Sexually Transmitted Infections: Overview and What’s New

Bradley Stoner, MD, PhD
Associate Professor
Washington University in St. Louis
Medical Director, St. Louis STD/HIV Prevention Training Center

What are STIs?

- Infections characterized by person-to-person transmission via sexual contact
- Significant cause of morbidity
  - immediate pain and suffering
  - sequelae of infection
- Significant expenditure of resources

STD vs. STI

- Sexually transmitted disease
  - Long-standing, generally accepted term in US
  - Replaced earlier term “venereal disease” (VD)
- Sexually transmitted infection
  - Seems to be term of choice in Europe
  - Perhaps less stigmatizing
  - Implies that asymptomatic infections may not cause actual clinical “disease”

Venus, the Roman goddess of love

Estimated incidence and prevalence of STIs in the US

<table>
<thead>
<tr>
<th>STD</th>
<th>Incidence</th>
<th>Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlamydia</td>
<td>2,800,000</td>
<td>1,900,000</td>
</tr>
<tr>
<td>Gonorrhea</td>
<td>718,000</td>
<td>?</td>
</tr>
<tr>
<td>Syphilis</td>
<td>37,200</td>
<td>?</td>
</tr>
<tr>
<td>Genital herpes</td>
<td>1,600,000</td>
<td>18,000,000</td>
</tr>
<tr>
<td>HPV</td>
<td>6,200,000</td>
<td>12,400,000</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>81,000</td>
<td>?</td>
</tr>
<tr>
<td>Trichomoniasis</td>
<td>7,400,000</td>
<td>?</td>
</tr>
<tr>
<td>HIV</td>
<td>40,000</td>
<td>900,000</td>
</tr>
</tbody>
</table>

ALL STD: 18.9 million new cases per year

Syphilis

- Bacterial agent -- *Treponema pallidum*
- Corkscrew-shaped microaerophilic organism = spirochete
  - Cannot be cultured in tissue or laboratory media
- 10-14 microns long, 0.15 microns wide
- Humans are sole host

**Syphilis – clinical presentation**

- **Primary infection**: painless genital ulcers
- **Secondary infection**: palmar-plantar rash
- **Tertiary infection**: neurological, cardiovascular, etc.

**Latent syphilis**: positive blood test but no signs or symptoms
Syphilis - Diagnosis

- Many laboratories are switching to screening tests based on detection of *treponemal* antibody
- This can lead to confusion in diagnosis

Syphilis Screening Paradigm

**TRADITIONAL**

Non-treponemal tests (i.e., RPR, VDRL)
- NON-SPECIFIC TO TP
- QUANTITATIVE
- REACTIVITY DECLINES WITH TIME

Treponemal tests (i.e., TPPA, FTA-Abs)
- SPECIFIC TO TP
- QUALITATIVE
- REACTIVITY PERSISTS OVER LIFETIME

Syphilis Screening Paradigm

**EMERGING / NEW…**

Treponemal tests (i.e., EIA, CLIA)
- SPECIFIC TO TP
- QUALITATIVE
- REACTIVITY PERSISTS OVER LIFETIME

Non-treponemal tests (i.e., RPR, VDRL)
- NON-SPECIFIC TO TP
- QUANTITATIVE
- REACTIVITY DECLINES WITH TIME

Why switch to EIA for screening?

- Automated (high throughput)
- Low cost in high volume settings
- Less lab occupational hazard (pipetting)

Low tech vs. high tech

180 tests per hour, no manual pipetting

Be careful…

- EIA tests cannot distinguish active disease from old (treated) disease
- Lots of confusion re: management of patients with discrepant serology (e.g., positive EIA and negative RPR)
**Syphilis**

1. **EIA**
   - Negative → **No Syphilis**
   - Positive → **RPR**

2. **RPR**
   - Negative → **Negative**
   - Positive → **Syphilis**

   - 1) Old Syphilis ?
   - 2) No Syphilis ? (False Pos EIA)
   - 3) Early syphilis ? (False Neg RPR)

**Treatment of syphilis**

- **Early syphilis:** primary, secondary, early latent -- infection less than 1 year
  - Benzathine PCN-G 2.4 million units IM x 1
- **Late syphilis:** infection greater than 1 year or unknown duration (NOT neurosyphilis)
  - Benzathine PCN-G 2.4 million units IM q week x 3 doses

**Gonorrhea**

- **Bacterial agent:** *Neisseria gonorrhoeae*
- non-motile Gram-negative diplococcus
- often referred to as “gonococcus” (GC)
- causes urethral inflammation in males
- causes cervical inflammation in females
Gonorrhea—Rates by Sex, United States, 1990–2010

Year

Total
Women
Men

Rate (per 100,000 population)

0
100
200
300
400

Gonorrhea—Rates by State, United States and Outlying Areas, 2010

NOTE: The total rate of gonorrhea for the United States and outlying areas (Guam, Puerto Rico, and Virgin Islands) was 99.6 per 100,000 population.

Gonorrhea—diagnosis

◆ Gram stain of urethral or cervical discharge
  – many PMNs
  – Gram-negative diplococci
  – provides presumptive diagnosis of infection

◆ Nucleic acid amplification tests (NAATs)
  – gold-standard, test of choice
  – detect small numbers of organisms
  – more sensitive, allows earlier diagnosis
  – can perform on genital, extra-genital, or urine specimens

Gonorrhea - diagnosis

◆ Culture
  – specialized media required with specific environmental conditions
  – More difficult, less reliable than non-culture tests (NAATs)

Gonorrhea - treatment

◆ Ceftriaxone 125 mg IM single-dose

PLUS

◆ Anti-chlamydial therapy
  – Azithromycin 1.0 gram single oral dose, OR
  – Doxycycline 100mg twice daily for 7 days

Gonococcal Isolate Surveillance Project (GISP)—Location of Participating Sentinel Sites and Regional Laboratories, United States, 2010
Gonococcal Isolate Surveillance Project (GISP)—Percentage of Neisseria gonorrhoeae Isolates with Resistance or Intermediate Resistance to Ciprofloxacin, 1990–2010

NOTE: Resistant isolates have ciprofloxacin minimum inhibitory concentrations (MICs) >1 µg/ml. Isolates with intermediate resistance have MICs of 0.125–0.5 µg/ml. Susceptibility to ciprofloxacin was first measured in GISP in 1990.

Gonococcal Isolate Surveillance Project (GISP)—Distribution of Minimum Inhibitory Concentrations (MICs) to Cefixime Among GISP Isolates, 2006 and 2009–2010

NOTE: Isolates were not tested for cefixime susceptibility in 2007 and 2008.

Chlamydia

- Bacterial agent: Chlamydia trachomatis
- Obligate intracellular prokaryotic bacterium
- 3 known species
  - trachomatis: urethritis, cervicitis, conjunctivitis
  - pneumoniae: respiratory infections
  - psittaci: respiratory infections
- Antigenically complex with multiple serovars
- Genus-specific LPS antigen and species-specific antigens in major outer membrane protein

Chlamydia—Rates by Sex, United States, 1990–2009

NOTE: As of January 2009, all 50 states and the District of Columbia had regulations that required all cases to be reported.
Clinical presentation (C. trachomatis)

- Nongonococcal urethritis
  - may progress to epididymitis
- Mucopurulent cervicitis
  - may progress to frank salpingitis, PID
- **But**: most cases of NGU and MPC are not caused by Chlamydia
  - (other pathogens may include Mycoplasma, Ureaplasma, Trichomonas, anaerobes)

Chlamydia - diagnosis

- Nucleic acid amplification tests (NAATs)
  - gold-standard, test of choice
  - detect small numbers of organisms
  - more sensitive, allows earlier diagnosis
  - can perform on genital, extra-genital, or urine specimens

Chlamydia - Treatment

- Macrolides
  - Azithromycin is drug of choice (single-dose)
- Tetracyclines / fluoroquinolones
  - Effective, but must take multiple doses over one week (lower compliance)
  - Quinolones more expensive
Chlamydia - Internet-based home testing

- Subject registers on site to request test kit
- Supplies sent to subject
- Specimen collects specimen, mails back to laboratory
- Results delivered by telephone using code and password
- Positive patients referred for treatment

Results (2004-08)

- 3,774 kits were requested
- 1,223 (32.4%) were returned
  - Median age 23
  - Chlamydia prevalence 9.1%
- Self-collected swabs acceptable
- Program expanded to males, additional sites

Iwanttheikit.org

- Now available to residents of:
  - Alaska
  - Maryland
  - West Virginia
  - Philadelphia, PA
  - Denver, CO
  - selected counties in IL

Self-collected vaginal swabs

- Useful to increase rates of initial screening
- Also increase rates of rescreening after initial infection

VSS (Vaginal Swab Study)

- STD clinic and family planning clinic populations in 3 cities
- Females (age ≥ 16) with chlamydia
- For re-testing at 3 months, pts were randomized to
  - home testing vial self-collected vaginal swab
  - routine testing upon return to clinic

Rescreening rates

<table>
<thead>
<tr>
<th></th>
<th>Home testing</th>
<th>Return to clinic</th>
</tr>
</thead>
<tbody>
<tr>
<td>STD Clinic</td>
<td>26.7%</td>
<td>19.1%*</td>
</tr>
<tr>
<td>Family Planning</td>
<td>40.8%</td>
<td>20.7%*</td>
</tr>
</tbody>
</table>

*p<0.001

Conclusion: Self-collected vaginal swab testing increased rescreening rates after initial chlamyidal diagnosis

Xu, Stoner, Taylor et al. 2011
Extra-genital NAATs

- CDC strongly urges more widespread testing of extra-genital NAAT tests
  - Increased yield of infection
  - Some persons are genital negative, but positive at pharynx or rectum

Study by Peters et al. (2011)

- Routine screening among STD clinic attendees in The Hague, Netherlands
  - oropharynx / anorectal sites tested if exposed

Original Study

Screening of Oropharynx and Anorectum Increases Prevalence of Chlamydia trachomatis and Neisseria gonorrhoeae Infection in Female STD Clinic Visitors

Sex Transm Dis 2011;38:783

**TABLE 1.** General Characteristics of Study Population

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Women</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultations</td>
<td>4299</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>24 yr (13–72 yr)</td>
<td></td>
</tr>
<tr>
<td>History of STD</td>
<td>514 (12)</td>
<td></td>
</tr>
<tr>
<td>Symptomatic suggestive of STD</td>
<td>114 (27)</td>
<td></td>
</tr>
<tr>
<td>Chlamydia trachomatis infection</td>
<td>475 (11)</td>
<td></td>
</tr>
<tr>
<td>Oropharyngeal infection</td>
<td>71 (15)</td>
<td></td>
</tr>
<tr>
<td>Anorectal infection</td>
<td>76 (16)</td>
<td></td>
</tr>
<tr>
<td>Neisseria gonorrhoeae infection</td>
<td>68 (15)</td>
<td></td>
</tr>
<tr>
<td>Endocervical infection</td>
<td>48 (76)</td>
<td></td>
</tr>
<tr>
<td>Oropharyngeal infection</td>
<td>30 (48)</td>
<td></td>
</tr>
<tr>
<td>Anorectal infection</td>
<td>15 (24)</td>
<td></td>
</tr>
<tr>
<td>Infectious syphilis</td>
<td>3 (0.1)</td>
<td></td>
</tr>
<tr>
<td>HIV*</td>
<td>6 (0.1)</td>
<td></td>
</tr>
</tbody>
</table>

Only 91% of infections would have been detected if endocervical sampling alone had been performed

**TABLE 2.** Distribution of C. trachomatis and N. gonorrhoeae Infection by Anatomic Site in Relation to Number of Sites Tested Among Women

<table>
<thead>
<tr>
<th>Anatomic Site</th>
<th>Total Number (%)</th>
<th>C. trachomatis Number (%)</th>
<th>N. gonorrhoeae Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical only</td>
<td>1641 (15)</td>
<td>1623 (15)</td>
<td>178 (15)</td>
</tr>
<tr>
<td>Oropharynx only</td>
<td>7 (0.1)</td>
<td>4 (0.1)</td>
<td>3 (0.1)</td>
</tr>
<tr>
<td>Anorectal only</td>
<td>1117 (10)</td>
<td>1095 (10)</td>
<td>22 (2)</td>
</tr>
<tr>
<td>Cervical &amp; anorectum</td>
<td>25 (0.2)</td>
<td>23 (0.2)</td>
<td>2 (0.2)</td>
</tr>
<tr>
<td>Oropharynx &amp; anorectum</td>
<td>5 (0.1)</td>
<td>3 (0.1)</td>
<td>2 (0.1)</td>
</tr>
<tr>
<td>Cervical, oropharynx &amp; anorectum</td>
<td>6 (0.1)</td>
<td>3 (0.1)</td>
<td>3 (0.1)</td>
</tr>
<tr>
<td>2 sites tested (n = 2021)*</td>
<td>475 (11)</td>
<td>472 (11)</td>
<td>3 (0.1)</td>
</tr>
</tbody>
</table>

*Tests for cervical and oropharyngeal infections were obtained from 2021 women and for cervical and anorectal infections from 25 women.

