Continuing Medical Education

# Contemporary Topics in OB-GYN

**Virtual Conference**
September 25-26, 2020

**Jointly Sponsored by**
Allegheny General Hospital
West Penn Hospital
Department of Obstetrics and Gynecology
Allegheny Health Network
Pittsburgh, Pennsylvania

**Register now at cme.ahn.org.**

AHN

## Conference overview

The Contemporary Topics in OB-GYN Virtual Conference will focus on current key topics in general obstetrics, obstetrical emergencies, and medical complications of pregnancy, gynecology, and gynecologic oncology.

## Intended audience

This conference is intended for practitioners in obstetrics and gynecology, internal medicine, and family medicine, and nurse practitioners, physician assistants, registered nurses, and other health care professionals who have direct responsibility for, or interest in, obstetrics and gynecology.

## Global objective

The overall purpose of this conference is to supplement the provider's current knowledge with updated evidence-based strategies, techniques, and best practices for managing common challenges in the ever-changing field of obstetrics and gynecology.

## Course director

### Marcia Klein-Patel, MD, PhD

Network Chair, Women's Institute
Allegheny Health Network

## Invited external speakers

### Richard Guido, MD

Associate Professor, Department of Obstetrics, Gynecology, and Reproductive Sciences
Division of Gynecologic Specialties
Director of Fibroid Treatment Center
Director of the Colposcopy Clinic
UPMC

### Megan L. Kavanaugh, PhD

Principal Research Scientist, Guttmacher Institute
Center for Women's Health, Research and Innovation
University of Pittsburgh

### Carolyn Beth Sufrin, AM, MD, PhD

Associate Director, Fellowship in Family Planning
Johns Hopkins Medicine

## AHN faculty

### Michael Aziz, MD

Maternal Fetal Medicine
Allegheny Health Network

### Janette Gomez,DO

Breast Surgical Oncology
Allegheny Health Network

### Mark E. Caine, MD

Maternal Fetal Medicine
Allegheny Health Network

### Jean Fitzgibbons, CRNP

Perinatal Hope Program
Allegheny Health Network

### Jessica Sassani, MD

Urogynecology
Allegheny Health Network

### Tracey Vogel, MD

Obstetrical nesthesiology
Allegheny Health Network

### Amy I. Whitsel, MD

Maternal Fetal Medicine
Allegheny Health Network

## STAR Center contributors

### Dawn Cicchini, BS, CHSOS

Simulation Specialist
Allegheny Health Network

### Nichole Cooper, BS, CHSE

Senior Simulation Technician
Allegheny Health Network

### Erin Killen

Simulation Technician
Allegheny Health Network

## Disclosure of significant relationships with relevant commercial companies

In accordance with the Accreditation Council for Continuing Medical Education (ACCME) and the policy of Allegheny General Hospital, presenters must disclose all relevant financial relationships, which in the context of their presentation(s), could be perceived as a real or apparent conflict of interest, (e.g., ownership of stock, honorarium, or consulting fees). Any identifiable conflicts will be resolved prior to the activity. Any such relationships will be disclosed to the learner prior to the presentation(s).

## Agenda

### Friday, September 25, 2020

| | |
|---|---|
| 2 p.m. - 5 p.m. | **Simulation Scenarios**<br>• **COVID-19 Preparedness**<br>• **Postpartum Hemorrhage**<br>• **Hypertensive Crisis**<br>**Presented by:**<br>Mark E. Caine, MD<br>Tracey Vogel, MD<br>Amy I. Whitsel, MD<br>**STAR Center Simulation Specialists:**<br>Dawn Cicchini, BS, CHSOS<br>Nichole Cooper, BS, CHSE<br>Erin Killen |

### Saturday, September 26, 2020

| | |
|---|---|
| 7:45 a.m. – 8 a.m. | **Welcome Remarks and Overview**<br>Marcia Klein-Patel, MD, PhD |
| 8 a.m. – 9 a.m. | **Reproductive Justice and Incarcerated Women: Understanding the Nexus of Reproductive Health, Mass Incarceration, and Social Justice**<br>Carolyn Beth Sufrin, AM, MD, PhD |
| 9 am – 9:45 am | **Recurrent UTI**<br>Jessica Sassani, MD |
| 9:45 a.m. – 10 a.m. | **Midmorning Break** |
| 10 a.m. – 10:45 a.m. | **High Risk Breast Cancer Management and Assessment**<br>Janette Gomez, MD |
| 10:45 a.m. – 11:45 a.m. | **Updated ASCCP Guidelines**<br>Richard Guido, MD |
| 11:45 a.m. – 12:30 p.m. | **Lunch Break** |
| 12:30 p.m. – 1:15 p.m. | **Hepatitis C Treatment Postpartum**<br>Jean Fitzgibbons, CRNP |
| 1:15 p.m. – 2 p.m. | **The ARRIVE Trial: Interpretation and Future Directions**<br>Michael Aziz, MD |
| 2 p.m. – 3 p.m. | **Contraception in the United States: Use, Access, Barriers and How COVID-19 Has Shifted This Landscape**<br>Megan L. Kavanaugh, PhD |
| 3 p.m. – 3:30 p.m. | **Closing Remarks and Evaluations** |

## Accreditation

This course will provide a total of 10.5 hours.

Friday 3.0 | Saturday 7.5

### Physicians

This activity has been planned and implemented in accordance with the essential areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through joint providership of Allegheny General Hospital and West Penn Hospital. Allegheny General Hospital is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Allegheny General Hospital designates this live activity for a maximum of 10.5 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

**American Nurses Credentialing Center (ANCC)** accepts *AMA PRA Category 1 Credits™* from organizations accredited by the ACCME.

**American Academy of Nurse Practitioners (AANP)** accepts *AMA PRA Category 1 Credits™* from organizations accredited by the ACCME.

**The National Commission on Certification of Physician Assistants (NCCPA)** states that the *AMA PRA Category 1 Credits™* are acceptable for continuing medical education requirements for certification.

### Non-physicians

Allegheny General Hospital certifies participation in this educational activity, which has been designated for a maximum of 10.5 *AMA PRA Category 1 Credits™*.

## Registration

Visit **cme.ahn.org** to register. Click on the **Course** tab and type in **Contemporary Topics in OB-GYN**. Click on **Register**. Registration for the **STAR Center Simulation Lab** is limited to 30 participants.

### AHN and Highmark employees

Log in using your AHN or Highmark email and network password. Once logged in, *make sure you complete your profile* to earn and track your credit.

### Visitors

**To create a new visitor account:**
Click **Visitor Login** at the top right corner of the homepage, then complete the required fields.

## Course fees

Physicians: $75

This course is complimentary for all other health care providers.

## Refund policy

Full refunds will be given up to **September 18** when requested by email. After that date, no refunds will be given.

# *Reproductive Justice and Incarcerated Women: Understanding the Nexus of Reproductive Health, Mass Incarceration, and Social Justice*

Carolyn Sufrin, MD, PhD
Dept. of Gyn/Ob
Johns Hopkins School of Medicine &
Dept. of Health Behavior and Society
Johns Hopkins Bloomberg School of Public Health


ARRWIP
Advocacy and Research on Reproductive Wellness of Incarcerated People

JOHNS HOPKINS MEDICINE
JOHNS HOPKINS HEALTH SYSTEM

## Disclosures

- I have no financial conflicts of interest.
- I serve on the board of Directors for National Commission on Correctional Health Care as the Liaison for the American College of Obstetricians and Gynecologists

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Miami Herald

BROWARD COUNTY

**Mentally ill woman gave birth alone in isolated jail cell, Broward public defender says**

BY CHARLES RABIN AND DAVID SMILEY
MAY 03, 2019 05:05 PM, UPDATED 4 HOURS 14 MINUTES AGO

**Texas woman claims she gave birth alone in jail, baby died**

By Shelby Lin Erdman and Carma Hassan, CNN
Updated 12:55 AM ET, Sat May 24, 2014

Thu, Aug 29, 2019 **Newsweek**

U.S. | World | Business | Tech & Science | Culture | Newsgeek | Sports | Healt


U.S.

**INMATE SAYS SHE WAS FORCED TO GIVE BIRTH ALONE IN HER JAIL CELL WITHOUT ANY MEDICAL TREATMENT: 'THIS IS NOT CIVILIZED'**

https://www.fox43.com/article/news/local/contests/woman-says-she-was-forced-to-give-birth-alone-in-denver-jail-cell-with-no-medical-treatment/521-90206bdc-1e9b-4e57-a50b-749da6254ee8

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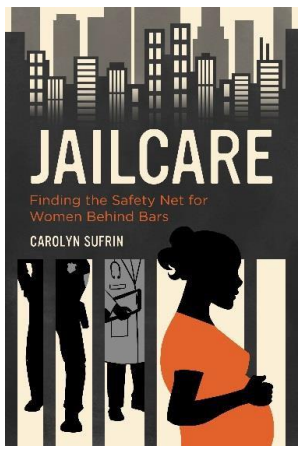
JOHNS HOPKINS HEALTH SYSTEM




*"Everyone says I got arrested, but I got rescued. I was so sick, I didn't want to get high no more. I just wanted to be in jail where I knew that I could eat, I could sleep, and that even if it's not the best of medical care, I was going to get some type of care."*

-Evelyn, 32 weeks pregnant, in jail

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Variability in care and experiences is the norm

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## Objectives

1. To understand the broader social context of mass incarceration and women's incarceration.
2. To recognize the unique reproductive health needs of incarcerated women including pregnancy, use of restraints in pregnant women, abortion, and contraception.
3. To understand variability in current availability pregnancy, postpartum, and family planning care for incarcerated people.
4. To gain knowledge so you can better care for incarcerated patients when they come to your hospital.

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# Jails and prisons are different

## Prison

- State & federal
- Convicted of felonies
- Parole violations
- Sentences > 1year
- Isolated from communities

## Jail

- City & county
- "Holding"- pre-trial, awaiting sentencing, prison
- Misdemeanors
- Probation violations
- Sentences < ~1 year
- High turnover
- Within communities

# Female incarceration rates continue to rise

Between 1980 and 2017, the number of incarcerated women increased by more than 750%, rising from a total of 26,378 in 1980 to 225,060 in 2017.


file:///Z:/Jail-%20articles/Incarcerated-Women-and-Girls%20sentencing%20project%20fact%20sheet.pdf

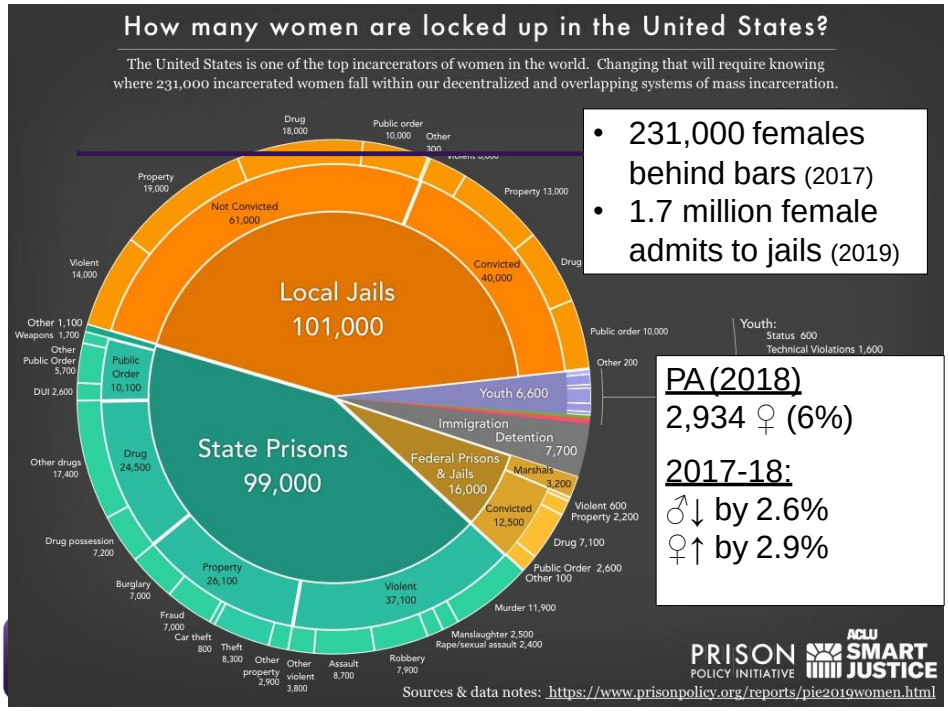
2016-2017 overall:

- ♀ ↑2.6%
- ♂ ↓0.6%

2008-2018, jails:

- ♀ ↑15%
- ♂ ↓9%

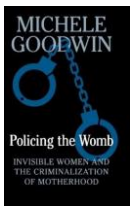
USDOJ BJS, Prisoners 2017; Jail Inmates 2018




# Who are the women behind bars in the U.S.?

- 62% are mothers to children <18 yo
- 75% ages 18-44
- 70% arrested for property, drug, minor charges
- Disproportionately affected by war on drugs
  - Overlapping criminalization and racialized control of pregnancy
  - Twinned systems of incarceration & child welfare system
- Systemic racism:

Women of reproductive age!




| | |
|---|---|
| White ♀: | 49/100,000 |
| Black ♀: | 92/100,000 |

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Glaze & Marusschak 2009

US DOJ/FBI, 2008
USDOJ BJS, Prisoners 2017; Jail Inmates 2017
US DOJ BJS Prisoners 2012 admissions

# High prevalence of STIs, mental illness, trauma

| Condition | Incarc. ♀ | Non-incarc.♀ | Incarc ♂ |
|---|---|---|---|
| Chlamydia[1,2,3] | 8.9-14% | 4.7% | 10% |
| Trichomonas[2, 4] | 26% | 3.1% | - |
| HIV [5,6] | 1.1% | 0.2% | 1.1% |
| Prior physical or sexual abuse [7,8,9] | Up to 80% | Up to 44% | Up to 16% |
| History of mental illness[7,8,10,13] | 68-73% | 20% | 41% |
| Substance dependence[11,14] | 69-72% | 6.9% | 57-62% |
| Hepatitis C[12] | 41% | 1.5% | 41% |


1. Bernstein 2006 Am J Public Health
2. Willers 2008 Sex Transm Dis
3. MMWR 2014 63(38)
4. Sutton 2007 Clin Inf Dis
5. Maruschak 2017 BJS HIV in Prisoners
6. CDC HIV Surveillance
7. Harlow 1999 USDOJ BJS
8. Belknap 2008 Violence Agnst Women
9. CDC 2014 NISVS
10. MMWR 2011, 60(03)
11. SAMHSA 2012 13-4795
12. CDC, Corr Facilities and Viral Hepatitis
14. Bronson BJS 2017a
15. Bronson BJS 2017b


# Incarceration in the U.S.: Harsh Realities

- Largest & most expensive prison system in the world

# Incarceration in the U.S.: Harsh Realities

- Largest & most expensive prison system in the world
- Characterized by:
  - High cost (and profit): 80 billion/year[1]

1. Brookings Instiitute 2014
2. USDOJ, Bureau of Justice Statistics (Zeng 2020; Carson 2020)

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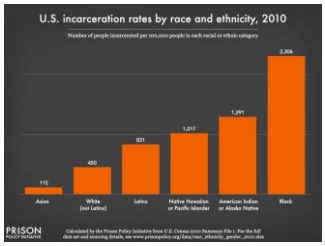


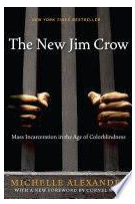


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  - High cost (and profit): 80 billion/year[1]
  - Systemic racism: Disproportionately Black
  - High recidivism: 50%-81%[1,2]

1. Brookings Instiitute 2014
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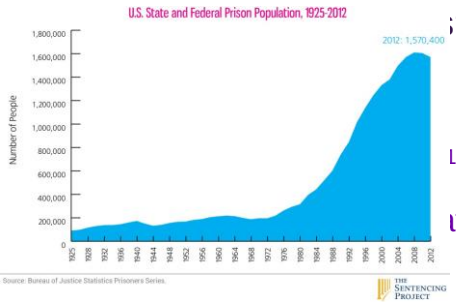
# Incarceration in the U.S.: Harsh Realities

- Largest ...stem in the world
- Charac...
  - High ...
  - Syst... ...itely Black
  - High ...
  - Mass proportion: 2.2 million adults[2]
    1979: 501,886

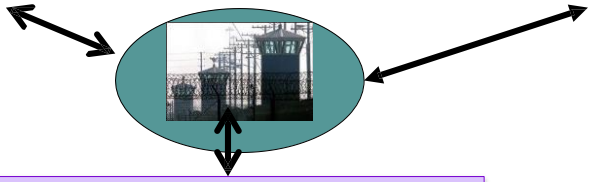



1. Brookings Instiitute 2014
2. USDOJ, Bureau of Justice Statistics (Zeng 2020; Carson 2020)

# Health Care for Incarcerated People: Public Health Perspective

**Pre-incarceration**
- Poor health status
- Poverty, malnutrition, homelessness, unemployment
- Medically underserved[1]

**While incarcerated**
**"opportunity"**
- New diagnoses→ Pregnancy
- Preventive health care
- Prisons & jails as health hazards



**Release, Re-entry, Re-arrest[3,4]**
- Continuity of care, competing priorities
- Mortality risk
  OR death w/in 2 wks: 12.7
- Perpetuates disparities

1. Clarke AJPH, 2006
2. Dumont et al JHCPU 2013
3. Wang Public Health Reports 2010
4. Binswanger NEJM 2007

# Health Care for Incarcerated People: Legal perspective


*8th Amendment*

*". . . nor cruel and unusual punishments inflicted."*

*Estelle v. Gamble* (1976)

IT DEPENDS

*"Deliberate indifference to serious medical needs of prisoners constitutes the unnecessary and wanton infliction of pain proscribed by the 8th amendment"*

-Justice Thurgood Marshall

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## Health Care for Incarcerated People: Service Delivery

- Standardization?
- Routine vs. requested services?
- C
- +
- Public or Private?

It depends

## What about women's health services?

- Inadequate services
  - Smaller population
- Limited attention to gender-specific needs

  Males as "default prisoner"→
  - Shackling in labor
  - Menstrual hygiene products

https://www.nytimes.com/2014/07/27/opinion/sunday/the-outrageous-shackling-of-pregnant-inmates.html

Weatherhead 2003 Jnl Law and Medicine
Mullen 2003 Fam Comm Health
Carson BJS 2018

# Incarceration and reproductive justice. . . What is reproductive justice?


Sister Song
Women of Color Reproductive Justice Collective

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# Mass incarceration disrupts the core rights of reproductive justice

| | |
|---|---|
| The right not to have children | • Limited access to contraception and abortion |
| The right to have children | • Coercive sterilization<br>• Limited prenatal care<br>• Conditions of birth dictated by prison or jail |
| The right to raise children with dignity and safety | • Separates parents and children<br>• Suspends custody rights<br>• Over-policing of communities of color<br>• $ to incarceration, not education etc. |

Sister Song

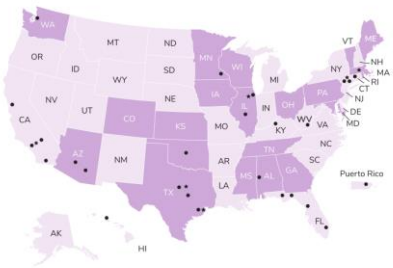
## Pregnancy and Access to Care in Carceral Settings

- Many first learn of pregnancy in jail

| Options counseling & abortion services | Prenatal care & safe environment | Support during and after childbirth |
|---|---|---|

## How common are pregnancy and childbirth in custody?

PIPS
Pregnancy in Prison Statistics




**Collecting Data on Pregnant Incarcerated People**

From 2016-2017, statistics were collected on pregnancy outcomes from a sample of prisons and large jails across the US, representing 57% of females in prison and 5% of females in jail. Participating prisons and jails reported aggregate data on a monthly basis for one year.

- State Department of Corrections
- Jails
- Federal Bureau of Prisons

RESEARCH AND PRACTICE

Pregnancy Outcomes in US Prisons, 2016–2017

Carolyn Sufrin, MD, PhD, Laura Beal, MPH, Jennifer Clarke, MD, MPH, Rachel Jones, PhD, and William D. Mosher, PhD

Original Research

Pregnancy Prevalence and Outcomes in U.S. Jails

Carolyn Sufrin, MD, PhD, Rachel K. Jones, PhD, William D. Mosher, PhD, and Lauren Beal, MPH

| | Pregnancy Admissions | Births | Miscarriages | Abortions | Preterm births | Cesarean |
|---|---|---|---|---|---|---|
| Prison (n=22 +BOP) | N=1396 4% (~3,000) | 753 (92%)* | 46 (6%)* | 11 (1%)* | 6%∫ (0-25%) | 32%∫ (0-63%) |
| PA DOC | N=43 | 32 (97%)* | 1 (3%)* | 0 | 1 (3%)∫ | 6 (19%)∫ |
| Jails (n=6) | N=1622 3% (~55,000) | 144 (64%)* | 41 (18%)* | 33 (15%)* | 8%∫ (0-20%) | 32%∫ (19-80%) |

** % of pregnancies that ended in custody*
*∫ % of live births*

- No maternal deaths
- 3 newborn deaths (2 prison, 1 jail)
- 6 stillbirth (4 prison, 2 jail)
- 6 ectopic (2 prison, 4 jail)

PIPS Pregnancy In Prison Statistics

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# Do incarcerated women have legal right to abortion?

## In theory:[1]

- Constitutional right to abortion (8th &14th Amendments)
- Restricting abortion serves no "penological interest"
- Not "elective" procedure (Monmouth v. Lanzaro 1987)
- Part of routine pregnancy care

## In practice:

- 1% of prison pregnancies ended in abortion
- [illegible]

*"You lose a lot of rights when you're in jail, whether it's trying to get an abortion or watching R-rated movies. . . or smoking or drinking coffee."*

*-Sheriff Arpaio, Arizona (Doe v. Arpaio 2005)*

PSRH
2. Sufrin 2019AJPH
3. Sufrin 2009PSRH

# Pregnancy & Incarceration: Prenatal Care

- Pregnancies at high risk of adverse outcomes
  - Coexisting substance and mental health issues
  - Poor nutritional status
- Variable prenatal care services
  - 12 states had no prenatal care policy
  - 24 had no pre-existing arrangements for delivery

PRISON POLICY INITIATIVE 2019

- "Special privileges"
  - Bottom bunk
  - Extra sandwich and a carton of milk


JOHNS HOPKINS MEDICINE

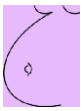
# Pregnancy & Incarceration: Treatment for Opioid Use Disorder

- % Pregnant people admitted with OUD:
  - State prisons: 26% (n=117), Jails: 14% (n=50)[1]
- MOUD not consistently available for pregnant people
  - 46% of jails forced opioid withdrawal[2]
- Most PIPS prisons continued (n=18, 82%) pre-incarceration MOUD for pregnant people, few start (n=4, 18%) [1]
- Most PIPS sites force withdrawal postpartum:[1]
  - Prisons: 61%, Jails: 75%
- Treatment should be non-coercive and patient-centered

JOHNS HOPKINS MEDICINE

1. Sufrin et. al. *Addiction* 2020
2. Kelsey et. al. 2017

# Pregnancy & Incarceration: Labor & Delivery



- Custody staff as triage for medical complaints
- Usually not allowed to have visitors
  - Doula support enhances birth experiences[1]
- **Conflict** over use of restraints in labor
  - "Safety & security"?
  - Human rights
  - Medical risk

JOHNS HOPKINS MEDICINE Nursing

1. Schroeder & Bell 2005 Public Health Nursing

# 30 states (and DC) have laws prohibiting shackling in labor

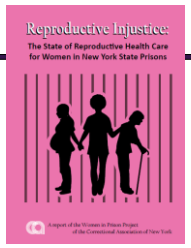

Penn. Statute § 5905 (2010):
--No restraints in labor, delivery, transport (2nd/3rd tri), "medical distress," immediate postpartum, unless correctional staff determine necessary;
--"least restrictive means"; no waist or leg restraints in labor.
--Correctional staff must immediately remove upon request of HC staff.
https://www.legis.state.pa.us/cfdocs/legis/LI/consCheck.cfm?txtType=HTM&ttl=61&div=0&chpt=59&sctn=5&subsctn=0

# Laws are not enough. . .

The New York Times

*Police Forced Bronx Woman to Give Birth While Handcuffed, Lawsuit Says*

2018




2015

JOGNN

RESEARCH

Perinatal Nurses' Experiences With and Knowledge of the Care of Incarcerated Women During Pregnancy and the Postpartum Period

Lorie S. Goshin, D. R. Gina Sissoko, Grace Neumann, Carolyn Sufrin, and Lorraine Byrnes

2019

# What happens after delivery?

Mother and infant separated:

- Infant to pre-designated guardian
- Foster Care
- Supervised family visits in jail

Mother and infant together:

- Mother-infant care programs?
- Invest in family-based alternative sentencing

JOHNS HOPKINS MEDICINE

1. Goshin 2013 Public Health Nursing

# Post-partum care


- Breastfeeding
  - Pumping arrangements?
  - Contact visits w/ newborn?
- Mental health
  - Post-partum depression
  - Cessation of methadone/buprenorphine
- Family Planning
  - Reproductive goals counseling
  - Safe pregnancy spacing
  - Contraception

# Why consider family planning for women in custody?

- Women of reproductive age
- Conjugal visits & furloughs

**Most women return to their communities**

*Thomas DQ 1996 All too Familiar
Clarke 2006 AJPH
Sufrin 2010 J. Urban Health
Clarke 2010 J Corr Health Care
LaRochelle 2012 J Corr Health Care

# Preparing for return: Unmet need for family planning

| Women want to access contraception. . . | |
|---|---|
| Plans to be sexually active when released[1] | 85% |
| Wanted to initiate contraception in custody[2] | 60% |
| Positive pregnancy attitude | 9%[1]-23%[3] |
| **BUT. . . limited availability[3]** | |
| Provide contraception in facility | 38% |
| Oral contraceptive pills | 22% |
| Injectable contraception (Depo Provera) | 18% |
| Intrauterine contraception | 2% |
| Not allowed to continue contraception | 55% |

1. Clarke et al 2006 AJPH
3. Sufrin et al 2010 J Urban Health
3. Sufrin et al 2010 Contraception

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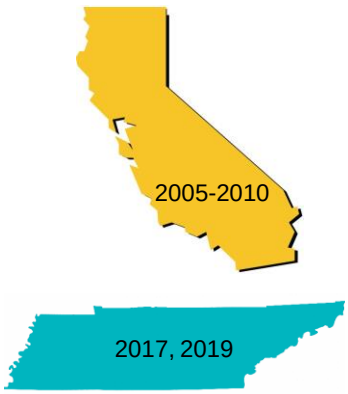
JOHNS HOPKINS HEALTH SYSTEM

# Pre-release contraception: Adaptation to carceral setting

## Potential for coercion

- Limited autonomy in everyday environment
- Fear of punishment
- Perception of message that they should not be reproducing
- Sterilization abuses

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# Pre-release contraception: Adaptation to carceral setting

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- Limited autonomy in everyday environment
- Fear of punishment
- Perception of message that they should not be reproducing
- Sterilization abuses

## Strategies to mitigate

- **Focus counseling on reproductive life goals**
- **Access to range of methods**
- 2 visit protocol for provider controlled methods (IUDs, implants)
- Defer sterilization until after release

ACOG

S HOPKINS
MEDICINE
JOHNS HOPKINS HEALTH SYSTEM

# Summary

- Mass incarceration is a public health and reproductive justice issue
- Reproductive health care in prisons and jails is highly variable in scope and quality
- Incarcerated women have unique reproductive health needs, including access to pregnancy and family planning services

What can you do????

