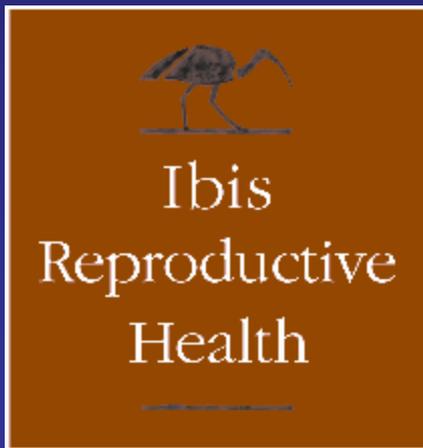


# Safety and effectiveness of OCs: Making the case for an OTC switch



Kelly Blanchard  
Dan Grossman  
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# Presenter disclosures

Kelly Blanchard

The following personal financial relationships with commercial interests relevant to this presentation existed during the past 12 months:

- No relationships to disclose

# Why consider OC OTC?

## Unmet need in the US 2002

43 million women at risk of unintended pregnancy  
(fecund and not pregnant or trying to get pregnant)

Of these, 11% are sexually active but not  
contracepting, an increase from 9% in 1995

49% of pregnancies are unintended

31% of contracepting women use OCs  
(the most popular method)

# Effectiveness of OC

Perfect use failure rate: 0.3%

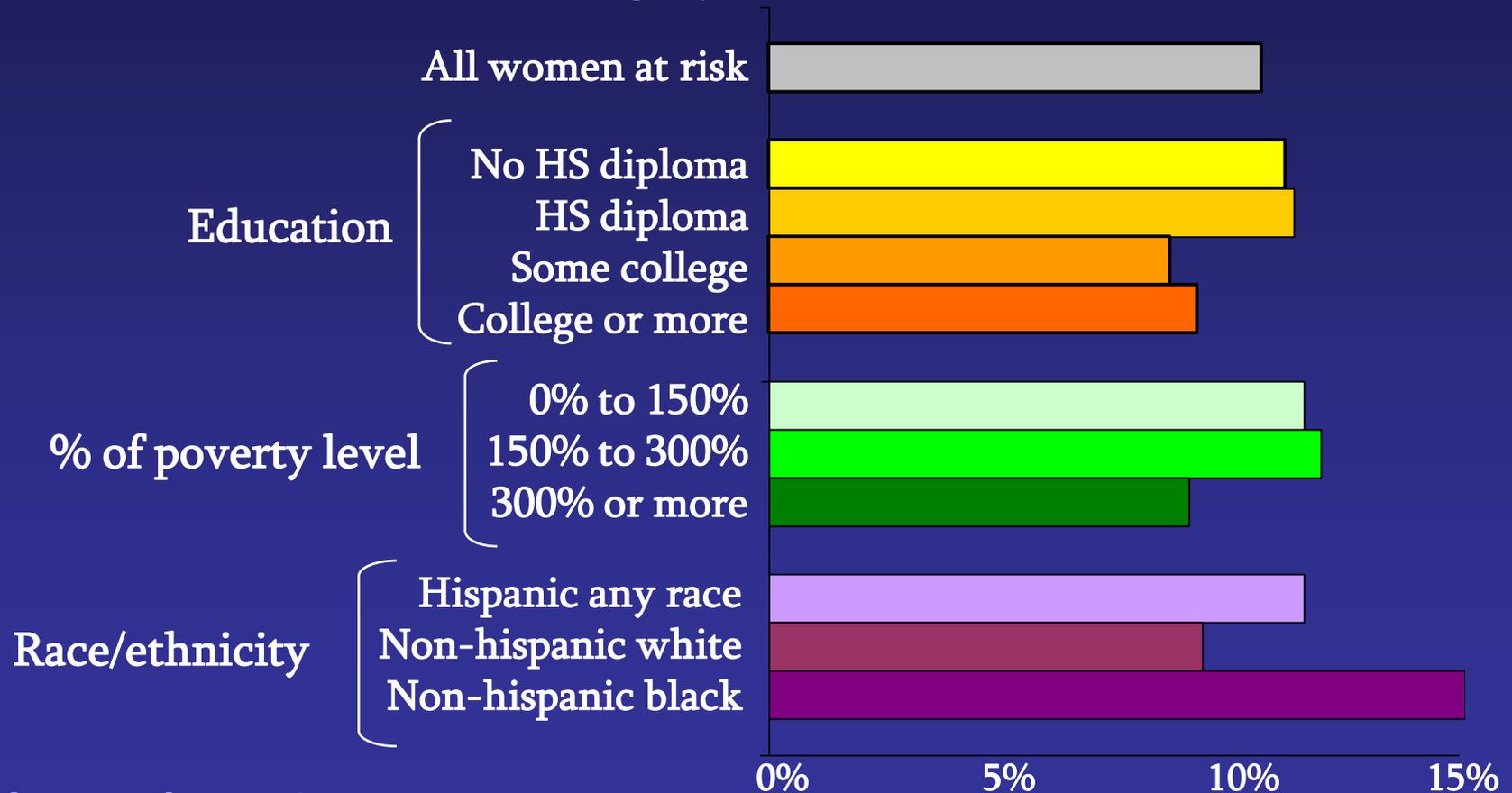
Typical use failure rate: 8%

% women continuing use at one year: 68%

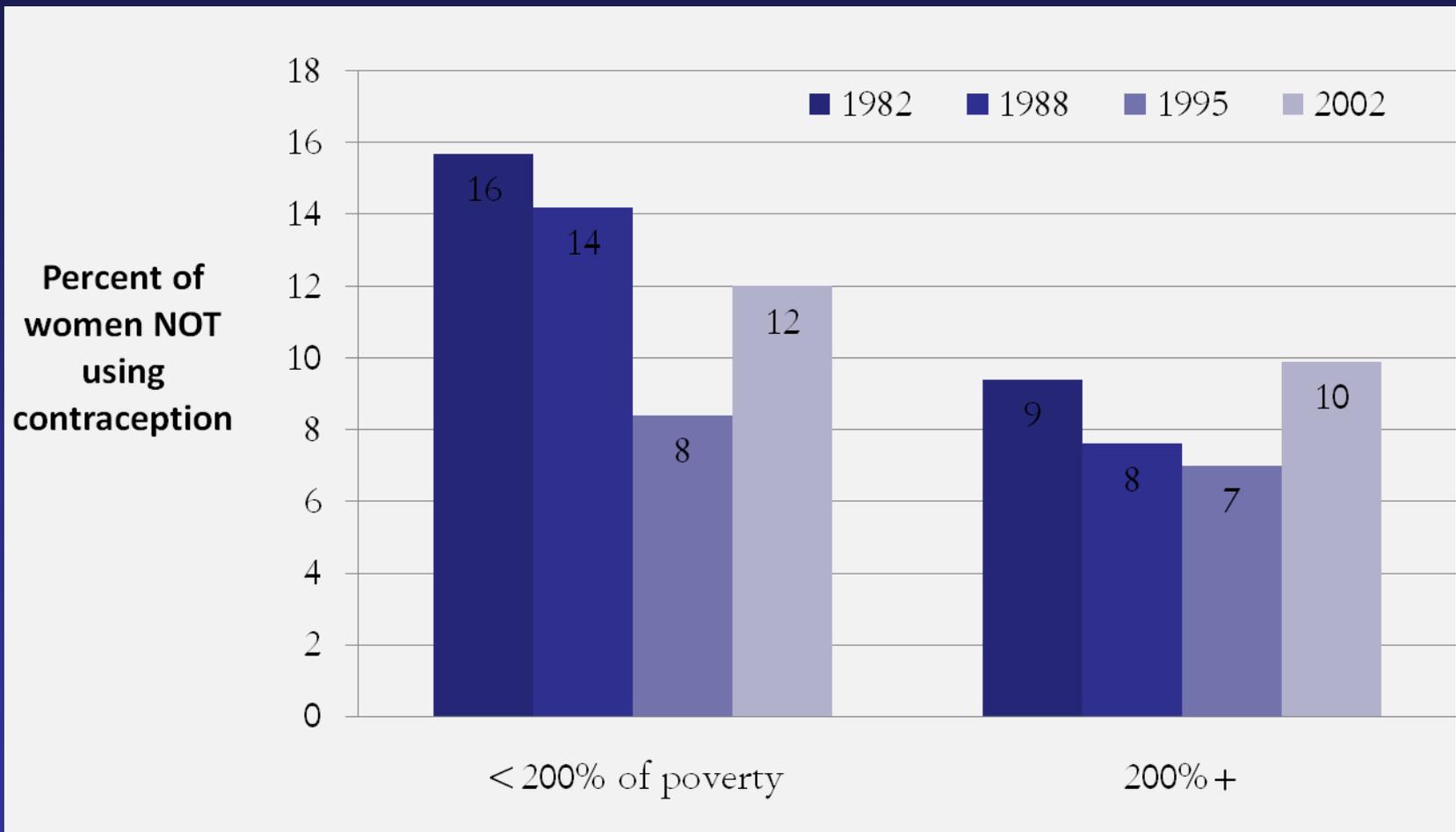
# Why OTC?