Extra-genital NAATs

- Study by Marcus et al. (2011)
  - Retrospective analysis of MSM screening at San Francisco STD clinic
    - assessed screening prevalence in 2008-09
    - oropharynx / anorectal sites tested if exposed

Infections Missed by Urethral-Only Screening for Chlamydia or Gonorrhea Detection Among Men Who Have Sex With Men

Julia L. Marcus, MPH*• Kay T. Beneski, PhD, MPH**• Robert E. Kolts, MPH*• Sally Lehto, MPH*• Susan P. Phillips, MD, MPH*

Sex Transm Dis 2011; in press

Extra-genital NAATs

- Total 3398 patient visits
  - asymptomatic MSM, tested at all 3 sites
  - prevalence of GC or chlamydia = 16.2%

- Urethral screening alone would miss
  - 95% of GC
  - 77% of chlamydia

- Rectal and pharyngeal screening were much more effective
Screening only urine would have missed 77% of chlamydia and 95% of gonorrhea in asymptomatic MSM.

Summary

- Syphilis, gonorrhea, and chlamydia epidemiology patterns are dynamic and changing.
- Clinical management is affected by changes in diagnostic technology, antimicrobial resistance.
- Additional research is needed in the STD arena.

Ordering extra-genital NAATs

- Many labs have performed validation studies.
- Commercially available through large laboratories.

<table>
<thead>
<tr>
<th>Company</th>
<th>Specific Ordering Codes for Combined Ecto Genital NAATS</th>
<th>Company Specific Ordering Codes for Ecto NAAT Test only</th>
</tr>
</thead>
<tbody>
<tr>
<td>LabCorp</td>
<td>188707</td>
<td>188706</td>
</tr>
<tr>
<td>Quest</td>
<td>188705</td>
<td>188706</td>
</tr>
<tr>
<td>NAATs</td>
<td>188706</td>
<td>188706</td>
</tr>
</tbody>
</table>

CPT Billing Codes

- CT detection by NAAT: 87485
- GC detection by NAAT: 87585
Cytology Screening
September 11, 2012
St. Paul, MN
JAN RAY RN, WHNP, BC

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Experts
- American College of OB/GYN (ACOG)
- American Society for Colposcopy and Cervical Pathology (ASCCP)
- American Cancer Society (ACS)
- American Society for Clinical Pathology (ASCP)
- U.S. Preventative Services Task Force (USPSTF)

Cervical Cancer Screening
- Most successful cancer screening program in the U.S.
- Most expensive cancer screening program in the U.S.
- Long-standing public health messages drive consumer behaviors, beliefs, and preferences

Advances in Cervical Cancer Prevention
- Evidenced based cytology screening intervals
- Cytology technology: liquid-based
- Adjunctive test modalities: HPV-DNA testing
- Primary prevention through HPV vaccination

Big Picture
- Half of all women in whom cervical cancer is diagnosed have NEVER HAD cervical cancer testing
- SO: increase rates of cancer screening among women who are not screened or who are screened infrequently.
Screening Intervals

- Screening interval of any test depends on the error rate and the progression of the disease
- SO: the less sensitive the test is the more often you screen
  OR
  the faster the disease progresses the more often you screen

Cervical Cancer

- Cervical cancer risk factors do not impact the interval for screening
- The SLOW rate of growth of pre-invasive cells is the same, regardless of behavior risk factors
- When the transit time is faster then we should screen more often eg. HIV positive, immunocompromised

Historically

- Annual screening was the practice for many years
- Tied to prescription for a birth control method
- Then evidenced based practice came and many of the screenings and practices that were the norm have been changed

Where are We Now


USPSTF

- Published their recommendations in the Annals of Internal Medicine, volume 156, number 12, June 2012
- The recommendations in these two documents were the same and were evidenced based.
- ACOG is reviewing the documents and it is expected they will be putting forth similar recommendations

Patient Population

- Women with a cervix
- Sexual history not a factor
- Does not apply to a women with a diagnosis of a high grade lesion, in utero DES exposure, or who are immunocompromised
Cytology Screening Intervals

Age 21
- Initiate screening
- Repeat every 3 years

Age 21
- Do not start screening earlier
- Initiation of sexual activity is not a consideration

Why not before 21

- HPV is wide spread in adolescents
- Very efficient in clearing the infection
- 81% no longer infected at 24 months

Adolescents and Cervical CA

- 0.1% of cervical cancers in U.S.
- 14 cases annually age 15-19
- Rate ~ 1/1,000,000
- Screening does not reduce mortality in teens
- Consequences of over screening and over treatment may be harmful and lack benefits in women at very low risk of cancer

ASC-US/ LSIL in adolescent

12 month repeat cytology
- If HSIL or worse colp
- IF < HSIL repeat cytology in 12 months

2nd 12 month cytology
- IF > ASC-US colp
- If both neg then routine screening

HSIL in adolescent

- Colposcopy
- Immediate loop excision is not acceptable
- Manage based on biopsy result

Biopsy Result - Adolescent

CIN 2
- Observe
- Colp and cytology every 6 months up to 2 years

CIN 3
- Treatment recommended
- LOOP or Ablation
AGE 21-29
- Screen every 3 years
- If negative no need to repeat cytology any sooner

Age 21-29

Screen every 3 years
- If negative
No need to repeat cytology any sooner

Age 21-29 with
- HPV positive following ASC-US or with an LSIL or worse cytology COLPOSCOPY is recommended
- ASC-US cytology with HPV negative repeat cytology in 3 years

Age 30-65

Preferred
- Cytology plus
  - HPV testing every 5 years

Acceptable
- Cytology alone
  - Every 3 years

Now What
- 1 have a cytology NEGATIVE and a HPV POSITIVE
  - TWO OPTIONS
    - Repeat cytology and HPV testing in 12 months
    - OR
    - HPV Genotype for 16 alone or 16 and 18
      - If genotype positive - immediate colp
      - If genotype negative - repeat cytology and HPV in 12 months

Repeated Cytology and HPV
- Women was POSITIVE for HPV or has LSIL or greater needs colposcopy
- Women was NEGATIVE for HPV and ASC-US or NEGATIVE cytology goes to routine screening which is 5 years with co testing or 3 years with cytology alone
Age 30-65 with ASC-US

- **HPV**
  - Negative
  - Repeat cytology in 3 years
- **HPV**
  - Positive
  - Colp
- **HPV not available**
  - Repeat cytology 6 and 12 months
  - ASC-US or > colp; Both paps neg routine screening

Age 30-65 LSIL = Colp

- Management based on Biopsy Result
- No CIN 2,3
  - Repeat Cytology at 6 and 12 months
  - OR
  - Repeat Cytology and HPV in 12 months
- CIN 2,3
  - Follow ASCCP algorithms

Age 30-65 with HSIL

**Immediate LOOP**

- or

**Colposcopy**

- Management based on biopsy result

When to stop cytology screening

- Older than 65
- With evidence of adequate negative prior screening
- No history of CIN 2 or greater in the past 20 years
- STOP screening and NO NOT restart even if women reports a new sexual partner
- HPV acquisition declines sharply with age

Definition of Adequate Prior Screening

- 3 consecutive negative cytology
  - OR
- 2 consecutive negative co tests
  - Within the 10 years before stopping screening
  - and
  - the most recent screening within the past 5 years

Over 65 with History of

- CIN 2
- CIN 3
- Adenocarcinoma In Situ

   - MUST
   - Continue screening for at least 20 years even if this is beyond age 65
Hysterectomy and no CIN 2 or >
- Do NOT need vaginal screening
- Evidence of negative prior vaginal screening is not needed
- Do Not resume screening for any reason

HIV Positive or Immunocompromised
- Do not start cytology screening before age 21
- Age 21-29 until more information is available annual cytology screening
- Age 30 or above
  Expert opinion recommends co-testing every 2-3 years

DES exposure
- No data to make specific recommendation
- ACOG Practice Bulletin 2009 recommends annual cytology of the cervix and all 4 vaginal walls

SO WHY all the changes
- Driver: HPV
- Persistent cervical infection with high-risk HPV genotypes is necessary for development of cervical cancer
- Precursor (precancer) lesion CIN 3

High- Risk Genotypes
- Nearly 100% of cervical cancer cases test positive for HPV
- HPV type 16 is the most carcinogenic and accounts for 55% to 60% of all cases
- HPV type 18 is the next most carcinogenic and accounts for 10% to 15%
- Approximately 10 other HPV genotypes cause the remaining 25% to 35%

Genital HPV
- Acquired through sexual and genital skin to skin contact
- Approximately 90% of HPV infections are transient
- Become undetectable within 1-2 years
- PERSISTANT infection especially with HPV 16 over 1-2 years strongly predicts CIN 3 or worse in subsequent years
  - 20% - 30% risk of CIN 3 over 5 years with 1-2 year persistent HPV 16
CIN 3
- 30% probability of becoming invasive cancer over a 30 year period
- 1% TREATED CIN 3 will become invasive
- SLOW GROWING disease

Maximize Benefits of Screening
- Identify those cervical cancer precursors likely to progress to invasive cancers
- Avoid the detection and unnecessary treatment of transient HPV that are not destined to become cancer

CO-Testing
- HPV testing for high risk types may better forecast which women will develop CIN3 or worse
- Over the next 5-15 years
- SLOW GROWING

Prevention
- “Safe Sex” – male and female condoms
- HPV vaccine
- Education

HPV Vaccine
- Under utilized in the U.S.
- 2010 only 32% of eligible females had received all 3 doses of the vaccine
- But if vaccinated cytology screening intervals do not change

Vaccine availability
- Gardasil
  - Covers 6,11,16,18
  - Women and Men 9-26
- Cervarix
  - Covers 16 and 18
  - Women 19 - 25
Vaccine
- 3 injections
- Gardasil – initially, at 2 months and then at 6 months from first injection
- Cervarix - initially, at one month and then at 6 months from the first injection
- If late with injection just give – do not have to start over with all 3

Cost of vaccine is expensive
- Vaccine for children Program
- Private insurance coverage
- Assistance Program
  - Merck for Gardasil
  - GlaxoSmithKline for Cervarix

Messages
- Do not initiate cytology screening before age 21
- Routine low risk women at any age no longer need annual screening
- 21-29 cytology screening interval is 3 years
- 30 – 65 with co-testing screening interval is 5 years
- Women over 65 can stop screening if they have had adequate prior screening
- Women with a history of CIN 2 or greater need follow-up for 20 years

Birth Control
- Cytology and Birth Control are independent of each other
- Do not limit or hold birth control because of the need for a pap

Cervical Cancer
- Needs Persistence
- Needs HPV
- Is Slow growing

Special Populations
- HIV Positive
- Immunocompromised
- In-utero DES exposure
- Women who are in follow-up for an abnormal result
Good Things

- 3 expert agencies came together
- Maximize benefits of screening
- Prioritize cases that could progress to cancer
- Minimize Risks related to anxiety with test results, expenses, false positives, and morbidity from overtreatment

What about the Patient

- Evidenced based practice information
- Current and relevant information
- Readable at their reading level

Messages for Patient’s with HPV

- Do not smoke – Stop if you currently smoke
- Vitamin once a day that has Vitamin C and Folic acid
- Use condoms – male and/or female
- Transient infection
- Allow body time to treat itself but treat body well
- Do follow-up as recommended

Resources – PT education Fact Sheets

- ASCCP
- National Cervical Cancer Coalition
- CDC
- ACOG
- Others

Thanks

- For your commitment to women’s health
- For your attention

Questions

• ????????????
Advanced Contraceptive Counseling: Motivational Interviewing (MI) in 5 Minutes or Less!

