Managing Asthma:
Asthma Management Goals
- Achieve and maintain control of symptoms
- Maintain normal activity levels, including exercise
- Maintain pulmonary function as close to normal levels as possible
- Prevent asthma exacerbations
- Avoid adverse effects from asthma medications
- Prevent asthma mortality

Managing Asthma:
Asthma Action Plan
- Develop with a physician
- Tailor to meet individual needs
- Educate patients and families about all aspects of plan
  - Recognizing symptoms
  - Medication benefits and side effects
  - Proper use of inhalers and Peak Expiratory Flow (PEF) meters

Managing Asthma:
Sample Asthma Action Plan
Describes medicines to use and actions to take:

Managing Asthma:
Peak Expiratory Flow (PEF) Meters
- Allows patient to assess severity of his/her asthma
- Persons who use peak flow meters should do so frequently
- Many physicians require for all severe patients

Managing Asthma:
Peak Flow Chart
People with moderate or severe asthma should take readings:
- Every morning
- Every evening
- After an exacerbation
- Before inhaling certain medications

Managing Asthma:
Indications of a Severe Attack
- Breathless at rest
- Hunched forward
- Speaks in words rather than complete sentences
- Agitated
- Peak flow rate less than 60% of normal
Managing Asthma:
Things People with Asthma Can Do

- Have an individual management plan containing
  - Your medications (controller and quick-relief)
  - Your asthma triggers
  - What to do when you are having an asthma attack
- Educate yourself and others about
  - Asthma Action Plans
  - Environmental Interventions
- Seek help from asthma resources
- Join an asthma support group
Advancements in Surgical Therapy For BPH

Roco Morabito, Jr, MD

St. Mary’s Medical Center, Huntington, WV
Building HIV Treatment Capacity in the Family Medicine Clinic

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This activity is supported by an educational grant from Gilead Sciences, Inc.

This educational activity is provided by the North Carolina Academy of Family Physicians in collaboration with Med-IQ.

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AMA PRA Category 1 Credit™ toward the AMA Physician’s Recognition Award. When applying for the AMA PRA, Prescribed credit earned must be reported as Prescribed credit, not as Category 1.

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Disclosure Statement

The content of this activity has been peer reviewed and has been approved for compliance. The faculty and contributors have indicated the following financial relationships, which have been resolved through an established COI resolution process, and have stated that these reported relationships will not have any impact on their ability to give an unbiased presentation.

Eugene Reynolds, MD, has indicated no real or apparent conflicts.

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Learning Objectives

Upon completion, participants should be able to:
• Describe the effectiveness of ART and sustained treatment with ART for patients with newly diagnosed HIV
• Explain the advantages and disadvantages of the initiation of ART for patients with newly diagnosed HIV

HIV in the US

- HIV epidemic in the US continues
  • Approximately 1.1 million people are living with HIV (2015)
  • About 50% of new cases are diagnosed
  • 40% of new HIV infections are male
  • Men who have sex with men (MSM) are at highest risk
  • Women, African-Americans, and rural populations are disproportionately affected

New HIV Diagnoses in the US for the Most-Affected Subpopulations, 2015

- Chart showing new HIV diagnoses by subpopulation, with the highest numbers in African-American males and females.
HIV in the Southern US

- In 2016, southern states accounted for an estimated 44% of all new HIV infections in the US, despite only being home to 37% of the nation's population.
- 6 of the 10 states with the highest rates of new HIV diagnoses are in the South, as well as the 10 MSAs with the highest rates.

HIV Care Outcomes Among Black Individuals With Diagnosed HIV—US, 2014

- 21.9% of infections diagnosed among blacks were classified as stage 3 (AIDS) at the time of diagnosis.
- 71.6% of blacks were linked to care within 1 month of diagnosis.
- Among blacks diagnosed with HIV infection diagnosed by the end of 2011, who were alive at the end of 2013, 33.5% were retained in care and 48.3% adhered to viral suppression.
- Linked care and viral suppression among persons with infection attributed to IDU, females and those attributed to heterosexual contact, and persons aged 19 years or older compared with those 20-35 years.

HIV Care in the Southern US

- In addition to a heavy burden of new HIV infections, those newly diagnosed with HIV in the South are less likely to be linked to care than those in the rest of the country.
  - In 2015, on average, 27% of patients nationally were linked to HIV care within 1 month of diagnosis.
  - Over half of the jurisdictions that fell below the national average were located in the South.
How ART Has Changed

- Over the last 30 years, preferred ART regimens have changed from monotherapy to STI and multi-drug regimens.
- Advances in ART have increased the lifespan of persons diagnosed with HIV, which also means people living with HIV are on ART for longer periods of time.
  - Average life expectancy after HIV diagnosis increased from 10.5 to 22.5 years from 1990 to 2005.
- Updates in DHHS treatment guidelines for persons living with HIV are in response to the development of ART regimens with improved patient adherence and higher tolerability.

How ART Has Affected HIV Treatment Goals

- ART has changed HIV from a terminal illness to a chronic health condition.
- Treatment goals have shifted from delaying HIV progression to maximizing viral suppression.
- Undetectable = Untransmissible.

Impact of ART on HIV Transmission: Key Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Methods</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study 1</td>
<td>100 participants</td>
<td>ART vs. no ART</td>
<td>Reduction in viral load and risk of transmission</td>
</tr>
<tr>
<td>Study 2</td>
<td>200 participants</td>
<td>ART vs. no ART</td>
<td>Reduction in viral load and risk of transmission</td>
</tr>
</tbody>
</table>

Early Initiation of ART

- ART is recommended for all individuals with HIV, regardless of CD4 count.
- Entry to HIV care within 1 month of diagnosis and access to highly effective ART regimens are associated with a shorter time to viral suppression compared with patients delayed 1 to 3 months after diagnosis (P < .0001).
- ART access reduces HIV-related morbidity and mortality, and the life expectancy of patients initiating ART early in the course of their disease approaches that of the general population.
INSIGHT/START Trial

- Subjects initiating ART with CD4 > 500 experienced a reduction in:
  - CD4
  - Progression to AIDS
  - Risk of death, progression to AIDS
  - TV
- CD4 count recovery directly associated with CD4 count at initiation of ART

Early Initiation of ART Has a Beneficial Effect on AIDS-Related and Serious Non-AIDS-Related Health Events

TEMPRANO

- 2,056 patients, 43% with a baseline CD4+ count of ≥ 500 cells/mm³, followed for 4-7 years.
- Primary end point was a composite of death from any cause, AIDS-defining illness, non-AIDS-defining cancer, or non-AIDS-defining multiple bacterial infections.
- Risk of death or severe HIV-related illness was:
  - 486 patients with early ART (with variable ART)
  - 465 patients with ART (with no ART)

Steps to ART Initiation

- HIV care before ART initiation includes laboratory tests and a baseline evaluation that assesses the patient's readiness for ART

HIV Care: Pre-ART

- ART eligibility
- Antiretroviral therapy
- Support and adherence
- Condom use
**Immediate ART Initiation on the Day of HIV Diagnosis**

- Challenge with traditional algorithm of ART initiation is the delay between initial HIV diagnosis and the time ART is prescribed can lead to a failure of patient engagement.
- In the US, same-day ART initiation is still an investigational approach.

**What We’ve Discussed So Far**

- Early initiation of ART following HIV diagnosis is associated with a shorter time to viral suppression, lower risk of transmission, and improved health outcomes.
- ART should be initiated in persons diagnosed with HIV regardless of their CD4 count.
- Individuals on ART with undetectable HIV levels cannot transmit the virus to others.
- Most current guidelines recommend ART initiation and what considerations are important when individualizing treatment.

