The Top 5 Questions to Ask Your Patients With IBD
A Patient-Centered Approach to Improving Quality of Care

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Faculty Disclosure

- Ms Norton: consultant: AbbVie Inc., Shire
Learning Objectives

- Apply evidence-based quality measures to improve care for patients with IBD
- Integrate strategies for preventing IBD- and treatment-related complications into the long-term management plans of patients with IBD
- Implement cancer surveillance strategies for patients with IBD who are at risk for colorectal, skin, or other malignancies, based on national guidelines

IBD = inflammatory bowel disease.
IBD: Chronic Immunologically Mediated Disease Characterized by GI Tract Inflammation

- 2 major forms: CD and UC
- Signs and symptoms: diarrhea, GI blood loss, weight loss, abdominal pain, anemia, malnutrition, bone density loss
- Course: progressive, relapsing and remitting
- Lifelong medical treatment usually required, with periodic adjustments for disease flares, aging-related physiological changes, treatment resistance

CD = Crohn’s disease; GI = gastrointestinal; UC = ulcerative colitis.
IBD: Treatment Goals

- Rapid, safe induction of remission
- Corticosteroid-free, durable maintenance of remission
- Restoration of growth and development, correction of malnutrition
- Avoidance of drug- and disease-related complications

### Medical Treatment Options: Nonbiologics

<table>
<thead>
<tr>
<th><strong>Aminosalicylates</strong></th>
<th><strong>Uses</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesalamine</td>
<td>CD, UC</td>
</tr>
<tr>
<td>Balsalazide</td>
<td>UC</td>
</tr>
<tr>
<td>Olsalazine</td>
<td>UC</td>
</tr>
<tr>
<td>Sulfasalazine</td>
<td>CD, UC</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Immunomodulators</strong></th>
<th><strong>Uses</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyclosporine</td>
<td>UC</td>
</tr>
<tr>
<td>Methotrexate</td>
<td>CD</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Thiopurines</strong></th>
<th><strong>Uses</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Azathioprine</td>
<td>CD, UC</td>
</tr>
<tr>
<td>6-mercaptopurine</td>
<td>CD, UC</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th><strong>Corticosteroids</strong></th>
<th><strong>Uses</strong></th>
</tr>
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<tbody>
<tr>
<td>Budesonide</td>
<td>CD, UC</td>
</tr>
<tr>
<td>Systemic</td>
<td>CD, UC</td>
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</tbody>
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### Medical Treatment Options: Biologics

<table>
<thead>
<tr>
<th>TNF-α Inhibitors</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adalimumab</td>
<td>CD, UC</td>
</tr>
<tr>
<td>Certolizumab pegol</td>
<td>CD</td>
</tr>
<tr>
<td>Golimumab</td>
<td>UC</td>
</tr>
<tr>
<td>Infliximab</td>
<td>CD, UC</td>
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<tr>
<th>α4-Integrin Inhibitors</th>
<th>Uses</th>
</tr>
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<tbody>
<tr>
<td>Natalizumab</td>
<td>CD</td>
</tr>
<tr>
<td>Vedolizumab</td>
<td>CD, UC</td>
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TNF-α = tumor necrosis factor-α.

Care Is Suboptimal for Many Patients With IBD

- Not managed per practice guidelines, with some patients receiving potentially harmful treatments
- Untreated or inadequately treated IBD is associated with high morbidity and diminished quality of life
- Variability in quality of care most pronounced in treatment: drug dosing, drug monitoring, cancer surveillance, severe disease management
- Estimated annual IBD-attributable direct costs: $6.3 billion
  - CD: $3.6 billion
  - UC: $2.7 billion

IBD Quality-of-Care Measures

• To improve quality of care for patients with IBD, both the AGA and CCFA have endorsed key evidence-based quality measures related to:
  – IBD treatment
  – Cancer surveillance
  – Health maintenance

AGA = American Gastroenterological Association; CCFA = Crohn’s and Colitis Foundation of America.