- Compassionate, non-coercive, non-judgmental care
- Provide services on site or in consultation
- Work with local prison/jail officials
- Educate hospital staff, write patient-centered policies

# Resources

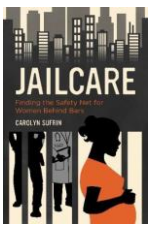
- American College of Obstetricians & Gynecologists acog.org
- American Public Health Association apha.org
- National Commission on Correctional Health Care ncchc.org
- Prison Policy Initiative prisonpolicy.org

# THANK YOU!!!!

ARRWIP
Advocacy and Research on Reproductive Wellness of Incarcerated People

arrwip.org
@arrwip

jailcare.org
@cbsufrin




email: csufrin@jhmi.edu

Jessica Sassani, MD
Division of Urogynecology

September 26th, 2020

# Recurrent UTIs

## Current Management & Best Practices

AHN

## Objectives

- Epidemiology & Pathophysiology
- Making the diagnosis
- Treatment options
  - Acute cystitis
  - Prevention strategies

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# Incidence of Acute Cystitis

Brubaker (2018), *FPMRS.*
Gupta (2013), *BMJ.*

8 million

8 million annual office visits

1 million annual ED visits

1 million

12.6%

Annual incidence of 12.6% (physician diagnosis)

Annual incidence of 3-5% (culture diagnosis) among women ages 20-79 years and 12% among women ages 80 and above

3-5%

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# After the 1st UTI…

Brubaker (2018), *FPMRS*
Gupta (2013), *BMJ.*

30-44% will have a second infection

50% will have a third infection



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## Overall Incidence of Recurrent UTI…

Brubaker (2018), *FPMRS.*
Gupta (2013), *BMJ.*

102 per 100,000 women per year



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## Microbial Pathogenesis

Brubaker (2018), *FPMRS.*
Gupta (2013), *BMJ.*

### Acute Cystitis

- *E. coli*

70-95%

- *Klebsiella pneumonia, Proteus mirabilis, Enterococcus faecalis*

### Recurrent UTIs

- *E. coli*

66%

- *Klebsiella pneumonia, Proteus mirabilis, Enterococcus faecalis*



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# Uropathogenic *E. coli*

Kaper (2004), *Nature Reviews.*

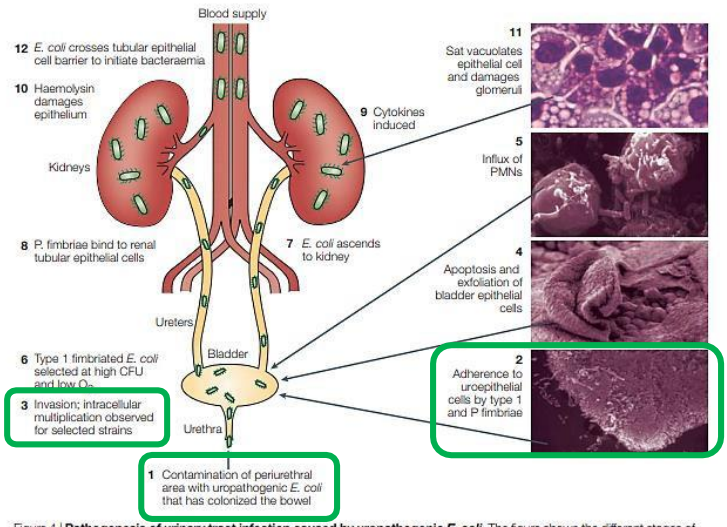


Figure 4 | **Pathogenesis of urinary tract infection caused by uropathogenic *E. coli*.** The figure shows the different stages of a urinary tract infection. Panels 2, 4, 5 and 11 are courtesy of N. Gunther, A. Jansen, X. Li and D. Auyer (University of Maryland), respectively. CFU, colony-forming units; PMNs, polymorphonuclear leukocytes.

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# Host Susceptibilities to UTI

Brubaker (2018), *FPMRS.*
Gupta (2013), *BMJ.*

## Hormone status

## Behavioral factors

- Shown to alter risk: sexual activity, spermicide use, increased fluid consumption
- Not shown to alter risk: post-coital voiding, cotton underwear, wiping away from the urethra

## Genetics

## Anatomy

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Brubaker (2018), *FPMRS.*

# Definition

## Acute Cystitis

- Infection of the lower and/or upper genitourinary tract diagnosed based on the presence of a pathogen in the urinary tract and associated symptoms

## Recurrent UTI

- At least 2 ***culture-proven*** UTIs in 6 months or ≥3 ***culture-proven*** UTIs in 1 year



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Brubaker (2018), *FPMRS.*

# Additional Definitions

- **Relapse:** symptoms caused by the same uropathogen within 2 weeks of completing appropriate antibiotic treatment
- **Recurrence:** symptoms from the same uropathogen more than 2 weeks after completing appropriate antibiotic treatment or symptoms from a different uropathogen at any time

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Chu (2018), *AJOG.*

# Symptoms and Likelihood Ratios (LR)

Increased UTI probability with dysuria (LR 1.5)

Increased UTI probability with dysuria and frequency (LR 1.8)

Decreased UTI probability with vaginal discharge (LR 0.3)

Increased UTI probability with dysuria and frequency, no vaginal discharge (LR 3.1)



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Chu (2018), *AJOG.*

# Urine Culture

## $10^5$ CFUs

- Traditional cut off for positive urine culture
- Based on *E. coli* behavior
- High false negative rate

## $10^2$ CFUs

- 30-50% of women with symptomatic UTIs



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Chu (2018), *AJOG.*

# Asymptomatic Bacteriuria

5% healthy, premenopausal women

2-10% of pregnant women

15% of older women

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# Symptom Overlap

Incontinence

Overactive bladder

IC/PBC


Atrophy



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Brubaker (2018), *FPMRS.*

# Further Evaluation

## Imaging

- Persistent symptoms despite appropriate treatment
- Suspected stone or obstruction
- Concern for abscess

## Cystoscopy

- Suspected foreign body
- Clinical suspicion for malignancy



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# Treatment Options



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## Acute Cystitis Treatment Options

Antibiotics

Non-antibiotic oral medications

Intravesical treatment

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## Acute Cystitis Treatment Options

Antibiot

Non-ant ications

Intraves


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# Acute Cystitis Treatment Options

Antibiotics

Non-antibiotic oral medications

Intravesical treatment

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Brubaker (2018), *FPMRS.*

| | Dose | Notes | Estimated Clinical Efficacy |
|---|---|---|---|
| **Nitrofurantoin (Macrobid)** | 100mg BID x5-10d | • Avoid if suspected pyelonephritis<br>• Included in Beers Criteria | 93% |

American Geriatrics Society 2019 Updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults

*By the 2019 American Geriatrics Society Beers Criteria® Update Expert Panel**

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Brubaker (2018), *FPMRS.*

| | Dose | Notes | Estimated Clinical Efficacy |
|---|---|---|---|
| Nitrofurantoin (Macrobid) | 100mg BID x5-10d | • Avoid if suspected pyelonephritis<br>• Included in Beers Criteria | 93% |
| **Trimethoprim/ sulfamethoxazole (Bactrim)** | 160/800mg BID x3-7d | • Avoid if resistance prevalence known to be ≥20%<br>• Included in Beers Criteria | 93% |

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Brubaker (2018), *FPMRS.*

| | Dose | Notes | Estimated Clinical Efficacy |
|---|---|---|---|
| Nitrofurantoin (macrobid) | 100mg BID x5-10d | • Avoid if suspected pyelonephritis<br>• Included in Beers Criteria | 93% |
| Trimethoprim/ sulfamethoxazole (Bactrim) | 160/800mg BID x3-7d | • Avoid if resistance prevalence known to be ≥20%<br>• Included in Beers Criteria | 93% |
| **Fosfomycin** | 3g single dose | • Avoid if suspected pyelonephritis<br>• In vitro activity against VRE, MRSA and ESBL<br>• Can be expensive or require prior authorization | 91% |

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## West Penn Hospital Antibiogram, January to December 2018
### % of Bacteria Susceptible to the Following Antibiotics

| Organism (Maximum No. Tested) (Based on No. Isolates) | Penicillin | Ampicillin | Oxacillin [Nafcillin] | Cefazolin | Ceftriaxone | Cefepime | Ceftazidime | Gentamicin | Tobramycin | Amikacin | Aztreonam | Ciprofloxacin | Levofloxacin | Imipenem/cilastatin [Meropenem on formulary] | Ertapenem | Erythromycin [Azithromycin] | Clindamycin | Tetracycline [Doxycycline] | TMP/SMX [Bactrim] | Nitrofurantoin | Ampicillin/sulbactam | Piperacillin/tazobactam | Vancomycin | Linezolid | Daptomycin | Colistimethate [Colistin] |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *Staphylococcus aureus* methicillin-susceptible (168) | 3 | | 100 | 100 | | | | 99† | | | | | | | | 61 | 80 | 95 | 99 | 99 | | | 100 | 100 | 100 | |
| *Staphylococcus aureus* methicillin-resistant (121) | 0 | | 0 | 0 | | | | 96† | | | | | | | | 10 | 60 | 92 | 90 | 100 | | | 100 | 100 | 100 | |
| Coagulase-negative *Staph.* (172) | 0 | | 45 | 39 | | | | 77† | | | | | | | | 30 | 53 | 82 | 54 | 96 | | | 100 | 99 | 100 | |
| *Enterococcus* spp. (227) | 81 | 81 | | | | | | 83† | | | | | | | | | | 34 | | 81 | | | 80 | 100 | 98 | |
| *Escherichia coli* (579) | | 52 | | 88 | 94 | 96 | 94 | 94 | 94 | 99 | 62 | 86 | 86 | 100 | 100 | | | | 76 | 97 | 59 | 97 | | | | |
| *Citrobacter freundii* (31)‡ | | 0 | | | 74 | 96 | 71 | 87 | 96 | 100 | | 94 | 96 | 100 | 100 | | | | 71 | 90 | 0 | 71 | | | | |
| *Klebsiella oxytoca* (42)‡ | | 0 | | 76 | 93 | 98 | 93 | 95 | 95 | 100 | 70 | 98 | 98 | 98 | 98 | | | | 95 | 88 | 74 | 95 | | | | |
| *Klebsiella pneumoniae* (150) | | 0 | | 94 | 95 | 96 | 95 | 95 | 94 | 100 | 77 | 95 | 97 | 99 | 99 | | | 50 | 94 | 37 | 87 | 97 | | | | |
| *Proteus mirabilis* (77) | | 79 | | 90 | 99 | 99 | 100 | 97 | 97 | 100 | 75 | 82 | 82 | 100* | 100 | | | | 82 | 0 | 92 | 100 | | | | |
| *Enterobacter aerogenes* (37)‡ | | 1 | | | | 100 | | 100 | 100 | 100 | | 97 | 97 | 100 | 100 | | | | 97 | 14 | 0 | 84 | | | | |
| *Enterobacter cloacae* complex (79) | | 20 | | | | 93 | | 96 | 96 | 100 | 45 | 97 | 97 | 94 | 94 | | | | 97 | 55 | | 80 | | | | |
| *Serratia marcescens* (32) | | 0 | | | 100 | 100 | 100 | 100 | 94 | 100 | 100 | 94 | 94 | 100* | 100 | | | | 100 | 0 | | 100 | | | | |
| *Morganella morganii* (21)‡ | | 0 | | | 100 | 100 | 95 | 100 | 100 | | | 100 | 100 | | | | | | 100 | | 14 | 100 | | | | |
| *Pseudomonas aeruginosa* (128) | | | | | | 97 | 93 | 97 | 99 | 100 | 61 | 91 | 80 | 98* | | | | | | | | 87 | | | | 100 |
| *Acinetobacter baumannii calcoaceticus* complex (18)‡ | | | | | | | | 78 | 83 | | | | | 67 | | | | 88 | | | 78 | | | | | 95 |
| *Stenotrophomonas maltophilia* (28)‡ | | | | | | | 57 | | | | | | 93 | | | | | | 100 | | | | | | | |

90 - 100%
75 - 89%
60 - 74%
<60%



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| Organism (Maximum No. Tested) (Based on No. Isolates) | TMP/SMX [Bactrim] | Nitrofurantoin |
|---|---|---|
| *Staphylococcus aureus* methicillin-susceptible (168) | 99 | 99 |
| *Staphylococcus aureus* methicillin-resistant (121) | 90 | 100 |
| Coagulase-negative *Staph.* (172) | 54 | 96 |
| *Enterococcus* spp. (227) | | 81 |
| *Escherichia coli* (579) | 76 | 97 |
| *Citrobacter freundii* (31)‡ | 71 | 90 |
| *Klebsiella oxytoca* (42)‡ | 95 | 88 |
| *Klebsiella pneumoniae* (150) | 94 | 37 |
| *Proteus mirabilis* (77) | 82 | 0 |
| *Enterobacter aerogenes* (37)‡ | 97 | 14 |
| *Enterobacter cloacae* complex (79) | 97 | 55 |
| *Serratia marcescens* (32) | 100 | 0 |



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Brubaker (2018), *FPMRS.*

## Second Line Antibiotics

- Ciprofloxacin
  - Black box warning for tendonitis and tendon rupture, peripheral neuropathy and CNS effects
  - Can also prolong QT interval and cause myasthenia gravis exacerbation
  - Only recommended for uncomplicated acute cystitis if no other treatment alternative
- Beta-lactams
  - High resistance profiles so not for empiric use
  - Decreased concentration in the bladder reduces efficacy

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## Acute Cystitis Treatment Options

Antibiotics

Non-antibiotic oral medications

Intravesical treatment

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# Non-antibiotic Oral Medication

- Ibuprofen
  - RCT of ibuprofen vs fosfomycin for uncomplicated UTI reported 2/3 ibuprofen group recovered without any antibiotic use but total symptom burden and number of pyelonephritis cases was higher

Gagyor (2015), *BMJ.*

# Non-antibiotic Oral Medication

- Chinese herbal medications (CHM)
  - A review of 7 studies found possible benefit to CHM either alone or with antibiotics; however, the authors noted the studies were at high risk of bias and the medications used are not readily available or subject to FDA regulation

Flower (2015), *Cochrane.*

## Acute Cystitis Treatment Options

Antibiotics

Non-antibiotic oral medications

Intravesical treatment

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## Intravesical Instillation

- Gentamicin instillations
  - 40-80mg in 50cc normal saline at night
  - Possible role in reducing antibiotic resistance among women with recurrent UTIs
- Colistin

Abrams (2017), *Neurourology &UDS.*
Brubaker (2018), *FPMRS.*

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## Preventative Options

Antibiotics

Vaginal estrogen

Other

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Brubaker (2018), *FPMRS.*

## Suppression Antibiotics

- Document a UCx before initiation
- Postcoital prophylaxis should be offered to women who have UTIs temporally related to intercourse
  - Postcoital therapy decreased recurrence rates compared with placebo (0.3 vs 3.6 per patient years, p=.001) and was equally as efficacious as continuous therapy

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Brubaker (2018), *FPMRS.*

# Suppression Antibiotics

- Continuous prophylaxis decreases recurrences by up to 95%
  - Cochrane review found 6-12 months continuous antibiotics were more effective than placebo (RR 0.15; 95% CI, 0.08-0.28)
  - 50-60% of women will have a UTI within 3 months of discontinuing
  - Continuous use *may* increase the risk of bacterial resistance
  - AUGS recommendations: reassess at 3 months and try to discontinue at 6 months

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Brubaker (2018), *FPMRS.*

# Preventative Dosing Regimens

**TABLE 7.** Recommended Antibiotic Prophylaxis Regimens[20,44,119–130]

| Antibiotic Regimens for Prevention | Dose | UTIs Per Year |
|---|---|---|
| Continuous | | |
| Trimethoprim daily | 100 mg | 0–1.5 |
| Trimethoprim/sulfamethoxazole daily | 40 mg/200 mg | 0–0.2 |
| Trimethoprim/sulfamethoxazole every 3 d | 40 mg/200 mg | 0.1 |
| Nitrofurantoin monohydrate/macrocrystals daily | 50 mg | 0–0.6 |
| Nitrofurantoin monohydrate/macrocrystals daily | 100 mg | 0–0.7 |
| Cephalexin daily | 125 mg | 0.1 |
| Cephalexin daily | 250 mg | 0.2 |
| Fosfomycin every 10 d | 3 g | 0.14 |
| Postcoital | | |
| Trimethoprim/sulfamethoxazole | 40 mg/200 mg | 0.3 |
| Trimethoprim/sulfamethoxazole | 80 mg/400 mg | 0 |
| Nitrofurantoin monohydrate/macrocrystals | 50–100 mg | 0.1 |
| Cephalexin | 250 mg | 0.03 |

Adapted from Hooton.[20]

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## Preventative Options

Antibiotics

Vaginal estrogen

Other

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Raz (1998), *NEJM.*

## Vaginal Estrogen Works!

- A RCT of postmenopausal women with rUTI randomized to vaginal estrogen vs placebo showed a significant decrease in UTIs in estrogen group (0.5 vs 5.9 per patient-year)
  - 0.5mg estriol cream daily for 2 weeks then twice weekly for 8 months
  - 0.5mg Premarin cream daily for 1 week then twice weekly
  - Estrogen ring 2mg estradiol, 1 ring for 12 weeks for a total of 36 weeks
- Oral estrogen has not been shown to prevent rUTIs

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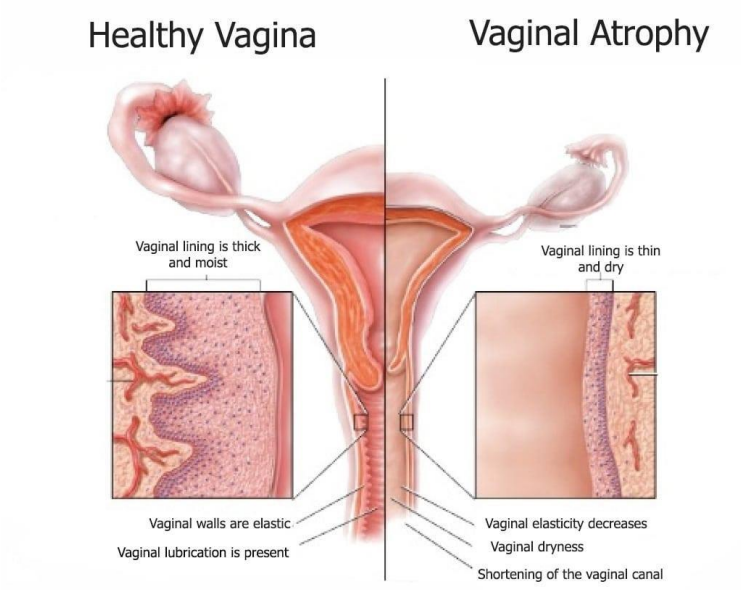
Raz (1998), *NEJM.*

## How does it work?



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## Preventative Options

Antibiotics

Vaginal estrogen

Other

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Hooten (2018), *JAMA*

# Other Preventative Measures

- Water!
  - RCT of young women with recurrent UTIs randomized to normal fluid intake or normal intake with the addition of 1.5L per day
  - Water group had fewer UTIs in a 12 month period than usual care group (1.7 vs 3.2, p<.001)
  - Water group had 2.4 more voids per day than usual care group (p<.001)

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Brubaker (2018), *FPMRS.*

# Other Preventative Measures – Do they work?

Methenamine salts

Cranberry

Probiotics

D-mannose

Vitamin C



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# Future Directions?

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# Clinical Resources

AUGS GUIDELINES FPMRS, 2018

American Urogynecologic Society Best-Practice Statement: Recurrent Urinary Tract Infection in Adult Women

*Linda Brubaker, MD,* Cassandra Carberry, MD,*† Rahel Nardos, MD,‡ Charelle Carter-Brooks, MD,§ and Jerry L. Lowder, MD||*

AHNcentral

Search: antibiogram

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# Patient Resources

www.voicesforpfd.org


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# High Risk Breast Cancer Assessment and Management

Janette P. Gomez D.O.
Breast Surgical Oncologist
High Risk Breast Care Clinic
Allegheny Health Network

## Overview

- Risk Stratification
- Tools for Assessment
  - Tyrer Cuzick Model
  - Gail Model
- Management Options
  - MRI
  - Chemoprevention
- Breast Density
  - Imaging options

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## Stats

- Breast cancer in the 2nd most common cause of cancer death in women in the US

- Average lifetime risk for women in the US is ~13% (1 in 8)
- In 2020 the American Cancer Society estimates that 276,480 cases of invasive breast cancer will be diagnosed in women and 48,530 cases of in situ disease
  - About 42,170 deaths are estimated

- Death rates have been falling an average of 1.8% each year over the course of 2006 through 2015

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We have become much better at preventing disease than treating it.