**Choices in ART**

- ART targets proteins that are essential for the reproduction of the HIV virus in a host cell.
- Preferred regimens have at least 3 drugs that target HIV at 2 different stages of replication.

**Tenofovir: TAF vs TDF**

- TAF is a prodrug of TDF that concentrates in cells and is converted to TDF there.
- TAF lowers plasma TDF levels than TDF.
- ART formulations with TAF allow for a smaller pill size and smaller drug doses without negatively affecting virologic response.
- Tenofovir alafenamide (TAF) is an analgesic to TDF/TAF (taftifine (TAF)).
- Lower TDF in the blood means less chance of kidney or BMD-harming side effects.
- TDF is associated with lower lipid levels than TAF.

**Recommended Initial Regimens for Most People With HIV**

- Guidelines highlight INSTIs as recommended treatment options because of their high tolerability, which is linked to improved adherence.
**Recommended Initial Regimens in Certain Clinical Situations**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Recommended STRs</th>
<th>Alternative STRs</th>
</tr>
</thead>
<tbody>
<tr>
<td>BIC/TAF/FTC</td>
<td>• DRV/PI</td>
<td>None</td>
</tr>
<tr>
<td>INSTIs plus 2 NRTIs</td>
<td>• DRV/PI</td>
<td>DRV/PI/FTC</td>
</tr>
<tr>
<td>HIVRTIs plus 2 NRTIs</td>
<td>• DRV/PI</td>
<td>ETV/FTC</td>
</tr>
<tr>
<td>Gilead cannot be used</td>
<td>• DRV/PI</td>
<td>ETV/FTC</td>
</tr>
</tbody>
</table>

**STR Options for People With HIV**

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Recommended STRs</th>
<th>Alternative STRs</th>
</tr>
</thead>
<tbody>
<tr>
<td>INSTIs</td>
<td>BIC/TAF/FTC</td>
<td>None</td>
</tr>
<tr>
<td>HIVRTIs</td>
<td>DRV/PI/FTC</td>
<td>ETV/FTC</td>
</tr>
</tbody>
</table>

**Which Treatment for Which Patients: Individualizing Initial HIV Therapy**

- Pre-ART characteristics
  - **Drive and Thrive:** Administer PI, and ART should be used.
  - **ART characteristics:**
    - **PI:** Food recommendations
    - **Coexisting conditions:**
      - **Collaboration:** HIV, CT, etc.
      - **Contraindications:** HIV

**Recommended Regimen: BIC/TAF/FTC**

- **Pre-ART characteristics:** Not recommended for patients with CrCl ≤ 30 ml/min or with severe liver impairment.
- **ART-specific characteristics:** Available as an STI and safe to use in pregnant women.
- **Concomitant conditions:** Not recommended for individuals with severe liver impairment.
- **Contraindications:** None.

**Recommended Regimen: DTG/ABC/3TC**

- **Pre-ART characteristics:** BIC-containing regimens are only for patients with negative HIV RNA ≥ 99% allele test.
- **ART-specific characteristics:** Available as an STI, taken once daily.
- **Contraindications:** BIC has no food considerations.
- **Contraindications:** DTG may be administered in individuals with high cardiac risk.
- **Contraindications:** Concomitant DTG-based regimens in patients with adherence concerns.
- **Contraindications:** None.
**Recommended Regimen: DTG Plus Tenofovir/FTC**

**Pre-ART characteristics**
- Recommended for patients in whom ART must be started before HIV resistance tests are available.

**ART-specific characteristics**
- DTG has no food considerations.

**Contraindications**
- TDF should be avoided in individuals with:
  - CKD
  - Osteoporosis
- Consider DTG-based regimens in patients with adherence concerns.

**Interactions**
- HBV Use TAF or TDF, with FTC or TIC.

---

**Recommended Regimen: EVG/c/Tenofovir/FTC**

**Pre-ART characteristics**
- None

**ART-specific characteristics**
- Both formulations available as 500mg tablets.
- Taken once daily.
- Both formulations must be taken with food.

**Contraindications**
- TDF should be avoided in individuals with:
  - CKD
  - Osteoporosis

**Interactions**
- HBV Use TAF or TDF, with FTC or TIC.

---

**Recommended Regimen:ral Plus Tenofovir/FTC**

**Pre-ART characteristics**
- None

**ART-specific characteristics**
- RA is not food considerations.
- RA can be taken once or twice daily.

**Contraindications**
- TDF should be avoided in individuals with:
  - CKD
  - Osteoporosis

**Interactions**
- RA may be advantageous in individuals with high circulating HIV RNA.

**Contraindications**
- Use TAF or TDF, with FTC or TIC, in individuals with HBV coinfection.

---

**Recommended Regimens: Common and/or Severe Adverse Effects**

<table>
<thead>
<tr>
<th>Adverse Effect</th>
<th>Symptom</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone density loss</td>
<td>Decreased bone density after initiation of ART</td>
<td>Increase bone density with calcium and vitamin D supplements</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>Nausea, vomiting, diarrhea</td>
<td>Reduce dose or change to another ART</td>
</tr>
<tr>
<td>Nephrotoxicity</td>
<td>Renal impairment</td>
<td>Monitor renal function, consider dose reduction</td>
</tr>
<tr>
<td>Metabolism</td>
<td>Lipid abnormalities</td>
<td>Adjust antiretroviral regimen</td>
</tr>
</tbody>
</table>

**Potential Side Effects**
- Rash, nausea, diarrhea, insomnia, dizziness, fatigue, headache, joint pain, back pain, abdominal pain, stomatitis.
- Increase in liver enzymes, lipid abnormalities, and nausea.
- Skin reactions, including photosensitivity.
- Hepatitis, including cases of acute hepatitis B and C.

---

**HIV Medication Adherence**

- Medication adherence means taking HIV medication(s) every day exactly as prescribed.
- Adherence can be challenging for many reasons, including:
  - Medication side effects
  - Difficulty adhering to a treatment regimen
  - Expensive
  - Frustration
  - Difficulty monitoring medication
  - Lack of health insurance
  - Substance abuse
  - Stigma surrounding a diagnosis.

---

**Benefits of Adherence**

- Sustained viral suppression
- Reduced risk of drug resistance
- Improved overall health
- Reduced risk of HIV transmission

---

- Image of a pill bottle with text:
  - SMTWFS
  - Sustained viral suppression
  - Reduced risk of drug resistance
  - Improved overall health
  - Reduced risk of HIV transmission
Strategies to Support Medication Adherence

- Have strategies in place at the start of treatment to support and maintain adherence
  - Pillboxes, pill reminders, task sheets, etc., including the CDC's Every Item Every Day mobile app.
- Involve the patient in the selection of ARV regimen
- Access adherence at every clinic visit
- Select from among effective interventions based on individual patient challenges to adherence
  - PIM support mobile treatment app
  - Calendar and phone assistance programs
  - Motivational interviewing
  - CDC's Every Item Every Day Training Training Toolkit

Therapies Falling Out of Favor

- FTC
  - First approved integrase
  - Decreased use due to side effects including glossiness, bad dreams, worsening mentalheath conditions, and elevated lipid levels
- RAL
  - First approved integrase
  - Decreased use due to issues with daily dosage
- CAR-T (CART) approved May 2017

Therapies Falling Out of Favor (continued)

- ETV/TDF/FTC
  - First approved integrase
  - Decreased use due to side effects including glossiness, bad dreams, worsening mental health conditions, and elevated lipid levels
- CCM (CART) approved May 2017

The Future of HIV Treatment

- DTG/DRV (approved November 21, 2017)
  - Smaller pill to take, well-tolerated, potential for decreased toxicity because it only contains 2 drugs
- DRV/CRTPI/FTC
  - First approved integrase
  - Initial trials showed that, at 24 weeks, patients who were virologically suppressed and switched from DTG/DRV/FTC to DRV/CRTPI/FTC remained virologically suppressed and BMI at the end of treatment increased.