Top 5 Questions to Ask Your Patients With IBD

1. Where is your disease activity?
2. What is your history of IBD treatment and therapy-related monitoring?
3. Do you have any extraintestinal manifestations of IBD?
4. Are you up to date on your bone health monitoring and immunizations?
5. Are you being screened for cancer prevention?
Case Study: Celeste, a 25-Year-Old New Patient

• Reports 4-5 bloody stools daily and persistent fatigue
• Physical findings
  – Height: 165 cm (65 in); weight: 54 kg (119 lb); BMI: 19.8 kg/m\(^2\)
  – Blood pressure: 118/72 mm Hg; temperature: afebrile
  – Lungs, heart: normal; abdomen: no obvious mass; no hepatomegaly or splenomegaly
  – Perianal examination: normal
  – No oral ulcers; no joint effusions; no skin lesions

1. You ask her about her disease activity:
   – Has she been diagnosed with IBD? If so, what type?
   – What part of her GI tract has been affected?
   – What has been her degree of disease severity?

BMI = body mass index.
## Characteristic Features of IBD: UC vs CD

<table>
<thead>
<tr>
<th>Feature</th>
<th>UC</th>
<th>CD</th>
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<tbody>
<tr>
<td>Presenting signs and symptoms</td>
<td>Abdominal pain, chronic or nocturnal diarrhea, bloody diarrhea</td>
<td>Abdominal pain, chronic or nocturnal diarrhea, nausea, vomiting, weight loss; can have obstructing or perforating symptoms</td>
</tr>
<tr>
<td>Location</td>
<td>Large intestine only</td>
<td>Entire GI tract involvement possible</td>
</tr>
<tr>
<td>Distribution pattern</td>
<td>Continuous; rectal origination, proximal progression</td>
<td>Discontinuous, with skip lesions</td>
</tr>
<tr>
<td>Rectal involvement</td>
<td>Very common</td>
<td>Uncommon</td>
</tr>
<tr>
<td>Perianal disease</td>
<td>Uncommon</td>
<td>Common</td>
</tr>
<tr>
<td>Depth of inflammation</td>
<td>Mucosal</td>
<td>Transmural</td>
</tr>
<tr>
<td>Fistulas/strictures</td>
<td>Very uncommon</td>
<td>Common</td>
</tr>
<tr>
<td>Smoking</td>
<td>Negative association</td>
<td>Exacerbation of disease activity</td>
</tr>
</tbody>
</table>

# IBD Severity Classifications

<table>
<thead>
<tr>
<th>IBD</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
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</table>
| UC  | • <4 stools daily with or without blood  
• No signs of toxicity\(^a\)  
• Normal ESR | • >4 stools daily  
• Minimal signs of toxicity\(^a\) | • >6 bloody stools daily  
• Signs of toxicity\(^a\)  
• Elevated ESR\(^b\) |
| CD  | • Ability to tolerate oral intake  
• No abdominal tenderness  
• No fever  
• No obstruction | • Abdominal pain  
• Anemia  
• Fever  
• Nausea, vomiting  
• No response to treatment for mild CD  
• Weight loss | • High fever  
• Persistent symptoms despite outpatient corticosteroid therapy |

\(^a\)Signs of toxicity include fever, tachycardia, and anemia; \(^b\)Some patients with severe UC may not have elevated ESR.

ESR = erythrocyte sedimentation rate.

Celeste’s IBD Activity

- Celeste tells you she has a 5-year history of UC (pancolitis)
- UC usually in remission on maintenance therapy (mesalamine 2.4 g/d orally), but she has a flare once a year, treated with short courses of corticosteroids
- Over the last year she has had 2-3 flares, and 2 months ago she began azathioprine 100 mg/d orally
- Says she always takes her medicine but continues to have urgency and frequent bowel movements
What did you learn about Celeste’s disease activity that will help you improve her care?

1. Her history of UC is inconsistent with physical findings
2. Pancolitis makes disease flare unlikely
3. Poor adherence vs inadequate response to thiopurine
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2. Pancolitis makes disease flare unlikely
3. Poor adherence vs inadequate response to thiopurine

Use your keypad to vote now!
Improving Celeste’s Quality of Care

- Laboratory findings
  - CBC with differential, ESR, serum chemistries, and liver function: normal
  - Hemoglobin: 12 g/dL (mild anemia), mean corpuscular volume 102 fL, white blood cell count 4100/uL
  - Thiopurine metabolites: confirm azathioprine adherence
  - Stool testing: positive for fecal leukocytes; negative for ova, parasites, enteric pathogens, Clostridium difficile toxins A and B
- Infection and treatment nonadherence ruled out as cause of worsening symptoms
- Although thiopurine therapy may require 2-3 months for optimal effect, Celeste likely requires a step up in therapy