## Nonuse of contraception is common

Percent of women at risk of unintended pregnancy who are not contracepting, by selected characteristics, 2002



# Contraceptive nonuse is now growing (more so among low-income women)



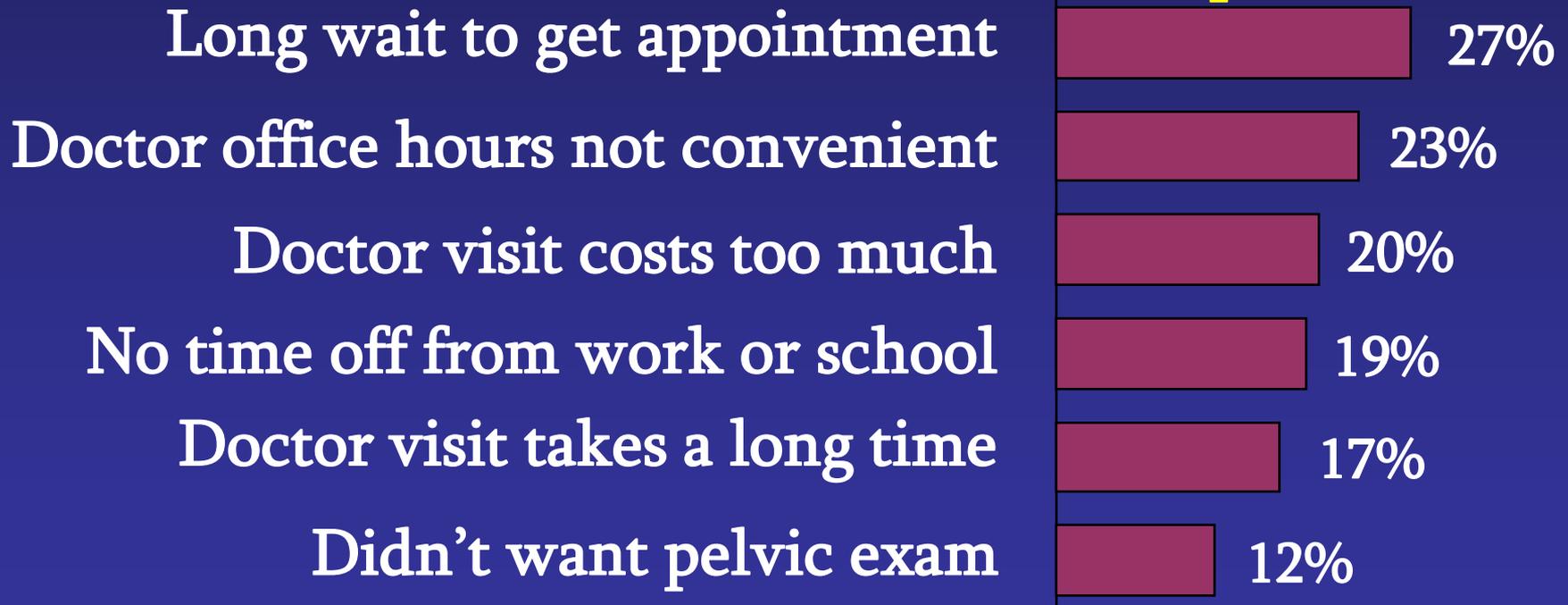
# Why OTC?