The Future of HIV Treatment (continued)

- Long-acting injectables
  - 8 weeks or 9 weeks dosing
  - Benefits include not having to manage daily pills and no daily reminder of HIV treatment status

Conclusion

- Undetectable = Untransmissible
- Individuals whose HIV levels are undetectable cannot transmit the virus to others
- ART is recommended for all individuals with HIV, regardless of CD4 count, and early access to ART reduces HIV-related morbidity and mortality
- The S-recommended ART regimens for patients living with HIV allow healthcare professionals to individualize first-line therapy based on patient preferences and treatment goals.
Track One: From Knowledge to Action: Strategies to Assist Primary Care Clinicians in the Uptake of Colorectal Cancer Screening and Identification of Individuals at Risk

1:00 PM Welcome/Overview
1:05 PM State of Colorectal Cancer in West Virginia; Stephen Blankenship, MS, Epidemiologist, Div. of Cancer Epidemiology, WVDHHR/BPH/OEPS
1:20 PM – 2:00 PM Improving Colorectal Cancer Screening Rates: Incorporating Recent Hot Topics into Practice; Francis R. Colangelo, MD, MS-HQS, FACP, Chief Quality Officer Premier Medical Associates
2:00 PM – 2:20 PM Patient Navigation: The Key to Improving Screening Rates; Andrea Cline, RN; Tug River Health Association
2:20 PM – 2:40 PM Effectiveness and Costs of Tailored Reminders to Increase Return of Fecal Immunochemical Tests (FIT); Mary Ellen Conn, MS, Asst. Dir., Cancer Prevention and Control, WVU Cancer Institute, Charleston, WV
2:40 PM – 3:55 PM Cancer Genetic Risk Assessment; Emily Edelman, MS, CGC, Assoc. Dir., Clinical & Continuing Education, The Jackson Laboratory
3:55 PM – 4:00 PM Closing Remarks
Colorectal Cancer in West Virginia

Reporting Requirements
- Cancer cases are to be reported within six months of diagnosis
- Anyone who diagnoses or treats cancer must report cases to the WVCR
- Health Care Facility - Any hospital, nursing home, clinic, cancer treatment center, laboratory, or any other facility which provides health care or diagnostic services
- Health Care Provider - Any physician, dentist, nurse, or other individual who provides medical, dental, nursing, or other health care services of any kind
- WVCR receives cases through interstate data exchanges when West Virginia residents are diagnosed or treated in other states

West Virginia Cancer Registry (WVCR)
- The WVCR is a population-based registry that maintains data on cancer among those who have a West Virginia address at the time of their diagnosis
- Any case of cancer diagnosed after December 31, 1992, where the primary tumor is determined to be malignant or carcinoma in situ, is to be reported
- Exceptions include basal and squamous cell carcinomas of the skin, and carcinoma in situ of the cervix
- Non-malignant brain and central nervous system tumors became reportable January 1, 2002

West Virginia Cancer Burden
- Nearly 11,573 West Virginians are diagnosed with cancer annually
- Cancer is a leading cause of death in West Virginia
- West Virginia has a higher rate of cancer than the nation overall

Distribution of Cancer in Males

Distribution of Cancer in Females
West Virginia Colorectal Cancer Burden

- Nearly 1,140 West Virginians are diagnosed with colorectal cancer annually.
- West Virginia has a higher rate of colorectal cancer than the nation overall.

Colorectal Cancer Trend

- The colorectal cancer rate in West Virginia fell between 2001 and 2010.
- Since 2010, the rate has been stable.

West Virginia Colorectal Cancer Rate by County

West Virginia Colorectal Cancer by Stage

Late-stage Colorectal Cancer by County, 2011-2015

WVCR Staff

- Thomas Belford, PA – Field Abstracter
- Leslie Boner, CTR – QA Lead Abstracter
- Steven Blankenship, MS – Epidemiologist
- Shawn Farley, MHA, CTR – Director
- Myra Fernatt, BS – Data Manager
- Michael Gray – Field Abstracter
- Neal Kerley, CTR – Training Coordinator & Data Quality
- Markie McCoy, MPH – Epidemiologist
- Morgan Thomas – Secretary
- Mark Wigal – Field Abstracter
References

- WVCR, data from 1999 to 2015.

Contact

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www.cancerregistry.wv.gov

Funding:
Centers for Disease Control and Prevention #NU56DP006300-02-00
Objective

- Attendees will be able to identify the 4 outpatient core elements of the outpatient antibiotic stewardship program
- Attendees will be able to identify one key action to implement for each core element

Core Elements for Outpatient Antibiotic Stewardship

- The CDC Core Elements for Outpatient Antibiotic Stewardship were released in November 2016
- Completion of at least one key action is required for each of the four core elements

1st Core Element: Commitment

- Can your facility demonstrate dedication to and accountability for optimizing antibiotic prescribing and patient safety related to antibiotics?
  - If yes, indicate which of the following are in place. (Select all that apply.)
    - Write and display public commitments in support of antibiotic stewardship
    - Identify a single leader to direct antibiotic stewardship activities within a facility
    - Include antibiotic stewardship-related duties in position descriptions or job evaluation criteria
    - Communicate with all clinic staff to set patient expectations

2nd Core Element: Action

- Has your facility implemented at least one policy or practice to improve antibiotic prescribing?
  - If yes, indicate which interventions are in place. (Select all that apply.)
    - Use evidence-based diagnostic criteria and treatment recommendations
    - Use delayed prescribing practices or watchful waiting, when appropriate
    - Provide communications skills training for clinicians
    - Require explicit written justification in the medical record for non-recommended antibiotic prescribing
    - Provide support for clinical decisions
    - Use call centers, nurse hotlines, or pharmacist consultations as triage systems to prevent unnecessary visits
3rd Core Element: Tracking and Reporting

- Does your facility monitor at least one aspect of antibiotic prescribing?
  - Self-monitor antibiotic prescribing (this intervention only applies to solo practitioners or practices with fewer than 5 clinicians as long as all clinicians participate.)
  - Participate in antibiotic monitoring and reporting activities to track and improve antibiotic prescribing (this intervention only applies if all clinicians in the group participate in the activity)
  - Track and report antibiotic prescribing for one or more high priority conditions.
  - Track and report the percentage of all visits leading to antibiotic prescriptions.
  - If already tracking and reporting one of the above, track and report, at the level of the health care system, complications of antibiotic use and antibiotic resistance trends among common outpatient bacterial pathogens.

Benefits of Participation

- All education, technical assistance, and tools/resources are free.
- Receive education on the fundamentals of outpatient antibiotic stewardship and implementing in the outpatient setting.
- Education on Core Elements.
- Receive education to educate patients and caregivers on antibiotic stewardship.
- Network with experts in WV and the country working on antibiotic stewardship.
- Be a member of a five-state LAN and participate in best practice activities on antibiotic stewardship.

4th Core Element: Education and Expertise

- Does your facility provide resources to clinicians and patients on evidence-based antibiotic prescribing?
  - If yes, indicate how your facility provides antibiotic stewardship education to patients. (Select all that apply.)
    - Use effective communication strategies to educate patients about when antibiotics are and are not needed.
    - Educate about the potential harms of antibiotic treatment.
    - Provide patient education materials.
  - If yes, indicate how your facility provides antibiotic stewardship education to clinicians. (Select all that apply.)
    - Provide face-to-face educational training (academic detailing).
    - Provide continuing education activities for clinicians.
    - Ensure timely access to persons with expertise.

