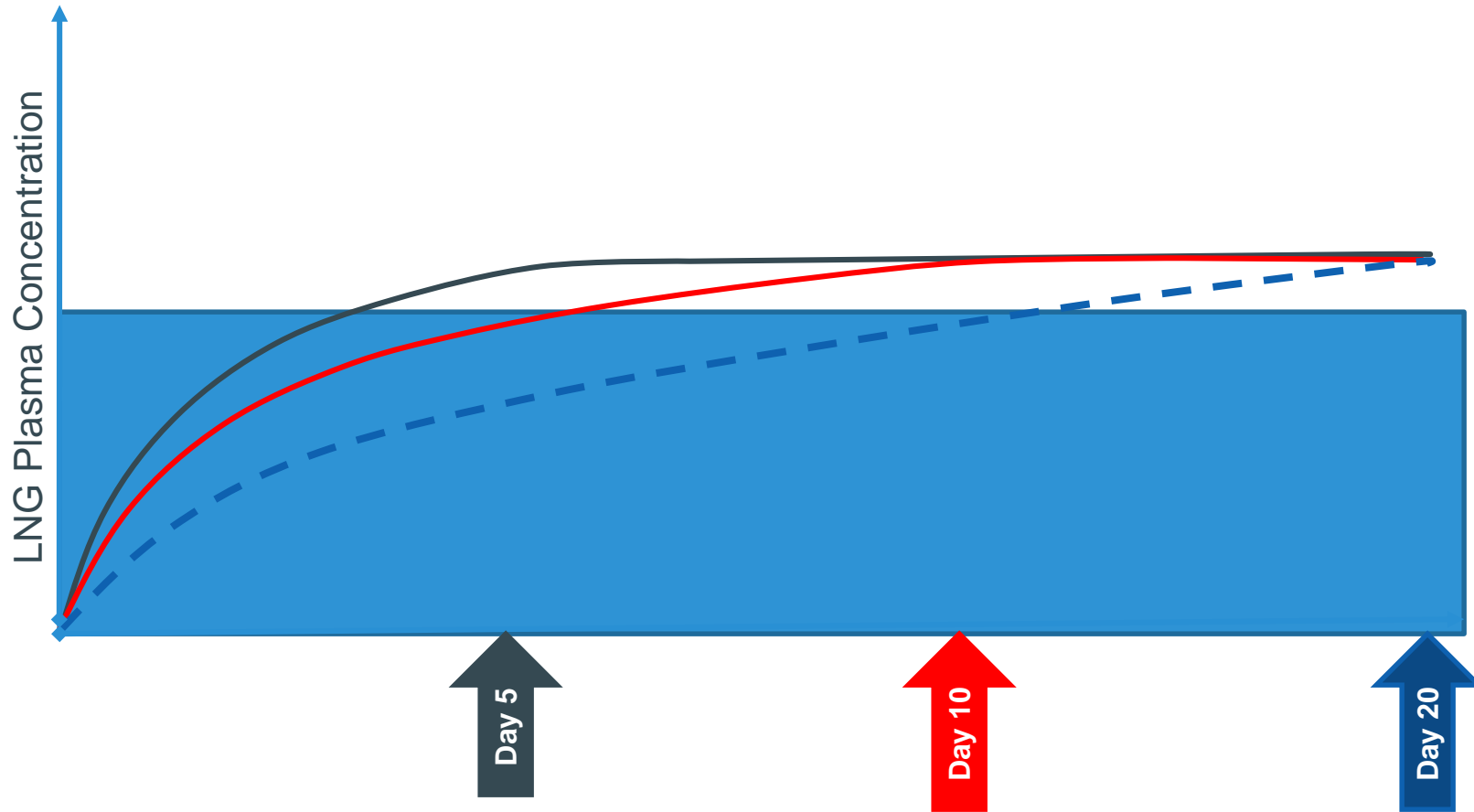


DaVinci



Botero

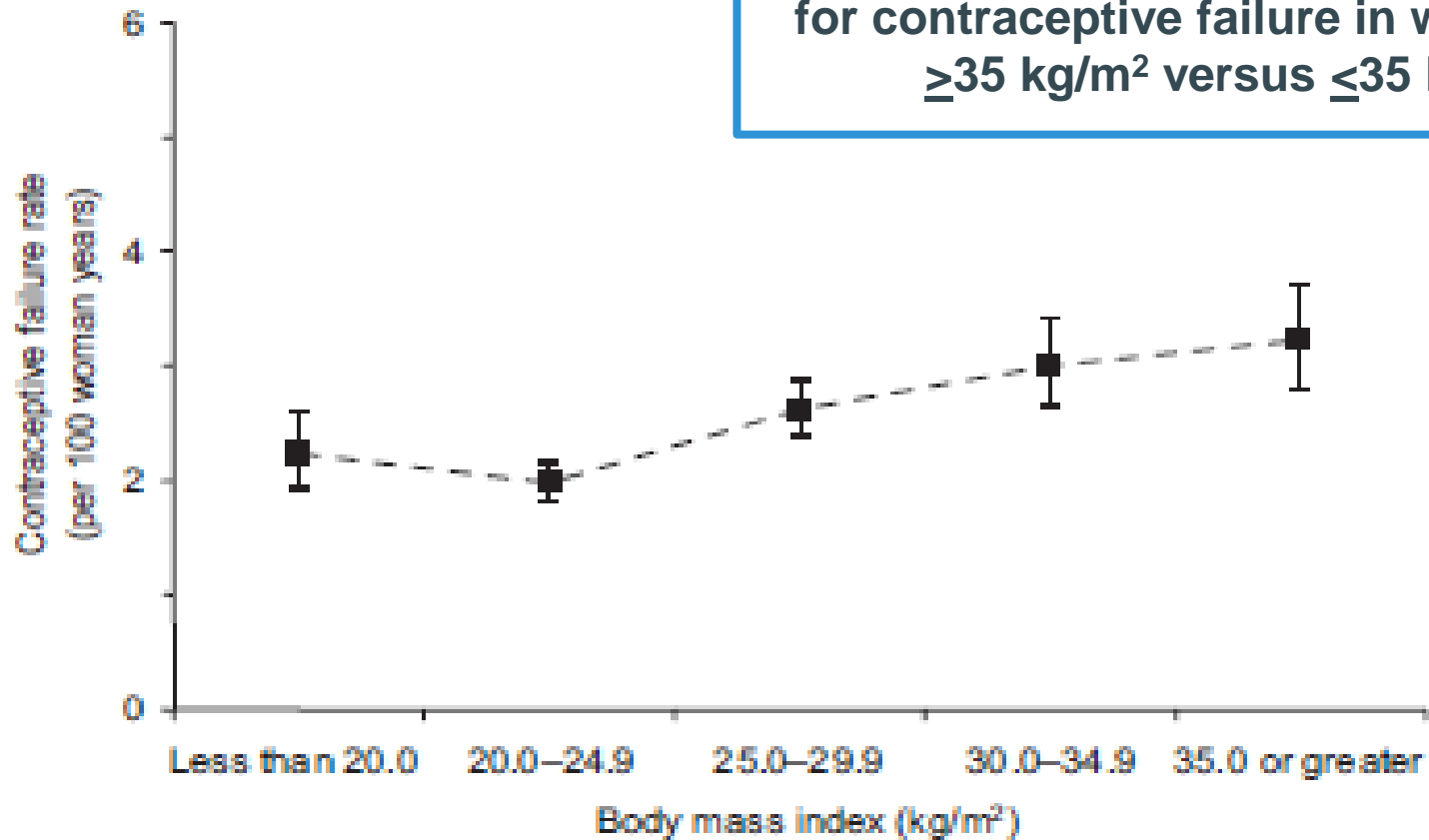
# Contraceptive steroid hormone levels & obesity





# “Pill” failure by BMI

Adjusted HR 1.5 (95% CI 1.3, 1.8)  
for contraceptive failure in women with  
 $\geq 35$  kg/m<sup>2</sup> versus  $\leq 35$  kg/m<sup>2</sup>