CBC = complete blood count.
Ask About IBD Activity

- AGA-endorsed quality measure: documentation of IBD type, anatomic location, and activity
- History of disease activity can help guide testing when disease flares are suspected
  - CCFA quality indicator: testing for *C difficile* toxins to rule out infection when patients with IBD present with new or worsening diarrhea and a disease flare is suspected
  - CCFA quality indicator: TPMT testing *before* initiation of thiopurine therapy
  - American College of Gastroenterology guidelines on UC management: measuring thiopurine metabolites can help assess adherence or resistance to thiopurine therapy

TPMT = thiopurine S-methyltransferase.

Ask About IBD Activity

- AGA-endorsed quality measure: documentation of IBD type, anatomic location, and activity
- History of disease activity can help guide testing when disease flares are suspected
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  - CCFA quality indicator: TPMT testing *before* initiation of thiopurine therapy
  - American College of Gastroenterology guidelines on UC

**ACTION ITEM:**
Ask your patients about their IBD activity.

TPMT = thiopurine S-methyltransferase.

Celeste: 2 Months Later, Her Symptoms Have Not Fully Resolved

- Celeste says her gastroenterologist wants her to start biologic therapy with a TNF-α inhibitor

2. You ask whether she has undergone treatment-related monitoring since you last saw her
- She replies that she has not had any tests since her last visit
How often should you monitor liver function once Celeste is placed on a biologic therapy?

1. Every month
2. Every 1-2 months
3. Every 2-4 months
4. Every 3-6 months
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Use your keypad to vote now!
Improving Celeste’s Quality of Care

- You tell Celeste that biologic therapy increases risk of opportunistic infection, particularly reactivation of *Mycobacterium tuberculosis* and progression of chronic HBV infection
- She undergoes screening:
  - QuantiFERON: negative for latent TB
  - HBV: negative for hepatitis B core antibody; negative for hepatitis B surface antigen; negative for hepatitis B surface antibody
- You have her schedule follow-up appointments every 3 months for routine monitoring of CBC and LFT

LFT = liver function tests.
## Adverse Effects Associated With Biologic Therapies for IBD

<table>
<thead>
<tr>
<th>Medication</th>
<th>Common</th>
<th>Rare</th>
</tr>
</thead>
<tbody>
<tr>
<td>TNF-α inhibitors</td>
<td>Headache; infection due to bacteria (eg, reactivation of <em>M. tuberculosis</em> infection), fungi (eg, histoplasmosis), or viruses (eg, chronic HBV infection progression); infusion/injection site reactions; psoriasiform dermatitis</td>
<td>Demyelination, heart failure, infection due to <em>Legionella</em> spp or <em>Listeria</em> spp, lymphoma, melanoma</td>
</tr>
<tr>
<td>α4-integrin inhibitors</td>
<td>Headache, upper respiratory tract infection, nasopharyngitis (vedolizumab), nausea, fatigue</td>
<td>Progressive multifocal leukoencephalopathy (natalizumab)</td>
</tr>
</tbody>
</table>

Adverse Effects Associated With Nonbiologic Therapies for IBD

<table>
<thead>
<tr>
<th>Medication</th>
<th>Common</th>
<th>Rare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aminosalicylates</td>
<td>Nausea, vomiting, headache, reversible male infertility (sulfasalazine), paradoxical worsening of colitis</td>
<td>Interstitial nephritis</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>Bone loss, cataracts, diabetes, glaucoma, hypertension, irritability, opportunistic infection</td>
<td></td>
</tr>
<tr>
<td>Cyclosporine</td>
<td>Hypertension, nephrotoxicity, neuropathy, seizures</td>
<td></td>
</tr>
<tr>
<td>Methotrexate</td>
<td>Nausea, vomiting, hepatotoxicity, opportunistic infection, myelotoxicity, teratogenicity</td>
<td>Fibrosing alveolitis</td>
</tr>
<tr>
<td>Thiopurines</td>
<td>Nausea, vomiting, hepatotoxicity, opportunistic infection, myelotoxicity, pancreatitis</td>
<td>Lymphoma, NMSC</td>
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</tbody>
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NMSC = nonmelanoma skin cancer.