- D. Lawerence Wickerham, MD

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## Risk Stratification

- Average Risk: <15%
- Intermediate Risk: 15-20%
- High/ Increased Risk: >20-25%

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## Risk Stratification

- Women at increased risk include:
  - Prior history of breast cancer
  - *Lifetime risk >20% as defined by models largely depends on family history*
  - Pedigree suggestive of or a known genetic predisposition
  - Patients who receives thoracic RT between ages of 10-30 years
  - *Women 35 years or greater with 5 year Gail Model risk of 1.7% or greater*
  - Women with a history of LCIS or ADH/ALH and greater than 20% lifetime risk

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## Risk Assessment

- Penn II
- BOADICEA
- BRCAPRO
- Myriad
- Claus
- NCCN guidelines
- Gail model
- Tyrer Cuzick

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## Tyrer-Cuzick

- IBIS model (International Breast Cancer Intervention Study)
- Calculates lifetime risk (to age 85) and 10 year risk
- Compares patient's risk to typical women of same age
- Risk factors chosen were those most supported by the literature
- Currently on version 8b
  - Include breast density (BIRADS density classification)
- The future of Tyrer Cuzick is the addition of SNP panels, alcohol consumption and physical activity

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## Tyrer-Cuzick

| Risk factor<br>*Nominal value and prevalence of high/low risk subgroup* | Specific Category | Residual Lifetime risk |
|---|---|---|
| **Average risk woman** | | 11.4% |
| **No family history** | | 9.9% |
| **Parity and age at first child** | | |
| *Median age: 24y* | First child aged 20y | 8.1% |
| *14% nulliparous* | Nulliparous | 12.1% |
| **Menarche** | | |
| *Median age 13y* | Age 15y | 9.2% |
| *14% 11y or younger; 20% 15y+* | Age 11y | 10.5% |
| **Height and weight** | | |
| *Mean BMI: 28 kg/m$^2$*<br>*33% BMI<25 kg/m$^2$* | 1.6m, 64kg (BMI 25.0) | 8.8% |
| *29% BMI>30 kg/m$^2$* | 1.7m, 87kg (BMI 30.1) | 11.7% |
| **Menopause** | | |
| *Median age 50y*<br>*3 in 4 aged 45-54y* | Postmenopausal at 50y, but exact age unknown | 8.7% |
| | Postmenopausal, at age 49y | 9.7% |
| | Premenopausal at age 50y | 10.7% |

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## Tyrer-Cuzick

| Risk factor<br>*Nominal value and prevalence of high/low risk subgroup* | Specific Category | Residual Lifetime risk |
|---|---|---|
| **HRT (previous use 2yr)** | | |
| *4% current users* [3] | Estrogen only (intend 2yrs more) | 11.1% |
| | Combination (intend 2yrs more) | 11.5% |
| | Combination (intend 5yrs more) | 12.2% |
| **Family history** | | |
| *12% with 1+ affected first degree-relative* [3] | Mother (age 55y) | 19.8% |
| | Mother and Sister (both age 55y) | 24.7% |
| | Mother (bilateral age 55y) | 24.8% |
| **Benign disease** | | |
| *At least 2% proliferative disease in screening sample* [11] | Normal *vs* Hyperplasia | 18.0% |
| | Atypical Hyperplasia | 39.9% |
| **Mammographic density (BI-RADS 4$^{th}$ edition)** | | |
| *Approx. 82% screening-age women BI-RADS 2/3* [10] | 1 (fatty, 0-25%),9% | 5.2% |
| | 2 (scattered, 25-50%), 44% | 8.1% |
| | 3 (heterogeneous, 50-75%), 38% | 12.5% |
| | 4 (extremely dense, 75-100%), 9% | 19.0% |

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## Gail Model

- Age 35 years or older
- Risk factors in the modified Gail Model:
  - Current Age
  - Menarche
  - First live birth or nulliparity
  - Number of female first degree relatives with BC
  - Number of previous benign breast biopsies
  - Atypical hyperplasia in a previous breast biopsy
  - Race
- Gives lifetime and 5 year risk

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## Gail Model

- Not an appropriate model for women with:
  - Predisposing genetic mutation
  - Strong family history of breast or ovarian cancer suggestive of a genetic predisposition
  - History of thoracic RT
  - LCIS
- May not accurately assess breast cancer risk in women who are not Caucasian, Asian or African American
- Since not predominantly based on family history, not recommended for determining benefit from screening breast MRI

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## Management Options

- Clinical encounters every 6-12 month
- Annual screening mammogram
- Breast MRI with contrast
- Referral to Genetic Counselor based on family history
- Chemoprevention
- Risk reduction lifestyle modifications
- Breast awareness

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## Imaging

- Annual screening mammogram (consider tomosynthesis) to begin:
  - 10 yrs prior to youngest family member
  - When diagnosed with atypia
  - When identified to be at increased risk by Gail Model
  - Not prior to age 30
- Breast MRI with contrast to begin:
  - 10 years prior to youngest family member with breast cancer
  - When diagnosed with atypia
  - Not prior to age 25

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## MRI

- Improves detection per nonrandomized studies but to date no randomized control trial that shows improved survival
- Overall, studies have found high sensitivity for MRI, ranging from 71% to 100% versus 16% to 40% for mammography in these high-risk populations
- Most of the available data are based on screening women at high risk due to family history and/or genetic mutations

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## MRI

Limitations:

- Lower specificity
- Call-back rates for additional imaging: 8% to 17%
- Biopsy rates: 3% to 15%
- Distress and anxiety
- Cost
- Limited access to high quality MRI breast screening services
- Physical limitations

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## MRI

- Women at average or intermediate risk?
  - "While the high rate of biopsies and further investigations is acceptable in women with a high risk of breast cancer, the number of such investigations in women at lower risk will be much higher than would be appropriate, leading to the need to counsel women in lower risk categories that MRI screening is not advisable and that the harms are believed to outweigh the benefits."

(NCCN Guidelines Version 1.2019, Breast Cancer Screening & Diagnosis)

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## Chemoprevention

- Gail Model's 5 year risk - 1.7% or higher

- NSABP P1 Trial established that Tamoxifen reduces risk of BC by ~50% in high risk population group
  - Women may be pre- or postmenopausal
  - ~86% reduction in women with atypia and 56% in LCIS
  - Tamoxifen to date is the only drug approved for prevention in BC in premenopausal women
  - Most significant side effects noted in the trial were PE, DVT, stroke, endometrial cancer and cataracts, more so in post-menopausal women

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## Chemoprevention

- Raloxifene (Evista)
  - FDA approved for risk reduction in postmenopausal women
  - Dual benefit of prevention and treatment effects on osteoporosis
  - Not approved for treatment of breast cancer
- P2 (STAR) trial compared Tamoxifen to Raloxifene
  - 19,747 post-menopausal women with Gail risk of 1.7%
  - Found both reduced risk of invasive BC by ~50%
  - Raloxifene had less side effects compared with Tamoxifen
    - Most common side effects: hot flashes and leg cramps
    - Reduced risk for PE, DVT and endometrial cancer

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## Lifestyle Modification

- Limit alcohol to 1 drink/day
- Exercise
  - 150 mins/ week of light-moderate exercise
  - 75 mins/ week of moderate to strenuous exercise
- Maintain proper weight
- No tobacco use
- Healthy diet

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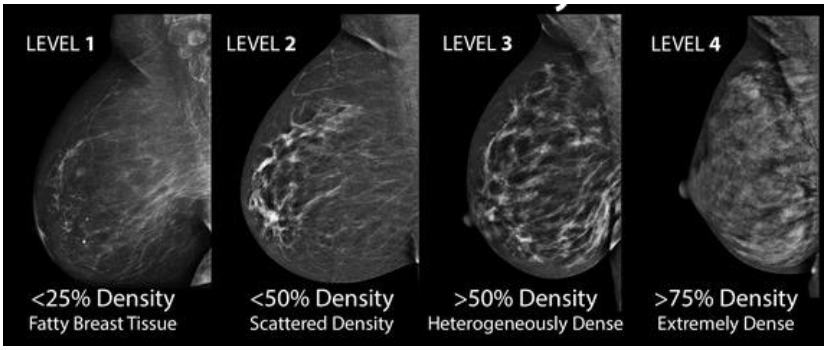
## Breast Density

- Based on mammogram




- "Heterogeneously dense" or "extremely dense" (Class C & D)
- Limit sensitivity of mammography
- Also associated with increased risk for breast cancer

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## Breast Density

- Counsel on risks an benefits of supplemental screening
- Hand held whole breast ultrasound or automated ultrasound can increased cancer detection rates in women with dense breast
  - May increase recall and benign breast biopsies
- MRI is also an option when the patient has dense breast and other risk factors
- Both lack evidence from RCTs on screening efficacy and survival benefits
- Many states have passed legislation mandating patient notification of breast density but few have required insurance coverage for supplemental screening…

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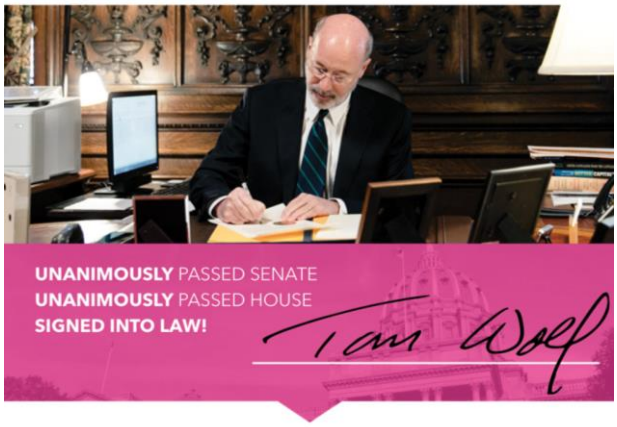
# IT'S THE LAW!

## Governor Wolf Signs Senate Bill 595

*SB 595 will require PA insurers to cover breast MRIs, ultrasounds for many women*




**Governor Tom Wolf** signed our **Senate Bill 595** requiring insurers to cover breast MRIs and ultrasounds for women with very dense breasts and other high-risk factors for breast cancer. The legislation, sponsored by **Sen. Bob Mensch** (R-24), requires insurers regulated under state law to provide coverage for women with:

- **Extremely dense breasts**
- **High-risk factors** for breast cancer such as a personal history of breast cancer, a family history of breast cancer or a genetic predisposition
- **Heterogeneously dense breast tissue** and one other high-risk factor

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## Closing

- Treat the patient, not the number
- Counsel on potential benefits, risks and limitations of breast screening
- Shared decision-making based on the woman's values, concerns and preferences
- Multi-disciplinary approach may be the future

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## Thank you!

Email: Janette.Gomez@ahn.org

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## References


- Saslow, D., et al. (2007), American Cancer Society Guidelines for Breast Screening with MRI as an Adjunct to Mammography. CA: A Cancer Journal for Clinicians, 57: 75-89. doi:10.3322/canjclin.57.2.75
- National Comprehensive Cancer Network (NCCN) Guidelines Version 1.2019 - Breast Cancer Screening and Diagnosis.
- Cuzick J, et al. "Models for Assessment of Breast Cancer Risk." Di Europe Breast Cancer, October 2016.
- https://mammalive.net/resources/decrease-breast-density-reduce-breast-cancer-risk/
- https://www.pabreastcancer.org/governorwolfsignssb595/


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# 2019 ASCCP CONSENSUS GUIDELINES: A PARADIGM SHIFT

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## Disclosures

- Paid Consultant to ASCCP for guidelines process
- Consultant to Inovio DSMB

## Objectives

1. Understand how HPV epidemiology drives risk-based cancer prevention
2. Understand why risk-based management represents an improvement in care
3. Learn fundamentals of risk-based guidelines for managing patients

How were these updated guidelines for management of abnormal screening tests and cancer precursors developed and finalized?

19 Participating Organizations

## Patient Advocacy Organizations

- American Sexual Health Association
- Cervivor
- Latino Cancer Institute
- Team Maureen

## Federal Agencies

- Centers for Disease Control & Prevention
- National Cancer Institute

- **Medical Professional Societies**
- ASCCP
- American Academy Of Family Physicians
- American Cancer Society
- American College Of Nurse-Midwives
- American College Of Obstetricians and Gynecologists
- American Society For Clinical Pathology
- American Society Of Cytopathology
- College Of American Pathologists
- Nurses For Sexual And Reproductive Health
- Nurse Practitioners In Women's Health
- Papanicolaou Society Of Cytopathology
- Society Of Gynecologic Oncology
- Women Veterans Health Strategic Healthcare Group

## What data were used/ how do we know they are representative?

### Kaiser Permanente Northern California Data (KPNC)

- Largest/longest real clinical experience with HPV-based screening in the world
  - Over 1.5 million women with routine cotesting from 2003-2017
  - HPV genotyping for ~19,000 patients

- Provides risk-based evidence for most of the common decision points that occur in screening
  - Long length of follow-up allows use of past-history for more personalized management

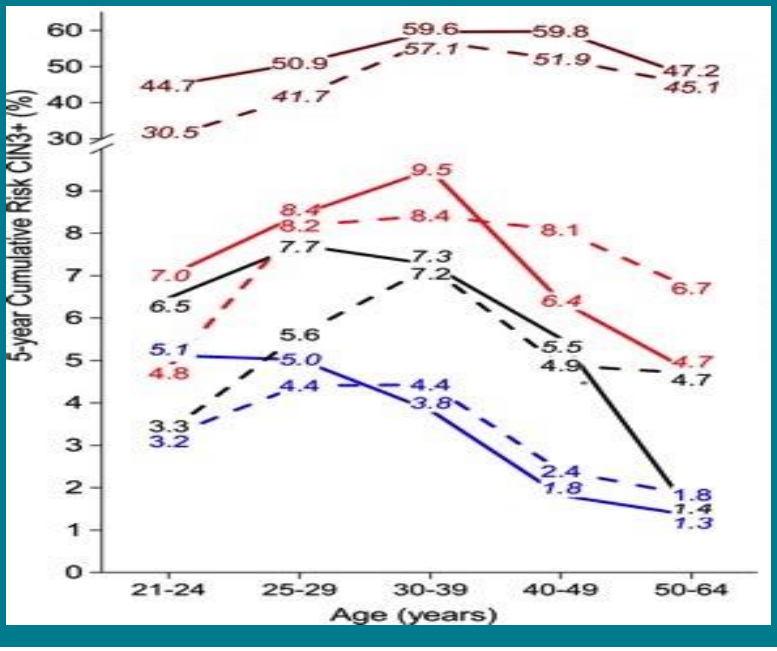
Cheung LC et al J Low Genit Tract Dis 2020;24(2):90-101.

## Validation of risk and risk-based management

- KPNC Cohort (~1.5m)

- New Mexico HPV Pap Registry (~450k, previous study)
- CDC NBCCEDP - well-screened (~200k)
- CDC NBCCEDP - rarely/never/unknown screened (~150k)
- BD Onclarity Trial (~30k with genotyping)

## Risks similar for KPNC and New Mexico

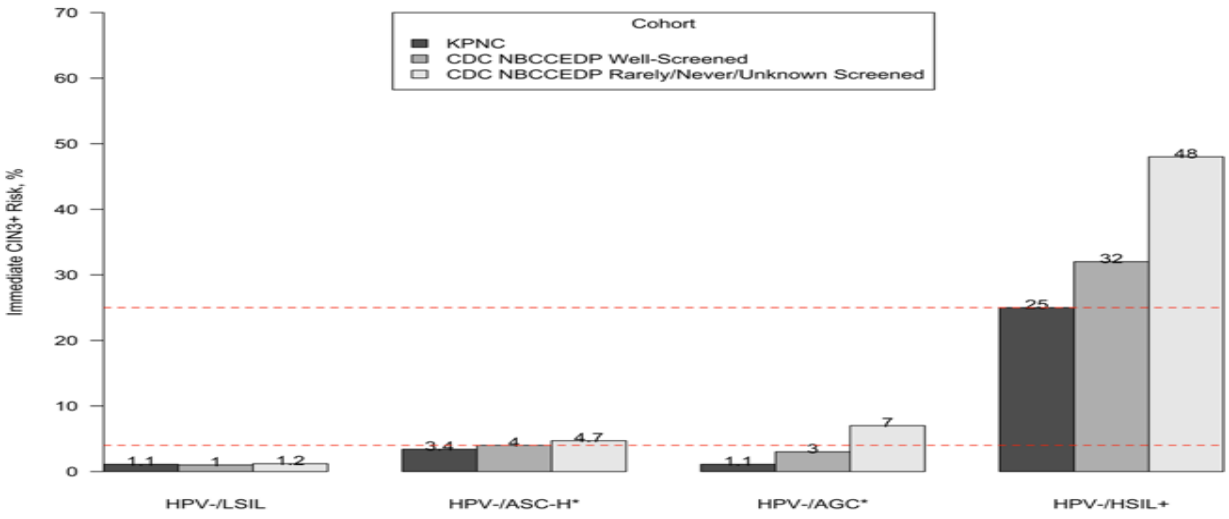



**Baseline Screen:**
**HSIL**
**LSIL**
**HPV-positive/ASC-US**
**ASC-US**
**HPV-negative/ASC-US**
**Pap-negative**

---- KPNC
NMHPVPR

Gage…Wheeler, Obstet Gynecol 2016

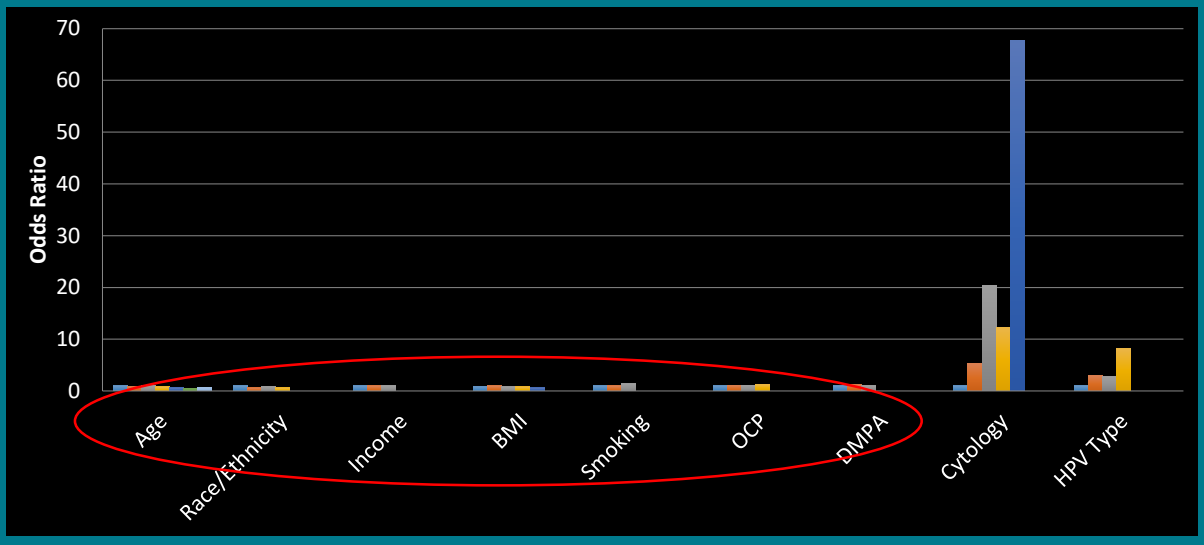
# Risk-based management portable to other studies




Perkins & Guido et al, JLGTD, 2020; Saraiya, submitted

# Which risk factors influence pre-cancer development?

## Risk factors and Risk of CIN2+ (KPNC data)




## HPV vaccination: important but NOT included (yet)

- HPV vaccination prior to age 18 reduces the CIN3+ risk by 50%

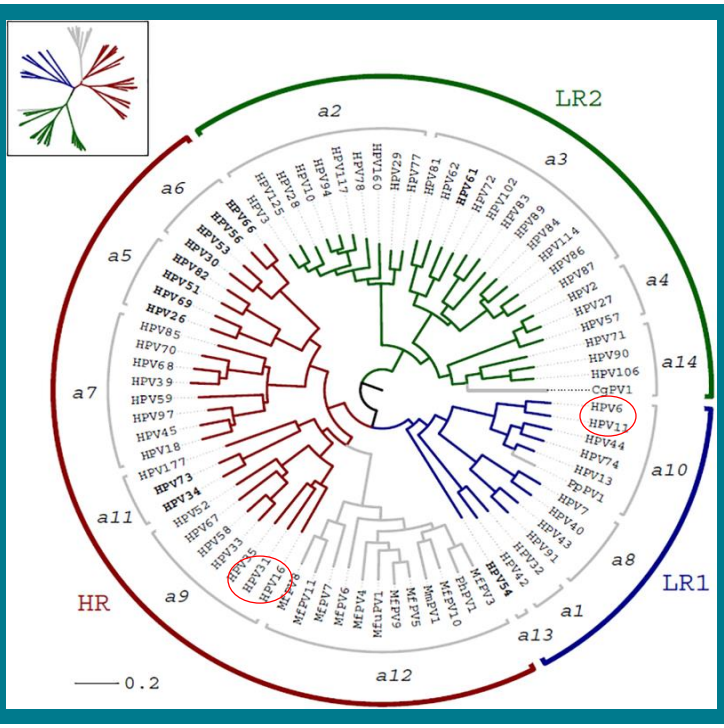
HOWEVER

- Current cohort is 21-24 years, a group already conservatively managed.
- 50% age eligible female first dose vaccine population coverage achieved 2015
- Documentation of vaccination and age at which vaccine is necessary to apply this factor correctly—*historically guidelines have not included factors clinicians can't document*
- Vaccination will impact age to start screening in the future
- Management will likely change as vaccinated cohorts age
- Target age 11-12 years, most not yet older than 25

# Fundamental Concept #1

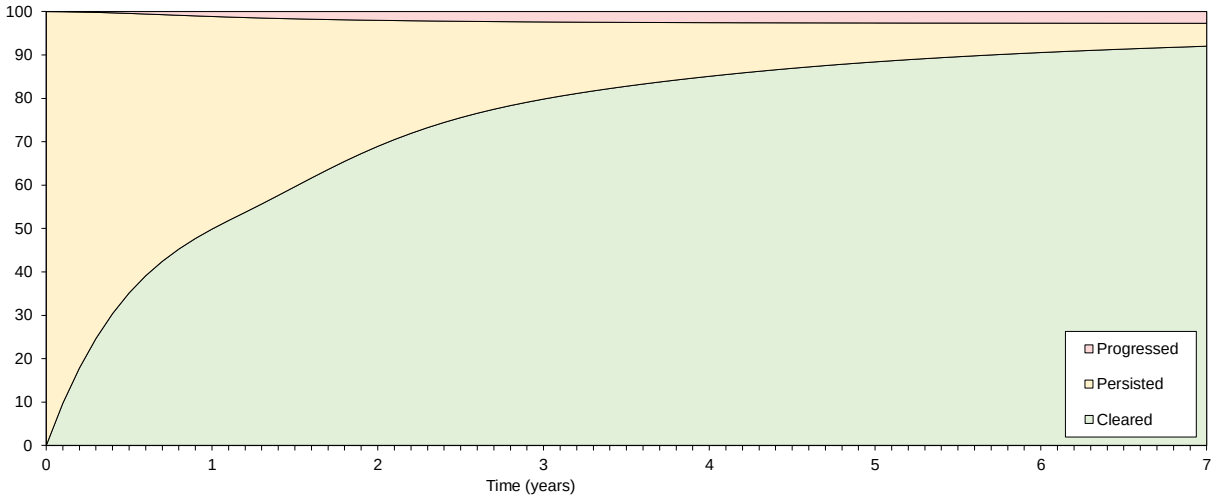
- The longer an HPV infection has been present, the higher the risk of pre-cancer and cancer
  - *Time matters*
  - *Type matters (HPV 16 most dangerous)*
  - *Other patient factors don't matter if you know about HPV*
  - *CLINICAL CORRELATE: Colposcopy is always needed following two consecutive positive HPV tests*

**High Risk HPV types are related and are causally linked to cancer**



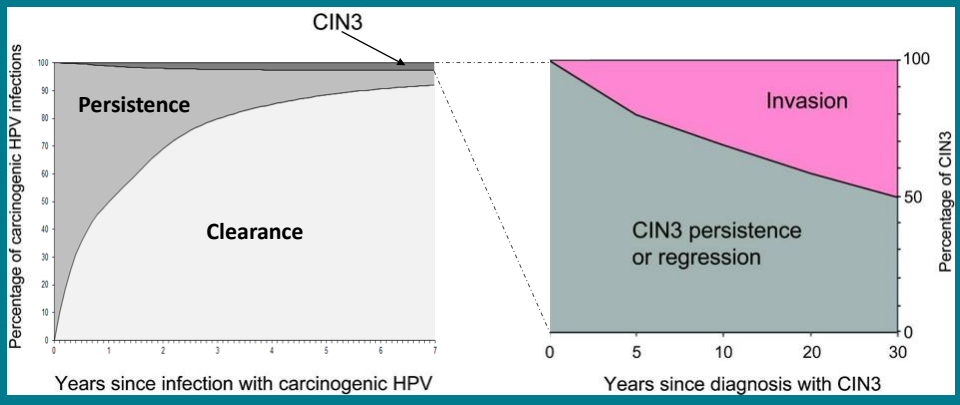

Chen Z, Schiffman M et a. Virology, 2018

## Most HPV infections become undetectable in 1-3 years those that persist cause CIN3+ over time




Rodriguez ac. Et al J Natl Cancer Inst. 2008 2;100(7):513-7

## Precancer and cancer increase markedly when infections persist for 5 years or more




McCredie et al., . Lancet Oncol. 2008 May;9(5):425-34.