Sharon Myoji Schnare
RN, FNP, CNM, MSN, FAANP
Motivating BESTSHORT2012.ppt 8/4/2012

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MILLER & ROLLNICK’S 5 PRINCIPLES of MOTIVATION

- EMPATHY
- DEVELOP DISCREPANCY
- AVOID ARGUMENT
- SUPPORT SELF EFFICACY
- ROLL WITH RESISTANCE

Respectful loving-kindness and positive regard and ...Expect success!

• Sharon Schnare reports that she is a consultant for Bayer HealthCare Pharmaceuticals, Inc. and a speaker for Azur Pharma, Bayer HealthCare Pharmaceuticals, Inc, Jazz Pharmaceuticals, Merch Sharp & Dohme Corp., and Teva Women’s Health Inc. Sharon Schnare agrees to present the following information fairly and without bias.
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• “If you treat the individual as she is, she will stay as she is, but if you treat her as if she were what she ought to be, she will become what she ought to be and could be.”

Johann Wolfgang von Goethe (modified)

Motivational interviewing: a systematic review and meta-analysis. Rubak s. et al Br J Gen Pract. Apr;55(513):305-12, 2005

“Motivational interviewing in a scientific setting outperforms traditional advice giving in the treatment of a broad range of behavioural problems and diseases.”
Motivational Counseling and Education
- Saves time
- Effective
- Stresses autonomy & self mastery
- Based on empathy

What Clinicians GAIN from Effective Counseling
- More satisfied patients AND clinicians!
- Helps clinicians make more effective decisions
- Results in less anxiety & improves clinician confidence

What MI is NOT
- Not transtheoretical model change
- Not a way of tricking people to do what you want them to do.
- Not technique
- Not cognitive behavioral therapy

Begin counseling with Empathy and Respect
- “Tell me only as much as you want me to know.”
- “Tell me only as much as you are comfortable sharing.”
- “May I share with you some information other women have found helpful?”

Initiating an Interview: Keep it Simple
- “How are you protecting yourself from pregnancy?”
- “How are you protecting yourself from STD’s?”

Feedback (Reflection)
- Personalized information about problem behavior & effects
- Non-coercive
- Always get feedback: What do you make of this? How does this fit or not fit with what you know about yourself? Do you think this could concern you?
Reflection
- To check what she means-
  - “Tell me more about why having this test is important to you.”
  - “At first you were worried about having your Pap, but now you seem more relieved.”

The Reluctant Person
- “Other women have shared concerns about how to use some methods.”
- Some women were concerned about....
- Women who are using birth control tell me they are relieved and not as much of a hassle as they thought.

Responsibility
Emphasize her freedom to choose
- “It’s up to you; you are free to decide to do this or not.”
- “You’re the only one who can succeed with this change.”
- “You’re the only one who can make this happen.”

Advice
- Must be supportive and concerned NOT authoritarian
- Be respectful: “Is it OK if I go over some of the birth control methods that may interest you?”
  “Do you mind if I share this with you...?”

Communication
- Change involves seeing the benefit for change
- Change involves considering (THINKING) or evaluating what is necessary to change and
- (FEELING) anticipation, anxiety about making change
- “What do you think about this and how do you feel about making these changes?”

Menu of Her Options
- Involve her
- Ask her to discuss what she sees as her options- “If you are not ready right now to start using a method, what other things can you do to prevent pregnancy?”
- If she can’t think of options: “Is it OK if I go over other ways you can protect yourself from pregnancy?”
SHOW women and men the actual contraceptive methods. Encourage them to TOUCH. Touching a method means they can control it! Very important.

Ask patients what THEY want to know.

More and more women are using contraception. Each day you take the pill it will be easier the next day and the day after that.

Let Women Know It’s OK to Experiment with Contraception!
• It’s OK when we experiment with new methods! Do not discourage experimentation.
• Feeling like we are “stuck” with only 1 or 2 methods will lead to frustration...and giving up.

EMPATHY
Genuine interest in her-you care about her success
Non-judgmental
Reflective listening “Let me see if I understand your feelings correctly?”
“I want to make sure I understand what you are saying.”

EMPATHY
Affirm her feelings “I can see how you could be anxious about the pelvic exam; I am very gentle.”

Empathy
• Palpable listening-understanding what people have to let go of to make changes...understanding these difficulties & losses
Putting ourselves in their shoes.
For some patients it will take a lot of courage.
Understanding what people have to give up… to change
- Denial that they are in control “What ever happens…happens.”
- Loss of a boy or girlfriend who is sabotaging contraception
- Loss of a sense of freedom…having sex means protecting oneself, responsibility

EMPATHY
- Let patients know you understand:
  “It’s not always easy to make changes. I appreciate this is difficult for you”
Use positive language and body language
  Loving-kindness is essential

Inadvertently Sabotaging with Words
- “Try” to remember to take your pills.
- You “should” take better care...
- I know a lot of women forget their pills, but you...
- Avoid telling someone you are proud of them. “It must feel terrific to be in charge and not worry about getting STD’s.”

Develop Self Efficacy
Self-Esteem
- Often people feel they “just can’t “ change. They lack confidence in their ability to succeed.
  - Encourage optimism

Develop Self Efficacy
Self-Esteem, a Sense of Mastery
- “Think back on all the things you have mastered in your life…school, driving, working…just as you succeeded in so many things, you are succeeding with this….”

Self Efficacy
- “I imagine it is difficult to take pills daily…what would make it easier for you to succeed?”
- “Thinking back on all the amazing things you have mastered, you begin to realize just how adaptable and effective you are.”
Affirming What the Person Says
- Compliments or statements of appreciation-understanding
  “I appreciate how hard it must be to come in and talk about this.”
  “It requires a lot of courage to discuss these issues.”
  “You have put a lot of thought into this issue.”

Encouraging Competence & Building Self-esteem
- “In a similar situation what advice would you give one of your girlfriends about contraception?”
  “If other guys asked you about getting STD’s what would you advise them to do?”

“May I ask you some questions?”
- “What are some examples of your successes?”
- “Looking back when you first learned your alphabet you probably missed a few letters…then it got easier and easier…and now you don’t even think about it…just like learning to use contraceptive methods.”

“I’m available if you need me…but I don’t think you will need me.”
- “You have been successful and mastered so many other skills…it will be interesting to see just how creative your ideas will be.”

What is Relapse?
RELAPSE IS GOOD!
The person has already proven they CAN change
“You were using condoms, then stopped…that’s great!”
THIS WILL GET HIS ATTENTION!

RELAPSE IS GOOD!
- Relapse is an opportunity to analyze where he tripped-up in continuing the behavior change
- Once he analyzes the obstacle he can avoid it in the future
Dealing with Relapse

- “So let’s talk about what worked well when you were using condoms…how were you so successful?
- When you didn’t use a condom, what got in the way? How would you change the situation next time?

Dealing with Relapse

“This is great opportunity to figure out how to succeed even better the next time.”
You are a smart women and creative, you will think of some good ways to be even more successful…you seem like a very creative person

Relapse: CASE

- Jena is 34 and just moved from Alaska
- She consistently used pills before her move; but since moving she has not seen a health care provider and stopped using pills.
- How will you talk with Jena?

The Questions: Keep it Simple

- “When you learned new skills before…how were you so successful?”
- “So we’re not talking about IF you can consistently use the Ring, we already know you can…we are just working on being more consistent. Do I have this right?”

DEVELOP DISCREPANCY

- It is hard to move from a learned behavior that has been comfortable to something new
- Ambivalence is part of discrepancy

DEVELOP DISCREPANCY

- DISCUSS THE DISCREPANCY BETWEEN HER/HIS GOALS & CURRENT BEHAVIORS
- EVEN “BAD” BEHAVIORS MEET IMPORTANT NEEDS
How to Elicit Information

- **ASK PERMISSION** to give advice or to give information that may be helpful
- Ask what the person already knows
- Elicit reaction to new information—“Now that you know this, what do you think? How do you feel about this new information?” “How might this help?”

Examples of Giving Advice

- “Would it be helpful if I shared some information that may be of specific interest to you?”
- “You are obviously a smart woman and knowing a few more things about smoking may interest you…”
  - *Increase ectopic pregnancies, increase cervical and bladder cancers*

Let’s encourage women NOT to leave their male partners out of the family planning loop

- “Most women I see are expecting their partners to pay for their BC methods and for their visits.”
- Discuss paternity laws in your state; especially with male clients; they need your protection too.

Even “bad” behaviors meet important needs

- “Louise, you have been out of pills for 2 months and had unprotected sex; are you planning a pregnancy right now?”
  - *Well, I guess what ever happens…happens.***

Ambivalence…what is it?

- Well it's NORMAL !…it’s no

DEVELOPING DISCREPANCY

Ask about current behaviors and how they differ from where he wants to be

- What steps does he see himself taking from where he is now to where he plans to be
  - Listen, keep suggestions to a minimum

Develop Discrepancy Between Where She is at…and Where She Wants to Be

- “What steps can you take to get from where you are now…worrying about pregnancy, to where you really want to be… feeling more control as succeed with a method you have chosen?”
Developing Discrepancy

- Amy doesn’t worry about her possibility of getting pregnant… but if she thinks about the impact, then it worries her.
- “What ever happens; happens” “Making a decision without making a decision.”

Response to Discrepancy

“Let me see if I have this right? On one hand you feel not too worried about getting pregnant; yet you also know it would be pretty hard not having a job.” “How do you see yourself wrestling with this?” “What would you like to get organized before you have a child?”

Developing Discrepancy

Clarice is nervous about getting pregnant, but she doesn’t always remember to take her pill.

“It’s normal to feel some ambivalence… that means one part of you would kind of like to be pregnant…and the other part of you… is not so sure… all women have some ambivalence.”

An approach to those missing pills

- Tell me about the times you are successful taking your pill (or using a condom)… what’s going on then that makes you so successful?

Developing Discrepancy

- “So you’re telling me you want to be safe, but you haven’t used condoms yet… but you are also afraid of getting an STD or AIDS. Do I have this right?” Reflection
- How do you see yourself moving from being scared to feeling secure?” “What steps do you see yourself taking to be safer?”