Expectations of Participation

- Complete the participation agreement form required by CMS.
- Agree to participate through July 2019.
- Agree to publicly disclose participation.
- Form an interdisciplinary team to implement the Core Elements.
- Identify a team champion and a day-to-day leader.
- Participate in LAN events, educational sessions, webinars, and conference calls.
- Share results, best practices, and lessons learned.

Thank you.
We look forward to working with you.
Improving Colorectal Cancer Screening Rates:
Incorporating Recent Hot Topics into Practice
Francis R Colangelo MD, MS-HQS, FACP
Chief Quality Officer
Premier Medical Associates

Outline
- Background of PMA
- Journey to improving screening rates
- Current screening recommendations
- Other news and updates
  - Early onset colorectal cancer
  - Closing the gap after a positive FIT

Premier Medical Associates
- Formed 1993
- 100 providers
- 23 specialties
- 1:1 ratio PCPs to specialists
- Part of Highmark Health
- Member of the Allegheny Health Network

Premier Medical Associates
- 2018 370,000 outpatient visits
- All adult and pediatric offices have level 3 PCMH certification

There was work to be done...
- Screening rate was 57.5%
- Many docs were only ordering colonoscopies
- Grand rounds presentation 12/13/12
- Formal kick off 1/1/13
Wise saying

"...the best screening test is the screening that gets done."
Sidney Winawer, MD

Practice Progress

- Initially was rapid
- 75% by March 2014
- Plateau
- Monthly progress reports
- Transparent provider reporting

FIT Registry

- Mailed kit on anniversary month of prior FIT
- > 90% of patients quickly complied
- Phone reminders for those delaying

Celebrating Success

80.2%
10/24/16
sDNA Pilot

- 3 years into this pop health effort, over 85% of Medicare beneficiaries had been screened
- Still 800 who had refused to be screened in spite of multiple outreach attempts
- Completed a pilot to see if sDNA was an acceptable alternative

Study Results

<table>
<thead>
<tr>
<th></th>
<th>sDNA</th>
<th>FIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity colon cancer (n=65)</td>
<td>92.3%</td>
<td>73.8%</td>
</tr>
<tr>
<td>Sensitivity advanced precancerous lesions (n=757)</td>
<td>42.4%</td>
<td>23.8%</td>
</tr>
<tr>
<td>Specificity-normal colon on colonoscopy (n=4457)</td>
<td>89.8%</td>
<td>96.4%</td>
</tr>
</tbody>
</table>

Results of sDNA Pilot

- 19.5% of these previously reluctant patients completed the sDNA test
- Identified as a result of follow up for those who had a positive sDNA
  - 3 advanced precancerous lesions
  - 2 colon cancers

SCREENING RECOMMENDATIONS
USPSTF

"...offering choice in colorectal cancer screening strategies may increase screening uptake. As such, the screening tests are not presented in any preferred or ranked order; rather, the goal is to maximize the total number of persons who are screened because that will have the largest effect on reducing colorectal cancer deaths."

ACS 2018

- Adults aged 45 years and older with an average risk of colorectal cancer undergo regular screening with either a high-sensitivity stool-based test or a structural (visual) exam, depending on patient preference and test availability.
- All positive results on non-colonoscopy screening tests should be followed up with timely colonoscopy.
CRC in Adults 45-49

- In 2018, an estimated 16,450 new CRC cases will be diagnosed in adults younger than 50.
- In 2014, approximately 43% of CRC cases under age 50 were in ages 45-49.

<table>
<thead>
<tr>
<th>Change in the Proportion of CRC in Adults Under Age 50, 1990 - 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990</td>
</tr>
<tr>
<td>2000</td>
</tr>
<tr>
<td>2010</td>
</tr>
<tr>
<td>2015</td>
</tr>
</tbody>
</table>

The proportion of CRC in adults under age 50 has doubled since 1990.

Percent of Years of Potential Life Lost

- Age to start screening
  - ACS, 2018: Starting at 45y (Q)
  - USPSTF, 2016: Screening at age 50y and older (S)

- Choice of test:
  - High-sensitivity stool-based test or a structural exam.
  - Different methods can accurately detect early stage CRC and adenomatous polyps.

- Acceptable Test options
  - FIT annually
  - FIT annually
  - iFOBT annually
  - iDNA every 1 or 3y
  - Colonoscopy every 10y
  - CTC every 5y
  - FS every 5y
  - FS every 10y plus FIT every year

Why the Increase?

- Rising rates of
  - Obesity
  - Red and processed meat intake
  - Type II diabetes
  - Antibiotic use (humans and livestock)
  - Hormone use in livestock
  - Unidentified environment risk factors (e.g., pesticides)
  - Unrecognized molecular/genetic factors

Age to stop screening?

- USPSTF
  - 76-85y individual decision making (C)

- ACS
  - Continue to 75y as long as health is good and life expectancy 10+y (Q)
  - 76-85y individual decision making (Q)
  - >85y discouraged from screening (Q)

High Risk Individuals

- Personal history
- Adenomatous Polyps
- Colorectal cancer
- Inflammatory bowel disease
- Prior radiation to abdomen/pelvis

- Family history
- Colorectal cancer or adenomas
- Hereditary syndrome (FAP, Lynch Syndrome)
High Risk Individuals

- Begin screening earlier (10 years before age at diagnosis of index case)
- Be aware that colonoscopy is the only recommended screening test

OTHER NEWS AND UPDATES

Less than half (49.1%) of 50- to 54-year-olds are up-to-date on screening

PMA Screening by Age Cohort

<table>
<thead>
<tr>
<th>age</th>
<th>total</th>
<th>% compliant with screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-54</td>
<td>2783</td>
<td>68.9%</td>
</tr>
<tr>
<td>55-59</td>
<td>3649</td>
<td>82.6%</td>
</tr>
<tr>
<td>60-64</td>
<td>4121</td>
<td>82.4%</td>
</tr>
<tr>
<td>65-69</td>
<td>3914</td>
<td>83.7%</td>
</tr>
<tr>
<td>70-75</td>
<td>3572</td>
<td>85.9%</td>
</tr>
</tbody>
</table>

Automated reminders

- All 50-54 year olds with no screening: in late January 2018 received text or voice reminder:
  "From Dr._________: Colon Cancer rates are on the rise in people age 50-54 yrs old. Please call today to schedule your screening 412_______!"
- Has since been occurring monthly for all 49 year olds turning 50 in the upcoming month

CRC Screening 50-54 Year Olds
Progress (?)

<table>
<thead>
<tr>
<th>Date</th>
<th>12/13/17</th>
<th>2/22/19</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>2,794</td>
<td>2,783</td>
</tr>
<tr>
<td>Current with screening</td>
<td>1,913</td>
<td>1,917</td>
</tr>
<tr>
<td>Overdue/Never Performed</td>
<td>627</td>
<td>605</td>
</tr>
<tr>
<td>Ordered</td>
<td>254</td>
<td>261</td>
</tr>
</tbody>
</table>

ACS 2018

- Adults aged 45 years and older with an average risk of colorectal cancer undergo regular screening with either a high-sensitivity stool-based test or a structural (visual) exam, depending on patient preference and test availability.

- All positive results on non-colonoscopy screening tests should be followed up with timely colonoscopy.