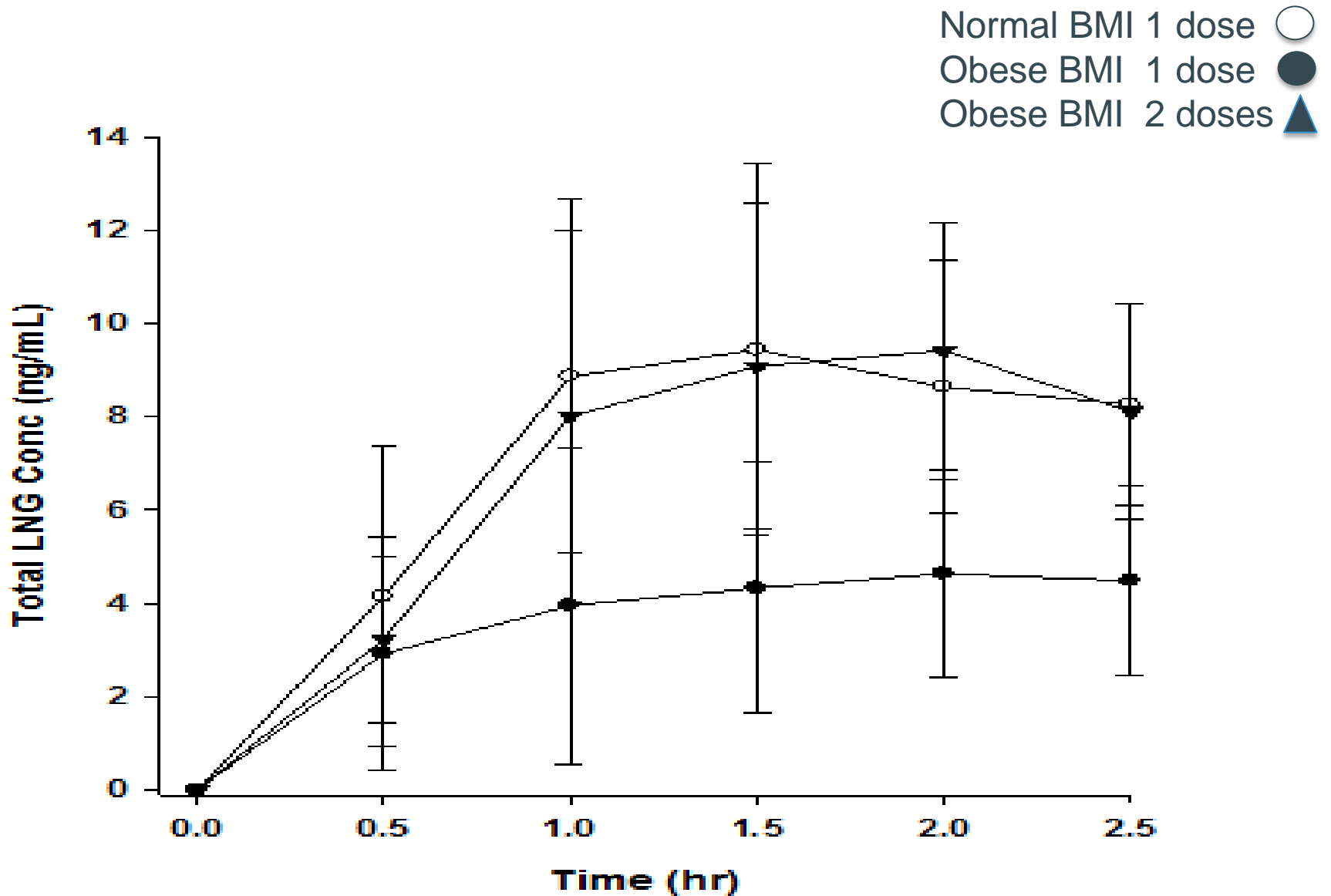


Uh

oh...

EC Failure: Obese vs. normal BMI  
Any EC: OR 3.6 (CI 1.96-6.53)  
LNG EC: OR 4.41 (CI 2.05-9.44)\*  
UPA EC: OR 2.62 (CI 0.89-7)