**Screening distinguishes normal from abnormal**

↓

**Colposcopy with biopsy detects CIN3 ("pre-cancer")**

↓

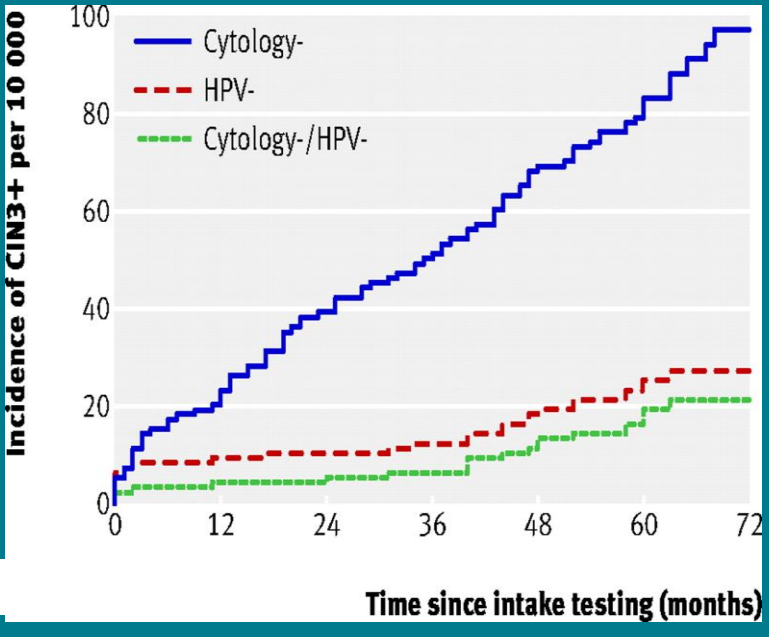
**Treating CIN3 prevents cancer**

↓

**Goal of screening is to detect CIN3 and *prevent* cervical cancer**

## HPV-based screening is better than cytology alone

- Cytology (Pap testing) is less sensitive than HPV testing
  - Detects 50-70% of CIN3+ vs >90%
- Cytology alone does not confer long-term protection against CIN3+ following a negative test




Dillner, BMJ 2008 Oct 13;337:a1754

## New guidelines prefer HPV testing for follow up

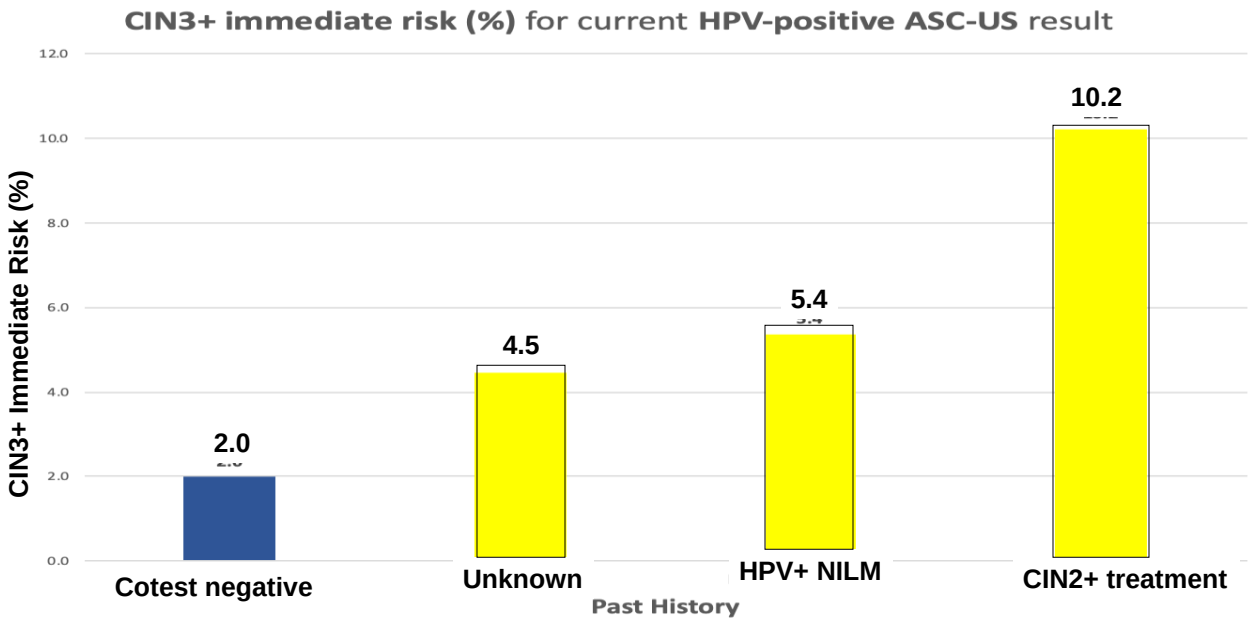
- Surveillance with cytology alone is acceptable only if testing with HPV or cotesting is not feasible.
- Cytology is less sensitive than HPV testing for detection of precancer, and is therefore recommended more often.

- **Cytology is recommended at 6-month intervals when HPV testing or cotesting is recommended annually.**
- **Cytology is recommended annually when 3-year intervals are recommended for HPV or cotesting**.

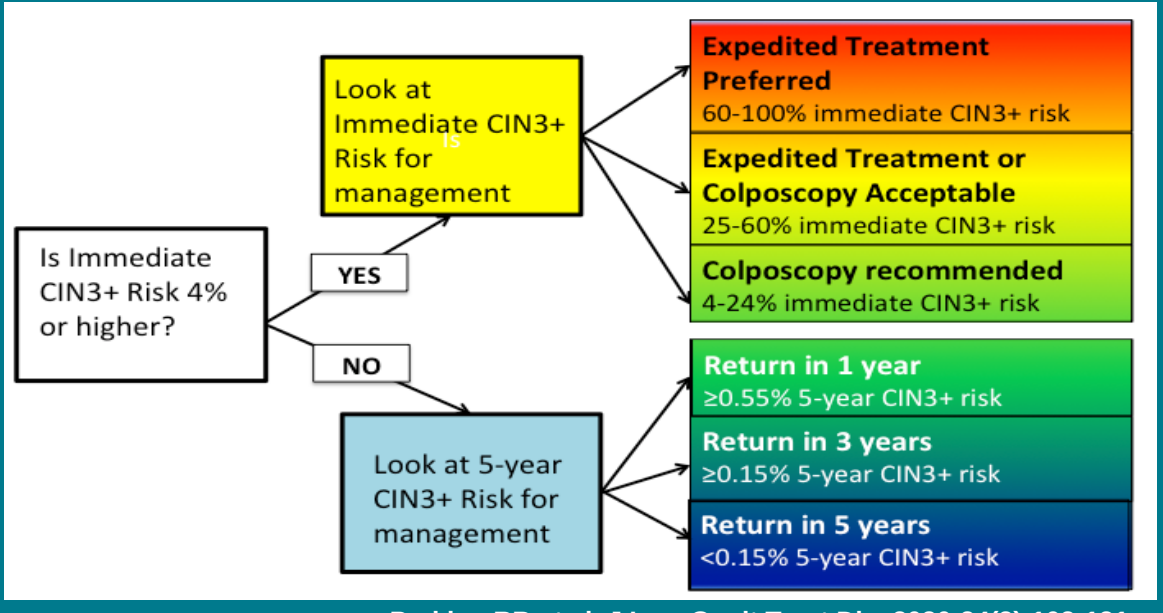
## Fundamental concept #2:
## Management is based on risk, not results

- Recommendations of colposcopy, treatment, or surveillance are based on a patient's risk of CIN3+ determined by a combination of **current results** and **past history** *(including unknown history)*.
- The same current test results may yield different management recommendations depending on the history of recent/ past test results and other risk factors.

# Past history influences current risk




# Patients stratified into risk levels




Perkins RB et al. J Low Genit Tract Dis. 2020;24(2):102-131.

***Safer* for high-risk patients**

***Fewer unnecessary invasive procedures* in low-risk patients**

***Enduring:* Clinical Action Thresholds allow cancer prevention to remain constant in a landscape of changing test options and decreasing HPV prevalence**

## Safer: Define high risk patients to focus resources

<u>High-risk concepts similar to 2012 guidelines:</u>

- Histologic HSIL (CIN2+) on biopsy remains the threshold for treatment in the general population
- CIN3 should always be treated (except in pregnancy)
- CIN2 has the option of treatment or observation with colposcopy/biopsy for those concerned with treatment effects on future pregnancy

**Safer:** Define high risk patients so resources can be focused on them

- High-grade cytology with HPV 16 infections are highest risk
  - >75% risk of any precancer (histologic HSIL or CIN2+)
  - >60% risk of highest-grade precancer (CIN3+)

Demarco M. et al. J Low Genit Tract Dis. 2020;24(2):144-147.

## 2019 Management Guidelines
## Highest risk patients receive expedited treatment

- Excisional treatment for patients at high risk of pre-cancer without requiring confirmatory biopsy

## Risk /Benefit Analysis

| HPV | Cytology | CIN 3+ Immediate Risk % | Number of LEEPs to treat 1 CIN3+ |
|---|---|---|---|
| POS | HSIL+ | 48.9 | 2.1 |
| POS | AGC | 26.3 | 2.3 |
| POS | ASC-H | 25.7 | 2.8 |
| NEG | HSIL+ | 25.2 | 2.8 |

https://CervixCa.nlm.nih.gov/RiskTables.

## Clinical Action Thresholds for Expedited Treatment (without confirmatory colposcopic biopsy)

**Immediate Risk of pre-cancer (CIN 3+)**

| | |
|---|---|
| <25% | Level below which colposcopy and biopsy is preferred |
| ≥25-59% | Immediate excisional treatment or treatment after colposcopy with biopsy confirmation are acceptable |
| >60% | Immediate excisional treatment is preferred, treatment after colposcopy with biopsy confirmation is acceptable |

**Not recommended for patients age <25 and pregnant women*

## Additional Key Changes in 2019 Guidelines

1) Excisional treatment is preferred to ablative treatment for histologic HSIL (CIN2 or CIN3) in the United States.
   - Excision is recommended for adenocarcinoma *in situ* (AIS).

2) Observation is preferred to treatment for CIN grade 1 (CIN1).
   - Treatment remains acceptable for patients with repeat diagnoses of CIN1 persisting 2 years or more.

## Changes to follow-up after treatment of CIN2/3

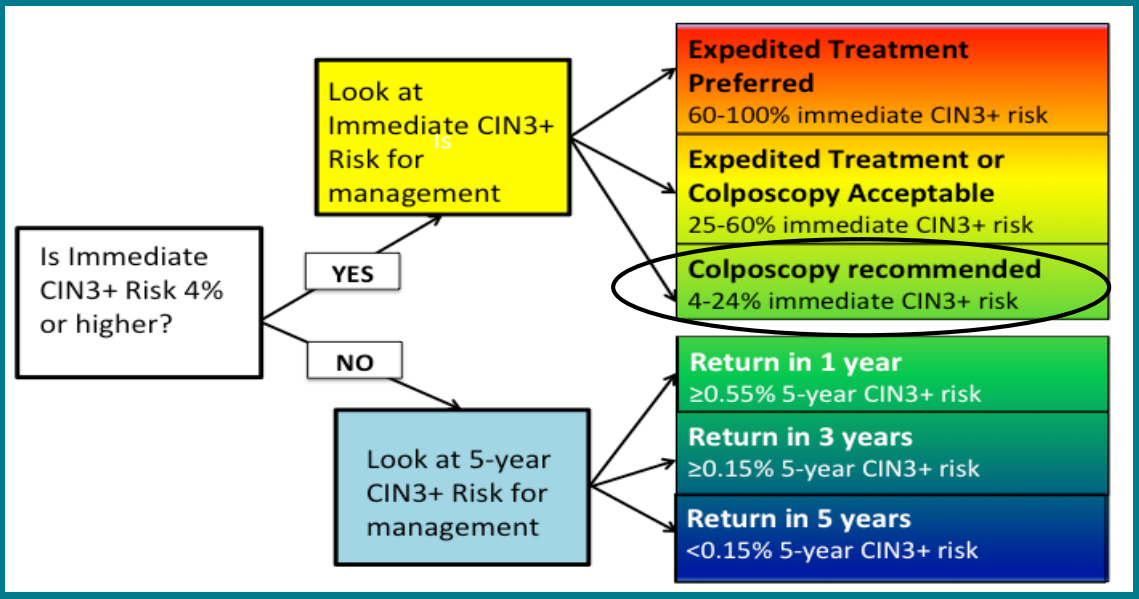
- HPV-based testing at 6 months, then annually for 3 years
- Continued surveillance with HPV testing or co-testing at 3-year intervals for at least 25 years
- Continued surveillance at 3-year intervals beyond 25 years is acceptable for as long as the patient's life expectancy and ability to be screened are not significantly compromised by serious health issues.

*Note: 2012 guidelines recommended return to 5-yr screening intervals and did not specify when screening should cease. New evidence indicates that risk remains elevated for at least 25 yrs, with no evidence that treated patients ever return to risk levels compatible with 5-yr intervals.*

## Avoid unnecessary procedures in low-risk patients

- Colposcopy with biopsy of the cervix is recommended based on risk, not just test results
- Low-grade abnormal results (ASCUS/LSIL) have historically been the colposcopy referral threshold
  - *Is this still valid?*

## Patients stratified into risk levels




Perkins RB et al. J Low Genit Tract Dis. 2020;24(2):102-131

## Immediate CIN3+ Risk by Co-test (KPNC)

| HPV | Pap | N | % | Immediate risk (%) | Colposcopies per CIN3+ diagnosis |
|---|---|---|---|---|---|
| Pos | HSIL+ | 3980 | 0.3% | 48.86 | 2.1 |
| Pos | ASC-H | 3766 | 0.2% | 25.73 | 2.8 |
| Neg | HSIL+ | 183 | 0.0% | 25.21 | 2.8 |
| Pos | ASC-US | 30506 | 2.0% | 4.45 | 8.6 |
| Pos | LSIL | 23659 | 1.5% | 4.27 | 11.3 |
| Pos | NILM | 63541 | 4.1% | 2.13 | 18.3 |
| Neg | LSIL | 3300 | 0.2% | 1.05 | 19.0 |
| Neg | ASC-US | 25331 | 1.6% | 0.04 | 22.6 |
| Neg | NILM | 1388153 | 89.8% | 0.002 | 219.4 |

https://CervixCa.nlm.nih.gov/RiskTables

## 2019 Management Guidelines Colposcopy Threshold

When individuals have an estimated immediate risk of diagnosis of CIN3+ of 4.0% or greater based on prior history and current results, referral to colposcopy is recommended.

## Documented prior negative HPV (KPNC)

| HPV | Pap | Immediate risk (%) after prior HPV neg | Immediate risk (%) no prior HPV test |
|---|---|---|---|
| Pos | HSIL+ | 32.28 | 48.86 |
| Pos | ASC-H | 13.56 | 25.73 |
| Neg | HSIL+ | 13.80 | 25.21 |
| Pos | LSIL | 2.10 | 4.27 |
| Pos | ASC-US | 2.03 | 4.45 |
| Pos | NILM | 0.74 | 2.13 |
| Neg | LSIL | 0.44 | 1.05 |
| Neg | ASC-US | 0.014 | 0.04 |
| Neg | NILM | 0.001 | 0.002 |

**LSIL/ASCUS no longer meets colposcopy threshold**

**Egemen D et al. J Low Genit Tract Dis 2020;24(2):132-143.**

## Impact of HPV type with prior negative HPV test (KPNC)

| HPV Type | PAP Category | CIN3+ Immediate risk (%) | Cancer Immediate risk (%) |
|---|---|---|---|
| HPV16+ | ASC-US | 5.34 | 0.33 |
| HPV 16+ | LSIL | 6.70 | 0.89 |

**HPV16 positive ASC-US and LSIL still exceed 4% threshold*

**https://CervixCa.nlm.nih.gov/RiskTables**

## Special Situations:
## HPV18, HPV-negative AGC, and ASC-H

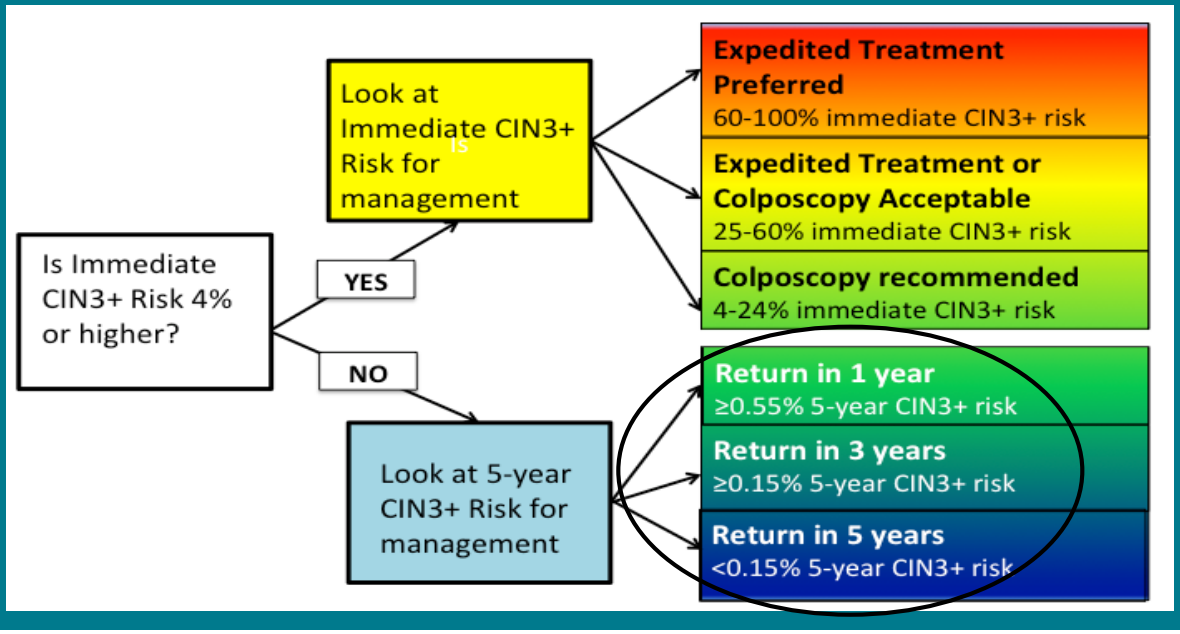
- Disproportionately important for invasive cancer
- Using medium-term risk of CIN3+ does not lead to colposcopy using Clinical Action Threshold of 4% risk.
- Consider absolute risk of cancer in addition to risk of precancer for safety

## Key change in 2019 Guidelines

**Colposcopy can be deferred for certain patients.**

- Repeat HPV testing or cotesting at 1 year is recommended for patients with minor screening abnormalities indicating HPV infection with low risk of underlying CIN3+ (e.g., low-grade cytologic abnormalities following a documented negative screening HPV test or cotest).

# Patients stratified into risk levels




# ASSUMPTION: Intervals for retesting should reflect underlying risk (*equal management for equal risks*)

- Define surveillance intervals
- Define threshold to release patients back to general population screening
- Define risk thresholds for short interval follow up at 1 and 3 years
- Determine which tests to use for surveillance and at what intervals
  - HPV alone, HPV/cytology cotesting, cytology (Pap) alone

## Surveillance intervals in 2019 Management Guidelines

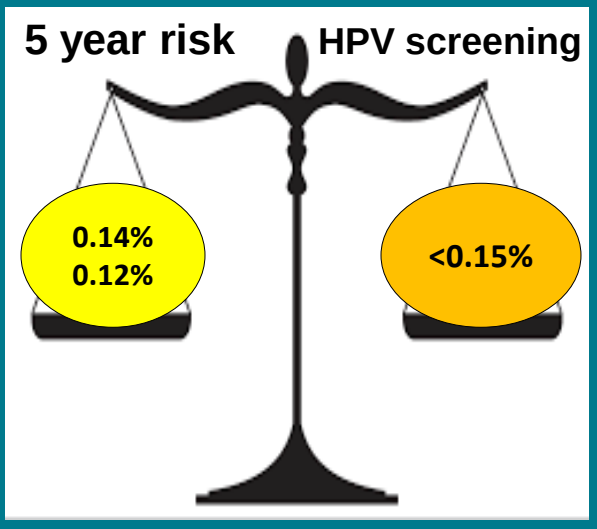
- Goal = simplicity and excellent care
- No compelling reason to change intervals
- Providers are familiar with 1, 3, and 5-year follow up intervals.
- Health systems/tracking features built around these intervals


## Surveillance intervals

| 5-Year Return: | 3-Year Return: | 1-Year Return: |
|---|---|---|
| CIN3+ risks equivalent to general population with one negative HPV or cotest | CIN3+ risks between 3 year and 5 year return thresholds | CIN3+ risks between colposcopy threshold and 3 year return threshold |

## 5-year Return Clinical Action Threshold

- Risk should be similar to that of negative HPV test or cotest in a screening population
- 5 year CIN3+ risk based on the general population at KPNC
  - HPV screening alone = 0.14%
  - Co-testing = 0.12%




Egemen D et al. J Low Genit Tract Dis. 2020;24(2):132-143

## 5-year Return Clinical Action Threshold

**Guideline:**

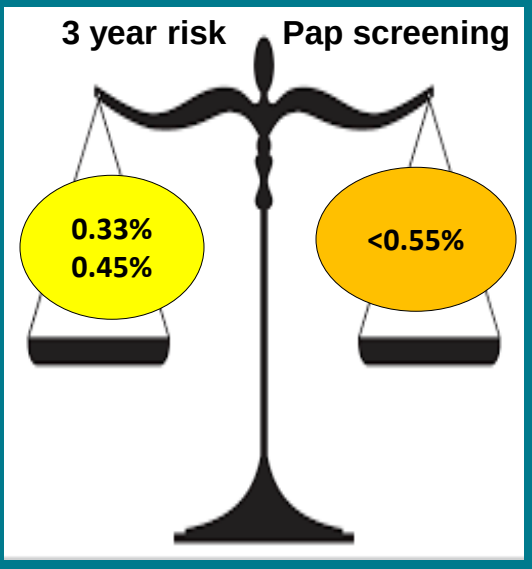
- **When patients have an estimated 5-year CIN3+ risk of <0.15% based on past history and current test results, return to routine screening at 5-year intervals using HPV-based testing is recommended.**

- *Note HPV-based testing is cotesting or primary HPV testing*

## 3-year return Clinical Action Threshold

- Risk should be similar to that of negative Pap test in a screening population

- Five-year CIN3+ risks:
  - **0.33%** estimated in KPNC
  - **0.45%** projected in CDC breast and cervical cancer screening program




Perkins RB et al. J Low Genit Tract Dis. 2020;24(2):102-131

## 3-year Return Clinical Action Threshold

**Guideline:**

- **When patients have an estimated 5-year CIN3+ risk ≥0.15% but <0.55% based on past history and current test results, repeat testing in 3 years with HPV-based testing is recommended**

- *Note HPV-based testing is cotesting or primary HPV testing*

## Clinical examples of 3-year return

| Result | CIN3+ risk at 5 years |
|---|---|
| HPV-negative ASC-US screening result | 0.40% |
| HPV-negative LSIL → HPV-negative NILM cotest | 0.40% |
| Low-grade cotest → colposcopy CIN1 → HPV-negative NILM follow-up | 0.42% |
| CIN2/3 treated with LEEP → 3 negative cotests | 0.35% |

## 1-year Return Clinical Action Threshold

**Guideline:**

- **When patients have an estimated risk of CIN3+ based on past history and current results that is below the threshold for immediate colposcopy (4.0% immediate risk) and above the 3-year follow-up threshold (≥0.55% at 5 years), repeat testing in 1 year with HPV-based testing is recommended**

- *Note HPV-based testing is cotesting or primary HPV testing*

## Screening results leading to *1-year Return*

| Result | CIN3+ immediate risk % |
|---|---|
| HPV-positive NILM | 2.1% |
| HPV-negative LSIL | 1.0% |

Egemen D et al. J Low Genit Tract Dis. 2020;24(2):132-143

## Post-colposcopy results leading to 1-year return

| Pre-colposcopy test result | Colposcopy result | Post-colposcopy test result | Immediate CIN3+ risk |
|---|---|---|---|
| Low-grade* | <CIN2 | HPV-positive NILM | 2.0% |
| Low-grade* | <CIN2 | HPV-positive ASCUS/LSIL | 3.1% |

**Low-grade defined as HPV+/NILM, ASC-US, or LSIL cytology*

Egemen D et al. J Low Genit Tract Dis. 2020;24(2):132-143

# Key changes to 2015 primary HPV testing interim guidance

All positive HPV tests, regardless of genotype, should have additional reflex triage testing performed from the same laboratory specimen (e.g., reflex cytology).

- Additional testing from the same laboratory specimen is recommended because the findings may inform colposcopy practice. For example, those with HSIL cytology and concurrent positive testing for HPV genotype 16 qualify for expedited treatment.
- HPV 16 or 18 infections have the highest risk for CIN3 and occult cancer, so additional evaluation (e.g., colposcopy with biopsy) is necessary even when cytology results are negative.
- If HPV 16 and 18 testing is positive, and additional laboratory testing of the same sample is not feasible, the patient should proceed directly to colposcopy.