Discrepancy

So you are telling me you have missed 4 or 5 pills in your last pack… why haven’t you missed more?

Now LISTEN…
IMPORTANCE (Why?)
-- Is it worthwhile?
-- Why should I?
-- How will I benefit?
-- What will change?
-- At what cost? (What do I lose?)
-- Do I really want to?
-- Will it make a difference?

SM Schnare

Importance Ruler
• On a scale from 0 to 10 where 10 is the most important and 0 is the least, what number would you give to how important it is to you to ... (behavior change) take your pills more regularly
• Why is it a ...(current number) instead of a ...(lower number)?
• What would need to happen to make it a ...(higher number)?

Melanie Gold DO

Discrepancy
The teen who is ambivalent...forgetting pills
“Do you plan to have children in the future? ...I imagine you will be a wonderful mother someday.”
“What do you want to accomplish to become an even better mother before you have a baby?”...and what else?...and what else?”

Importance Ruler
5 2 4 6 8 10
Least Most

SM Schnare

Reflection
“Let me make sure I understand you completely.”

Clarify the goals/outcomes VERY specifically

Have HER make arguments for Change
• “How do you see yourself working on this goal”
• “What do you think will be the biggest benefit to you?”
• “You are obviously smart (or have given this some thought) ...so what do you make of this situation?”
Listening with Reflection
- Understating or Overstating what someone says.

“So getting pregnant right now would NOT be a problem in any way at all.”

Reflection
- “So what do you see as the benefits of using birth control? And what else? And how will you feel after starting a method?
- What gets in the way of using birth control for you?”

Getting Clarification
- “May I ask you some questions? What types of strategies have you used before that were successful for you…and what else? You have some very creative ideas.
- “So you have learned some very detailed skills before…so you know you CAN accomplish this as well.”

ROLL WITH RESISTANCE
- Resistance is toxic to change.
- Resistance occurs when we are pushing the person beyond their stage of change. (comfort level)
Pushing too fast causes the person to resist, re-balance for control.
Resistance is caused by us!

Signs Of Resistance
- Arguing, challenging
- Hostility, apathy
- Interrupting, talking-over
- Cutting us off, denying, blaming, excusing, minimizing, pessimism, reluctance
- Ignoring, inattention, no answers-no response, side-tracking

AVOID ARGUMENT
- Be aware of signs of resistance.
- Resistance is toxic to change.
- Let ego drop away:
  - It’s her/his success-not ours
  - People may not be ready to make changes when we want them to.
What are Signs of Resistance?

- “I don’t have a car.”
- “My dog ate my second appointment slip.”
- “I have to lose weight first.”

Resistance, Secondary Gains: Challenges to Change

- When you feel frustrated; the patient has a problem, but doesn’t seem to accept change or help.
- “What does this symptom, issue, behavior keep you from doing?”
- Is the behavior protective? Is the person ambivalent about the change?

Reducing Resistance

- Double-sided reflection: present both sides of the ambivalence.
- “So I hear you saying that on one hand you feel getting pregnant right now would be a good thing for you; yet, on the other hand...you are concerned about how to care for a child right now. Do I have this right?”

Reducing Resistance

- Amplified Reflection: present the negative side, or resistance with exaggeration.
- “So you will never use condoms in a million-zillion years!”
- “Are there some situations where you might use a condom?”

When the patient isn’t ready to make changes

- Educate about health benefits of contraception...Brief! Only 1 or 2 points
- Let the person know you are there to help...when she/he is ready

- “How do you see your life changing once you have met your goal?”
- Now listen...this will tell you a lot! “Once I get my vasectomy I won’t have to use condoms with my girlfriends.”
- Are the changes reasonable?
- Are the changes within the person’s character or previous experience?
The Couple with the STD:  
“He gave it to me!...No, She gave it to me!”

Avoid trying to figure out who gave what to whom…it’s a slippery slope…and you’ll all fall off the slope. “This is a crises, like other crises you may have survived as couple. If you have history together & commitment to each other you will survive this crises too.”

The Couple with the STD:  
“He gave it to me!...No, She gave it to me!”

- If they love and care for each other, they can rebuild trust.  
- However, getting an STD may be the event that ends a very unhealthy relationship

When She is Resistant

- Charlene, this may not be the best time for you to have this test done.
- May I tell you a couple things that may reassure you?  
- When you do decide to come in for the test it will be easier than you thought it would.

Dealing with Hostility

- Anger often hides FEAR: speak to the person’s fear; do not get mad; be loving and kind Ex: angry Mom wants to be with her daughter in exam room: “it’s obvious you love your daughter very much and worry that she is OK…this is a time for her to learn how to interact with her clinician; part of adolescent her development. other examples?

The Reluctant Person

“Tell me only as much as you want me to know.”
- “May I share with you some of the information I have discussed with other women?”
- “Some women at first have had concerns, but once they realized…”

MI in Action

- It will be interesting to see just how creative your plans will be.
- Tell me a little about why you plan to succeed … and why else? and why else?
Remember that to change, people have to give something up.

“How do you feel about asking your boyfriend to use condoms? What do you think about this?”

…what does he/she have to give up?

How does she plan to ask her partner to use condoms? Listen Once change has occurred… what has she gained?

**Getting Clarification**

- “So you’re telling me you want to use your Patch more consistently…do I have this right?”
- “How do you see yourself moving from where you are now to being more consistent?”
- “What steps do you see yourself taking to move from where you are now…to becoming even more successful?”

**MI in Action**

- “Tell me the types of strategies you used before that were successful for you…and what else? and what else?”
- “So you have learned very detailed skills before…so you know you CAN accomplish this as well.”

**CONFIDENCE (How and What?)**

- Can I?
- How will I do it?
- How will I cope with ……?
- Will I succeed if…..?
- What change…..?

**Confidence Ruler**

- On a scale from 0 to10 where 10 is the most confident and 0 is the least, what number would you give for how confident you are that you could … (take your pills more regularly); if it was important to you
- Why is it a …(current number) instead of a … (lower number)?
- What would need to happen to make it a …(higher number)?

**Confidence Ruler**
Using Agenda Setting Chart

- “On this sheet are some things that may affect you. We could talk about some of the issues which affect your progress. You will be the best judge of what to consider changing. Which of these do you think we could talk about?”
- “These blank spaces here are for any other things that you think might be of greater concern to you today. What should be in these spaces?” “What do you think? What would you like to talk about today?”

Assessing Readiness with a Ruler

- “On a scale from 0 to 10 where 10 is the most ready and 0 is not ready at all, what number would you give to how ready you are right now to …” (behavior change)
- “Why is it a …(current number) instead of a …(lower number)? (elicit reasons why she ready)
- “What would need to happen to make your readiness be a …” (higher number)?
- If number is 6 or higher ask: “How soon are you planning to make this change?”

Assessing Readiness to Change

- “Are you currently _____ (forgetting to use your Ring?)” If yes, “how long have you been doing ______ (behavior)?”
- If no, “when do you plan to start ______ (behavior)?”

MI Techniques are Evidence-Based

- ACOG Committee Opinion: Motivational Interviewing: A Tool for behavior Change; 423; Jan 2009.
- Lopez et al. Theory-based interventions for contraception. 2009 Jan, Cochrane Database. 
MI Techniques are Evidence-Based

Pleasure Education is Health Education

Minnesota Reproductive Health Update
September 11th, 2012

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Why Pleasure?

Topics to be covered include

• The importance of teaching about pleasure

Topics to be covered include

• The importance of teaching about pleasure
• Basic information that is vital to pleasure education
Topics to be covered include

• The importance of teaching about pleasure
• Basic information that is vital to pleasure education
• Concrete skills for pleasure education

Important reasons to teach about pleasure

• Teaching about pleasure is factual
• Pleasure is healthy for you
  – Pleasure improves your immune system (Charnetski & Brennan, 2001)
Important reasons to teach about pleasure

• Teaching about pleasure is factual
• Pleasure is healthy for you!
  – Pleasure improves your immune system (Charnetski & Brennan, 2001)
  – The SIECUS Report states “Good sex can enhance physical fitness, strengthen the heart, and reduce stress.” and “People with fulfilling sex lives tend to be less anxious or depressed and have greater self-esteem and better marriages.” (Resnick, 2002)

Important reasons to teach about pleasure

• Avoiding pleasure education makes pleasure seem dirty or secretive

Important reasons to teach about pleasure

• Avoiding pleasure education makes pleasure seem dirty or secretive
• Young people and adults are more likely to ask questions if the subject of pleasure is brought up to them first

How pleasure education will help your students or clients

• Fosters sexual self-esteem which is the basis for mutually fulfilling sexual relationships

How pleasure education will help your students or clients

• Fosters sexual self-esteem which is the basis for mutually fulfilling sexual relationships
• Teaches independence and empowerment through understanding our bodies
How pleasure education will help your students or clients

• Fosters sexual self-esteem which is the basis for mutually fulfilling sexual relationships
• Teaches independence and empowerment through understanding our bodies
• Aids harm reduction

When we choose to omit pleasure education…

• We set people up to expect or put up with non-satisfactory sexual experiences.

When we choose to omit pleasure education…

• We set people up to expect or put up with non-satisfactory sexual experiences.
• Focusing on “reproductive health” excludes the majority of forms of sexual acts and expressions
  – Talking about “sex” as if it means “penis in vagina” excludes many people

• Focusing on “reproductive health” excludes the majority of forms of sexual acts and expressions
  – Talking about “sex” as if it means “penis in vagina” excludes many people

– We disadvantage people with vulvas and LGBT identified people
“My personal experience as a sexuality educator has found that teen girls routinely complete sexuality education courses without learning about the clitoris...Few people would argue that 12-year-old boys shouldn’t know about their penises. Yet the same people consider 12-year-old girls too young to know about their clitorises.”

-Fay (2002)

When does “sex education” turn into “no sex education?”

- Abstinence only education

When does “sex education” turn into “no sex education?”

- Abstinence only education
- Comprehensive education is usually “sex = risk”

When does “sex education” turn into “no sex education?”

- Abstinence only education
- Comprehensive education is usually “sex = risk”
- Where do we teach healthy sexuality?

“We need to incorporate positive messages about sexuality with public health concerns about STDs and adolescent pregnancy. In order to be able to provide this, we need to first challenge ourselves to resolve our contradictions regarding pleasure. Only then will we be able to raise a generation of sexually healthy adults.”

-Kreinin (2002)
Basic information for pleasure education

- Pleasure Anatomy
- Pleasure Function
- Lube/Safer Sex
- Toys

Small group activity: Addressing the challenges of pleasure education in a clinical or school setting

In a small group of people in a similar field as yourself (clinicians, educators, therapists), spend 3 minutes discussing challenges to addressing pleasure education in the professional setting you work in. As a group, come up with a few ideas for how to address these issues appropriately within the confines of your professional role.
How to talk appropriately about pleasure

• Language and phrasing
• Inclusivity

• Pleasure concerns are valid concerns

• Don’t use yourself as an example

• Refer to other professionals or resources
Some final thoughts about pleasure:

“As our clients accept their right to pleasure, not only does it enrich their sex lives and deepen their bond with their partner, it also enhances their sense of personal well-being.”

-Resnick (2002)

“Teens with generally sex-positive emotions were more likely to admit to themselves that they were sexually active and take all of the steps necessary to protect themselves, including communication with their partner and the acquisition and consistent use of contraception. Conversely...sex negative emotions ‘interfered’ with the performance of each pregnancy and STD/HIV preventative behavior studied.”

-Fay (2002)

In conclusion...

Sexual pleasure isn’t dangerous. Uninformed, hurried, scared, ashamed sex is dangerous.