Implications of Lack of Follow-up

- Up to 1 in 10 with abnormal FIT, and 1 in 27 with abnormal FIT-DNA have colorectal cancer

- Up to 1 in 3 with abnormal FIT, and 1 in 4 with abnormal FIT-DNA have a large polyp or cancer

Follow Up Rates are Variable and Often Suboptimal

- Studies report colonoscopy completion after abnormal gFOBT or FIT ranging from 22% to 83%*

- ~1 in 3 not followed up in most studies

- Significant variation even in expert screening sites (PROSPR)**

*Jimbo M Ams Fam Med 2009; Humphrey LL JGIM 2011; Ronk SE JGIM 2009; Gwarte S Nudronia JNIO 2017 | ** Chubbik JCEBP 2016

- Dallas,TX safety net system

- 1,267 patients with abnormal FIT

- 536 (42.3%) failed to undergo follow-up colonoscopy within 12 months
Multiple Factors Can Lead to Delays
- Failure was attributable to:
  - Patient-level factors in 307 cases (57%)
  - Provider factors in 97 cases (18%)
  - System factors in 118 cases (22%)

PMA Missing Opportunities
- March 2013 a list of all positive FIT results from the past year was requested from PMA’s lab information system
  - 205 positive results
  - 118 had completed colonoscopy
  - 57.5%

Provider Education
- Some providers would order confirmatory FITs for patients with positive FITs
- Reminded them that all positive screening tests must be followed by a diagnostic test

Provider Education
- Gave providers a new script:
  - “I will agree to allow you to be screened with a FIT if you promise me that you will have a follow up colonoscopy if the FIT result is positive”

Staff Education
- Explained the absolute need for the follow up diagnostic testing
- Armed staff with scripted responses for reluctant patients
- Made contact back with ordering provider a must when patients are hesitant
Other Action Plans

- Created a positive FIT registry
- Emailed from lab every Monday

Alert added to EHR Banner

Reported in Positive FIT Registry

On the 1st of each month

Latest PMA Data

- From 3/30/2012 to 2/21/2019:
  - 1,632 positive FITs
  - 1,433 completed colonoscopies
  - 14 colonoscopies scheduled/pending
  - 185 refusers/procrastinators
  - 88.7% completion rate

JAMA, 317(10), 1631-1641,
Contact info

- Frank Colangelo
- fcolangelo@pmamail.com
- 412-380-2800
Patient Navigation: The Key to Improving Colorectal Cancer Screening Rates

**Role of the Patient Navigator**

<table>
<thead>
<tr>
<th>Role</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chart Review</td>
<td>Ensures accurate medical documentation</td>
</tr>
<tr>
<td>Patient Education</td>
<td>Provides education on colorectal cancer risks and screenings</td>
</tr>
<tr>
<td>Task of colorectal screening</td>
<td>Tracks all colonoscopies and FIT tests</td>
</tr>
<tr>
<td>Patient Reminder to call</td>
<td>Sends reminders to patients about upcoming screening dates</td>
</tr>
<tr>
<td>Fitness test results</td>
<td>Informs patients of test results and when they should make their next screening</td>
</tr>
</tbody>
</table>

**Benefits of Patient Navigation**

- Personalized approach to care management
- Assessment confirmed a greater number of patients returned FIT tests after the patient navigators called them personally, as a reminder.
- **Patient Education**
  - The patient navigator met with the patient and explained the importance of screening, effectiveness of the screening methods, and thorough collection instructions. An FIT was completed both in person and over the phone.
High-Quality Care is Worth the Investment

What is the true ROI for patient navigators?

Success of Patient Navigation through Community Empowerment & Equity Grant

- 2,493 one-on-one patient education sessions
- Assisted 332 patients needing complex navigation assistance
- 3,758 patient reminders through personal calls and email campaigns
- Received 669 FIT tests and Colonoscopy referrals
- 10 positive FIT tests, with 4 cancer diagnoses after diagnostic colonoscopy

Colorectal Cancer Screening Rate Improvement

October 2017 Screening Rate: 23%
October 2018 Screening Rate: 37%

Importance of Annual Screening:

1. Early detection can save lives.
2. Prevents advanced cancer stages.
3. Cost-effective in the long term.
4. Simple and non-invasive.
5. Recommended by medical guidelines.

Questions?
Cancer Genetic Risk Assessment

Emily Edelman, MS, CGC
April 4, 2019

Disclosures

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dedicated to improving human health and providing personalized therapies to help treat, cure and prevent disease

Research Areas

IMMUNOLOGY  METABOLIC DISORDERS & AGING  DEVELOPMENTAL/REPRODUCTIVE BIOLOGY
CANCER  NEUROSCIENCES  COMPUTATIONAL SCIENCE

50+ Principal Investigators

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  Join a presentation, jaxclinicalated is username

- Use any web browser
  www.PollEv.com/jaxclinicalated

- Text jaxclinicalated to 22333
How to vote via texting

How's my presentation so far?

- It's amazing, A
- It's incredibly amazing, B
- It's aw'right, C

Text: To 22333, A, B, C, or D
Web: PoliEv.com/ajaclinedated

Q: What proportion of people have a hereditary cancer syndrome?

A. 1/25
B. 1/250
C. 1/2,500
D. 1/25,000

What proportion of people have hereditary cancer?

DO YOU KNOW WHO THEY ARE?

Current state of CRC risk assessment

- Among individuals with a family history of CRC:
  - <50% received appropriate screening
  - <40% have talked with a clinician about their family history
- Among individuals presenting with rectal bleeding:
  - <40% have insufficient family history into documented to complete evaluate

Pletcher 2007 JOMI, Cameron 2014 Patient Tdy
Crowe, Abington 2017 J Cancer Oral/Hereditary Bas
Meet Abbi

Reason for visit
Family history of endometrial cancer
Medical hx
34 yo
Social hx
Married, one son

Q: What else do you want to know about Abbi's family history?

Family History

Risk stratification

HIGH
Single gene
Rare

INCREASED
Clustering of related diseases
Familial

AVERAGE
Sporadic diseases
Common

Q: Are you concerned about Abbi's cancer risk?

Please check next to any condition that affects your child, parent, sibling, aunt/uncle or grandparent. For each checked box, explain below who is affected.

- Blood clot
- Heart attack
- Stroke
- Skin problems
- Diabetes
- Kidney problems
- Strokes
- X Cancer
- Sister - uterine

- High blood pressure
- I.D or ID
- Birth defects
- Miscarriage/Stillbirth
A: Interview for sufficient detail
Clarify family structure and relationships
Don’t forget about unaffected relatives
At least 1st and 2nd degree relatives
Both sides of the family
Details about extent of disease
Ages of onset and death

Q: What is Abbi’s cancer risk?
A. High
B. Increased
C. Average

Q: Why is Abbi at high risk?

Q: What is Abbi’s cancer risk?
A. High
B. Increased
C. Average

To show this poll
1. Install the app from pollevs.com/app
2. Start the presentation

Convince me!
Q: Are there any red flags?

A: Genetic Red Flags
- Family history of multiple affected relatives
- Earlier age at onset of disease than expected
- Disease in the absence of known risk factors
- Multiple primary tumors in the same person
- Non-cancer findings suggestive of a syndrome or primary genetic defect, such as adenomatous colon polyps
- Ethnic predisposition
- Consanguinity

Q: Are there recognizable patterns of cancer?

Colon, endometrial, and gastric cancers are associated in Lynch syndrome
- Colon: 10-47%
- Endometrial: 16-41%
- Gastric: 3-13%
- Ovary: 1-21%

Associated cancers form a pattern
- Colon
- Endometrium
- Ovary
- Breast
- HBC
- Pancreas
- Small bowel
- Hepatobiliary
- Prostate
Including related cancers reveals a dominant pattern

Abbi is at high risk
- Multiple affected relatives
- Early age of onset
- Dominant pattern of associated conditions
- Complete family history information

RULE OF THUMB
High Risk: Think 3-2-1
- 3 RELATIVES
- 2 GENERATIONS
- 1 YOUNGER THAN USUAL

Meet Steve
Reason for visit:
Establishing care
Medical hx:
41 yo
Social hx:
Divorced, one daughter and one son

What questions would you ask Steve about his family history?