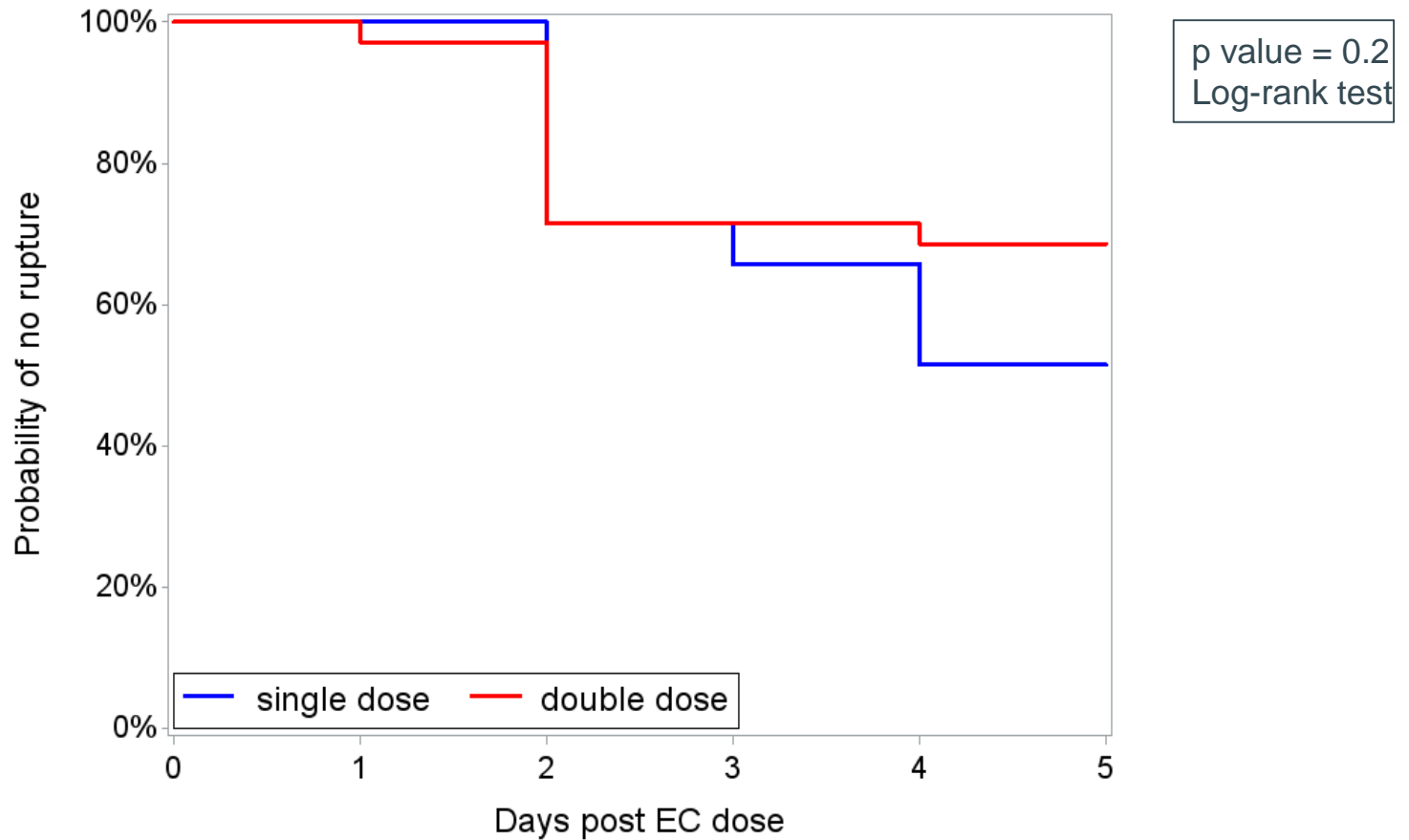
# Levonorgestrel Emergency Contraception Single & Double Dosing





# Single vs. double dosing LNG EC

## Time to rupture



Per Protocol Analysis. Censored at day 5  
75% probability of no rupture is day 2 for both groups

# FDA In Brief: FDA issues draft guidance aiming to clarify recommendations for clinical trials for hormonal contraceptives