Resources


# 2012 Minnesota Reproductive & Sexual Health Update

September 11, 2012  Saint Paul, Minnesota

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<tr>
<td>8:00-8:30</td>
<td>Registration, exhibits, continental breakfast</td>
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<td>8:30-8:45</td>
<td>Welcome</td>
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| 8:45-10:00 | **What's New in Contraception 2012**  
Sharon Schnare, RN, RNP, CNM, MSN, FAANP |
| 10:00-10:15| Break, networking, exhibits                                         |
| 10:15-11:45| Concurrent Sessions                                                   |
| Room 135 AC| A1: **Pleasure Education is Health Education**  
Lindsey Hoskins and Laura Rademacher, MA |
| Room 155   | A2: **A Conversation with Sharon Schnare**  
Sharon Schnare, RN, RNP, CNM, MSN, FAANP |
| 11:45-12:45| Lunch, networking, exhibits (lunch provided)                         |
| 12:45-2:00 | **Sexually Transmitted Infections: Overview and What's New**        |
| Room 135 AC| Bradley Stoner, MD, PhD                                              |
| 2:00-2:15  | Break, networking, exhibits                                         |
| 2:15-3:45  | Concurrent Sessions                                                   |
| Room 135AC | B1: **Advanced Contraceptive Counseling: Motivational Interviewing in 5 Minutes or Less!**  
Sharon Schnare, RN, RNP, CNM, MSN, FAANP |
| Room 155   | B2: **Cytology Screening**                                            |
|           | Jan Ray, RNC, WHNP                                                   |
| 3:45-3:50  | Five -minute Transition                                              |
| 3:50-5:05  | **Navigating Health Care Reform**                                   |
| Room 135 AC| Tim Stanley, MA, and Ellen Samuelson Young, JD                       |
| 5:05-5:15  | Evaluations and Adjourn                                              |
Thank you to our Sponsors and Exhibitors!

**Gold Sponsor:** Minnesota Department of Health

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**Bronze Sponsor:** Planned Parenthood Minnesota, North Dakota, South Dakota

![Planned Parenthood](image)

Dr. Bradley Stoner’s presentation sponsored by the St. Louis STD/HIV Prevention Training Center

Additional support from the Healthy Youth Development Prevention Research Center, Division of Adolescent Health and Medicine, Department of Pediatrics, Medical School, University of Minnesota

**Exhibitors:**

Merck  
The Family Tree Clinic  
Teenwise Minnesota  
Minnesota Department of Health, Community and Family Health Division

Thank you to the 2012 Planning Committee!

Emily Erickson, Annex Teen Clinic  
Gary Greenfield, Division of Community and Family Health; Maternal and Child Health Section  
Jen Stephenson, Health Care Education and Training, Inc.  
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What’s New in Contraception 2012

Sharon Myoji Schnare
RN, FNP, CNM, MSN, FAANP
Member CDC Advisory Board for MEC

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Sharon Schnare reports that she is a consultant for Bayer HealthCare Pharmaceuticals, Inc. and a speaker for Azur Pharma, Bayer HealthCare Pharmaceuticals, Inc, Jazz Pharmaceuticals, Merch Sharp & Dohme Corp., and Teva Women’s Health Inc. Sharon Schnare agrees to present the following information fairly and without bias.

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Contraception has reduced women’s death rates and has been the single most important factor impacting women’s health, education and freedom in the 20th century.

It is estimated that more than a quarter of pregnancies worldwide are unintended.
Between 1995 and 2000, approximately 700,000 women died as a result of unintended pregnancy; and morbidity from pregnancy affected even more women.
This is why ALL options must be available to ALL women.
CDC Prepregnancy Contraceptive Use Among Teens with Unintended Pregnancies – Pregnancy Risk Assessment Monitoring System (PRAMS)

- Approx. 400,000 teens aged 15-19 give birth every yr in U.S. Highest rate in developed world.
- Study: Hispanic, White, Black teens in 37 states & NY City (75% of all live births in U.S.)

PRAMS Data

- 50.1% teens were not using contraception at time of conception
- 22.1% of teens said: “I did not mind if I got pregnant.”
- 23.6% said partner did not want to use contraception
- 31.4% believed they could not get pregnant at time of conception

THIS IS AMBIVALENCE

Why is Teen Pregnancy a Problem?

More likely suffer negative social outcomes:
- School drop out
- Infants: increased low birth wt.
- Daughters of teen mothers: more likely to become teen mothers themselves
- Lower academic achievement

Perceptions of Risk

Remind women and men that NO method of contraception confers a higher risk of death than pregnancy

The Good News: Teen Pregnancy has Declined this year 2012

Contraception is not as Effective Without Counseling & Education

- SHOW women & men actual methods, encourage them to touch and handle methods. Carry methods in your pocket!
- Use motivational interviewing style of counsel—may be more effective.
- Realize ambivalence is normal
- Ask women what they want to know; avoid telling people what to do.
Pill Side-Effects: The “Nocebo” Response

“nocebo”? Negative placebo effect. Non-specific complaints caused by negative perceptions of pill which WE bring up NO evidence for most complaints! Telling women to expect side effects becomes a “self fulfilling prophecy”; increases discontinuation

**BENEFITS: FAR OUTWEIGH THE DANGERS**
Frequency of most pill side-effects are no greater than placebo pills!
Optimistic Counseling Discussion of Beneficial Effects of Pills! Grimes 2011

**Should Contraceptive Pills be Over the Counter? YES**

Border Contraceptive Access Study N= >1000 Latina low-income women-9 mo study. Half received Rx (El Paso), other half went to Juarez, Mexico for OTC pills
Those in US: 60% more likely to stop pills, than those getting pills in Mexico.
If given fewer than 6 packs: 80% more likely to stop pills than those taking OTC pills

**Should Contraceptive Pills be Over the Counter in the U.S.? YES**

ACCESS decreases unintended pregnancy.
Mexican women using OTC pills in Mexico more likely to have health conditions: HTN, smoking >34 (more relative contraindications but no absolute contraindications 13% vs 9% in Rx grp.) However no medical complications occurred. PROVIDE YEAR SUPPLY WHEN POSSIBLE (40) Potter 2011

**WHO and CDC Medical Eligibility Criteria for Contraception**

at last...evidence-based contraceptive management!
Is changing contraceptive practice in the U.S and Worldwide

**U.S. (2010) Medical Eligibility Criteria for Contraceptive Use is**

Available 5/28/2010
Updated 7/8/2011
[http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm](http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm) CDC/MEC
**Medical Eligibility Criteria for Contraceptive Use CDC, 2010**

What's new (July 8, 2011)

Safety of CHC’s during postpartum period
First 21 days postpartum:
- Changed from category 3 to category 4: unacceptable risk for all women
Days 21-42 Postpartum:
- Changed from category 1 to category 2 or 3 depending on other risk factors
- >42 days postpartum: category 1 unless other medical conditions present

CDC 2011

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**Rationale for the Change**

- Risk of VTE first 42 days postpartum 22-84 times greater than non-postpartum women
- Risk decreases rapidly post delivery over first 21 days
- Most women will not ovulate until 42 days postpartum so no clear benefit to CHC
- Women can be given Rx at delivery and advised to start after 42 days
- Recommendation is not based on any direct evidence on postpartum use of CHC

Jackson 2011, CDC 2011

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**CONTRACEPTION AND THROMBOSIS**

**Risk Factors for Thrombosis Related to Pregnancy**

- Age > or = 35 years
- Previous VTE
- Thrombophilia
- Smoking
- Immobility
- BMI > or = 30
- Postpartum hemorrhage
- Transfusion at delivery
- Caesarean delivery
- Pre-eclampsia
- Peripartum cardiomyopathy

CDC 2011

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**Drospirenone: Thrombogenic…or just bad press?** Cont...

EURAS European Active Surveillance study (2000-2004) requested by regulators. 58,674 enrolled followed for 142,475 person yrs. DRSP with 30 mcg EE with 2 comparators (Lng & other COCs) Each women checked q 6 mos for adverse events. Results: no increase risk of VTE, ATE (arterial thrombotic events): MI, ischemic stroke or mortality between grps. Adjusted for age, BMI, smoking, HTN, duration of use, VTE Hx. Showed NO difference between Lng, DRSP or other COCs

Dinger 2007
Cont...Drospirenone: Thrombogenic...or just bad press? EURAS data

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Hazard Ratio (HR)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>VTE venous thromboemboli</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DRSP vs LNG</td>
<td>1.0</td>
<td>0.6-1.8</td>
</tr>
<tr>
<td>DRSP vs CHC</td>
<td>0.8</td>
<td>0.5-1.3</td>
</tr>
<tr>
<td>ATE (arterial thrombotic events-stroke, MI)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DRSP vs LNG</td>
<td>0.3</td>
<td>0.1-1.2</td>
</tr>
<tr>
<td>DRSP vs CHC</td>
<td>0.3</td>
<td>0.1-1.5</td>
</tr>
</tbody>
</table>

Dinger 2007

MEGA Study Study listed in package insert by FDA

<table>
<thead>
<tr>
<th>Compared to nonusers</th>
<th>Relative Risk of DVT</th>
<th>Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levonorgestrel</td>
<td>3.6</td>
<td>2.9 — 4.6</td>
</tr>
<tr>
<td>Gestodene</td>
<td>5.6</td>
<td>3.7 — 8.4</td>
</tr>
<tr>
<td>Desogestrel</td>
<td>7.3</td>
<td>5.3 — 10</td>
</tr>
<tr>
<td>Cyproterone</td>
<td>6.8</td>
<td>4.7 — 10</td>
</tr>
<tr>
<td>Drospirenone</td>
<td>6.3</td>
<td>2.9 — 13.7</td>
</tr>
</tbody>
</table>

van Hylckama Vlieg 2009

Drospirenone and Thrombotic Events

FDA requested U.S. based study: i3 Ingenix (2001-2004): to identify all instances of death, hospitalization, syncope, arrhythmia, hyperkalemia, electrolyte disturbances, dialysis & MI among DRSP initiators. Reviewed insurance claims, medical records Risk of VTE: >40 yrs, DM, HTN, Hx MI, arrhythmia; BUT suggested no difference in incidence of VTE between users of DRSP and other COCs.