<table>
<thead>
<tr>
<th>Condition</th>
<th>father</th>
<th>mother</th>
<th>sibling</th>
<th>child</th>
<th>spouse</th>
<th>cousin</th>
<th>grandson</th>
<th>great-grandparent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood problems</td>
<td></td>
<td></td>
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<td></td>
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<td>Heart attack</td>
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<td></td>
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<td>Stroke</td>
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<td>Skin problems</td>
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<td></td>
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<td>Diabetes</td>
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<td></td>
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<tr>
<td>Kidney problems</td>
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<tr>
<td>Gastrointestinal</td>
<td>F</td>
<td>M</td>
<td>S</td>
<td>C</td>
<td>G</td>
<td>U</td>
<td>G</td>
<td>G</td>
</tr>
<tr>
<td>Cancer</td>
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<tr>
<td>High blood pressure</td>
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<td>Low blood pressure</td>
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<tr>
<td>Birth defects</td>
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<tr>
<td>Miscarriage/Stillbirth</td>
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</tr>
</tbody>
</table>

Family history
Q: What is Steve's cancer risk?

A. High
B. Increased
C. Average

Q: What is Steve's cancer risk?

A. High
B. Increased
C. Average

Q: Why is Steve at increased risk?
Steve is at increased risk

- Multiple affected relatives
- No clear pattern of inheritance

RULE OF THUMB

Increased Risk: familial clustering of cancer that does not meet the criteria for high risk
- At least 1 FDR OR 2 SDRs with common cancer at average ages on the same side of the family
- Personal history risk factors

Familial/increased risk is more common than high/hereditary risk

1 in 250 individuals have a hereditary cancer syndrome
1 in 10 individuals have increased risk for cancer based on family history.

Most cancers are not inherited

- 5-10% Hereditary High risk
- 10-15% Familial Increased moderate risk
- 75-85% Sporadic Average risk

Abbi is at high risk
**Q:** What would you recommend next for Abbi?

A: Collect more family history

B: Refer to genetics

C: Order genetic testing

**Q:** With whom should testing start?

A: Test an affected relative first

---

**A:** Refer high risk patients to genetics

Referral to cancer genetics

Genetic counseling

Genetic testing for Lynch syndrome, and potentially other genes

(APC, MUTYH, PTEN, SMAD2/3)

Personalized management, prevention and surveillance

---

**Abbi has homework**

Talk to family members with cancer

Learn more about cancer history

Be aware testing may be recommended for affected relatives first
Testing for Lynch syndrome has multiple steps

1. Tumor testing (relative with CRC / uterine)
2. Targeted testing based on tumor test, or
3. Broad germline testing based on personal/family history (relative with CRC or uterine)
4. Single mutation germline testing for relatives (Abbi, sister, other adults)

Tumor screening is the best first-line test for Lynch syndrome

immunohistochemistry (IHC) detects presence or absence of mismatch repair proteins

Tumor screening can direct germline testing

Cascade screening provides definitive risk information to relatives

Cascade screening provides definitive risk information to relatives

What questions might Abbi have about her positive result? Next steps?
**Q:** How would you discuss management?

**A:** Positive test results impact management in multiple ways

- Prevention
- Psych Response
- Surveillance
- Family Impact

**National and local resources to guide management**

- National Comprehensive Cancer Network
- American Society of Clinical Oncology
- Local cancer genetic counselors
- Support groups

**Genomic Risk Assessment Key Points**

- **Collect** history that indicates family structure and manifestations of disease
- **Assess** patterns and red flags
- **Assign** to risk category: Average, Increased, High
- **Use** risk to adapt plan for genetic counseling, testing, prevention, surveillance, etc.

**Lynch Genetic Testing & Management Key Points**

- **Positive** results have implications for the patient and family members
- Test an **affected** individual first
- Manage high risk patients based on guidelines for prevention & surveillance
- Genetics professionals are a **resource** and can provide counseling and guidance
Risk Assessment & Screening Toolkit

Develop a system that helps practices:
- Identify patients at increased/high risk based on personal and family history
- Apply screening guidelines based on risk
- Refer high risk patients to genetics
- Recognize and rapidly diagnose patients with a presenting CRC

Curated risk assessment tools

Toolkit design supports applying skills and implementing processes and tools
- Step-wise instruction to help practices:
  - Establish a structured process
  - Improve clinical skills
- Tools and worksheets with worked examples
- Case studies and tips
- Appendix of guidelines, educational resources and websites
- Customizable, "build your own toolkit"

Risk Assessment & Screening Toolkit

www.jax.org/crc toolkit
http://nccrt.org/resource-center/

FAST EASY FREE
Public health campaign
to increase education
access to evidence-based
Cancer genetics
recommendations

11  +  15
modules minutes

A comprehensive family history and early onset CRC toolkit for PC
Evaluation and Workup for Pelvic Pain in Women: The Critical Role of Family Physicians

Sponsorship and Support
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Evaluation and Workup for Pelvic Pain in Women:
The Critical Role of Family Physicians

Pelvic Pain in the Family Medicine Clinic

- Variable etiologies
- Delayed diagnosis, especially in younger patients
**Definition**

CPP is defined as persistent or intermittent pain in the lower abdomen or pelvis occurring for a minimum of 6 months and does not occur exclusively with menstruation, pregnancy, or intercourse.

**Epidemiology**

- Occurs in 15% of reproductive-aged women.
- Cited as a diagnosis in up to 10% of all outpatient gynecologic consultations, 40% of all laparoscopies, and 36% of all hysterectomies.
- Over $2 billion estimated annual costs in the US.

**Epidemiology**

- Women with pelvic pain have higher rates of abuse.
- Of 713 women seen in a pelvic pain clinic:
  - 40% had a history of sexual or physical abuse.
  - 31% had PTSD.
  - Women with a past history had more severe symptoms.

**Categories of Pain**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Acute Pain</th>
<th>Chronic Inflammatory Pain</th>
<th>Chronic Malignant Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain Type</td>
<td>Acute</td>
<td>Chronic Inflammatory</td>
<td>Chronic Malignant</td>
</tr>
<tr>
<td>Associated Pathology</td>
<td>Pelvic</td>
<td>Inflammation</td>
<td>Malignancy</td>
</tr>
<tr>
<td>Associated Procedure</td>
<td>Painful</td>
<td>Indirect</td>
<td>Direct</td>
</tr>
<tr>
<td>Associated Problem</td>
<td>Interstitial</td>
<td>Depression</td>
<td>Anxiety</td>
</tr>
<tr>
<td>Hormone Condition</td>
<td>Regular</td>
<td>Dysfunctional</td>
<td>-</td>
</tr>
<tr>
<td>Treatment</td>
<td>Medical</td>
<td>Surgery</td>
<td>Radiation Therapy</td>
</tr>
</tbody>
</table>

**Comorbid Pain Conditions Also Common in Adolescents With Endometriosis & Pelvic Pain**

- Mean age at diagnosis = 17.8 ± 2.0 years.
- Recent study (N=138) showed:
  - 5.7% of patients with endometriosis/pelvic pain had 1 or more chronic comorbid pain conditions.
  - 27% had 2 or more chronic comorbid pain conditions.
  - 48% had 1 or more mood disorders.
COPCs:
- Cluster of prevalent pain conditions that frequently co-occur
- Predominantly female
- Increased risk of developing a new COPC as the number of pain conditions a person has increases
- Research priority for National Institutes of Health (NIH)