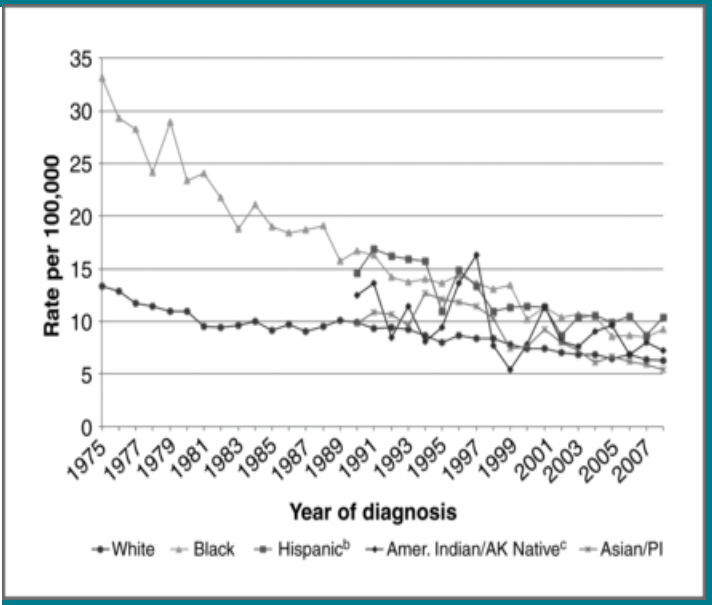
***Safer for high-risk patients***

***Fewer unnecessary invasive procedures in low-risk patients***

***Enduring: Clinical Action Thresholds allow cancer prevention to remain constant in a landscape of changing test options and decreasing HPV prevalence***

## *Enduring:* designed to accommodate future changes

- Programs based on cervical cytology (Pap tests) with colposcopy referral for LSIL+ have been very successful
- Meaning of LSIL is changing: less risky following prior negative HPV test
- Risk thresholds designed around existing colposcopy referral patterns to preserve existing standard of cancer prevention while avoiding unnecessary procedures




Pierce Campbell. et al. CEPB 2012 21(9):1402

## *Enduring:* defined risks for referral to colposcopy and treatment based on successful historical standards

- Historically, ASCUS HPV+/LSIL as a referral threshold has been very successful to detect CIN3+ and prevent cancer
  - Risks of CIN3+ for these results were historically 4-12%
- HPV-positive ASCUS/LSIL results are becoming LESS RISKY
  - Risks of CIN3+ are halved following a prior negative HPV test or on time HPV vaccination (prior to age 18)

## *Enduring:* defined risks for referral to colposcopy and treatment based on successful historical standards

- 2019 Guidelines Framework designed to preserve cancer prevention while decreasing unnecessary colposcopy in the setting of
  - Decreasing CIN3+ prevalence as vaccinated populations age into screening cohorts
  - Decreasing CIN3+ prevalence as populations undergo multiple rounds of HPV-based screening

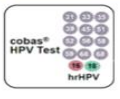
## *Enduring:* accommodates new tests in development

**Cytology-based**

Cytology / Automation

**Molecular**

HPV genotyping



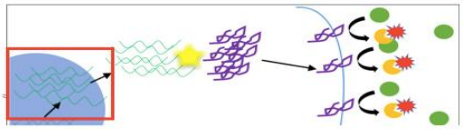

Methylation


**Visual**

VIA / Automation

p16/Ki-67 / Automation

In-vivo imaging



## *Enduring:* accommodates new tests in development

- Previously, new guidelines and interim guidance were required as each new test became clinically available
- As the nature of HPV carcinogenesis is better understood, the pace of technology development would lead to frequent interim guidance
- Frequently changing guidelines are confusing for clinicians and can create errors in patient care

## *Enduring:* accommodates new tests in development

- Establishment of risk-based thresholds means that new tests can be evaluated against existing thresholds instead of making new algorithms for each new test
  - Test characteristics will be objectively compared to existing Clinical Action Thresholds
  - Standardized, transparent clinical guidance will logically follow from test characteristics and existing consensus thresholds
  - Reduces the need for interim guidance and frequent consensus conferences

## With tremendous thanks to:

- NCI statistical team
- KPNC team
- ASCCP staff
- Working Group participants
- Steering committee members
- Consensus Voting Participants

Allegheny Health Network

# Hepatitis C and Pregnancy

Jean FitzGibbons, CRNP

Allegheny General Hospital | Allegheny Valley Hospital | Canonsburg Hospital | Forbes Hospital | Jefferson Hospital | Saint Vincent Hospital | Westfield Hospital | West Penn Hospital

## Objectives

- Epidemiology of Hepatitis C
- Hepatitis C screening
- HCV transmission
- Acute vs. chronic HCV
- HCV treatment
- General guidelines when caring for HCV patients

# Prevalence of HCV

- 2.4 million Americans are living with HCV
- In 2018, 9% of newly reported chronic HCV cases were in Pennsylvania
- Rate of acute HCV infections in Pennsylvania was 1.9 per 100,000 (national average: 1.2)

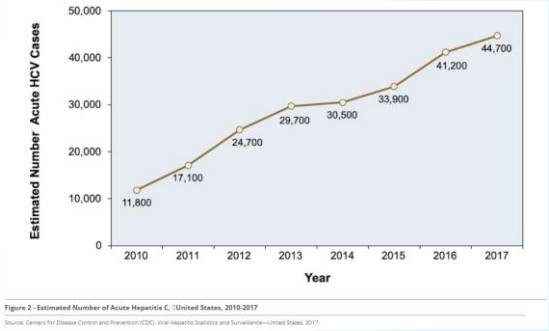


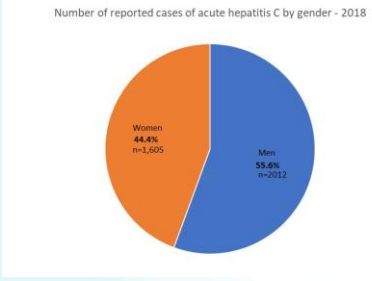

Figure 2 - Estimated Number of Acute Hepatitis C, United States, 2010-2017

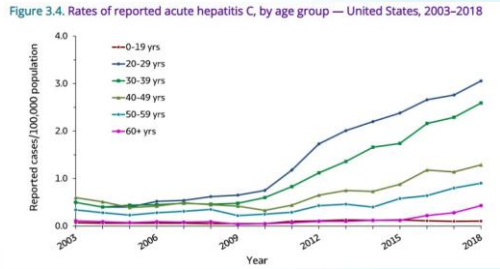
Source: Centers for Disease Control and Prevention (CDC). Viral Hepatitis Statistics and Surveillance—United States, 2017.

Sources:
Centers for Disease Control and Prevention (CDC). Viral Hepatitis Surveillance Report 2018 - Hepatitis C. https://www.cdc.gov/hepatitis/statistics/2018surveillance/HepC.htm#Table3.4.
Hofmeister MG, Rosenthal EM, Barker LK, et al. Estimating prevalence of hepatitis C virus infection in the United States, 2013–2016. *Hepatology*. 2019;69(3):1020-1031.doi: 10.1002/hep.30297



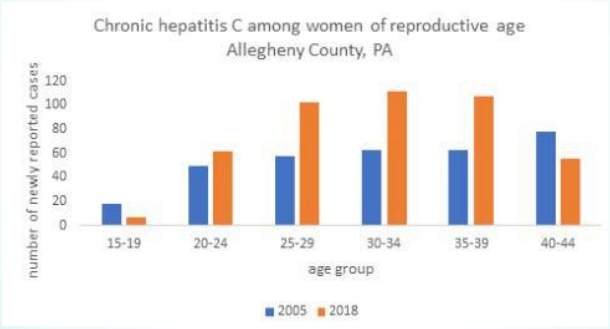
# Demographics of Acute HCV in the US




Source:
Centers for Disease Control and Prevention (CDC). Viral Hepatitis Surveillance Report 2018 - Hepatitis C. https://www.cdc.gov/hepatitis/statistics/2018surveillance/HepC.htm#Table3.4. Published August 28, 2020. Accessed September 7, 2020

# Hepatitis C in Allegheny County




Source:
Fiddner, J (2020, Sept 6). Personal communication [Email].



## Hepatitis C Screening in Pregnancy

### CDC Recommendations for Hepatitis C Screening Among Adults in the United States

- Universal hepatitis C screening:
  - Hepatitis C screening at least once in a lifetime for **all adults** aged 18 years and older, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is less than 0.1%*
  - Hepatitis C screening for **all pregnant women during each pregnancy**, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is less than 0.1%*

Source:
Centers for Disease Control and Prevention (CDC). Testing Recommendations for Hepatitis C Virus Infection. https://www.cdc.gov/hepatitis/statistics/2018surveillance/HepC.htm#Table3.4.

# Hepatitis C Screening in Pregnancy

AASLD AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C

IDSA Infectious Diseases Society of America

## HCV Testing and Linkage to Care

### One-Time Hepatitis C Testing

**Recommendations for One-Time Hepatitis C Testing**

| RECOMMENDED | RATING |
|---|---|
| One-time, routine, opt out HCV testing is recommended for all individuals aged 18 years or older. | I, B |
| One-time HCV testing should be performed for all persons less than 18 years old with activities, exposures, or conditions or circumstances associated with an increased risk of HCV infection (see below). | I, B |
| Prenatal HCV testing as part of routine prenatal care is recommended with each pregnancy. | I, B |

Source:
American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA). HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. https://www.hcvguidelines.org/evaluate/testing-and-linkage.



# Hepatitis C Screening in Pregnancy

ACOG The American College of Obstetricians and Gynecologists

***The following recommendations are based on limited or inconsistent scientific evidence (Level B):***

- Routine prenatal HCV screening is not recommended; however, women with significant risk factors for infection should be offered antibody screening.
- Route of delivery has not been shown to influence the risk of vertical HCV transmission, and cesarean delivery should be reserved for obstetric indications in women with HCV infection.

Source:
The American College of Obstetricians and Gynecologist. Viral hepatitis in pregnancy. ACOG Practice Bulletin No. 86. American College of Obstetricians and Gynecologists. Obstet Gynecol 2007;110:941–55.

# When considering HCV transmission

- Was discovered in 1989
- Many individuals have no symptoms with acute infection
- HCV can survive outside of the body at room temperature for up to 3 weeks
- HCV survives longer in liquids
- HCV survival is longer at lower temperature

Sources:
Doerrbecker J, Friesland M, Ciesek S, et al. Inactivation and survival of hepatitis C virus on inanimate surfaces. *J Infect Dis*. 2011;204(12):1830-8. doi: 10.1093/infdis/jir535.
Paintsil E, Binka M, Patel A, Lindenbach BD, Heimer R. Hepatitis C virus maintains infectivity for weeks after drying on inanimate surfaces at room temperature: implications for risks of transmission. *J Infect Dis*. 2014;209(8):1205-11. doi: 10.1093/infdis/jit648.
Song H, Li J, Shi S, Yan L, Zhuang H, Li K. Thermal stability and inactivation of hepatitis C virus grown in cell culture. Virol J. 2010;7:40.



# Transmission risks: Injection drug use

- Most commonly reported transmission route for new cases
- Within 5 years of use, nearly 50% of individuals will contract HCV
- Within PHP, HCV rate is 48%

Counseling points:

- Referral to Prevention Point Pittsburgh
- Avoid IVDU
- Decrease frequency of injection
- Do not share syringes or injection materials or use first

Sources:
Hagan H, Pouget ER, Des Jarlais DC, Lelutiu-Weinberger C. Meta-regression of hepatitis C virus infection in relation to time since onset of illicit drug injection: the influence of time and place. *Am J Epidemiol*. 2008;168:1099-109.
University of Washington Infectious Diseases Education & Assessment. Hepatitis C Online: 1 Screening and diagnosis Topic 2. Injection Drug Use and HCV Transmission. https://www.hepatitisc.uw.edu/custom/screening-diagnosis/counseling-prevention/2

# Transmission risks: Sexual Transmission

- Less than 1% with monogamous heterosexual partners

Counseling points:

- CDC does not recommend altering sex practices based on HCV status
- Pregnancy considerations
- Sexual practices potentially leading to bleeding
- Monogamy and substance free sex reduce transmission

Sources:
Terrault NA. Sexual activity as a risk factor for hepatitis C. Hepatology. 2002;36(5 Suppl 1):S99-105.
Kao JH, Liu CJ, Chen PJ, Chen W, Lai MY, Chen DS. Low incidence of hepatitis C virus transmission between spouses: a prospective study. J Gastroenterol Hepatol. 2000;15:391-5.
Tahan V, Karaca C, Yildirim B, et al. Sexual transmission of HCV between spouses. Am J Gastroenterol. 2005;100:821-4.
Vandelli C, Renzo F, Romanò L, et al. Lack of evidence of sexual transmission of hepatitis C among monogamous couples: results of a 10-year prospective follow-up study. Am J Gastroenterol. 2004;99:855-9.
Recommendations for the prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. Centers for Disease Control. MMWR Recomm Rep. 1998;47(RR-19):1-39.



# Transmission risks: Tattoos

- Low rates of transmission when tattoos/piercings done in a professional environment

Counseling points:

- Have tattoos/piercings done only in a professional setting.
- If in a non-professional group setting, try to have tattoo done first


Source:
Tohme RA, Holmberg SD. Transmission of hepatitis C virus infection through tattooing and piercing: a critical review. Clin Infect Dis. 2012;54:1167-78.

# Transmission risks: Household contact

- Overall transmission risk is low

Counseling points:

- No sharing razors, shaving equipment, toothbrushes, nail clippers
- Cover cuts/sores
- Clean blood spills using 1 part bleach:10 part water using gloves
- Not spread through food, water, eating utensils or casual contact (sneezing, coughing or hugging)
- If living with someone who has HCV no routine screening indicated

Source:
University of Washington Infectious Diseases Education & Assessment. Hepatitis C Online: 1 Screening and diagnosis Topic 3. Household HCV Transmission.
https://www.hepatitisc.uw.edu/custom/screening-diagnosis/counseling-prevention/3



# Transmission risks: Perinatal transmission

- Definition:
  - Mother must have been HCV antibody positive
- Overall transmission rate:
  - 6%
- When newborn will be tested:
  - 18 months with antibody testing
    - If positive, HCV VL (HCV RNA) at 3 years of life
  - Could consider obtaining a VL at 2 months of age
- When can children be treated:
  - 3 years of age

Sources:
American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA). HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C: HCV in children. https://www.hcvguidelines.org/unique-populations/children
Centers for Disease Control and Prevention (CDC). Increases in hepatitis C threaten young women and babies. https://www.cdc.gov/nchhstp/newsroom/2016/hcv-perinatal-press-release.html. Published July 29, 2020. Accessed September 12, 2020

# Transmission risks: Perinatal transmission

- Factors that increase transmission:
  - HIV coinfection
  - Maternal IVDU
  - Maternal viral load
  - Female gender infant
  - ROM >6 hours
  - Intrapartum events that lead to infant exposure to maternal blood (FSE, Vaginal/perineal lac)
- Things that do not matter
  - Mode of delivery
  - Breastfeeding

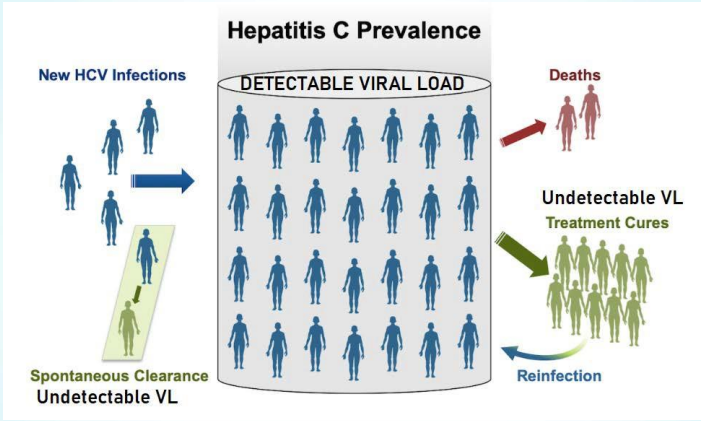
Sources:
European Paediatric Hepatitis C Virus Network. A significant sex--but not elective cesarean section--effect on mother-to-child transmission of hepatitis C virus infection. J Infect Dis. 2005 Dec 1;192(11):1872-9. doi: 10.1086/497695.
Mast EE, Hwang LY, Seto D, et al. Risk factors for perinatal transmission of hepatitis C virus (HCV) and the natural history of HCV infection acquired in infancy. J Infect Dis. 2005 Dec 1;192(11):1880-9. doi: 10.1086/497701. Epub 2005 Oct 28.
Mazza C, Ravaggi A, Rodella A, et al. Prospective study of mother-to-infant transmission of hepatitis C virus (HCV) infection. Study Group for Vertical Transmission. J Med Virol. 1998 Jan;54(1):12-9.
Molin GD, D'Agaro P, Ansaldi F, et al. Mother-to-infant transmission of hepatitis C virus: rate of infection and assessment of viral load and IgM anti-HCV as risk factors. J Med Virol. 2002 Jun;67(2):137-42. doi: 10.1002/jmv.2202./jmv.2202.



# Transmission risks: Other

- Non-injection drug use
- Recipient of blood products, clotting factors or immune globulins before the early 1990s
- Workplace exposures
- Organ transplant
- Chronic hemodialysis

Source:
University of Washington Infectious Diseases Education & Assessment. Hepatitis C Online: 1 Screening and diagnosis Topic 4. Risk Factors for Acquiring HCV.
https://www.hepatitisc.uw.edu/custom/screening-diagnosis/epidemiology-us/4




Source:
Spach D. University of Washington Hepatitis C Online 1 Screening and Diagnosis Topic 2. HCV prevalence in United States. https://www.hepatitisc.uw.edu/custom/screening-diagnosis/epidemiology-us/2

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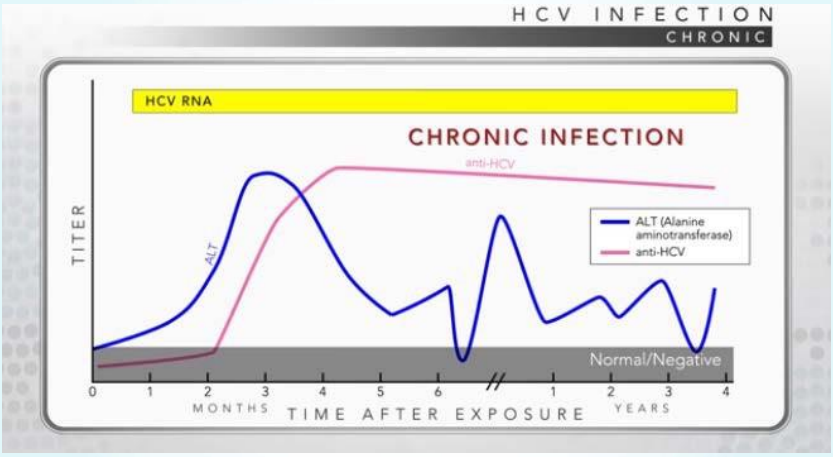


Source:
Centers for Disease Control and Prevention. Hepatitis C: CDC Viral Hepatitis Serology Training. Retrieved from:
https://www.cdc.gov/hepatitis/resources/professionals/training/serology/videos/HCV-CDC_SerologyTraining-2015_low.mp4

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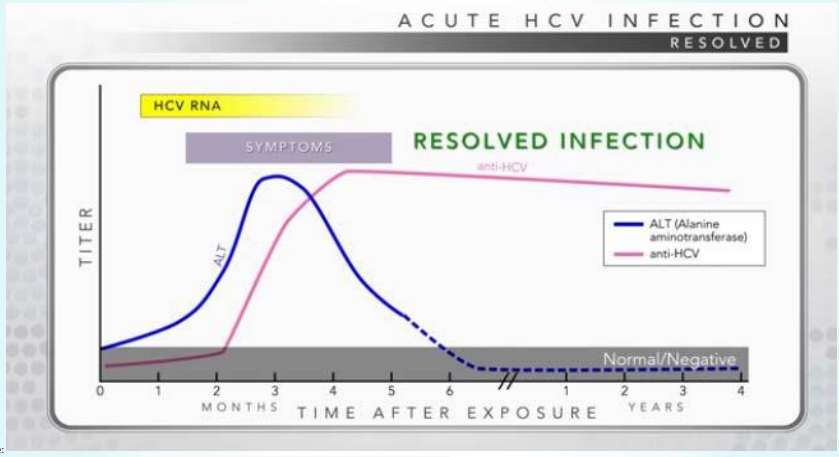
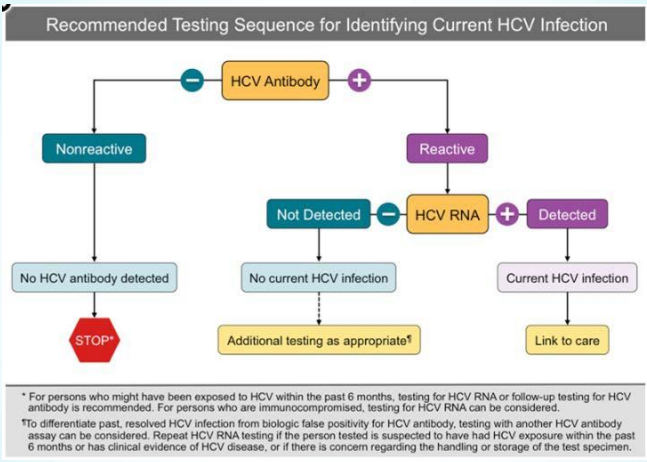



Source:
Centers for Disease Control and Prevention. Hepatitis C: CDC Viral Hepatitis Serology Training. Retrieved from: https://www.cdc.gov/hepatitis/resources/professionals/training/serology/videos/HCV-CDC_SerologyTraining-2015_low.mp4






Source:
Centers for Disease Control and Prevention (CDC). Testing for HCV infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18)

# Hepatitis C antibody with reflex to VL

- Pros:
  - Reduce the number of venipuncture visits
  - Early detection of HCV
- Cons:
  - More tubes
- Excellent choice for individuals with no recent exposures with history of exposures, patients with poor follow up, patients with a fear of venipuncture
- **Do not do if there is concern for acute HCV because could miss the diagnosis due to negative antibody result**



# Acute HCV

- Occurs within 6 months after acquisition of HCV
- Signs and symptoms:
  - Jaundice
  - Dark colored urine
  - Clay colored stool
  - Nausea
  - Abdominal pain
  - Fatigue
- Lab considerations
  - Antibody may be undetectable, VL will be detectable
    - Most will develop positive antibodies within 12 weeks
  - Typically aminotransferases elevated
- Only seen with about 15-30% of infections

Sources:
Blackard JT, Shata MT, Shire NJ, Sherman KE. Acute hepatitis C infection: a chronic problem. *Hepatology*. 2008 Jan; 47(1): 321–331. doi: 10.1002/hep.21902
Busch MP, Shafer KA. Acute-phase hepatitis C virus infection: implications for research, diagnosis, and treatment. *Clin Infect Dis.* 2005;40:959-61.

# Acute HCV

- Labs to order:
  - Initial presentation: HCV antibody, HCV VL and ALT
  - At 4 weeks: HCV antibody, HCV VL and ALT
  - At 12 weeks: HCV antibody, HCV VL and ALT
  - At 24 weeks: HCV antibody and VL



# Spontaneous clearance

- Younger patients (<20 years old)
- Women
- Symptomatic acute infection
- Non-black race
- Genetic factors (cc allele on IL28B gene)
- Postpartum
  - Hashem M, Jhaveri R, Saleh DA, et al. Spontaneous viral load decline and subsequent clearance of chronic hepatitis C in postpartum women correlates with favorable interleukin-28B gene allele. *Clin Infect Dis.* 2017 Sep 15; 65(6): 999–1005.
  - Hattori Y, Orito E, Ohno T, et al. Loss of hepatitis C virus RNA after parturition in female patients with chronic HCV infection. *J Med Virol.* 2003 Oct;71(2):205-11. doi: 10.1002/jmv.10471.

Sources:
Alter MJ, Kruszon-Moran D, Nainan OV, et al. The prevalence of hepatitis C virus infection in the United States, 1988 through 1994. *N Engl J Med.* 1999;341:556-62.
Kenny-Walsh E. Clinical outcomes after hepatitis C infection from contaminated anti-D immune globulin. Irish Hepatology Research Group. *N Engl J Med.* 1999;340:1228-33.
Micallef JM, Kaldor JM, Dore GJ. Spontaneous viral clearance following acute hepatitis C infection: a systematic review of longitudinal studies. *J Viral Hepat.* 2006;13:34-41.