Seeger 2007, Eng 2008

Lidegaard Re-analysis

Reanalysis and time extension of Danish retrospective cohort study of national database hospital discharge and prescriptions 2001-2009—8,010,290 woman-years DVT events compared to levonorgestrel + 30-40 mcg of EE:

<table>
<thead>
<tr>
<th>Comparison groups</th>
<th>Events</th>
<th>RR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drosipirenone + 30 μg EE</td>
<td>196 v 123</td>
<td>2.12 (1.68 to 2.66)</td>
</tr>
<tr>
<td>Desogestrel + 30 μg EE</td>
<td>168 v 123</td>
<td>2.20 (1.74 to 2.77)</td>
</tr>
<tr>
<td>Gestodene + 30 μg EE</td>
<td>575 v 123</td>
<td>2.07 (1.70 to 2.52)</td>
</tr>
</tbody>
</table>

FDA Funded Study Continued

Retrospective cohort study data from 2 US HMO sites and Medicaid data from WA and TN 2001-2007 835,826 women, ages 10-55 years drospirenone/ethinyl estradiol tablets (DRSP) norelgestromin/ethinyl estradiol transdermal patch (NGMN) etonogestrel/ethinyl estradiol vaginal ring (ETON) group of 4 common COCs with progestins: LNG, NETA, NGM with EE doses ranging from 20-35 mcg (COMP) group of COCs with LNG and EE 30 mcg (LNG2)

FDA 2011

<table>
<thead>
<tr>
<th></th>
<th>ATE</th>
<th>VTE</th>
<th>CVD mortality</th>
<th>Total mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Users</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DRSP</td>
<td>0.99 (0.58, 1.69)</td>
<td>1.74 (1.42, 2.14)</td>
<td>0.37 (0.11, 1.29)</td>
<td>0.85 (0.59, 1.23)</td>
</tr>
<tr>
<td>NGMN</td>
<td>1.31 (0.63, 2.74)</td>
<td>1.55 (1.17, 2.07)</td>
<td>0.20 (0.03, 1.56)</td>
<td>0.80 (0.51, 1.26)</td>
</tr>
<tr>
<td>ETON</td>
<td>1.72 (0.61, 4.83)</td>
<td>1.56 (1.02, 2.37)</td>
<td>0.62 (0.08, 4.72)</td>
<td>1.31 (0.71, 2.40)</td>
</tr>
<tr>
<td>New Users</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DRSP</td>
<td>2.01 (1.04, 3.81)</td>
<td>1.77 (1.33, 2.36)</td>
<td>0.25 (0.03, 1.59)</td>
<td>0.88 (0.52, 1.53)</td>
</tr>
<tr>
<td>NGMN</td>
<td>1.07 (0.34, 3.23)</td>
<td>1.35 (0.95, 1.82)</td>
<td>insufficient data</td>
<td>1.07 (0.58, 2.03)</td>
</tr>
<tr>
<td>ETON</td>
<td>1.69 (0.36, 7.12)</td>
<td>1.35 (0.95, 1.82)</td>
<td>insufficient data</td>
<td>0.96 (0.29, 3.14)</td>
</tr>
</tbody>
</table>

FDA 2011
<table>
<thead>
<tr>
<th>Problems with Progestin Studies</th>
<th>Problems with Progestin Studies</th>
</tr>
</thead>
</table>
| Technical design flaws especially with using data collected for other purposes  
  - Difficulty validating diagnosis coding for billing vs chart review  
  - Matching controls  
  - Lumping various CHC’s as comparison  
  - Including rarely prescribed drugs and drugs not relevant to US prescribers | Bias in prescribing: Newer products considered safer (or riskier) depending on when prescribed  
Prescribing for secondary indications or perceived advantages like antiandrogenic effects to women with conditions that may affect risk (PCOS linked to obesity etc.) |

<table>
<thead>
<tr>
<th>Problems with Progestin Studies</th>
<th>So…?</th>
</tr>
</thead>
</table>
| Diagnostic bias: when patient or clinician thinks an OC may cause thrombosis this can lead to more aggressive workup | Has a greater thrombotic risk in CHC with some progestins been firmly established? NO  
  - Multiple studies with various methods, strengths and weaknesses and varying results  
  - Will we ever get level I evidence to answer this question? NO  
  - Events too rare to do a prospective randomized trial  
  - Will we ever get consensus on this question? Maybe.  
  - More and better comparable studies needed |

<table>
<thead>
<tr>
<th>Result of FDA inquiry: Label Change DRSP containing COC’s</th>
<th>Result of FDA inquiry: Label Change DRSP containing COC’s</th>
</tr>
</thead>
</table>
| New Yasmin label approved February 2012 by the FDA  
Added reference to new data from FDA funded study  
No specific indication that FDA considers drospirenone more of a risk than other COC’s | Safety Announcement 4/10/2012  
  - “FDA has concluded that drospirenone containing birth control pills may be associated with a higher risk for blood clots than other progestin-containing birth control pills.”  
New labeling approved April 2012 by the FDA for all drospirenone containing OC’s |

FDA SA 2012
Labeled added reference to new data from FDA funded study

From: Yasmin Prescribing Information April 2012

No Increase in VTE Risk with:
Levonorgestrel
Norethisterone
Hormone releasing and copper IUD’s

Putting VTE Risk in Perspective: the Data
200,000 new cases diagnosed in U.S./each year
2/3 VTE’s are DVTs; DVTs have 6% mortality rate
1/3 are pulmonary emboli (12% mortality rate)
40% of VTEs are idiopathic

Nelson 2011

VTE and COC’s
VTE risk pregnancy: 98.5 per 100,000 women yrs, BUT rises to 511.2 per 100,000 women-yrs in postpartum period!
Risk of PE during pregnancy: 10.6 per 100,000 women-yrs
During Postpartum the risk rises to 159.7 per 100,000 women-yrs.!
VTE risk is reversible within 30 days after discontinuation

Nelson 2011

When is the Greatest Risk of VTE?
- In the 1st 3 to 12 mos of COC use, then declines thereafter
- Obese users have 3 fold increased risk
- ACOG recommends women over 35 with BMI>30 should use estrogen containing contraception with caution; however US MEC rates obesity as Cat 2
- Smokers 18-39 yrs who DID NOT use COC’s had 2X VTE risk; smokers who did: 8.8 X higher risk

Nelson 2011
# Risk Factors for VTE

**Contraceptive Technology 2011**

- Obesity: >1/3 adult women have BMI>30
- Age, smoking, hypertension

*Thrombophilias: factor V Leiden accounts for 30% of ALL DVT’s*

- Other clotting defects: prothrombin factors
- Deficiencies in antithrombin, protein C, Protein S

With these defects the VTE risk may be 120-150/100,000 a year Nelson 2011

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# CONTRACEPTION:

**Medical Illnesses and Postpartum**

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# Antimicrobial, Antifungals and Antiparasitics Medications: Impact on Contraceptive Efficacy CDC MEC 2010

- Broad spectrum antibiotics: All Cat 1
- Antifungals: All Cat 1
- Antiparasitics: All Cat 1
- Rifampicine or Rifabutin
  - Cat 3 for CHC’s and POP
  - Cat 1 for MPA injection
  - Cat 2 for Implant
  - Cat 1 for IUDs

---

# Morbidly Obese Women Following Roux-en-Y Gastric Bypass Procedure

- Pregnancy should be avoided for 12-18 mos post surgery
- Etonogestrel (ENG) implant (Implanon®)
  - Subcutaneous delivery unaffected by malabsorptive surgery (N=3)
  - ENG serum levels decreased with wt loss, but remained above level necessary for effective contraception for at least 6 mos

Ciangura 2011

---

# Contraception for Women with UNcomplicated Organ Transplant CDC MEC

- Lng IUD 2
- Cu IUD 2
- Uncomplicated All methods: 2

---

# DMPA Injection: Postpartum

- Breastfeeding < 1 mo PP 2
- Breastfeeding 1 mo or more PP 1
- Postpartum < 21 days 1
- Postpartum 21-42 days with other risk factors for VTE 1
- More than 42 days PP 1

U.S. Med Eligibility Criteria for Contraceptive Use June 2012
Magnetic Resonance Imaging and IUDs and Implants

YES is safe for women with IUDs, implants, microimplants (inserted during hysteroscopy)


NEWER CONTRACEPTIVES

2010-New Quadriphasic COC

Estradiol valerate /dienogest (aka Natazia® (US) Qlaira® (EU)
19-nortestosterone-derived DNG (dienogest) an antiandrogenic progestin with estradiol valerate (E2V)
No clinically relevant effects on most hemostatic parameters.

Nelson 2010, Borgelt 2012

Cont... Cycle Control with new COC

Dienogest (DNG) (19-nortestosterone-derived with estradiol valerate (E2V)
- Ist 2 days: 3 mg estradiol valerate (E2V) alone (primates endometrium)
- Then 5 days of 2 mg E2V with DNG 2 mg
- Dose of DNG is raised the next 17 days to 3 mg while E2V dose stays at 2 mg
- Then 2 active pills contain only E2V 1 mg
- 2 placebo pills end the 28 day cycle

Cont... New Oral Contraceptive Pill

Dienogest + Estradiol valerate
Showed superior bleeding profile to EE 20 mcg with Lng 100 mcg pills
67% reduction in bleeding compared with typical OC reduction of 35% to 43%
Low discontinuation rate
New Drug application (NDA) requested indication for “prolonged menstrual bleeding…” BUT approved by FDA 5/6/2010 only for contraception.

Fraser 1991, Jensen 2011, Nelson 2010

Two New Drospirenone Combined COC’s with Folate

- FDA approved two new drospirenone (DRSP) containing pills with folate
- Beyaz 24/28 pills with 20 mcg EE & 3 mg DRSP
- Safyral 21/28 pills with 30 mcg EE & 3 mg DRSP
Levomefolate calcium 0.451 mg per tablet in all 28 pills in both brands
**The “Chewable” Pill**

- Norethindrone 0.8 mg
- Ethinyl estradiol 25 mcg
- Ferrous fumarate 75 mg (no therapeutic value: Prenatal dose is 325 mg/d)
- 24 active pills and 4 “inactive pills” which contain iron
- iPhone app available as pill reminder
  (Generess Fe)

**WHAT’S NEW ON THE HORIZON**

**New Injectable Contraceptive: On the Horizon**

- Levonorgestrel butanoate suppresses ovulation for up to 5-6 months after single injection of 50 mg; 12.5 mg dose... inhibited ovulation for another 2-3 months
- CCNT: Contraceptive Clinical Trial Network investigation potential
  Garza 1991, Jensen 2011

**Progestin-Only Patch In Development**

- Progestin-only (levonorgestrel)
  Benefits women with contraindications to estrogen:
  Migraine with aura
  Thrombophilias
  Postpartum or nursing mothers

**New Transdermal Combination Patch on the Horizon**

- Using 50 mcg gestodene, a synthetic progestin from the 19-nortestosterone family and ethinyl estradiol 20 mcg
- Patch is applied once/week: 21 days on and 1 week off
- Inhibits ovulation
  Heger-Mahn 2004, Jensen 2011,

**Progestin-Nestorone Vaginal Ring**

- Potent 19-norprogesterone derivative, neutral metabolic effects (not active orally); can be used in gel, ring or spray formulas
- 2 Phase 3 trials completed
- Vaginal ring releasing 150 mcg/d nestorone with 15 mcg/d of EE
- 21 days on, 7 days off regimen
- The same ring reinserted every month for 1 year
  Developed by Population Council
  Sitruk-Ware 2007
Natural Progesterone as a Contraceptive Ring?

Designed for lactating women
10 mg/d progesterone release vaginal ring
Effective for 3-4 months
No effects on breast-feeding or infant development

Nath 2010, Massai 2005

New Oral Contraceptive pill...On the Horizon: Nomegestrol Acetate

Estradiol with nomegestrol acetate (NOMAC) 19-norprogesterone derivative-lacks affinity for steroid receptors other than progesterone receptors: antiestrogenic and antigonadotropic effects on endometrium without androgen or glucocorticoid effects
Treatments: dysmenorrhea, heavy menstrual bleeding, premenstrual syndrome
Combined with estrogen for OC, inhibits ovulation & follicle development

2011 Jensen, Lello 2011

Oral Contraceptives: Treatment for Hirsutism?

Prospective RCT comparing 2 drospirenone OC’s:
(1) 21/7 grp: 3 mg DRSP+0.03 mg EE
(2) 0.02 mg EE + 3 mg DRSP
N=50 (24 and 23 pts in each grp) 6 mo study
Both grps comparable effects; well tolerated (T & free T decreased significantly; SHBG increased; no change in DHEAS levels)

Oner 2011

Contraceptive Vaccines

Target | Who can use | Limitation | Available
--- | --- | --- | ---
GnRH: Gonadotropin releasing hormone | Male & Female Felines | Causes impotency | Equity®, Improvac®, GonaCon®, Repro-BLOC®
FSH: follicle stimulating hormone | Male & Female Primates | Oligospermia | No
Luteinizing hormone | Male and Female lab animals, primates | Causes impotency | No
HCG: Human chorionic gonadotropin | Women and female primates | Successful in women. Difficult to get high antibody titre | No
Zona pellucida (ZP) | Female animals, dogs, primates | Causes irreversible oophoritis | Wildlife/dogs PZP vaccine/Spayvac®

Can Nurse Clinicians Perform Manual Vacuum Aspiration (MVA)?