Common Etiologies of CPP*
- Endocrinology
  - Hyperthyroidism
  - Hypothyroidism
  - Cushing's disease
  - Addison's disease
- Urology
  - Benign prostatic hyperplasia
  - Urinary tract infection
- Gastroenterology
  - Peptic ulcer disease
  - Hepatitis
- Neurology
  - Migraine headaches
  - Stroke
  - Multiple sclerosis
- Psychiatric
  - Depression
  - Anxiety
- Infectious
  - Bacterial urinary tract infection
  - Viral hepatitis
- Mechanical
  - Sacroiliac joint pain

Diagnostic Workup: The Role of the Physical Exam, Imaging, and Surgery
- Phases in making a differential diagnosis
- The MIP and the most important parts of the evaluation; can go decades to decades
- Complementary MRI form available at [link to website]
- Labs: urine (uric acid, bilirubin, pregnancy test)
- Consider pelvic ultrasonography to exclude ovarian pathology
- Using a systematic approach to evaluate each of the points
- Other related organ systems within the pelvis and the spine
- Use of pain medications
- Treatment of CPP depends on the cause
- Thorough investigation of both specific causes; may be targeted to general pain management with a more effective therapy

History
- Pain history
  - When did the pain start?
  - In what areas?
    - Acute or chronic?
  - Rate of severity:
    - Factors of history; relieved or exacerbated by factors
      - Fatigue
      - Stress
  - Associated symptoms:
    - Fatigue, weight loss, sleep disturbance
    - Ask all questions
- Associated symptoms:
  - Any other pain symptoms? (e.g., numbness, tingling)
- Physical exam:
  - Inspection
  - Palpation

Clinical Evaluation
- Careful history:
  - PMH, PSH, family history, psychiatric history
  - Occurrence of pain frequent on daily activities
  - Associated symptoms
    - Which were helpful?
- Medical history (includes menstrual history, STDs, pregnancies)
- Surgical history (think about adhesions, torsion, etc.)
- Sexual history (current practices, history of abuse, etc.)
- Psychological history (depression, anxiety, abuse history)
- Ask the patient about their goals and expectations
Physical Exam

1. O-tube evaluation of the vulvar vestibule
2. Single-gift exam
   - Evaluates pelvic floor muscles
   - Labia majora
   - Obturator internus
   - Perineum
   - Vaginal walls
   - Vaginal length
   - Cervix
   - Cervical os
   - Posterior cul-de-sac
   - Bladder
   - Urethra

Pelvic Exam

Imaging Considerations

- Pelvic ultrasonography is the first line imaging modality in children and women with pelvic pain
- CT is often used in emergency settings, particularly in patients where ultrasonography is inadequate for diagnosis
- MRI may be considered for the evaluation of female pelvic pain and, like ultrasonography, has the benefit of no radiation exposure

Endometriosis—Ultrasoundography or MRI

Key Considerations for Effective Patient/Provider Dialogue and Symptom Tracking

- Importance of shared decision making
  - Desired pregnancy status for contraception
  - Goals of treatment
  - Management of side effects and potential treatments
- CPP
- Other assessments?

Diagnosis: Endometriosis

- Initial management of pregnancy is the goal
- Pain management and symptom control is the goal
- Treatment options for endometriosis
  - Medical management
  - Surgical management
- Key considerations for younger patients
  - Recommendations for oral contraceptive pill
  - Recommendations for those with affected fallopian tubes
- What is next?
Endometriosis — Symptoms

- Pelvic pain
  - 20-75% of women with endometriosis
  - Usually not related to daily living
  - Can include:
    - Dysmenorrhea
    - Dyspareunia
    - Premenstrual dysphoric symptoms
    - Lower abdominal or back pain
    - Infertility

Physical Findings

- Tender nodules along the uterine fundus or in the cul-de-sac, especially just before menses
- Pain or induration commonly in the cul-de-sac or rectovaginal septum
- Uterine or adnexal fixation, or an adnexal mass

Laparoscopy/Laparotomy

- Pros:
  - Can also excise lesions
- Cons:
  - Invasive procedure
  - Risk of conversion to laparotomy and/or longer hospital stay
  - Delay:
    - May be difficult to detect microscopic and/or subclinical lesions
    - Accuracy depends on the skill level of the surgeon
    - Does not take into account the dynamic nature of disease

Surgical Diagnosis

Sites of disease

- Most common:
  - Peritoneum
  - Ovaries
  - Cul-de-sac
- Others:
  - Bladder
  - Bowel

Challenges in Diagnosing Endometriosis

- Many primary care providers are uncomfortable making the diagnosis
- Symptoms are nonspecific or associated with other disorders
- Survey of 7,095 women from 52 countries:
  - 67% undiagnosed
  - 48% saw a provider to get the correct diagnosis
  - 6.7 to 11 years from symptom onset to diagnosis and treatment

Benefits of Early Diagnosis

- Can reduce uncertainty, discomfort, and later complications
- May help to slow the disease progression
- Can increase quality of life
- May benefit long-term fertility
**Lifestyle Changes**

- **Sleep**: Shorten days by 3-5 hours of sleep; ideally, between 8-9 pm and 6 am.
- **Exercise**: Light to moderate exercise.
- **Exercise**: Moderate exercise.

**NSAIDs**

- Good evidence for treatment of dysmenorrhea.
- Insufficient evidence to treat women with endometriosis pain (Cochrane review).
- Minimal side effects, readily available, reasonable first-line treatment.

**Evidence-Based Pain Treatment**

- OCPs, especially for dysmenorrhea.
- Daily high-dose progesteron for endometriosis and pelvic venous congestion syndrome.
- GnRH analogues for endometriosis.
- NSAIDs for moderate pain.
- Laparoscopic destruction/excision of endometriosis lesions.
- Medical treatment plus counseling is more effective than medical treatment alone.

**Estrogen-Progestin Combinations**

Changes in mean dysmenorrhea score during the 4 menstrual cycle trial:

- Total dysmenorrhea scores significantly decreased at the end of treatment in both the OCP and placebo groups.
- The reduction in pain score was significantly higher in the OCP group (-2.0) compared with the placebo group (-0.6) \( P < 0.0001 \).

**Continuous** rather than cyclic administration appears to be more effective in reducing the recurrence of dysmenorrhea but not non-cyclic pelvic pain or dyspareunia.
**Progestins**

<table>
<thead>
<tr>
<th>Progestin</th>
<th>Dose</th>
<th>Mechanism of Action</th>
<th>Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norethindrone acetate</td>
<td>10-20 mg orally daily</td>
<td>Increase FSH, LH, decrease progesterone</td>
<td>Weight gain, mood swings, headache</td>
</tr>
<tr>
<td>Dienogest</td>
<td>2 mg orally daily</td>
<td>Negative feedback on hypothalamic-pituitary axis</td>
<td>Nausea, headache</td>
</tr>
<tr>
<td>Yuzuncii</td>
<td>350 mg orally daily</td>
<td>Decrease progesterone, increase estrogen</td>
<td>Nausea, headache</td>
</tr>
<tr>
<td>Levonorgestrel-releasing IUS</td>
<td>5-10 mg monthly release</td>
<td>Localized release of progestin</td>
<td>No data provided</td>
</tr>
</tbody>
</table>

**Oral progestin regimens**
- Norethindrone acetate: 10 mg daily, 20 mg twice daily, or 30 mg daily for 12 cycles
- Dienogest: 2 mg daily for 28 days
- Yuzuncii: 350 mg daily for 21 days

**Levonorgestrel IUD for Endometriosis**
- Systematic review after surgery for endometriosis
- Efficacy of 1 mg IUD in expectant management for the reduction of painful periods
  - Multicenter, prospective study in the treatment of painful periods
  - 107 women treated with 1 mg IUD in 17 centers
  - 50% reduction in pain at 6 weeks
  - Lower pain scores compared with women on GnRH agonists (non-significant)
  - 75% (71/95), 95% (70/74), 81% (74/90), 81% (75/92)