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July 11, 2019



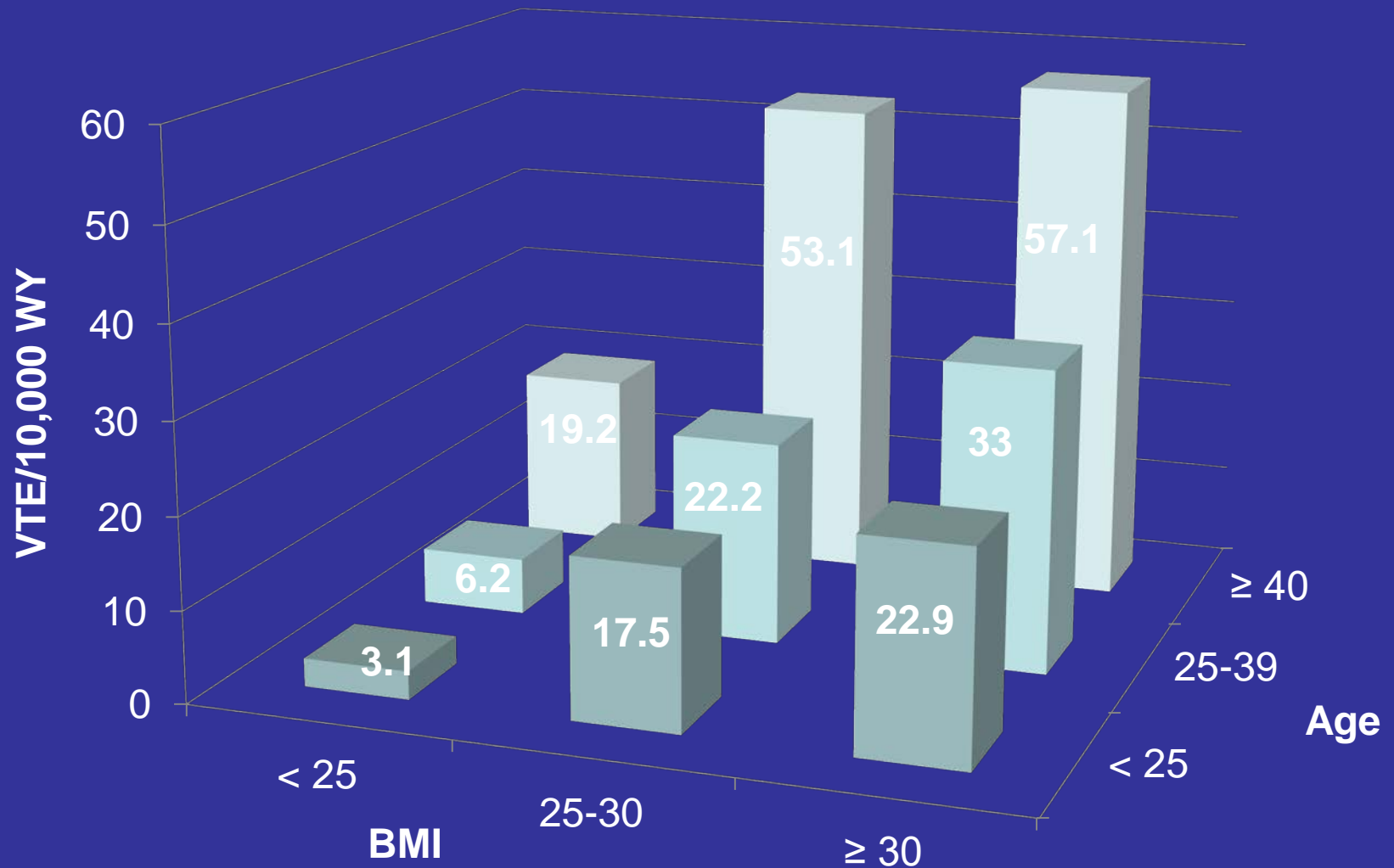
## Media Inquiries

[Lyndsay Meyer](#)

240-402-5345

**“Over the years, the FDA has recommended that companies study contraceptives in the most inclusive way possible to help ensure clinical trials reflect how these products are actually used and the latest science around them,”** said Amy Abernethy, M.D. Ph.D., FDA’s principal deputy commissioner of food and drugs. **“Today, the agency is issuing, for public comment, a new draft guidance to support innovation and scientific advances in women’s health and help ensure contraceptive products are adequately studied. For example, it recommends that clinical trial design for contraceptives should include women of all childbearing ages regardless of their weight, including those who are younger and older, and women who are obese.”**

# Contraceptive Pill: Age, BMI, & VTE Risk







Picture Source: Vectorstock.com



# Summary

1. Obesity impacts contraceptive steroid levels
2. Adherence plays a major role in contraceptive failure
3. Values & preferences play key roles in contraceptive choice
4. Using contraception prevents more pregnancies than not using contraception.



Thank you!

