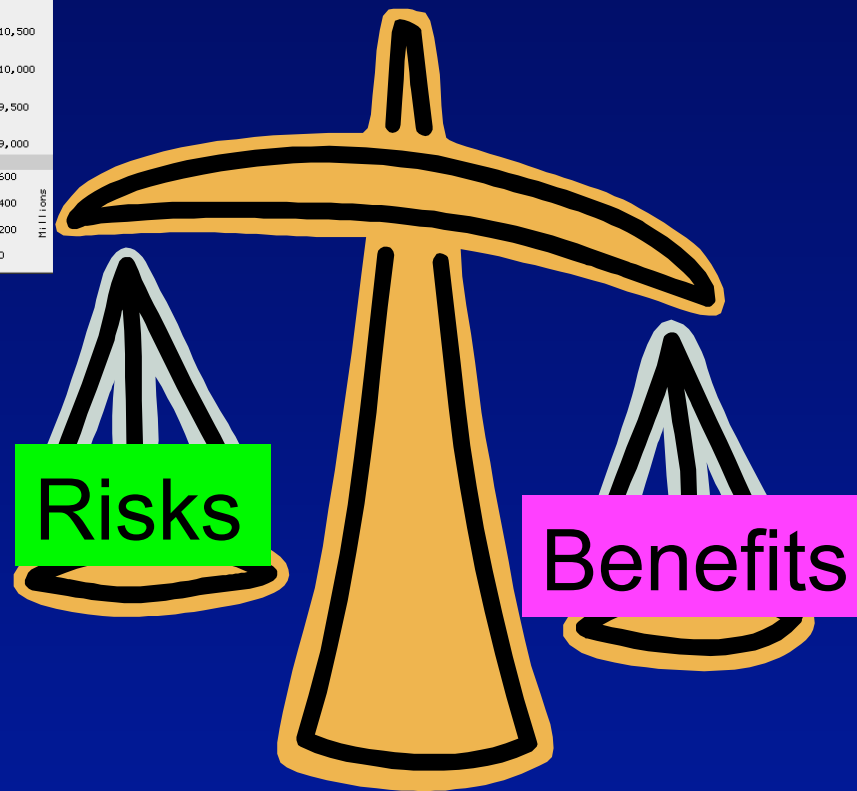


What are the Risks of Infections with IBD Therapies?

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Risk vs. Benefit



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Case

- 34 year-old man diagnosed with Crohn's at age 18
- Required one surgery to remove part of his intestine & multiple surgeries for perianal fistulae
- Infliximab (Remicade) was started in Fall 2008, but discontinued in Dec 2008 due to recurrent skin infections
- Adalimumab (Humira) was started in March 2009



Case

- June 2009—Left hand abscess that ultimately required surgery



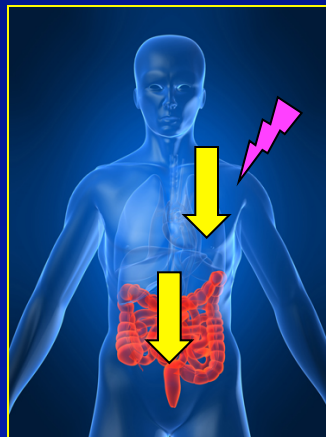
Case

- Adalimumab (Humira) was stopped for two months while the hand healed
- Due to worsening of his Crohn's, adalimumab (Humira) was restarted and hand infections returned prompting us to stop adalimumab permanently
- He has not had any skin infections since then
- However, his Crohn's disease has become very severe