**GnRH Agonists**

<table>
<thead>
<tr>
<th>GnRH Agonist</th>
<th>Dose</th>
<th>Mechanism of Action</th>
<th>Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leuprolide</td>
<td>3.75 mg IM every month</td>
<td>Decrease FSH, LH, increase estrogen</td>
<td>Hot flashes, decreased libido, mood swings</td>
</tr>
<tr>
<td>Goserelin</td>
<td>11.25 mg IM every month</td>
<td>Inhibit gonadotropins</td>
<td>Hot flashes, decreased libido, mood swings</td>
</tr>
<tr>
<td>Nafarelin</td>
<td>3.75 mg IM every 2 months</td>
<td>Reduce gonadotropins</td>
<td>Hot flashes, decreased libido, mood swings</td>
</tr>
</tbody>
</table>

**Efficacy of depot Leuprolide**
- 95 women completed the study
- 49 in the leuprolide group and 46 in the placebo group
- Women in the leuprolide group had a statistically significant 44% reduction in pain
- 75% of patients in the leuprolide group had a 50% reduction in pain
- 95% of patients in the leuprolide group had a 50% reduction in pain
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Efficacy of Goserelin and Nafarelin

- Goserelin vs. OCP: after 6 months, no clear evidence of a difference between groups for self-reported pain:
  - Visual analog scale (0-100 mm) (0-100 mm): 50 patients on Goserelin (0-100 mm: 30, 95th CI: -2.8 to 1.8); 65 patients on OCP (0-100 mm: 30, 95th CI: -7.0 to 2.1). 61% of women were using secondary contraception.
  - Side effects: headache, nausea, sleep disturbances.
- Nafarelin (intra nasal): 200 mg twice daily vs oral: 100 mg 3 times daily:
  - After 12 months of treatment, endometriosis pain and symptoms significantly improved during treatment in both groups (P < 0.001).
  - Side effects: headache, sleep disturbances, increased axillary and abdominal pain, vaginal dryness, dysmenorrhea, etc.

GnRH Antagonists

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Mechanism of Pain Relief</th>
<th>Side Effects</th>
<th>Observation of Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elagolix</td>
<td>150 mg orally daily OR 200 mg orally twice daily</td>
<td>Inhibition of gonadotropin secretion; Down regulation of estrogen receptors</td>
<td>Hot flashes; Lipid abnormalities; Decreased bone density</td>
<td>OR 150 mg once daily for 24 months OR 150 mg twice daily for 6 months</td>
</tr>
</tbody>
</table>

Oral GnRH Antagonist

- Eligolix: Approved in May 2016
- Improved dysmenorrhea, non-menstrual pain, and frequency of pelvic pain during study
- Symptom improvement - year 3 months and sustained throughout the study
- Reduced fibroids, bleeding.

Safety
- Most common side effects: nausea, bloating, diarrhea, constipation, headache, hot flashes, joint pain, arthralgia, back pain, breast pain, breast tenderness, cough, diarrhea, dysmenorrhea, fatigue, headache, hot flashes, joint pain, muscle weakness, nasal congestion, nausea, nasopharyngitis, urinary tract infection, vomiting, weight gain.

Effects of Elagolix on Nonmenstrual Pelvic Pain

Aromatase Inhibitors

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Mechanism of Pain Relief</th>
<th>Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Letrozol</td>
<td>2.5 mg orally daily</td>
<td>Inhibition of aromatase preventing conversion of androgens to estrogens</td>
<td>Hot flashes; Headaches; Breast tenderness; Breast tenderness; Decreased bone density</td>
</tr>
</tbody>
</table>

- 15 premenopausal women who had tried and failed at least 2 forms of endometriosis treatment completed the study.
- 14/15 who completed the study had a significant reduction in pain levels throughout the study.
- 1 mg anastrozole and continuous once tablet 20 mg ethinyl estradiol: 2 mg levonorgestrel orally daily.
- Mean and median pain scores fell starting at month 1 and continued to decrease with each subsequent month of treatment.
Letrozole Efficacy

- After 6 months of treatment, intensity of pain symptoms was significantly lower in patients treated with letrozole (0.5 mg/day) vs those treated with placebo.
- Adverse effects include hot flashes, hair loss, joint/bone/muscle pain, fatigue, nausea, diarrhea.

Androgenic Steroids

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Mechanism of Pain Relief</th>
<th>Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Danazol</td>
<td>500-400 mg/week, daily</td>
<td>Induction of prolactin, growth retardation, local growth inhibition</td>
<td>Gain in lean mass, weight gain, acne, hirsutism</td>
</tr>
</tbody>
</table>

Danazol Safety/Efficacy

- In a 6-month randomized trial, danazol significantly (P < 0.01) improved endometrial lesions and pain symptoms in 85 women with endometriosis.
- 11.5% of patients withdrew from study due to adverse events.
- Treatment duration limited to 6 months.
- Should not be used in women with liver disease or hyperlipidemia.
- Women using danazol must also use effective contraception during danazol treatment.

Selective Progesterone Receptor Modulators

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Mechanism of Pain Relief</th>
<th>Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milipristone</td>
<td>50 mg orally daily</td>
<td>Induction of prolactin, reduction of local growth inhibition</td>
<td>Gaining, cramping, acne, hirsutism</td>
</tr>
<tr>
<td>Luprostal acetate</td>
<td>25 mg orally every other day</td>
<td>High activity at the progesterone receptor</td>
<td>Gaining, hirsutism, nausea, severe breast tenderness</td>
</tr>
</tbody>
</table>

Mifepristone Safety/Efficacy

- Cochrane Database of Systematic Reviews reported:
  - Moderate-quality evidence that mifepristone reduces dysmenorrhea (OR 0.48, 95% CI 0.29 to 0.79, p = 0.02)
  - Lower quality evidence: no reduction in dysmenorrhea (OR 0.21, 95% CI 0.01 to 0.92, p = 0.03)
  - Common side effects were nausea, vomiting, and breast pain.

Ulipristal Acetate Safety/Efficacy

- Cochrane did not find enough data to determine efficacy.
- Case reports demonstrate improvement in symptoms:
  - Pain scores decreased to a median of 7 (p < 0.01, patient became asymptomatic).
Endometriosis Treatment Algorithm

When Medications Aren’t Enough: Next Steps
- Referrals
  - Gynecologist
  - Pain management
  - Pelvic floor physical therapy
- Trigger point injections of the pelvic floor muscles (levator ani, obturator internus)
- Botulinum toxin (Botox®) of the levator ani muscles
- Nerve blocks — pudendal, obturator

When to Refer to a Gynecologist
- Pregnancy desired but not accomplished after 6-12 months of unprotected intercourse
- Pain not controlled with hormonal treatment and GnRH antagonist (GnRH agonist)
- Pain not controlled with hormonal treatment in young adolescents
- Evidence of large endometriomas, adherent disease, or deep infiltrating disease

Conclusions
- Pelvic pain due to endometriosis is common in primary care
- Primary care providers can effectively diagnose endometriosis and treat the majority of women
- Early diagnosis is important to slow future progression of the disease

Abbreviations and Acronyms
- WHO: World Health Organization
- ICF: International Classification of Functioning, Disability and Health
- SD: standard deviation
- BMI: body mass index
- CT: computed tomography
- MRI: magnetic resonance imaging
- DRE: digital rectal examination
- 3D: three-dimensional
- CT scan: computed tomography scan
- MRI scan: magnetic resonance imaging scan
- diffuse adenomyosis
- pelvic inflammatory disease
- deep infiltrating endometriosis
- dyspareunia
- deep dyspareunia
- chronic pelvic pain
- chronic pelvic pain syndrome
- chronic pelvic discomfort
- chronic pelvic discomfort syndrome