# Chronic HCV in pregnancy

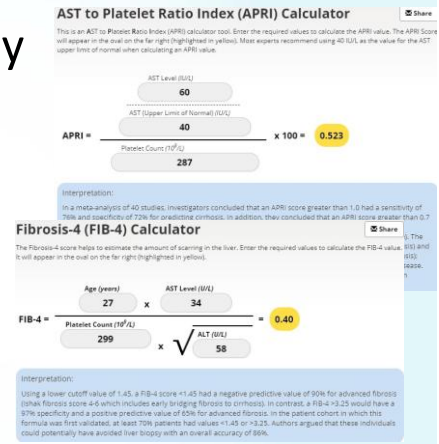
- Generally, ALT will decrease in the first and third trimester and increase postpartum
- HCV viral load will rise in the first trimester, peak in the 3rd trimester and decrease postpartum
- Increased risk of intrahepatic cholestasis of pregnancy
- Newborns of HCV positive mothers:
  - Higher rates of low birth weight
  - Higher rates of SGA
  - More likely to require mechanical ventilation
  - More likely to have a NICU admission

Sources:
Conte D, Fraquelli M, Prati D, Colucci A, Minola E. Prevalence and clinical course of chronic hepatitis C virus (HCV) infection and rate of HCV vertical transmission in a cohort of 15,250 pregnant women. *Hepatology*. 2000;31(3):751-755.
Gervais A, Bacq Y, Bernuau J, Martinot M, Auperin A, Boyer N, et al. Decrease in serum ALT and increase in serum HCV RNA during pregnancy in women with chronic hepatitis C. *J Hepatol*. 2000;32(2):293-299
Pergam SA, Wang CC, Gardella CM, Sandison TG, Phipps WT, Hawes SE. Pregnancy complications associated with hepatitis C: data from a 2003-2005 Washington state birth cohort. *Am J Obstet Gynecol*. 2008;199(1):38.e1-38.e389. doi:10.1016/j.ajog.2008.03.052



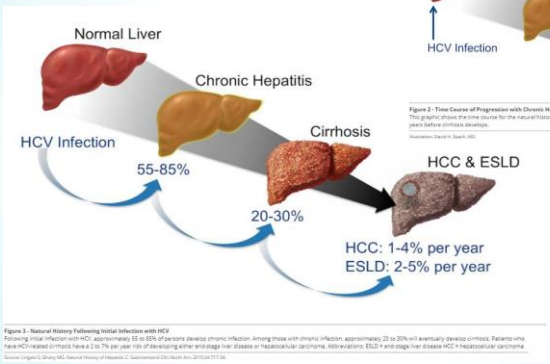
# Chronic HCV in pregnancy

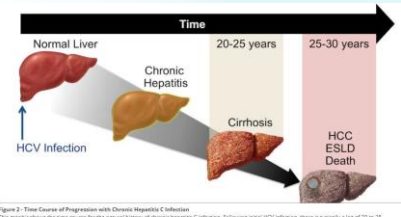
- HCV VL and LFTs at beginning of pregnancy
- HBV surface antigen, HBV core antibody and HBV surface antibody
- If curious about fibrosis/cirrhosis:
  - APRI and FIB-4
- If concern for ICP, LFTs and bile acids
- Consider HCV VL at delivery for all women who are antibody positive




Sources:
American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA). HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C: HCV in pregnancy. https://www.hcvguidelines.org/unique-populations/pregnancy
University of Washington Infectious Diseases Education & Assessment. Clinical calculators. https://www.hepatitisc.uw.edu/page/clinical-calculators/

# Why is treating HCV so important?




Source:
Spach D. University of Washington Hepatitis C OnlineSection 2. Evaluation, Staging, and Monitoring of Chronic Hepatitis C Topic 2. Natural History of Hepatitis C Infection.
https://www.hepatitisc.uw.edu/go/evaluation-staging-monitoring/natural-history/core-concept/all

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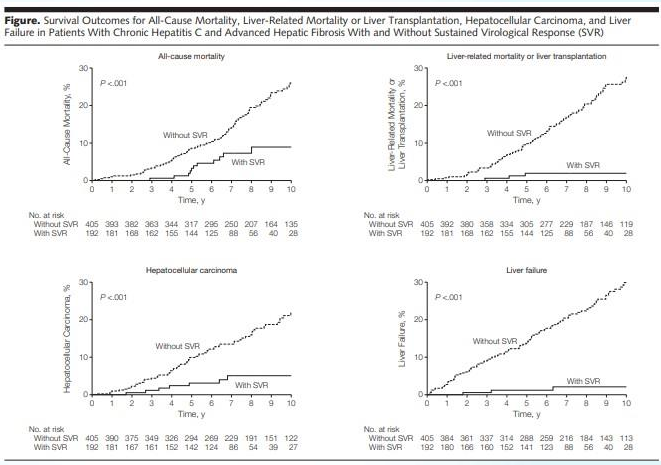
# Why is treating HCV so important?




Source:
van der Meer AJ, Veldt BJ, Feld JJ, et al. Association Between Sustained Virological Response and All-Cause Mortality Among Patients With Chronic Hepatitis C and Advanced Hepatic Fibrosis. *JAMA*. 2012;308(24):2584–2593. doi:10.1001/jama.2012.144878

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# Why is treating HCV so important?

## Extrahepatic manifestations of HCV

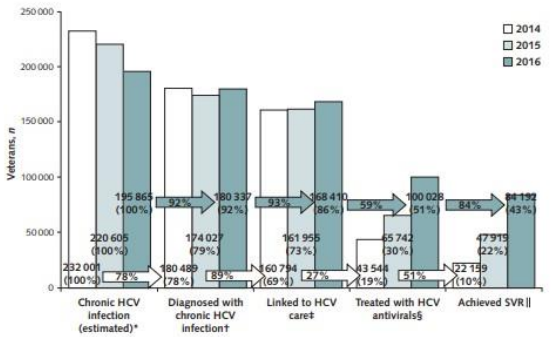
- Endocrine
  - Hypothyroidism
  - Diabetes
- Ocular
  - Corneal ulcers
  - Uveitis
- Dermatologic
  - Lichen planus
  - Necrolytic acral erythema
  - Porphyria cutaneous tarda
- Renal
  - Glomerulonephritis
- Neuromuscular
  - Weakness/myalgia
  - Peripheral neuropathy
  - Arthritis/arthralgia
- Autoimmune
  - Sjogren's syndrome
- Hematologic
  - Non-Hodgkin's B-cell lymphoma
  - Mixed cryoglobulinemia
  - Aplastic anemia
  - Thrombocytopenia

Source:
Cacoub, P. Extrahepatic manifestations of chronic hepatitis C viru infection. *Ther Adv Infect Dis*. 2016 Feb; 3(1): 3–14. doi: 10.1177/2049936115585942



# Why is PHP treating HCV?

*Figure 3.* Cascade of HCV care in the VA in 2014, 2015, and 2016.




Source:
Belperio PS, Chartier M, Ross DB, Alaigh P, Shulkin D. Curing Hepatitis C Virus Infection: Best Practices From the U.S. Department of Veterans Affairs. *Ann Intern Med*. 2017;167:499-504. doi:10.7326/M17-1073

# HCV Treatment: Who to treat

- Anyone willing and ready for treatment
  - Must remain adherent with medications for 8-12 weeks
- Life expectancy longer than 1 year
- NOT contraindications to treatment:
  - IVDU
    - Grebely J, Dalgard PO, Conway B, et al. Sofosbuvir and velpatasvir for hepatitis C virus infection in people with recent injection drug use (SIMPLIFY): an open-label, single-arm, phase 4, multicentre trial. *Lancet Gastroenterol Hepatol*. 2018;3(3):153-161. doi:10.1016/S2468-1253(17)30404-1



# HCV Treatment: Initial visit

- Obtain history
- Assess for liver dysfunction
- History of past treatments
- Assess ability to be compliant
- HAV and HBV vaccine history
- Family history
- Physical
- HCV education and counseling
- Contraception!

# HCV Treatment: Labs

- HCV RNA
- Genotype
  - RAV if genotype 1a and planning to use Zepatier (VERY rarely used)
- Evaluate for fibrosis/cirrhosis
  - FibroTest/FibroSure
- CBC with diff, CMP, PT/INR
- Hepatitis B surface antibody (quant), surface antigen, core antibody
- Hepatitis A antibody, total
- HIV
- Pregnancy test

Source:
Afdhal NH, Zeuzem S, Schooley RT, et al. The new paradigm of hepatitis C therapy: integration of oral therapies into best practices. *J Viral Hepat.* 2013 Nov; 20(11): 745–760.



# HCV Treatment: Labs

- HCV genotype
  - 1a, 1b, 2, 3, 4, 5 and 6
  - Will dictate which DAA will be used
- FibroSure/FibroTest
  - F0-F4, F4=cirrhosis
  - Uses 6 biomarkers

| TEST NAME | RESULT | UNITS | REF INT | LAB |
|---|---|---|---|---|
| HCV FibroSure | | | | |
| HCV FibroSURE Results: | | | | 01 |
| Fibrosis Score | 0.12 | | 0.00 - 0.21 | 01 |
| Fibrosis Stage | | | | 01 |
| | F0 - No fibrosis | | | |
| Necroinflammat Activity Score | | | | |
| | 0.22 High | | 0.00 - 0.17 | 01 |
| Necroinflammat Activity Grade | | | | |
| | A0-A1 | | | 01 |
| Analysis: | | | | 01 |
| Alpha 2-Macroglobulins, Qn | | | | |
| | 228 | mg/dL | 110 - 276 | 01 |
| Haptoglobin | | | | |
| | 81 | mg/dL | 34 - 200 | 01 |
| Apolipoprotein A-1 | | | | |
| | 158 | mg/dL | 110 - 205 | 01 |
| Bilirubin, Total | | | | |
| | 0.3 | mg/dL | 0.0 - 1.2 | 01 |
| .com | | | | |
| | 11 | IU/L | 0 - 60 | 01 |
| ?SP | | | | |
| | 48 High | IU/L | 0 - 40 | 01 |
| ions: | | | | 01 |
| : results of 6 biochemical tests are analyzed | | | | |
| utational algorithm to provide a quantitative | | | | |
| irker (0.0-1.0) for liver fibrosis | | | | |
| -F4) and for necroinflammatory activity | | | | |
| -A3). | | | | |

| | Ref Range & Units | 11/8/18 1000 |
|---|---|---|
| Fibrosis Score | 0.00 - 0.21 | 0.39 ^ |
| Fibrosis Stage | | F1-F2 |
| Necroinflammat Activity Score | 0.00 - 0.17 | 0.56 ^ |
| Necroinflammat Activity Grade | | A2-Moderate activity |
| Alpha 2-Macroglobulins, Qn | 110 - 276 mg/dL | 217 |
| Haptoglobin | 34 - 200 mg/dL | <10 v |
| APOLIPOPROTEIN A-1 | 101 - 178 mg/dL | 223 ^ |
| Total Bilirubin | 0.0 - 1.2 mg/dL | 0.6 |
| GGT | 0 - 65 IU/L | 96 ^ |
| ALT | 0 - 55 IU/L | 91 ^ |

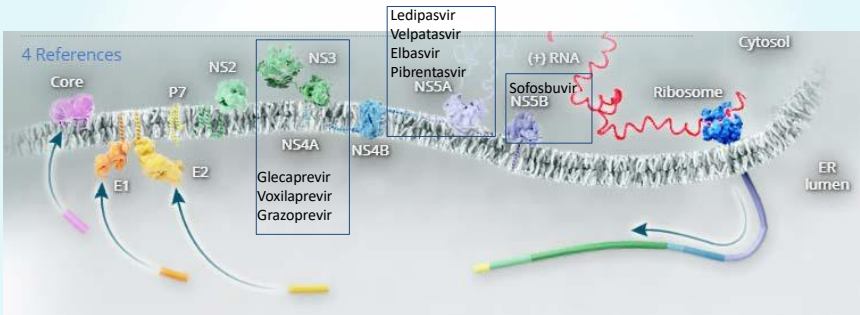
Source:
Germer JJ, Mandrekar JN, Bendel JL, Mitchell PS, Yao JD. Hepatitis C virus genotypes in clinical specimens tested at a national reference testing laboratory in the United States. *J Clin Microbiol.* 2011;49:3040-3.

# HCV Treatment: When to refer

- Decompensated cirrhosis
  - Fibrosis stage of F4
- Hepatitis B
- HIV
- Previous treatment exposure
- Other liver diseases

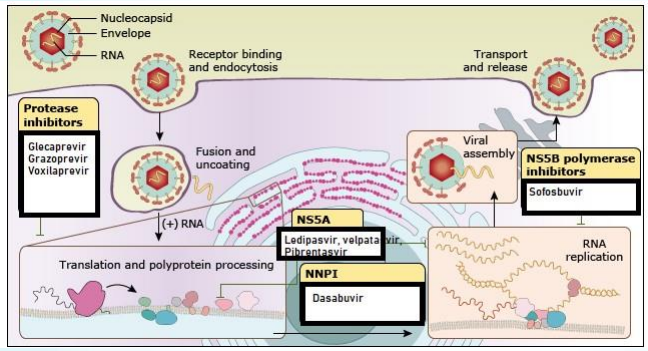


# HCV Treatment: DAAs




Source:
University of Washington Hepatitis C Virus Biology. https://www.hepatitisc.uw.edu/biology/proteins. Published 2020. Accessed September 7, 2020

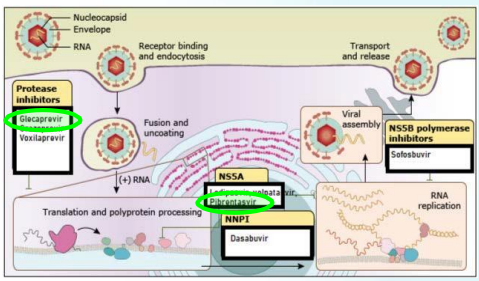
# HCV Treatment: DAAs




Source:
Au JS, Pockros PJ. Novel therapeutic approaches for hepatitis C. *Clin Pharmacol Ther*. 2014;95(1):78-88. doi:10.1038/clpt.2013.206



# HCV Treatment: DAAs



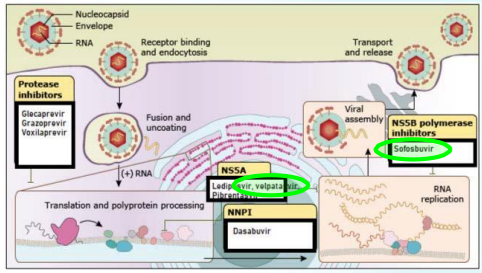

**Mavyret (Glecaprevir/Pibrentasvir)**

- Pangenomic
- 3 tablets once a day for:
  - 8 weeks noncirrhotic
  - 12 weeks with cirrhosis
- Cost ~$13,000/mth
- Needs to be taken with food
- Contraindicated with estrogen containing contraceptives, SJW, phenytoin, carbamazepine, HIV medications. Relative CI with statins
- SE: headache, fatigue, nausea

# HCV Treatment: DAAs

**Epclusa (Sofosbuvir/Valpatasvir)**

- Pangenomic
- 1 tablet once a day for 12 weeks
- Cost ~$23,000/mth



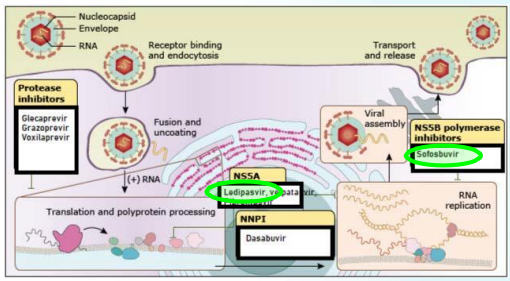

- Contraindicated with: SJW, Phenytoin, tegretol, HIV meds. Relative CI with statins
- Separate antacids and PPIs by 4 hours and H2RA by 12 hours
- SE: headache, fatigue



# HCV Treatment: DAAs

**Harvoni (Sofosbuvir/Ledipasvir)**

- Genotypes 1, 4, 5, and 6
- 1 tablet once a day:
  - 8 weeks in non-black, HIV neg, HCV RNA <6 million
  - 12 weeks otherwise
- Cost ~$30,000/mth




- Contraindicated with: amiodarone. Relative CI with statins
- Separate antacids and PPIs by 4 hours and H2RA by 12 hours
- SE: headache, fatigue, weakness

# HCV Treatment: DAAs

- University of Liverpool Hep C drug interaction check
- https://www.hep-druginteractions.org/
- Will offer alternative therapies if contraindication noted

| | G/P | LED/SOF | SOF/VEL |
|---|---|---|---|
| Hydroxyzine | ♦ | ♦ | ♦ |
| Iron supplements | ♦ | ♦ | ♦ |
| Norgestimate/ethinylestradiol (COC) | ● | ♦ | ♦ |
| Sertraline | ♦ | ♦ | ♦ |

www.hep-druginteractions.org

Interaction Report

Report ID:
Date Produced: 13 September 2020

| Hepatitis Treatment | Co-medications |
|---|---|
| Glecaprevir/Pibrentasvir | Hydroxyzine<br>Iron supplements<br>Norgestimate/ethinylestradiol (COC)<br>Sertraline |

This report lists the summaries of potential interactions (i.e. "red", "amber" and "yellow" classifications) for the drugs in the table above.

Interactions with a "green" or "grey" classification (i.e. no clinically significant interaction or no clear data) have been checked and are listed at the end of this report, but summaries are not shown. Please note that some co-medications with a green classification may require dose adjustment due to hepatic impairment.

For full details of all interactions, see www.hep-druginteractions.org .

Description of the interactions

Drugs that should not be coadministered (RED)

Glecaprevir/Pibrentasvir + Norgestimate/ethinylestradiol (COC)
Coadministration with glecaprevir/pibrentasvir and ethinylestradiol is contraindicated. In interaction studies evaluating ethinylestradiol and glecaprevir/pibrentasvir in healthy female subjects, ALT elevations were observed in some subjects during coadministration. Based on increased ALT levels, coadministration of ethinylestradiol containing hormonal contraceptives or hormone replacement therapies is not recommended.

No clinically significant interaction expected (GREEN)

Glecaprevir/Pibrentasvir + Hydroxyzine
Glecaprevir/Pibrentasvir + Iron supplements
Glecaprevir/Pibrentasvir + Sertraline

HEP iChart



# HCV Treatment: Prior to treatment

- Get required information to specialty pharmacy
  - Within last 3 months: HCV VL, CBC, CMP, HIV
  - Genotype
  - Fibrosure
  - HBV serology (may require immunization)
  - HAV serology
- Risk reduction counseling
- Adherence counseling
- Notify patient to reach out to office on the day they start their DAA

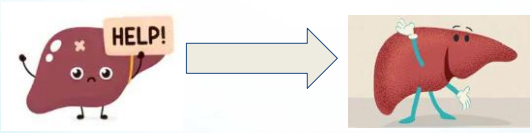
# HCV Treatment: Treatment monitoring

- Start day
  - Adherence counseling
  - Notify office of new medications
- Week 1
  - Discuss side effects, adherence, new medications, risk reduction counseling
  - Patient to reach out if they have not received their refill when they are on their last week
- Week 4
  - Visit to discuss side effects, adherence, new medications, risk reduction counseling
  - Labs: HCV VL, CMP
- Week 8
  - If end of therapy will order HCV VL. If 12 week therapy, will ensure patient has refill and counsel on adherence, new meds, risk reduction
- Week 12
  - End of therapy, HCV VL



# HCV Treatment: Follow up

- 90 days after last dose:
  - Labs:
    - HCV VL
    - CBC
    - CMP
  - If VL undetectable, patient is cured. Rescreen yearly or based on risk factors
  - APRI and Fib-4 calculated to ensure diagnosis of cirrhosis was not missed as a result of postpartum lab changes
  - Counsel patient on importance of avoiding reinfection!
  - If ≥F3, liver ultrasound, CMP and AFP every 6 months. EGD every 2 years



# Hepatitis C treatment in pregnancy

- Chappel C, Scarsi K, Kirby B, et al. Ledipasvir plus sofosbuvir in pregnant women with hepatitis C virus infection: a phase 1 pharmacokinetic study. *Lancet.* 2020 Sep 1; 1(5): E200-E208 doi:https://doi.org/10.1016/S2666-5247(20)30062-8
- 9 pregnant women were treated for HCV at Magee in phase 1 study
- All participants had genotype 1 and were treated with ledipasvir/sofosbuvir
- All but one participant had undetectable VLs at delivery. One with detectable VL was with non-adherence and missed approximately 15 doses during treatment period.
- Side effects were similar to non-pregnant population

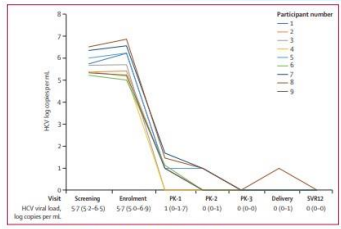



**Figure 3: HCV viral response to ledipasvir-sofosbuvir during pregnancy**
Data stated below the chart are median (range). PK-1 visit was between 10 and 21 days after treatment initiation. PK-2 visit was between 32 and 47 days after treatment initiation. PK-3 visit was between 59 and 74 days after treatment initiation. HCV=hepatitis C virus. PK-1=first pharmacokinetic visit. PK-2=second pharmacokinetic visit. PK-3=third pharmacokinetic visit. SVR12=sustained virological response 12 weeks after completion of treatment.

Allegheny Health Network

# General Points: Medications with HCV

- Acetaminophen
  - 2g daily safe if non cirrhotic (1g daily if cirrhotic)
  - Remind of other Rx with acetaminophen in them
  - If taking acetaminophen regularly, consider CMP q3-6mths
- NSAIDS
  - Safe at typical doses if no cirrhosis (avoid if cirrhotic)
- Iron
  - Evaluate risk/benefits of iron supplement
- Milk thistle
  - No harm or benefit

Source:
University of Washington Infectious Diseases Education & Assessment. Hepatitis C Online: 2 Evaluation, staging, and monitoring: Counseling patients with chronic hepatitis C overview. https://www.hepatitisc.uw.edu/custom/evaluation-staging-monitoring/counseling-liver-health

Allegheny Health Network

# General Points: Hepatitis B Vaccination

- Consider checking for immunity in pregnancy:
  - vaccination in pregnancy?

CONTENTS: CURRENT COMMENTARY

**Universal Screening and Vaccination for Hepatitis B in Pregnancy**

**The Time Is Now**

Prabhu, Malavika MD; Riley, Laura E. MD **Author Information**

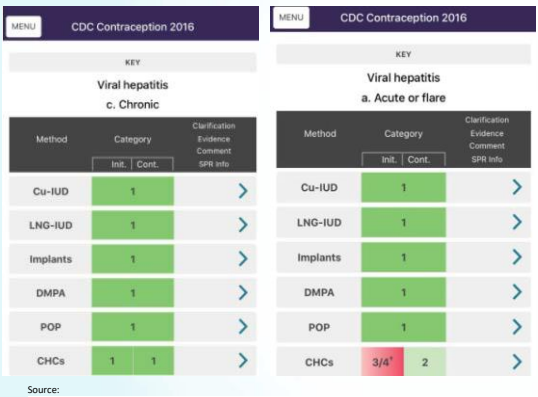
Obstetrics & Gynecology: April 2020 - Volume 135 - Issue 4 - p 808-811
doi: 10.1097/AOG.0000000000003706

| | | |
|---|---|---|
| **HBsAg**<br>**anti-HBc**<br>**anti-HBs** | negative<br>negative<br>negative | Susceptible |
| **HBsAg**<br>**anti-HBc**<br>**anti-HBs** | negative<br>positive<br>positive | Immune due to natural infection |
| **HBsAg**<br>**anti-HBc**<br>**anti-HBs** | negative<br>negative<br>positive | Immune due to hepatitis B vaccination |
| **HBsAg**<br>**anti-HBc**<br>**IgM anti-HBc**<br>**anti-HBs** | positive<br>positive<br>positive<br>negative | Acutely infected |
| **HBsAg**<br>**anti-HBc**<br>**IgM anti-HBc**<br>**anti-HBs** | positive<br>positive<br>negative<br>negative | Chronically infected |
| **HBsAg**<br>**anti-HBc**<br>**anti-HBs** | negative<br>positive<br>negative | Interpretation unclear; four possibilities:<br>1. Resolved infection (most common)<br>2. False-positive anti-HBc, thus susceptible<br>3. "Low level" chronic infection<br>4. Resolving acute infection |

Source:
Centers for Disease Control and Prevention (CDC). Interpretation of Hepatitis B Serologic Test Results. https://www.cdc.gov/hepatitis/hbv/pdfs/serologicchartv8.pdf

Allegheny Health Network

# General Points: Contraception








- DAAs are not FDA approved for use in pregnancy
- Some DAAs are contraindicated with CHCs
- Adherence is important

Source:
Centers for Disease Control and Prevention (CDC). Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use.
https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf

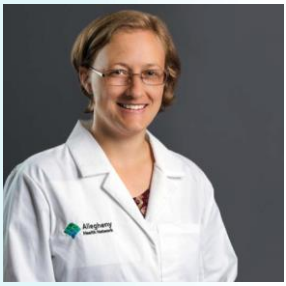
Allegheny Health Network

# Resources

- University of Washington Hepatitis C Online
  - https://www.hepatitisc.uw.edu/
- American Association for the Study of Liver Diseases (AASLD) & Infectious Diseases Society of America (IDSA): HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C
  - https://www.hcvguidelines.org/
- UCSF National Clinician Consultation Center Hepatitis C Management
  - https://nccc.ucsf.edu/clinician-consultation/hepatitis-c-management/
- Hep C Free Allegheny County
  - https://www.hepcfreeallegheny.org/about-us
- Community Liver Alliance
  - https://www.communityliveralliance.org/

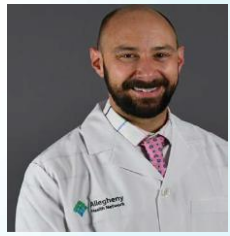


# AHN Support



Dr. Holly Bean
Infectious Diseases

Dr. Michael Babich
Gastroenterology



# Questions?

# ARRIVE Trial: Interpretation and Future Directions

Michael M. Aziz MD MPH FACOG
Allegheny Perinatal Associates

## Objectives

- Review recent history of relationship between induction of labor and spontaneous delivery
- Review the ARRIVE trial along with its strengths and weaknesses
- Compare ARRIVE trial to our current policies on induction of labor
- Review answered and unanswered questions from subsequent literature
- Try not to get off topic!