# Laboratory Testing for Patients Receiving Medical Therapy for IBD

<table>
<thead>
<tr>
<th>Category</th>
<th>Laboratory Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General Recommendations</strong></td>
<td></td>
</tr>
<tr>
<td>Baseline testing before any treatment initiation</td>
<td>CBC, LFT, C-reactive protein, and/or ESR</td>
</tr>
<tr>
<td><strong>Medication-Specific Recommendations for Monitoring</strong></td>
<td></td>
</tr>
<tr>
<td>Aminosalicylates</td>
<td>Creatinine (annual); urine protein (every 2 years)</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>Serum 25(OH)D, metabolic panel, glucose</td>
</tr>
<tr>
<td>Thiopurines</td>
<td>TPMT (before treatment initiation); CBC with differential and LFT (every 2 weeks for the first 3 months; at least every 3 months thereafter)</td>
</tr>
<tr>
<td>Methotrexate</td>
<td>CBC and LFT (every 3 months)</td>
</tr>
<tr>
<td>Biologics</td>
<td>HBV and active or latent TB (before treatment initiation); CBC and LFT (every 3-6 months); John Cunningham virus antibody testing before starting natalizumab and then every 6 months</td>
</tr>
</tbody>
</table>

Do Not Overlook the Need for IBD Treatment-Specific Monitoring

- All nonbiologic and biologic therapies for IBD have adverse effects, and laboratory monitoring should be incorporated into management plans as part of routine health maintenance.
- Medication-specific monitoring is also recommended to improve quality of care for patients with IBD.
- AGA and CCFA quality measures: documentation of latent TB screening and HBV assessment before initiation of anti-TNF therapy.

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**ACTION ITEM:** Work collaboratively with your patients to monitor therapy and institute screening measures as necessary.

Case Study: Jerry, a 33-Year-Old Man With a 15-Year History of Ileal-Colonic CD Presents for Routine Follow-up

- Has no complaints; takes 6-mercaptopurine for his CD
- Physical findings
  - Height: 183 cm (72 in); weight: 75 kg (165 lb); BMI: 22.4 kg/m²
  - Blood pressure: 122/78 mm Hg; temperature: afebrile
  - Lungs, heart: normal; abdomen: normal, no hepatomegaly or splenomegaly, mild right lower quadrant tenderness without palpable mass
  - Perianal examination: normal
  - No oral ulcers; no joint effusions; no skin lesions

3. You ask him if he has any extraintestinal manifestations
   - Is he satisfied with his symptom control?
Jerry: Routine Follow-up (cont’d)

- Jerry says his CD symptoms have become bothersome lately, despite adherence to his 6-mercaptopurine regimen and persistence with his smoking cessation.
- He has had eye redness, pain, and light sensitivity recently, which he blames on seasonal allergies.
Are Jerry’s ocular symptoms related to his IBD care?

1. Yes, the symptoms are side effects of treatment with 6-mercaptopurine
2. Yes, he has uveitis due to inadequate control of his IBD
3. No, his symptoms are mild and unrelated to his IBD
Are Jerry’s ocular symptoms related to his IBD care?

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Use your keypad to vote now!

42% 47% 11%
IBD: Extraintestinal Manifestations

- Dermatologic
  - Erythema nodosum, pyoderma gangrenosum
- Hematologic
  - Anemia, venous thromboembolism
- Hepatobiliary
  - Cholelithiasis, PSC
- Musculoskeletal
  - Peripheral arthralgias and arthritis, spondyloarthritis
- Ocular
  - Episcleritis, uveitis, scleroconjunctivitis
- Renal
  - Nephrolithiasis

PSC = primary sclerosing cholangitis.