## Prescription status deters use

Pharmacy Access Partnership national phone survey, spring 2004  
811 women at risk for unintended pregnancy

### Obstacle

### % reporting it as a problem



# Why OTC?

## Easier access motivates use

Pharmacy Access Partnership survey, continued

% of non-users who report they would start if had pharmacy access: **42%**

Support for pharmacy access among	All non-users:	<b>63%</b>
	Uninsured non-users:	<b>73%</b>
	Low-income non-users:	<b>66%</b>

% of ever-users who report past problems getting prescription or supplies **28%**

# Why OTC?

OCs meet FDA criteria for OTC status

- ✓ Benefits outweigh risks for most women of reproductive age
- ✓ Potential for misuse or abuse is low
- ✓ Women can recognize their need for the drug
  - ✓ Directions for use are straightforward
- ✓ Women can self-screen for contraindications

# Safety

## Major contraindications to OC use

Condition	FDA Guidelines	WHO MEC
Hypertension	Contraindicated	3 or 4
Smoking over age 35	Warning	3 or 4
History of CVD or VTE	Contraindicated	4
Migraine with aura	Contraindicated	4
Diabetes*	Contraindicated	3 or 4
Current breast cancer	Contraindicated	4
Hx of breast/cervical cancer*	Contraindicated	3 and 2

\* Not supported by the literature

# OC labeling and guidelines do not reflect best evidence

Contraindications not supported by clinical data

- i.e. breast feeding

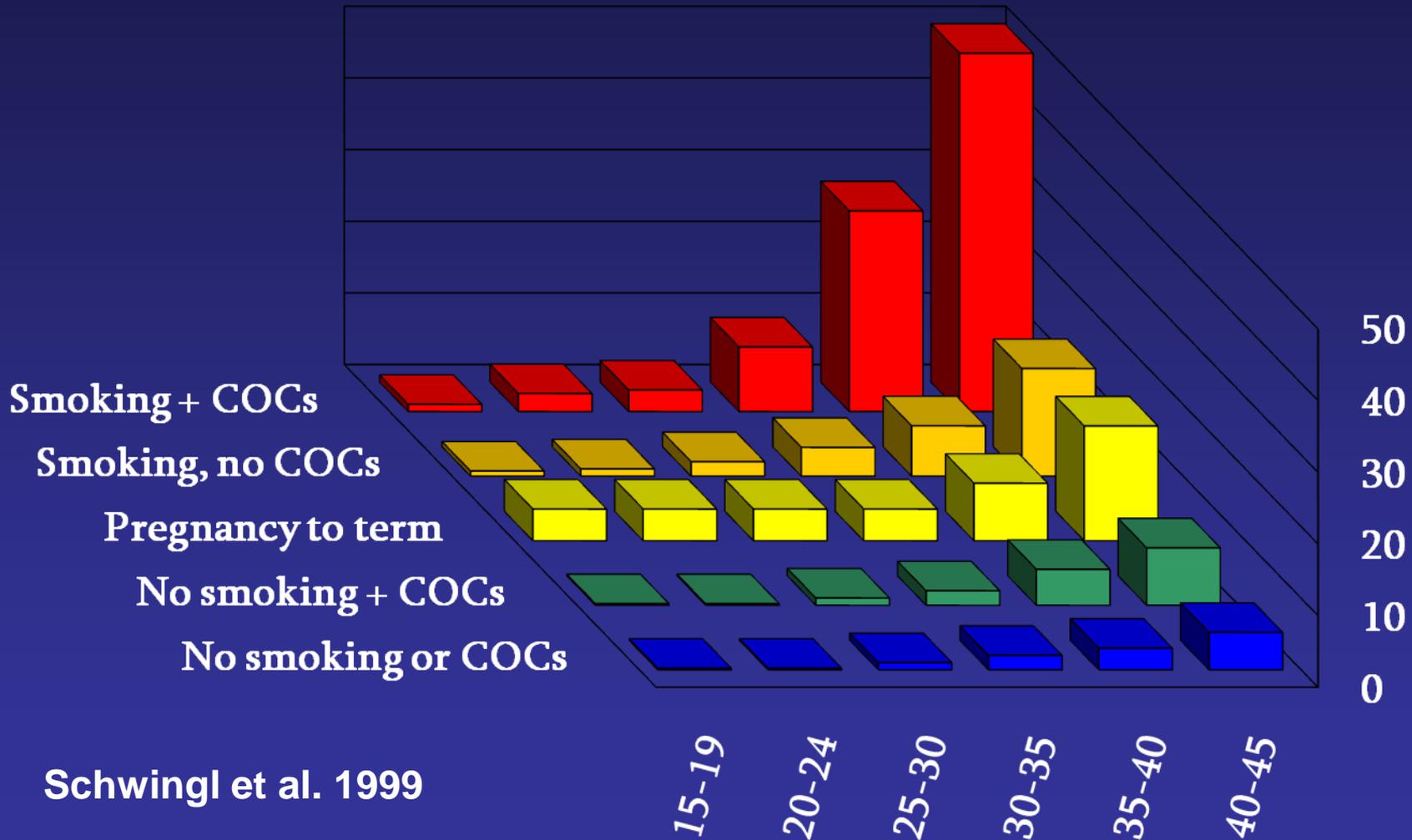
Labeling does not reflect newer data on provision innovation to improve access and acceptability