# Induction of Labor

- 23% of all births
- Meta-analysis of 11 RCTs and 25 observational studies
  - 37-41.6 weeks of gestation
- Expectant management
  - CD OR 1.22 (95% CI 1.07-1.39)
  - Meconium 2.04 (95% CI 1.34-3.09)
  - Similar maternal and perinatal outcomes

Martin et al. *Natl Vital Stat Rep*. 2015
Caughey et al. *Ann Intern Med*. 2009

# Induction of Labor

- Bishop Score
- <5 at start of IOL associated with 2-3x risk of CD
- >=(8/9) similar rate of CD

Bishop. *Obstet Gynecol*. 1964
Vrouenraets et al. *Obstet Gynecol*. 2005
Vahration et al. *Obstet Gynecol*. 2005
ACOG PB. *Obstet Gynecol*. 2009

# Induction of Labor

- Studies had false comparison:
  - IOL vs Spontaneous Labor
  - IOL vs Expectant Management
- Studies which compared IOL to Expectant Management
  - Lower CD rates
  - More favorable perinatal outcomes

Vardo et al. *J Repro Med*. 2011
Dunne et al. J *Obstet Gynaecol Can*. 2009
Guerra et al. *Bull WHO*. 2011
Osmondson et al. *Obstet Gynecol*. 2011

# Induction of Labor

- RCT in the UK “35/39” trial
- IOL vs expectant management
- Rate of Cesarean Delivery was not different*
- 30%
- Underpowered for neonatal outcomes

Walker et al. (2016) NEJM

# ARRIVE Trial

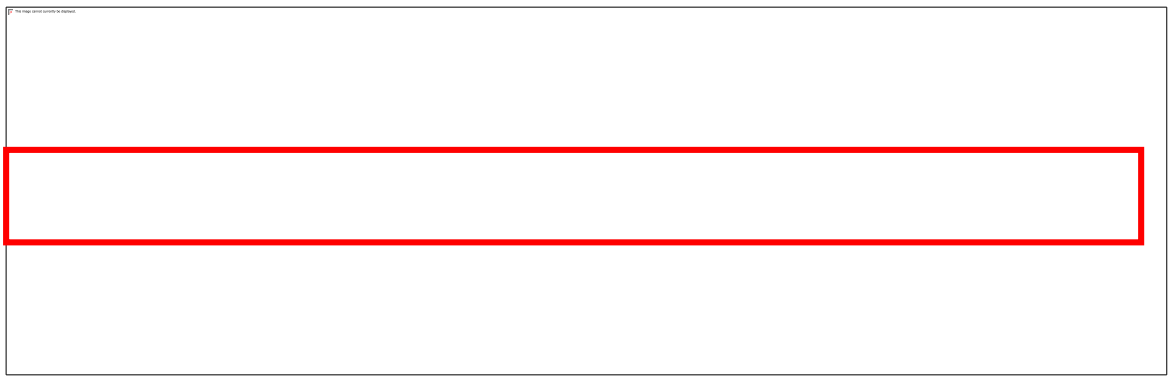
- “Low risk” nulliparous women from 34-38w6d
- No indication for delivery prior to 40w5d
- No contraindication to vaginal delivery
- Not planning on having CD
- “Good” dating

# ARRIVE Methods

- Random sampling with site stratification
- Cervical Exam
- Exposure group: IOL from 39-39w4d
- Control group: No elective delivery prior to 40w5d and initiation of delivery by 42w2d
- NO mandated induction protocol
- Abstracted records, pain and personal control questionnaires

# Modified Bishop

# Induction



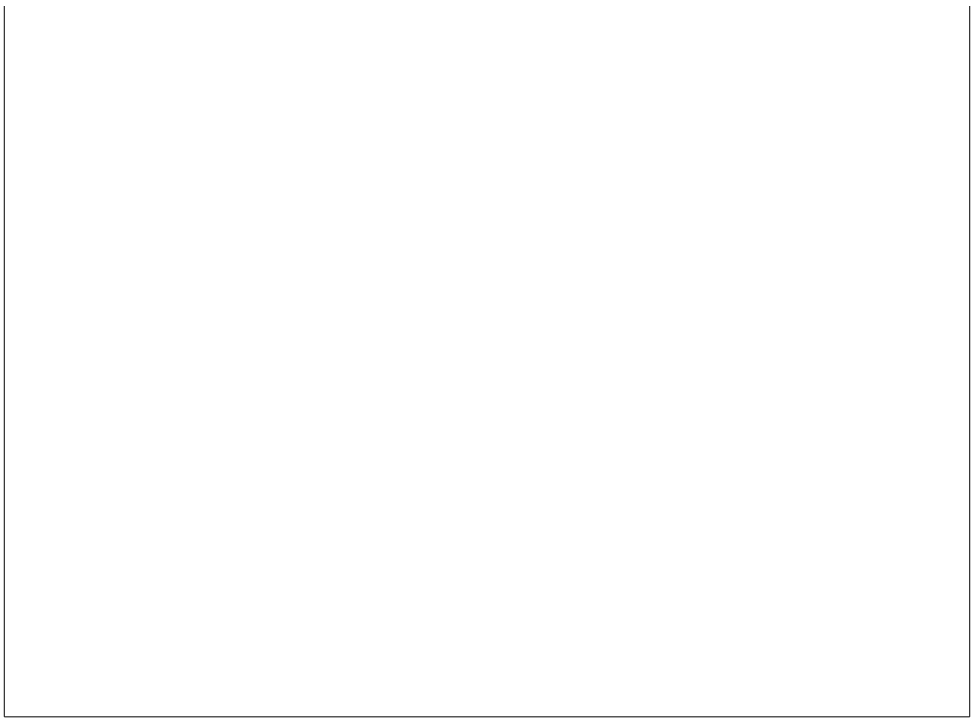
# ARRIVE Outcomes

- Abstracted records, pain and personal control questionnaires
- Primary outcome: Composite of perinatal death or severe neonatal outcomes
- Secondary outcome: Cesarean Delivery
- Prespecified subgroups based on maternal characteristics*

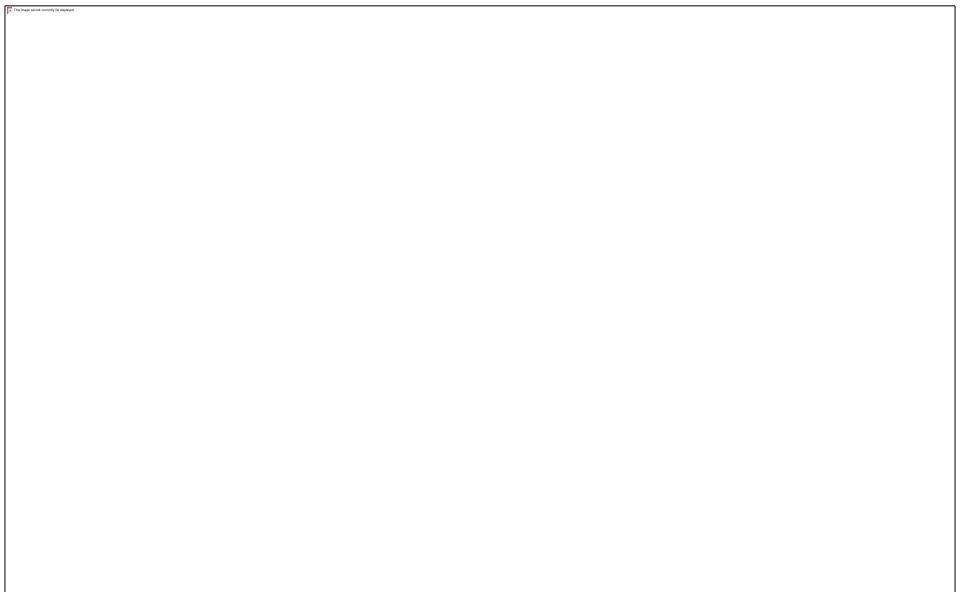
# ARRIVE Power Analysis

- Expected primary composite outcome of 3.5%
- Magnitude of effect 40%
- 85% power, p of <=5% was considered significant
- 7.5% loss rate

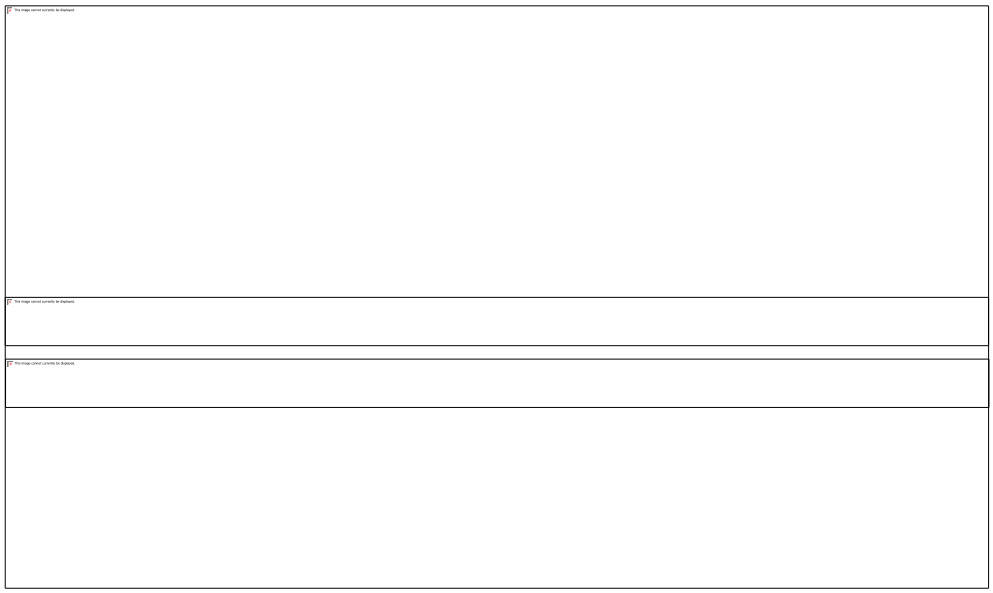
- Exposure based on intention to treat principle



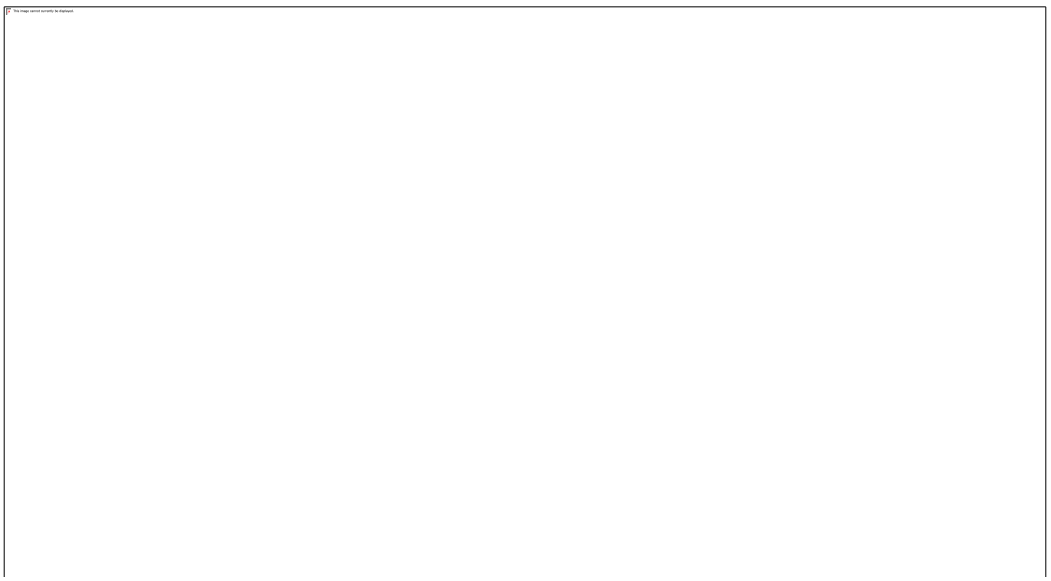
# ARRIVE Results



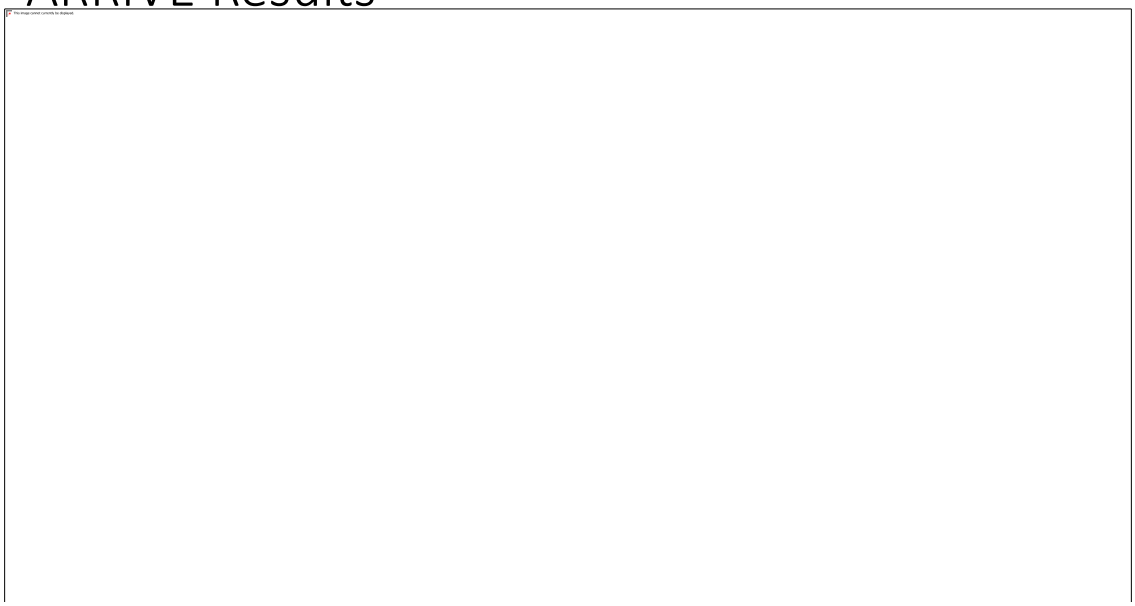
# ARRIVE Results



# ARRIVE Results



# ARRIVE Results



# ARRIVE Results

- No difference in primary (neonatal composite) outcomes
- Reduces CD rate anywhere from 7-24%, NNT=28

# ARRIVE Discussion

- IOL at 39 weeks did not increase maternal or perinatal morbidity
- "probably not" and "may"
- Largest trial of IOL vs expectant management, stringent criteria

- "…Policies aimed at the avoidance [of IOL in 39 week nulliparas] are unlikely to reduce the rate of cesarean delivery on a population level."

# ARRIVE- Remaining Questions

- Underpowered for rare outcomes
- Cost effectiveness
- Ascertainment bias, Elective primary cesarean delivery
- Generalizability
  - Yes: No set IOL or labor protocols, multiple settings and providers
  - No: Highly organized research centers. Unclear as to coverage models
- Acceptability

# Which questions have been answered*

- 184 Citing Articles as of 9/18/20
- Most consequential-
- In my opinion!

# Rare outcomes

## The impact of IOL at 39 weeks in low-risk women on the incidence of stillbirth

- Po, Oliver, Reddy, Silver, Berghella
- AJOG, January 2020

- Epidemiologic study
- US Vital Statistics Data from 2014-16, 12 million births vs 155k stillbirths
- Rate was 0.6/1000, NNT 1675

Induction of labor at full-term in pregnant women with uncomplicated singleton pregnancy: A systematic review and meta-analysis of randomized trials

- Saccone, Corte, Maruotti, Quist-Nelson, Raffone, De Vivio, Esposito, Zullo, Berghella
- AOGS, February 2019

- Meta-analysis of RCTs
- Similar CD risk, but more meconium (7.5%) and lower birthweight (98g)
- Significant Limitations: Multiparous included, heterogeneous induction methods

# Cost

## Induction of labor at 39 weeks of gestation versus expectant management for low-risk nulliparous women: a cost-effectiveness analysis

- Hersh, Skeith, Sargent, Caughey
- AJOG, June 2019

- Cost-effectiveness analysis, theoretical cohort of 1.6 million women
- Mode, hypertensive disorders, macrosomia, stillbirth, permanent BP injury, and neonatal death
- Incremental cost-effectiveness of ~$88k/QALY
- If cost was increased by $180, IOL no longer cost-effective
- Additional $2billion in healthcare costs

## Cost of Elective Labor Induction Compared With Expectant Management in Nulliparous Women

- Einerson, Nelson, Sandoval, Esplin, Branch, Metz, Silver, Grobman, Reddy, Varner
- Green Journal, July 2020

- Economic analysis of relative direct healthcare costs in the Utah ARRIVE cohort
- 1,201 patients
- No difference in total costs
- Induction group costs: 47% lower outpatient, 17% higher inpatient

## Maternal and Neonatal Hospitalization Costs Associated With Elective Induction of Labor at Term in California, 2007–2011

- Hersh, Greiner, Garg, Skeith, Caughey
- Green Journal, June 2020

- Cohort study of uncomplicated singleton elective inductions of labor
- 190,409 women
- ~$700 more for successful vaginal delivery
- ~$1400 more for attempts which ended in cesarean delivery

# Ascertainment Bias/ Primary Cesarean Delivery

## Ascertainment

- High proportion of screened patients excluded
- Elective primary cesarean accounts for 5-15% of all primary cesarean deliveries
- No blinding

# Generalizability

# Generalizability- Still waiting

- 42-14% in NJ alone
- Mix of delivery personnel and location
- Mix of practice types
- Differing induction and labor protocols
  - This could go either way!

# Induction of labor at or beyond 37 weeks' gestation

- Middleton, Shepherd, Morris, Crowther, Gomersall
- Cochrane Reviews, July 2020

- IOL vs expectant management at or beyond 37 weeks
- 34 RCTs of 21,000 women
- Decreased: Cesarean Deliveries 10%, Perinatal death by 69% (NNT 544), NICU admission 12%
- No increase in major complications or operative vaginal delivery

# Patient and Hospital Factors Associated With Unexpected Newborn Complications Among Term Neonates in US Hospitals

- Klapp, James, Bates et al.
- JAMA Open, January 2020

- Population based cross-sectional study
- ~1.7 million term births >2500g in 576 US hospitals, 2015-2017
- Wide variation 0.6 to 90 per 1000 births (median 15)

# Acceptability

Physicians, midwives, and nurses

## Editorial: 39 week inductions are not elective

- Ghartey and Macones
- AJOG 6/1/2020

- “Elective” implies not medically necessary
- ARRIVE is higher level of evidence than some “medically-indicated” scheduled deliveries
- Propose “risk-reducing”

## Editorial: Assessing the Value of the ARRIVE Trial for Clinical Practice: Sea Change or Just a Splash?

- Phillippi and King
- J Midwifery and Women's Health, October 2018

- Elective [IOL] is not consistent with… commitment to physiologic labor and birth
- Several valid criticisms
- Compare and contrast professional organization's statements
- "Shared decision making, informed consent, and high-quality, evidence-based care is essential"

## Patients' perspectives regarding induction of labor in the absence of maternal and fetal indications: are our patients ready for the ARRIVE trial?

- Gallagher, Liveright, Mercier
- AJOG MFM, May 2020

- Cross-sectional survey of 100 women in their third trimester
- 55% not interested in IOL without a maternal or fetal indication
- Driven by concern that IOL worsens neonatal outcome (OR=3.9)

# Conclusions

- Different populations?

- "Risk reducing" IOL in the 39th week appears to be:
- Safe, Effective
- Cost-effective?

# Conclusions

- Changes in the obstetric population

- How do these findings apply to our center(s)
  - Do we have similar rates
- Future directions

# Contraception in the United States: Use, access, and how COVID-19 has shifted this landscape

Megan Kavanaugh, DrPH
Principal Research Scientist

Contemporary Topics in OB-GYN AHN Virtual Conference
September 26, 2020





## Disclosures

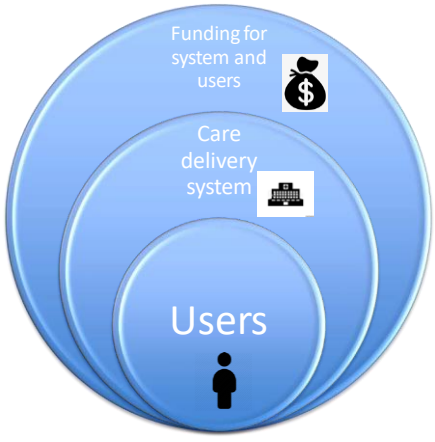
- **I have no financial relationships with commercial interests to disclose**

## Outline – Contraceptive Use and Access

- Trends in contraceptive use
- Characteristics associated with use
- Access to contraceptive services
- How COVID-19 has impacted use and access

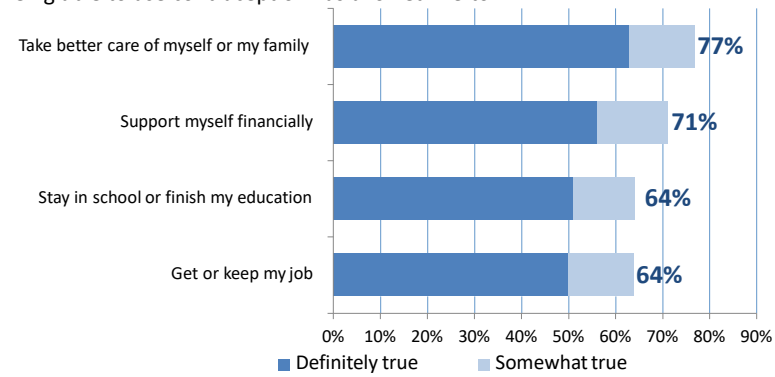



## Contraceptive services landscape



## Importance of contraception in women's lives

Being able to use contraception has allowed me to….