Jerry’s 6-Week Follow-up: Benefits of Team-Based Care

• Gastroenterologist consulted because:
  – Jerry’s GI symptoms are worsening
  – Eye redness, pain, and light sensitivity may indicate ocular inflammation and inadequate control of IBD-associated systemic inflammation
  – Decision made to switch to TNF-α inhibitor therapy

• Primary care evaluation: screenings for TB and HBV prior to starting biologic agent:
  – Negative for TB
  – Negative for HBV
Jerry’s 6-Week Follow-up: Benefits of Team-Based Care (cont’d)

• Urgent ophthalmologic referral required
  – Evaluate Jerry’s eye symptoms and make sure no ocular infection is present prior to initiation of TNF-α inhibitor therapy
  – Diagnosis: anterior uveitis
• Care plan
  – Topical corticosteroids prescribed to control uveitis
  – Discontinue sulfasalazine; initiate TNF-α inhibitor therapy
• 6-week follow-up
  – IBD symptoms well controlled
  – Tapered off topical corticosteroids without recurrence of uveitis symptoms
Remember That IBD Is a Systemic Disease That Warrants Team-Based Care

- IBD is a systemic disease
- Extraintestinal manifestations may occur in any patient with IBD regardless of disease control
- Team-based care is critical for managing IBD-related extraintestinal manifestations
- Gastroenterology consults and referral to other specialists may be needed

Remember That IBD Is a Systemic Disease That Warrants Team-Based Care

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ACTION ITEM:
Ask your patients about any extraintestinal manifestations of IBD.

Case Study: Alice, a 48-Year-Old Woman With a 10-Year History of CD With Segmental Colitis Presents for Routine Examination

- Until she stopped smoking, Alice had multiple disease flares and took several courses of oral prednisone
- CD well controlled with infliximab and azathioprine combination therapy
- She has no current complaints but mentions in passing that she broke her wrist when she tripped over a curb 6 months ago

4. You ask her if she has had a bone density test and if she is up to date with immunizations
Alice’s History of Bone Health Monitoring and Immunizations

• She has not had bone density testing: no one recommended it
  – Thought test was unnecessary until after menopause
• She does not get the influenza vaccine because it “does not do any good”
Bone Disease Risk Factors in Patients With IBD

• IBD-related
  – Malnutrition due to malabsorption or reduced oral intake during high IBD activity
  – Bone demineralization due to reduced physical activity during high IBD activity or after surgical treatment
  – Increased osteoclast activity due to high TNF-α levels
• Treatment-related
  – Impaired calcium absorption, increased calcium excretion, inhibited osteoblast activity due to prolonged or repeated courses of corticosteroids

In addition to bone density testing, what immunizations should Alice receive?

1. Influenza vaccination now and pneumococcal vaccination at age 65
2. Influenza and pneumococcal vaccinations now
3. Influenza vaccination now
4. No immunizations until age 65
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1. Influenza vaccination now and pneumococcal vaccination at age 65
2. Influenza and pneumococcal vaccinations now
3. Influenza vaccination now
4. No immunizations until age 65

Use your keypad to vote now!
Immunization Guidelines for Patients With IBD

• Immunization rates are low for patients with IBD at risk for vaccine-preventable illnesses
• Adhere to standard immunization schedules
  – Annual influenza vaccine
  – Pneumococcal vaccine, with second vaccination after 5 years
  – Human papillomavirus vaccine for males and females <26 years
  – Varicella vaccine offered to patients with no history of the infection
• Pneumococcal and influenza antibody responses may be blunted in patients receiving immunosuppressive therapy

You counsel Alice about her risks for bone loss, including:
- Repeated courses of corticosteroids
- History of a low-trauma fracture
She undergoes bone density assessment; already has low bone mass
Alice is also counseled on:
- Her increased risk for infection resulting from her immunosuppressive therapy for IBD
- The benefits of receiving annual influenza vaccine
- Her need for pneumococcal vaccination now rather than at age 65 because of her immunosuppressive therapy
Do Not Overlook Bone Health and Vaccine-Preventable Illness in Patients With IBD

- AGA quality measures include documentation of:
  - Recommending bone loss assessment for patients at risk for corticosteroid-related iatrogenic injury
  - Recommending influenza and pneumococcal immunizations
- CCFA quality indicator: patients with IBD receiving immunosuppressive therapy should be educated about appropriate vaccinations, including:
  - Annual inactivated influenza
  - Pneumococcal vaccination with a 5-year booster
  - General avoidance of live virus vaccines

Do Not Overlook Bone Health and Vaccine-Preventable Illness in Patients With IBD

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  – Recommending bone loss assessment for patients at risk for corticosteroid-related iatrogenic injury
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• CCFA quality indicator: patients with IBD receiving immunosuppressive therapy should be educated about appropriate vaccinations, including:
  – Annual inactivated influenza
  – Pneumococcal vaccination with a 5-year booster

ACTION ITEM:
Ask your patients if they are up to date on bone health monitoring and immunizations.