YES
Study from India determined that nurses performing MVA’s are as safe as physician colleagues.
Nurse provided MVA’s increases access to safe abortions

Shireen J et al Contraception 84(2011) 615-21
Jejeebhoy 2011

Vaginal Contraceptive Ring
Extended use Vaginal Ring Contraceptive
- No hormone-free interval
- Potential for breakthrough bleeding
- Probably continuous 30 day cycle

Teaching Women How to Use the Ring: It’s easy!
- Hand a ring sample to her - “soft, small”
- Quick demonstration of insertion and removal technique(s) and positions (“Ring Macarena”)
- Assure her that vast majority of women find it very easy to use and she will too.

LARC: Long-acting Reversible Contraceptive Methods
Methods that are as effective as surgical sterilization, yet reversible.
IUD’s (copper and levonorgestrel)
Implant
Cost effective, reduce need for clinic visits, safe
Implant and IUCs effective for 3, 5 or 10+ years.

Gestrinone and Mifepristone for Emergency Contraception
- Double-blind controlled trial N=998 with 499 in each arm; unprotected intercourse within 72 hrs.
- Pregnancy rate for 10 mg gestrinone (anti-progestin not available in U.S.): 2.5%
- Pregnancy rate for 10 mg mifepristone: 1.8%

Wu 2010 Obst Gynecol
Cheng 2012 Cochrane Database
Syst Rev
Emergency Contraception (EC): What’s on the Horizon?

Mifepristone 25-50 mg superior to Lng IUD and Yuzpe (combined COC regimens)
Ulipristal acetate may be more effective than Lng IUD
Lng IUD more effective than Yuzpe
COPPER IUD MOST EFFECTICE EC and ONLY METHOD TO PROVIDE ONGOING CONTRACEPTION WHEN LEFT IN SITU

Cheng Cochrane Database Syst Rev. 2012
Richardson Clin Ther. 2012

Cu IUD for Emergency Contraception

Emergency placement of Cu-IUD: significantly more effective (99%) than EC pills.
May also prevent pregnancy after fertilization
Can be placed within 120 hrs of UPIC (only 0.23 preg/100 women)

Cheng 2008

IUD UPDATE and NEWER USES

Frameless (FibroPlant) LNG-IUD reduces menstrual blood loss in women with/without heavy menstrual bleeding
Releases 14 mcg LNG/day for contraception
Amenorrhea occurred in 80% of women
Andrade 2009
Smaller devices may be beneficial for nulliparous women.
Jensen 2011

Lng IUD: What’s New?

Look for smaller version of the Lng IUD
Greater use of post-placental placement of IUDs

Immediate Post-placental Placement of IUDs

Safe, effective
Expulsion rates appear higher than interval placements
Early F/U to identify expulsions
Grimes Cochrane Database Syst Rev. 2010
No increase in excessive bleeding or endometritis Welkovic Contraception. 2001
Broader Use of Cu IUD

- Immediate post abortion (copper) IUD insertion is safe. Can decrease repeat unintended pregnancy and decrease repeat abortion by two-thirds!
- Higher expulsion rates: typical rate 1-3%, post abortion rate: 5-6%

Grimes 2004, Goodman 2008

Offer LARC Contraceptives Immediately Post Abortion

Data: Having a previous abortion does not deter future abortions. Women are more likely to choose IUD or implant if offered immediately post abortion compared with women without Hx of recent AB. Offer LARC methods IMMEDIATELY post AB…don’t wait for another visit!

In clinic: Candidates for IUDs should have them placed on same day visit

Broader Use of Lng IUD

- Nulliparous women & adolescents (smaller IUCs will be available)
- With previous history of PID

Levonorgestrel (Lng) IUD: Treatment of:
- idiopathic menorrhagia (19)(20)(29) and pelvic pain due to endometriosis (15)(17)(18) or adenomyosis (14) or dysmenorrhea (14)(20) chronic pelvic pain (16) protection against ectopic pregnancy Naz 2011 and for HRT


Broader Use of Lng IUD

- Prevent iron deficiency anemia
- Endometrial polyp & fibroid protection for women using tamoxifen. In lieu of endometrial ablation for uterine bleeding and an alternative to hysterectomy
- Menopausal women- inhibit hyperplasia with estrogen therapy (a smaller version of the Lng IUD is in progress)
- Immediate postpartum & post abortion-regardless of lactation status


Lng IUC as Therapy for Endometriosis?

- Prospective, non-randomized 12 month VERY SMALL STUDY
N=11 symptomatic women with endometriosis: recto-vaginal septum
Pelvic pain, deep dyspareunia, dysmenorrhea greatly improved. Size of endometriomas significantly reduced per TVUS

Fedele 2001

Lng IUD: Endometrial Protection with Tamoxifen & ERT

- 122 postmen-1 yr tamoxifen use- randomized to endometrial surveillance or Lng IUD with surveillance x 12 months
- Baseline-all women showed only benign changes
- Lng IUD-protective against tamoxifen, initial bleeding resolved, no new polyps, 13% fewer fibroids
- Lng IUD may be used with ERT to inhibit hyperplasia

Gardner 2009, Wan 2011
Cu and Lng IUDs Lower Risk of Endometrial Cancer

Mechanism of action of Cu IUD unknown; may be related to alteration in endometrium & preferred for recent breast cancer; Lng IUD is used with tamoxifen tx

Lng IUD prevents endometrial hyperplasia in peri & post menop women on estrogen and used in tx of non-atypical hyperplasia

May be effective for atypical hyperplasia, and 1I endometrial cancer as well.

Contraceptive Tech 2011

IUDs may lower cervical cancer risk

May reduce risk of cervical cancer by 45%

Protective affect occurred in 1st year and continued up to 10 yrs (>15,000 women)

Squamous cell ca reduced by 44%

Adenosquamous risk reduced by 54%


Lng IUD: Treatment for Menorrhagia and HRT

Systematic review: Lng IUD use for menorrhagia- 9 studies showed statistically significant reduction in blood loss (74% to 97%)

1 study- 64% women with menorrhagia (given Lng IUD) cancelled surgery vs 14% of controls

Acceptance and continuation of Lng IUD for HRT has been high Stewart 2001, Luukkainen 2000

Risk of PID Reduced with IUDs

RCT: PID rates in Lng IUD vs. Nova-T (Cu) Salpingitis significantly lower in Lng IUD vs. Nova-T users at 3 and 5 yrs.

7 yr randomized study, PID rates did not differ between devices and mild to marked increases in hemoglobin levels occurred in users of BOTH IUDs AND...Continuation rates were similar: 29.4% for the CuT380A IUD and 24.9% for the Lng IUD


IUD’s, Implant: Duration of Efficacy

Lng IUD, approved duration-5 yrs, some studies show efficacy to 7 yrs

Implant approved for 3 yrs; but stable concentrations of etonogestrel up to 36 months

OFF LABEL


PAIN MANAGEMENT FOR IUD PLACEMENT
Pain Management for IUC Placements

Paracervical block (PCB) generally not indicated; may not reduce overall pain
May be useful for difficult placements or cervical dilation.
PCB is used for ALL IUC placements in Finland.

Paracervical Anesthetic Block

Anatomy: Cervical nerve innervations from Lee-Frankenhäuser plexus, located lateral to the junction of the cervix and uterus. Sensation is carried to the spinal cord at the T10-T12 and L1 segmental nerves.

Paracervical Block (PCB) for IUC Placement or Difficult Removal

- Have adequate visibility of cervix. Lift cervix with tenaculum and apply anesthetic gel to injection sites
- Use a needle extender to reach the cervix

Continued...
**Paracervical Anesthetic Block Cont...**

- At each site the needle depth should only be 2-3 mm; just cover the bevel of the needle in the tissue
- **Avoid** uterine arteries at 3:00 and 9:00
- Use sites 4:00 OR 5:00 and 7:00 OR 9:00
- Prior to instillation, **ASPIRATE** to assure the needle is not in a vessel.

**Paracervical Anesthetic Block Cont...**

- As you slowly instill 1% lidocaine NO epinephrine, the area around the needle tip will blanch; a good sign. There is resistance with the injection and often two thumbs are needed for instillation.

**Cont... Paracervical Anesthetic Block**

- Watch the lower vagina to assure the lidocaine is not pooling...this means the needle bevel is not covered & lidocaine is leaking. If this occurs, advance the needle slightly, **ASPIRATE TO ASSURE NOT IN VESSEAL, THEN CONTINUE WITH THE INSTILLATION.**
- Wait 10 min for full anesthetic effect

**PCB Complications are Very Rare**

- Hypersensitivity to lidocaine (ask about allergies)
- Bleeding from injection sites (usually very minor)
- Infection (very rare)

**Etonogestrel Progestin Implant** *(Nexplanon replaces Implanon)*

- Flexible, white ethylene vinyl acetate rod with 68 mg etonogestrel, subdermal implant 4 cm x 2 mm
- Action: Inhibits ovulation
- Effective for 3 years. Releases 60-70 mcg/day in 1st 1-2 yrs, then 25-30 mcg in 3rd yr. of use
- Inserted subdermally between the biceps and triceps muscles
- Now radio-opaque (visible on X-ray or CT scan) and new inserter
- Must be inserted and removed only by clinicians completing a training program
Does Etonogestrel (ETG) Implant Effect Carbohydrate Metabolism?

ETG Implant does not affect carbohydrate metabolism after 12 months in healthy women.
Use of low dose combined OC’s may cause slight insulin resistance & rise in fasting insulin levels, however glucose levels are unchanged or reduced-
Non-randomized, open label, prospective controlled trial. N=40
Oderich 2012

Cervical Neoplasia and Contraception

Condons marginally effective at preventing abnormal cytology by preventing HR-HPV or persistence of HPV
Hormonal contraceptives may increase HPV acquisition; but risk not as great as that of women with high parity
Curry 2012, Nelson 2011

Do COCs Impact HIV Acquisition?

NO
HIV uninfected women using either COCs or injectable progestins were not at any significantly increased risk for acquiring HIV compared with women who used other non-barrier methods. Contraceptive Technology 2011

Update to USMEC 6/22/12

<table>
<thead>
<tr>
<th>Condition</th>
<th>COC/P/R</th>
<th>POP</th>
<th>DMPA</th>
<th>Implants</th>
</tr>
</thead>
<tbody>
<tr>
<td>High risk for HIV</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>HIV infection</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>AIDS</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

CDC 2012

Depo-medroxyprogesterone acetate (DepoProvera®)

- Questionable link with epithelial ovarian cancer in premenopausal women according to WHI? WHO Collaborative Study Neoplasia Steroid Contraceptive Lancet 1991
- Probably not.
- May actually have a protective affect against according to Women’s CARE Study (CDC)
- Breast cancer is rare among premenopausal women. Strom Contraception 2004

What’s Else is New in Women’s Contraception?
**Newest Progestin: In Clinical Trials: Nestorone**
- Nestorone similar to progesterone
- Population Council: in clinical trials as an intra-vaginal ring (2 1/4 inches)
- Also evaluated as transdermal metered dose spray and gel
- May be efficacious for men when used with testosterone

(36) 2010 (37) 2007

**MANAGING SPOTTING AND BLEEDING WITH CONTRACEPTIVE METHODS**

**Managing Challenging Idiopathic Spotting-Bleeding with Implant**
- RCT: effect of mifepristone with EE on ovulatory function in women with Implanon®
- Mifepristone 25 mg bid with EE 20 mcg q d x 2-5 days
- Would this regimen work as well with IUD idiopathic bleeding? No data

Weisberg 2011

**Managing Challenging Idiopathic Spotting-Bleeding with Hormonal Contraceptives**
- Continuous use, no pill free interval
- Spotting or light bleeding (short-term treatment): Nonsteroidal anti-inflammatory drugs (NSAIDS) Ibuprofen 600-800 mg qd x 5 days
  - Mefenamic acid (Ponstel®)
  - Doxycycline 100 mg bid x 1-2 wks
- Heavy-prolonged bleeding
  - NSAIDS
  - Hormonal: Ethinyl estradiol or add CHC

**Effects of hormonal contraception on vaginal flora**
- Compared to COC’s, contraceptive vaginal ring showed an increase in the number of lactobacilli in vaginal flora…this could be protective.