- i.e. no need for pelvic/Pap, Quickstart, self-screen for contraindications, pharmacist or self-test to evaluate BP (more from Dan later)

Prescription requirement itself may lead to misperceptions about OC safety

# Safety

Estimated annual CVD mortality rate per 100,000 women



Schwingl et al. 1999

# Safety

Most women have no contraindications to OC use, especially under age 35

Among non-sterile women of reproductive age, NHANES 1999-2001

	Under 35	Age 35+
No contraindications	95%	70%
Most common:		
Smoking over age 35	-	18%
Hypertension	1.6%	9.5%
Diabetes	1.3%	2.4%
Relevant cancers	1.4%	1.9%
Severe headache	30%	30%

(Migraine with aura not measured in this data)

# Safety

Some women with contraindications currently use OCs, even under prescription status

Among current OC users, NHANES 1999-2001

No contraindications 94%

Most common:

Smoking over age 35 2.0%

Hypertension 1.6%

Diabetes 0%

Relevant cancers 2.2%

# Health benefits of OCs

OC use can help alleviate conditions that worsen during menses including epilepsy, endometriosis, and treat acne.

A recent paper in the Lancet concluded, “Use of OCs confers long-term protection against ovarian cancer.” The editors of the Lancet called for OTC access.

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Ovarian cancer and oral contraceptives: collaborative reanalysis of data from 45 epidemiological studies including 23 257 women with ovarian cancer and 87 303 controls

*Collaborative Group on Epidemiological Studies of Ovarian Cancer\**

## Summary

**Background** Oral contraceptives were introduced almost 50 years ago, and over 100 million women currently use them. Oral contraceptives can reduce the risk of ovarian cancer, but the eventual public-health effects of this reduction will depend on how long the protection lasts after use ceases. We aimed to assess these effects.

[Lancet 2008; 371: 303-14](#)

See [Editorial](#) page 275

See [Comment](#) page 277

\*Authors listed at end of paper

# Cost and access

## Under the current system

Average out-of-pocket cost per pack:	<b>\$14</b>
Additional OOP costs:	Clinic visit Transportation Child care Lost work time
% of users who obtain only one pack/month: (due to insurance dispensing limits)	<b>73%</b>

Medicaid covers OCs in **50 states and DC**

**26 states** require private insurance to cover OCs,  
but with many loopholes.

# Cost and access

## Under an OTC system

Much simpler access for many women, possibly leading to increased uptake and continuation.

Medicaid or private insurance may withdraw OC coverage, raising out-of-pocket costs.

Systemic changes may be required to maintain access for low-income women.

Providers' revenue streams will likely be affected.

# Acknowledgements

Kate Miller

Dan Grossman

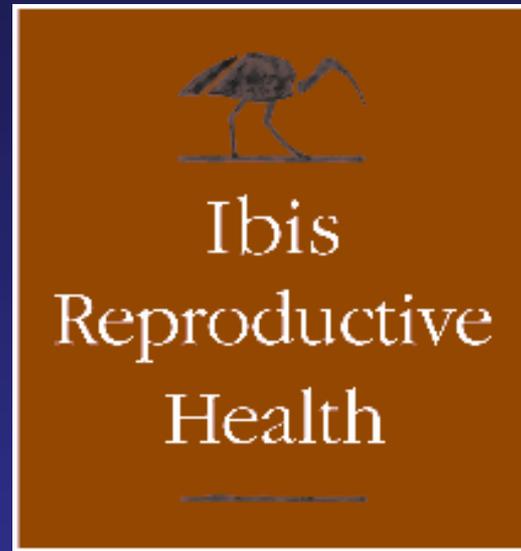
Amanda Dennis

Steering Committee and members of the Working  
Group on OCs OTC

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Thank you!



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