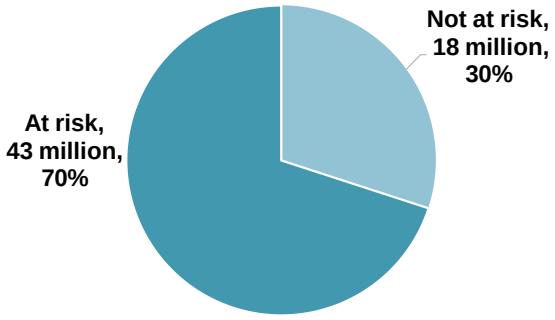

Source: Frost et al 2012




# Contraceptive use

## Who is the U.S. reproductive-age population?

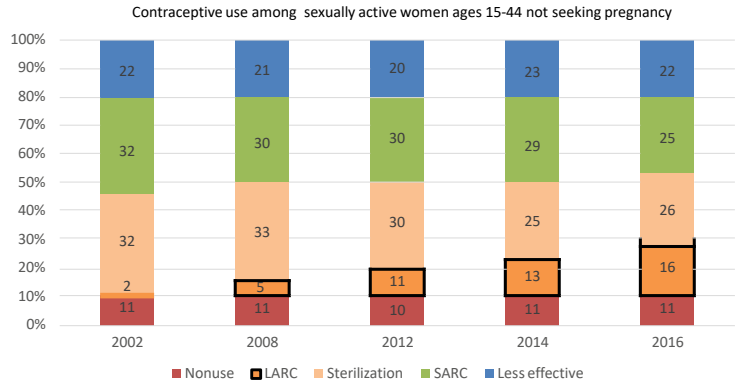
Of the 61 million women ages 15-44, 43 million may be at risk of a pregnancy they aren't seeking




Source: Jones et al, 2012

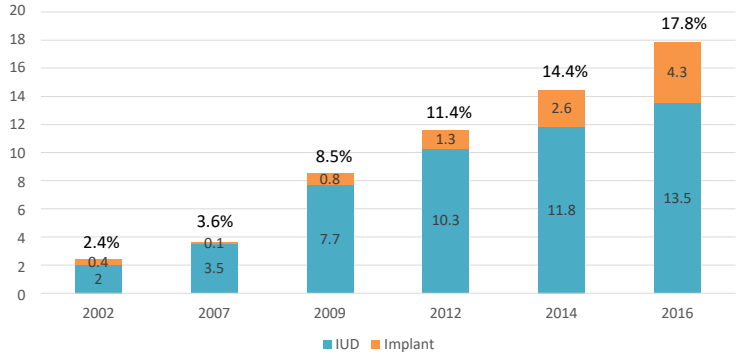


## Shifts in method use occurring within contraceptive users, not from nonusers to users




Source: Kavanaugh, et al 2015; Kavanaugh and Jerman, 2018; Kavanaugh and Pliskin, 2020

## IUD use drives overall LARC use among contraceptive users aged 15-44

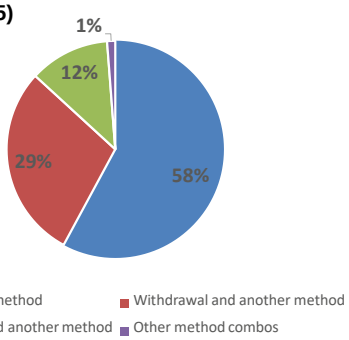



Source: Kavanaugh et al, 2015; Kavanaugh and Jerman, 2018; Kavanaugh and Pliskin, 2020



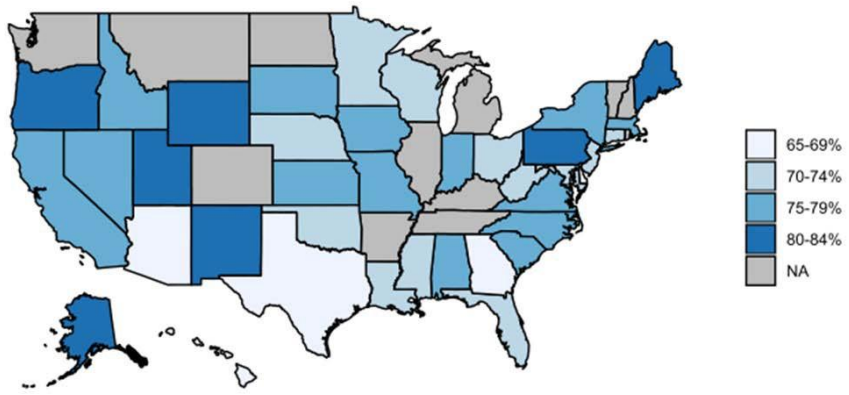
## Multiple method use

- As of 2015, 18% of women used more than one method at last sex
- Multiple method use groupings among dual contraceptive method users at last sex, 2013-2017 (N = 925)




Source: unpublished data

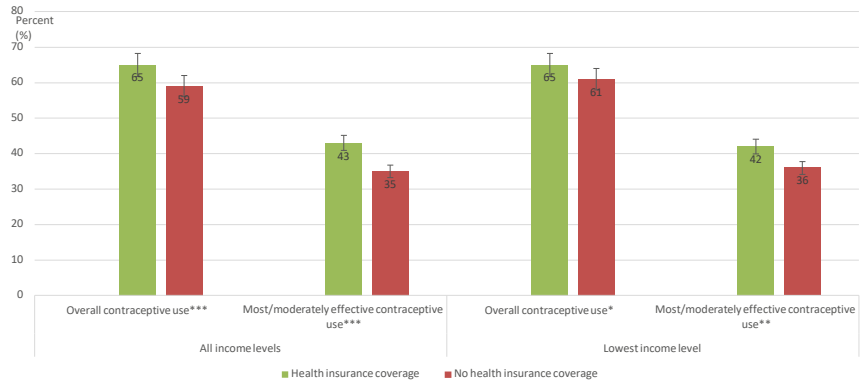
**Contraceptive use among women aged 18-49 at risk of unintended pregnancy, by state, 2017**




Source: Douglas-Hall et al, 2018; unpublished data



**Across US jurisdictions, insurance is significantly associated with higher levels of contraceptive use, especially among low-income individuals at risk of pregnancy**

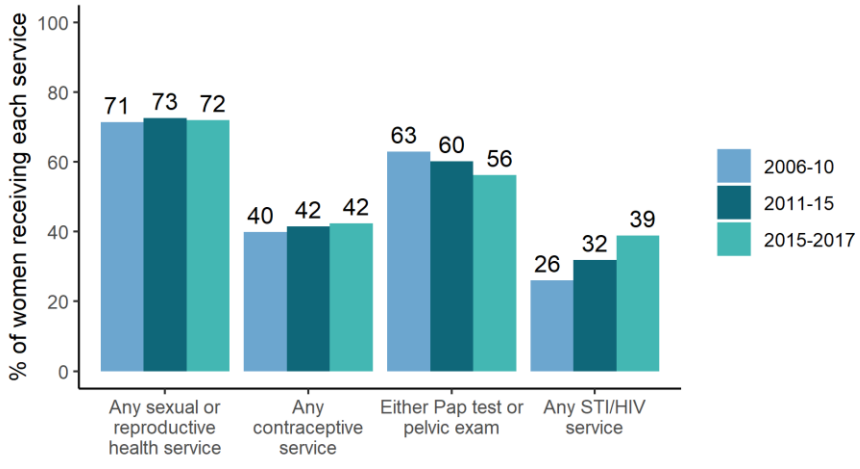



Source: Kavanaugh et al 2019

# Contraceptive access: Source of care

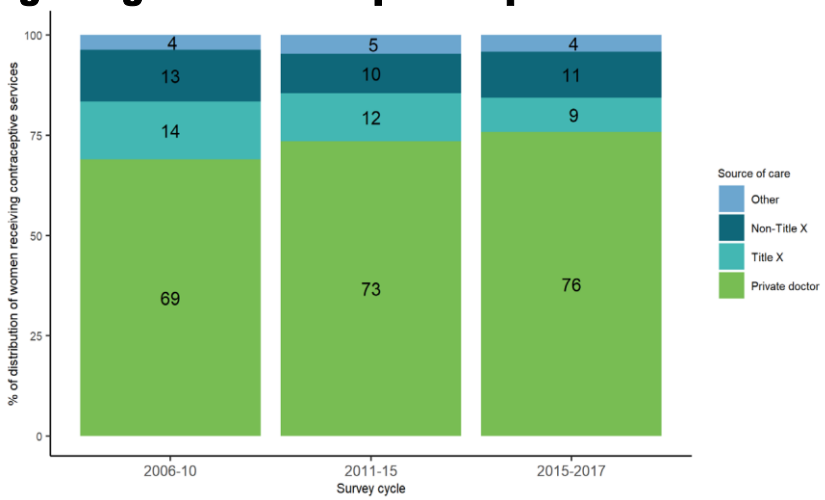


## Women are getting fewer Pap tests/pelvics and more STI services




Source: unpublished data

## Most women have been shifting towards getting SRH care at private providers




Source: unpublished data

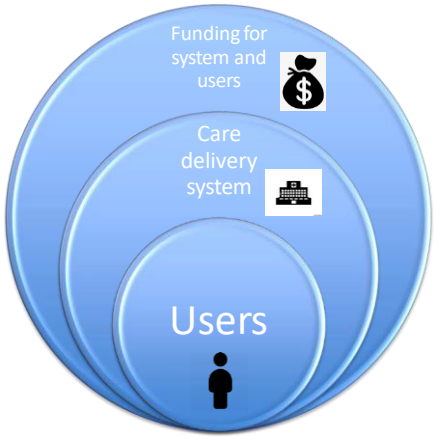


## Reliance on clinics for contraceptive services has declined for most population groups, except NH Black women and immigrants, 2006-2017

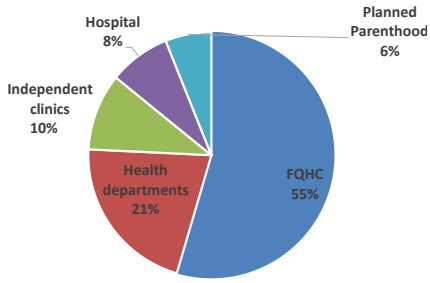

**Type of provider visited for contraceptive services, NSFG 2006-10, 2011-15, 2015-17**

Source: unpublished data

## Publicly funded family planning: 2015



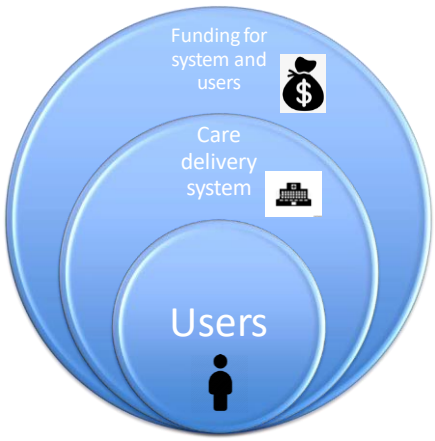

- Funded through a variety of sources
- 10,700 clinic sites



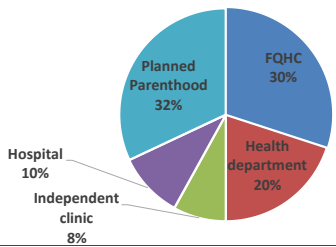

- 6.2 million clients served



## Publicly funded family planning: 2015



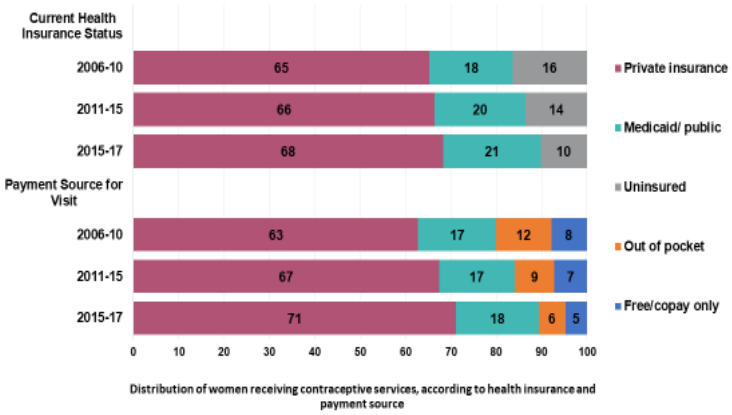

- Funded through a variety of sources
- 10,700 clinic sites
- 6.2 million clients served
  - 2.4 million by private physicians
  - 3.8 million by family planning clinics



# Contraceptive access: Payment and funding for care



## Trends in health insurance coverage and payment for contraceptive services

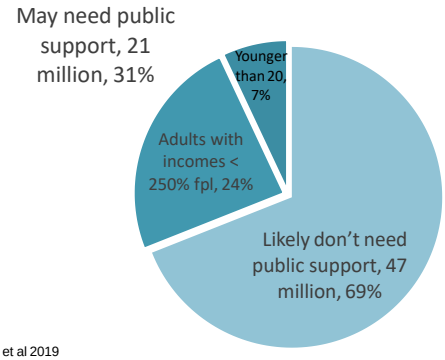



Distribution of women receiving contraceptive services, according to health insurance and payment source

Source: unpublished data

## Who may need support for contraceptive care?

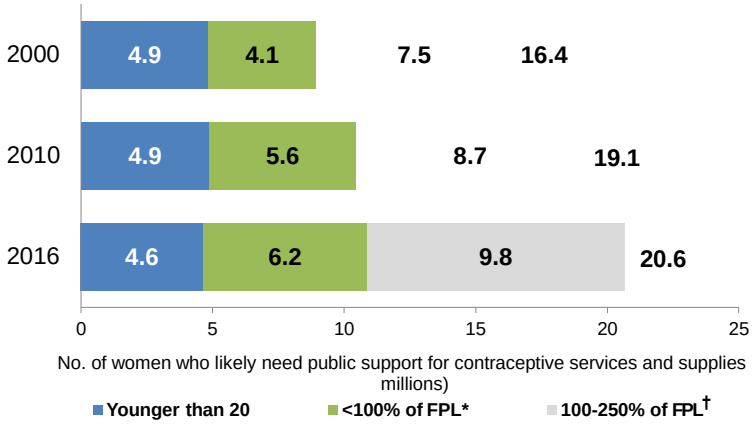
Of the 68 million women ages 13-44, 21 million are likely in need of public support for contraceptive services




Source: Frost et al 2019



**Increasing numbers of low-income adult women account for the growing numbers of women who likely need public support for contraceptive care**




*Women aged 20–44 with family income less than 100% of the federal poverty level (FPL).
†Women aged 20–44 with family income at 100–249% of FPL.

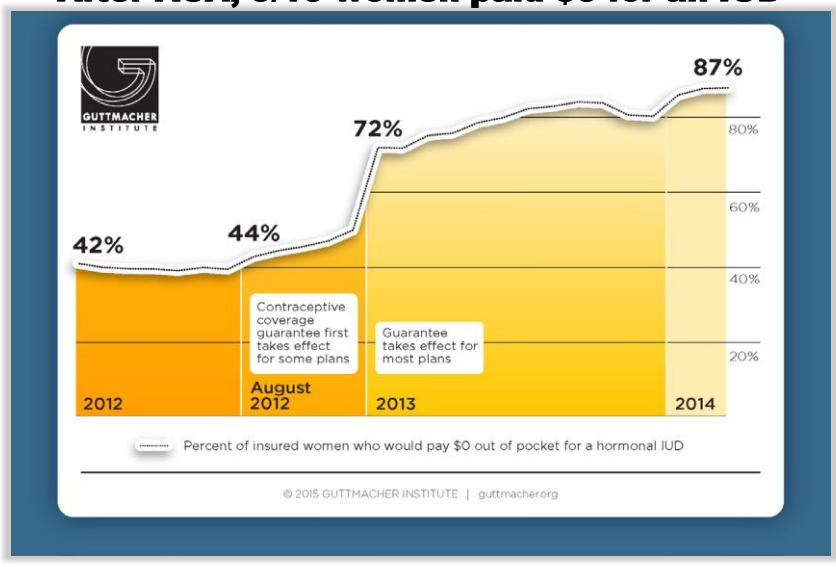
Source: Frost et al 2019

## Where does funding to support contraceptive access come from?

- Policies that affect comprehensive health insurance coverage for women—Affordable Care Act
- Policies that affect insurance coverage only for women's health or family planning services—Medicaid family planning programs
- Policies that directly affect the availability of contraception—Title X

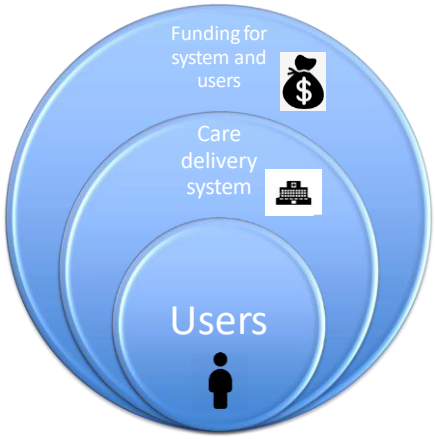
 

## After ACA, 9/10 women paid $0 for an IUD

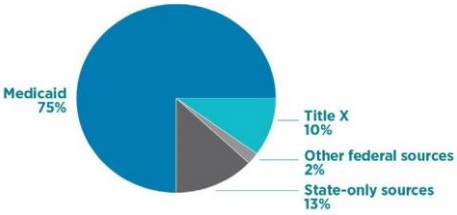


## Publicly funded family planning: 2015




- Funded through a variety of sources

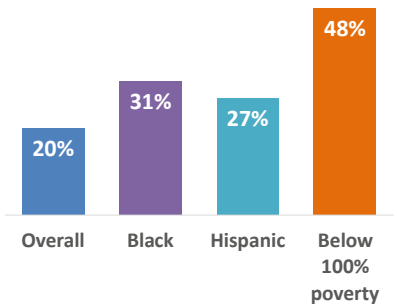



- 10,700 clinic sites
- 6.2 million clients served




## Medicaid is an essential source of U.S. health coverage

- 74 million enrollees in Medicaid and CHIP
- 20% of U.S. population (vs. 14% for Medicare)
- 12.9 million women of reproductive age

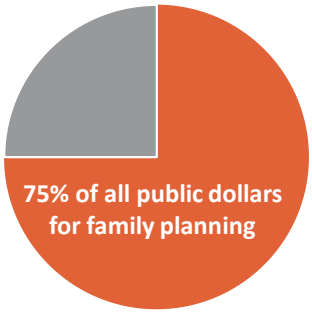



Women aged 15–44 covered by Medicaid or CHIP

CHIP = Children's Health Insurance Program

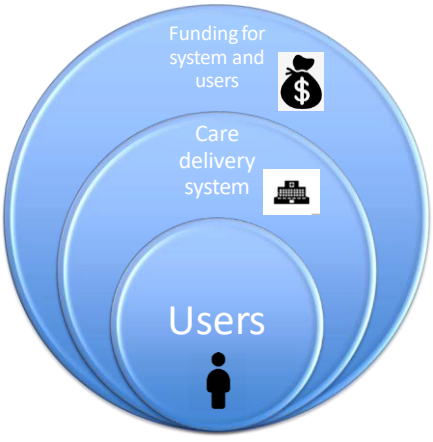
## Medicaid is central to publicly funded family planning

- Required coverage
- No cost sharing
- No coercion
- Free choice of providers
- Medicaid family planning expansions

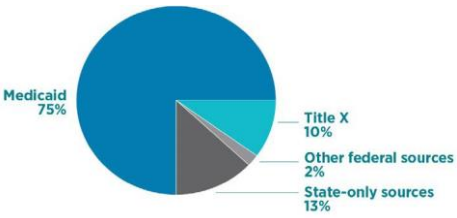





## Publicly funded family planning: 2015




- Funded through a variety of sources




- 10,700 clinic sites
- 6.2 million clients served

## Medicaid and Title X: Fundamentally Different Programs

- Title X is a *grant* program:
  - Funding goes to providers
  - Standards, principles, etc. apply to all funded clinics
  - Fundamental principles
  - Standards for high-quality care
- Medicaid is an *insurance* program:
  - Entitlement program
  - Within broad federal frame, states design programs
  - Federal, state governments split costs

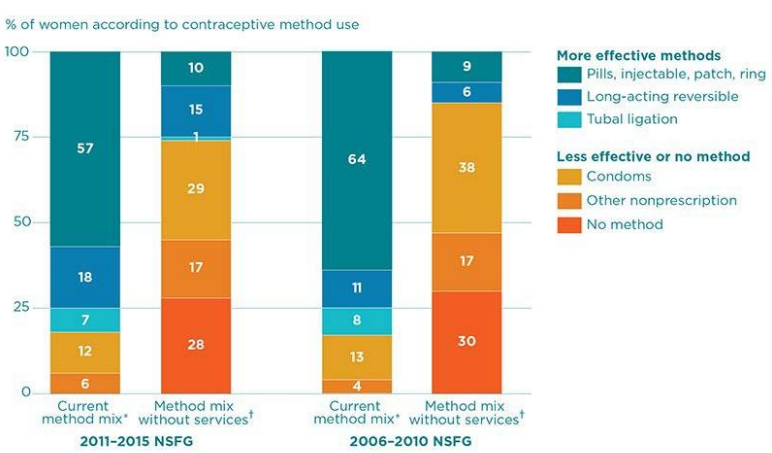



## Title X: Fundamental Principles

- All care must be voluntary; all clients are entitled to:
  - Broad range of contraceptive methods
  - Same package of services
  - Confidential care (special rule for teens' income)
- No client may be denied care because of an inability to pay
  - Poor clients served at no charge
  - Sliding fee scale
- Abortion is not a method of family planning; Title X funds cannot be used for abortion services

**COMPARING METHOD USE ACROSS SCENARIOS**

**If current users of publicly supported contraceptive care had no access to these services, most would rely on a less effective method or use no method.**




*Method mix among women who received publicly supported contraceptive services in last 12 months.
†Hypothetical method mix among similar women if no publicly supported services were available.
NOTE: NSFG=National Survey of Family Growth.



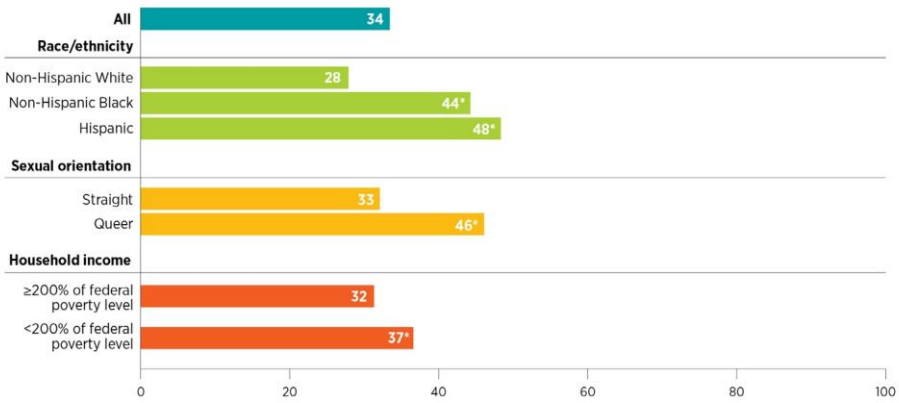
**Early impacts of COVID-19 on women's SRH and reproductive autonomy**

## 2020 Guttmacher Survey of Reproductive Health Experiences

- **Purpose: Examine impact of COVID-19 on SRH**
  - Employment, economic well-being
  - Fertility preferences
  - Access to contraceptive care and SRH services
  - Intimate partner violence (IPV)
  - Equity, disproportionate burdens
- **Study Design**
  - National internet-based survey
  - 2,009 cisgender women aged 18-49
  - Fielded week of April 30-May 6, 2020

## Percentage of women wanting to delay childbearing or have fewer children

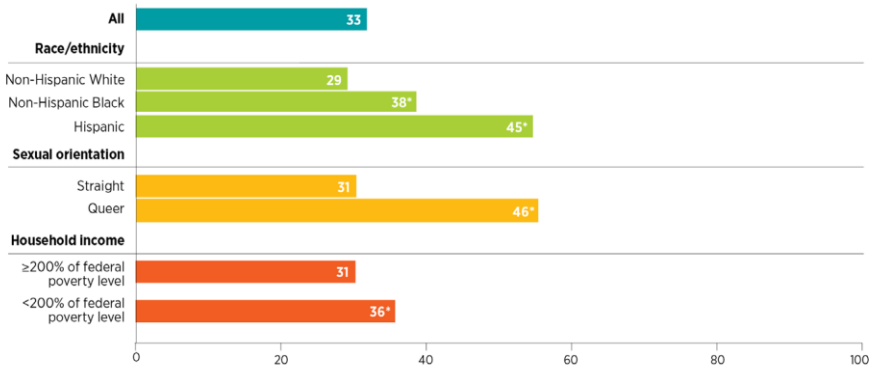



*Difference is statistically significant at p<.05. *Note:* Queer category includes responses of "gay or lesbian," "bisexual" and "other."

Source: Lindberg et al, 2020

## Percentage of women reporting delaying or canceling obtaining contraceptive or other sexual and reproductive healthcare

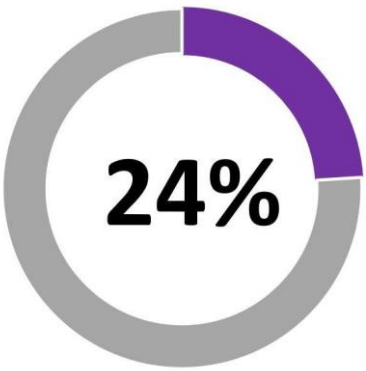



*Difference is statistically significant at p<.05. *Notes:* SRH=sexual and reproductive health. Queer category includes responses of "gay or lesbian," "bisexual" and "other."

Source: Lindberg et al, 2020

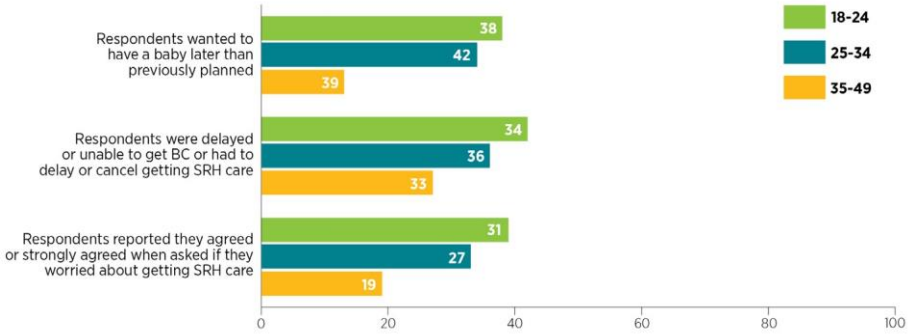


## Among pill users, nearly one in four users had switched to a telemedicine appointment




Source: Lindberg et al, 2020

## Younger women report a greater impact of the COVID-19 pandemic on their sexual and reproductive health



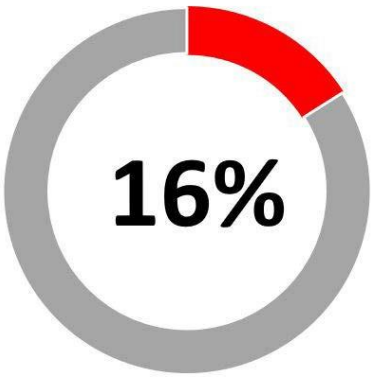

Source: Lindberg et al, 2020



## Intimate Partner Violence

**Respondents reported that since January 2020, their current or past partner:**

- **Humiliated or emotionally abused them**
- **Forced them to engage in any kind of sexual activity**
- **Kicked, hit, slapped or otherwise physically harmed them**
- **Made them feel afraid**




Source: Lindberg et al, 2020

## 1 in 3 women experiencing IPV had trouble or were unable to seek services due to the COVID-19 pandemic

Source: Lindberg et al, 2020



## What's on the horizon?

- Challenges for public funding of SRH care
- Contraceptive services and supplies already moving out of traditional clinical settings
- COVID-19 lessons for telemedicine?

# Thank you!

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