Health Benefits of Contraception

All methods of contraception are safer than pregnancy!

Health Benefits of Combined Oral Contraceptives

Protects against ovarian, endometrial cancer and possibly colorectal carcinoma
Decreases dysmenorrhea, menorrhagia, anemia, cyclic mood problems (PMS), protects against ectopic pregnancy and symptomatic PID
AND…reduces acne…and as an aside…it reduces death.
Maguire 2011

Health Benefits of Progestin-Only Pill and Lng IUD

POP: Lactation not disturbed (Cat 2 MEC)
Lng IUD: decreases menstrual blood loss, menorrhagia, PID, endometriomas, adenomyosis, endometrial hyperplasia, polyps, chronic pelvic pain, fibroids, provides progestin for HRT and reduces endometrial polyps in women using tamoxifen

Fraser 2010

Health Benefits of Medroxyprogesterone acetate

Fewer seizures
Fewer sickle cell crises
Decreased risk ectopic
Decreased risk pelvic inflammatory disease (PID)
No estrogen
Benefits women with myomas
AND

Emergency Contraception: What’s New: Ulipristal acetate “ELLA”

Progestosterone receptor modulator
More effective than Lng EC on days 4-5 postcoital Dose: 30 mg
Advise to abstain or use a barrier method to end of current menstrual cycle.

HA (18%)
Abdominal pain (12%)
Nausea (12%)
R/O ectopic

Contraceptive technology Update 5/2010, CDC 2010
### Contraception for Women with Cancers
- Copper T380A IUD first line for women with history of hormonally mediated cancer
- Lng IUD preferable in women using tamoxifen, or have non-hormonally mediated cancers.
- Women with IUD’s can undergo CT and MI imaging

### Cancers and Contraception
- Breast: benign disease and family history of cancer-all methods acceptable
- Current Breast Cancer: all category 4, except Cu IUD is 1
- Past breast cancer and no evidence of current disease for 5 yrs: all category 3, except Cu IUD is 1

### Cervical Cancer and Contraception (2)(3)
- Cervical cancer awaiting treatment:
  - CHC, P/R: 2; POP: 1
  - DMPA; ETG Implant: 2
  - Cu and Lng IUDs: Initiation-4, Continuation-2
- CIN: same as above, except Cu IUD is 1 and Lng IUD is 2

### “Quick Start” and Combined Hormonal Contraceptives
- Conventional OC initiation may delay start for several weeks.
- Initiate OC during office visit!
- Applicable to Pills, Patch, Ring, DMPA, IUD insertion, Implant
  - Advise backup method first 7 days

### DMPA Initiation or Late Injections
- Use a backup method for first 7 days post injection to allow time for cervical mucus to thicken to inhibit sperm motility.

### CONTRACEPTION FOR MEN:
**WHAT’S NEW OVER THE RAINBOW?**
Men’s Use of Contraception

In 2002 male methods accounted for 32% of contraceptive use in the U.S.
- Vasectomy 9%
- Condom use: 18%
- Withdrawal: 4%
- Periodic abstinence: 1%

Darroch 2008

Transdermal Gel for Male Contraception?
- Population Council and National Institute of Health are working on Nestorone gel combined with a testosterone gel for male contraception

Contraceptive Transdermal Gel for MEN

Testosterone transdermal gel with nestorone 8mg significantly reduced sperm concentration to 1 million/mL or less after a 20 wk tx
- Testosterone levels were maintained within adult range in the men. Adverse events: minimal

Contraceptive Technology Update. May 2010

Contraception for Men
- Let men know that hormonal contraceptives are over the horizon!
- Discuss effective methods their partner can use & help with cost
- Cu IUD EC with men
- Discuss state paternity laws with men for their protection

Male Contraception: Where are we at?

Progestins (cyproterone, etonogestrel) also suppress gonadotropins and work synergistically with testosterone.
- Studies on-going.

Amory 2008

Male Contraception: The Challenges
- Goal: Reducing sperm count to low enough levels to ensure infertility. Recent studies have reduced counts to 1 million sperm per mL in ~80-90% of subjects.
- Testosterone therapies involve injections or implants along with progestins.
- Side effects: weight gain, mood changes, acne, sweating, libido change.

Mommers 2008
Male Contraception: New Possibilities?

No new male contraceptives have emerged in the past century…but that’s changing!

RISUG (Vasalgel™): reversible inhibition of sperm under guidance (not yet approved)
1. Polymer gel coats vas deferens lumen-kills sperm & blocks lumen.
2. Flushing vas with dimethyl sulfoxide (DMSO) or sodium bicarbonate solution to reverse

Tulsiani 2010, Male Contraception Information Project

Male Contraception: Is Ultrasound (US) Promising?

US treatments to inhibit spermatogenesis. Post US sperm counts in dogs showed no sperm. US intensity is that used by physical therapists to treat injuries. 15 min treatment has 4-6 mos contraceptive effect. The transducer is placed directly on testes; painless.

Gates Foundation is funding FHI

Male Contraception Information Project

Male Contraception

Indonesian herb: Gandarusa Justicia gendarussa
1. Research supported by Indonesian Gov’t
2. Currently in clinical trials with 350 couples Male Contraception Information Project 2012

Gamendazole: Research supported by NIH (100% effective in rats & monkeys)

Male Contraception Information Project

Vasectomies

Can nurse practitioners perform vasectomies? YES!
Both scalpel and Non-scalpel vasectomies:
Less bleeding
Less infection

Hormonal Contraception…. Progestins, Progestins, Progestins

1st Generation Progestins Estranes
- Norethindrone
- Norethindrone acetate
- Ethynodiol diacetate
- Lynestrenol (not in US)
- Norethynodrel (not in US)

2nd Generation Progestins Gonanes
- More potent, longer half-lives, more androgenic activity: avoid in those with hirsutism, acne, dyslipidemia

- Norgestrel
- Levonorgestrel
### 3rd Generation Progestins

- **Desogestrel**
- **Norgestimate**
- **Gestodene (not in US)**

Less androgenic activity, allows greater expression of estrogens. Significant increase in SHBG

**Labeling:** For cystic acne

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### 4th Generation Progestin

- **Drospirenone**
  - Parent drug is spironolactone, a potassium sparing diuretic
  - Low androgenicity

**Abbreviations**

- BCM birth control method
- OC oral contraceptive
- OCP oral contraceptive pills
- DMPA depot medroxyprogesterone acetate
- BTL bilateral tubal ligation
- VTE venous thromboembolism
- IUD: intrauterine device
- IUC: intrauterine contraceptive
- Lng IUD levonorgestrel intrauterine device
- Cu IUD copper IUD
- BMD bone mineral density

**References**


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**Abbreviations**

- SHBG sex hormone binding globulin
- CHC combined hormonal contraceptives
- STI sexually transmitted infection
- ETG etonogestrel
- NET-EN norethindrone enanthate
- DVT deep vein thrombosis
- PE pulmonary emboli
- CDC MEC Centers for Disease Control Contraceptive Medical Eligibility Criteria

**References**

References

Grenin MD et al. Progestosterone receptor modulator for emergency contraception: a randomized controlled trial. Obstet Gynecol 2006; 108;1,089-1,097.

Darroch JE. Male fertility control: where are the men? Contraception. 78. 2008: 7-17.
Dinger JC et al. The safety of a drospirenone-containing oral contraceptive: Final results from the European Active Surveillance Study (EURAS) on oral contraceptives based on 142,475 women-years of observation. Contraception 2007;75:334-54.

References

MEGA data analysis
Multiple Environmental and Genetic Assessment of Risk Factors for Venous Thrombosis Study
Case control study
Analysis of data collected for thrombosis risk men and women
Patients at anticoagulation clinics in Netherlands 1999-2004
Analysis included women only 18-50 years
1524 patients 1760 controls (40.5% were “partners” of patients others random phone contacts)
van Hylckama Vlieg 2009

Lidegaard Re-analysis
Reanalysis and time extension of Danish retrospective cohort study of national database hospital discharge and prescriptions 2001-2009---8,010,290 woman-years
DVT events compared to levonorgestrel + 30-40 mcg of EE:

<table>
<thead>
<tr>
<th>Comparison groups</th>
<th>events</th>
<th>RR</th>
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</thead>
<tbody>
<tr>
<td>Drosiprone + 30 μg EE</td>
<td>196 v 123</td>
<td>2.12 (1.68 to 2.66)</td>
</tr>
<tr>
<td>Desogestrel + 30 μg EE</td>
<td>168 v 123</td>
<td>2.20 (1.74 to 2.77)</td>
</tr>
<tr>
<td>Gestodene + 30 μg EE</td>
<td>575 v 123</td>
<td>2.07 (1.70 to 2.52)</td>
</tr>
</tbody>
</table>

Estimates that 2000 women would need to switch to OC with levonorgestrel to prevent 1 venous thrombosis a year

Jick Pharmetrics US Drug Database
- VTE data from prescription and insurance code database women 15-44 yo 2002-2008
- Nested case-control and cohort study
- Comparison of COC’s with drospirenone vs levonorgestrel
  - OR 2.3 (1.6-3.2)
  - Incidence rate 3.1/10,000 yr vs 1.3/10,000 yr
  - Age adjusted RR 2.8 (2.1-3.8)
Jick 2011

Parkin UK General Practice Database
- Nested case control study 61 cases
- Database from general practice records 2001-2009--women 12-44 starting a new course of COC
- COC’s containing 30 mcg estrogen and drospirenone vs levonorgestrel
  - OR 3.3 (1.4-7.6) adjusted for BMI
  - Incidence 3.1 vs 0.9 cases per 10,000 woman years
  - IRR 2.7 (1.5-4.7) age adjusted
Parkin 2011

Israeli Health Provider Study
- Retrospective cohort study
- Databases of a health care provider in Israel 819,749 woman-years
- COC’s with Drospirenone vs second generation (norgestrel, levonorgestrel) progestins
  - DVT/PE RR 1.43 (1.15-1.78)
- COC’s with Drospirenone vs third generation (desogestrel, gestodene, norgestimate) progestin
  - DVT/PE RR 1.65 (1.02-1.78)
- No increase RR for arterial thrombosis
Gronich 2011
Progestins ALONE have NO impact on clotting system

BUT when some progestins are combined with estrogen they can modulate the strength of estrogens production of extrinsic clotting factors (antithrombin, fibrinolytics)

Pills with 3rd generation progestins (desogestrel & gestodene) assoc with 2-fold risk VTE compared with 2nd generation progestins (Lng & norgestrel)

Nelson 2011