5. You ask Alice if she is undergoing cancer screenings

- She tells you she has:
  - Never undergone any cancer screening
  - Had a small patch of basal cell carcinoma removed from her nose last summer but was not told any follow-up screening was needed
What screenings should Alice undergo?

1. Annual screening for lymphoma
2. Biannual skin cancer screening examinations with her dermatologist
3. CRC surveillance colonoscopy as soon as possible
4. Lymphoma and skin cancer screenings as soon as possible
What screenings should Alice undergo?

1. Annual screening for lymphoma
2. Biannual skin cancer screening examinations with her dermatologist
3. CRC surveillance colonoscopy as soon as possible
4. Lymphoma and skin cancer screenings as soon as possible

Use your keypad to vote now!
Malignancy Risks in Patients With IBD: CRC

- UC and colonic CD increase CRC risk because of chronic colonic inflammation
- Risk factors: younger age at diagnosis, longer disease course, anatomic extent of colitis, degree of microscopic inflammation, presence of PSC
- Older age at diagnosis possibly associated with earlier CRC development
- For most patients, begin colonoscopic surveillance 8-10 years after symptom onset
  - Surveillance begins at diagnosis for patients with coexisting PSC

Improving Alice’s Quality of Care

• You counsel Alice about the biologic- and thiopurine-related risks of skin cancer
• Reinforce need for routine photoprotection
• Have her schedule annual skin cancer screenings with her dermatologist
• Because her CD symptoms began 10 years ago, she needs a CRC surveillance colonoscopy as soon as possible
Do Not Overlook Disease- and Treatment-Related Cancer Risks in Patients With IBD

- Both IBD-related immune dysfunction and IBD immunosuppressive therapies may increase the risk for certain malignancies.
- Lymphoma and skin cancer risks associated with biologics and/or thiopurines are low but should be considered in the overall health maintenance plans for patients with IBD.
- CCFA quality indicator: patients with extensive UC or colonic CD should begin surveillance colonoscopy within 8-10 years of disease onset, with follow-up examinations every 1-3 years.
- CRC surveillance should begin at diagnosis for patients with coexisting PSC.

Do Not Overlook Disease- and Treatment-Related Cancer Risks in Patients With IBD

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- CRC surveillance should begin at diagnosis for patients with coexisting PSC

ACTION ITEM:
Ask your patients with IBD if they are being screened for cancer prevention.

References:
PCE Action Plan

- Ask your patients about their IBD activity
- Work collaboratively with your patients to monitor therapy and institute screening measures as necessary
- Ask your patients about any extraintestinal manifestations of IBD
- Ask your patients if they are up to date on bone health monitoring and immunizations
- Ask your patients with IBD if they are being screened for cancer prevention

PCE Promotes Practice Change
Q & A
What is the role of diet and nutrition in treating CD and UC?
Q & A

What is the John Cunningham virus?
How often do you screen for TB?
If someone is traveling to a region of the world where TB is more common, should they stop their biologic a month before they go?
Q & A

Do you continue patients with latent TB on isoniazid or any other medication once their test results have come back negative?
Q & A

What do you do for a mother who is breastfeeding while taking mesalamine, but has a flare every month with bloody stools?
Does going on a biologic during pregnancy reduce the probability of genetic transmission of IBD to the baby?
Q & A

When should a biologic agent be stopped before a patient is administered a live vaccine, such as varicella vaccine, and, once immunized, when can they resume their biologic therapy?
In patients who know that they are to undergo an elective surgery, such as total joint replacement, how many weeks ahead of time should they stop taking a biologic agent?
What precautions can be taken for a patient on a biologic who requires emergency surgery, such as an appendectomy or hip fracture?
Do patients who develop nephrolithiasis while on steroid therapy require calcium supplementation?
What is polymultifocal leukoencephalopathy?
What is the tipping point in terms of corticosteroid dosing, whether inhaled, oral, or injectable, for someone to require an early bone mineral density test?
Do patients with IBD need to have an upper endoscopy to screen for GI cancers?