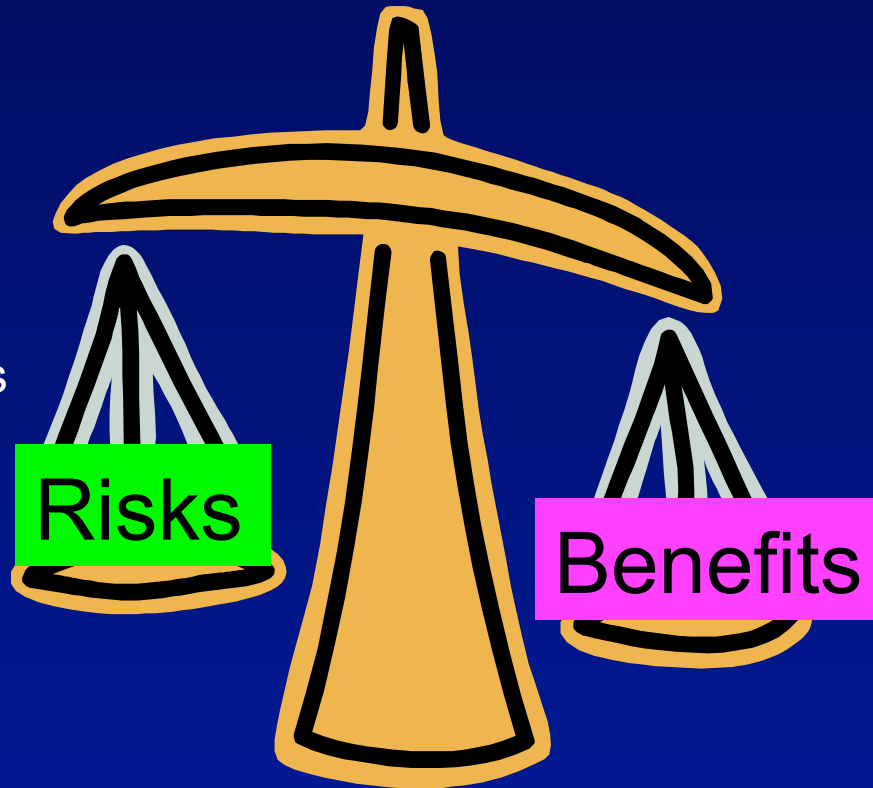
Problem

- Crohn's disease and UC are due in part to an over-active immune response in the intestine
- Most of the effective medications used to treat Crohn's disease and UC suppress the immune response not only in the intestine, but throughout the body, resulting in an increased risk for infections



Solution

- Potential side effects
- Worsening of other medical conditions
- Infections
- Malignancy



- Prevention of complications related to IBD
- Improved quality of life



All Infections are Not Created Equal

Infections in the normal population

- Usually resolve on their own and are not life-threatening
- Common cold, minor skin infections, minor gastrointestinal illnesses, flu

Infections in the immunosuppressed population

- Some are known as opportunistic infections
- Common infections that overpower the body

Infections in IBD

Non-therapy related

Abscess

Urinary tract infection

Therapy related (Opportunistic)

Viruses

HSV, VZV, CMV, EBV, HPV

Bacteria

C. difficile, TB

Fungus

Candida, Histoplasmosis

Other

P. jiroveci



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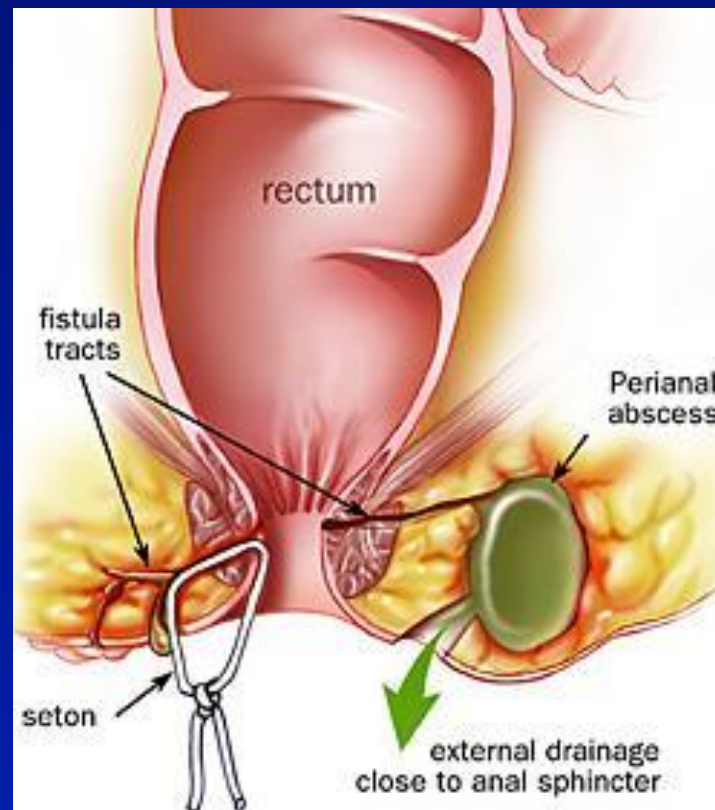
Non-Therapy-Related Infections in IBD

Non-therapy related

Abscess

Urinary tract infection

Crohn's Disease



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Opportunistic Infections in IBD

Therapy related

Viruses

HSV, VZV, CMV, EBV, HPV

Bacteria

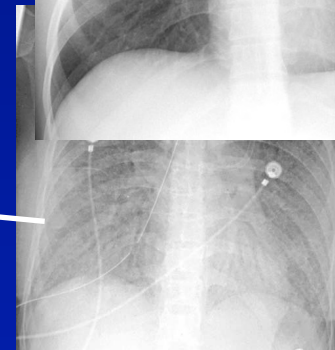
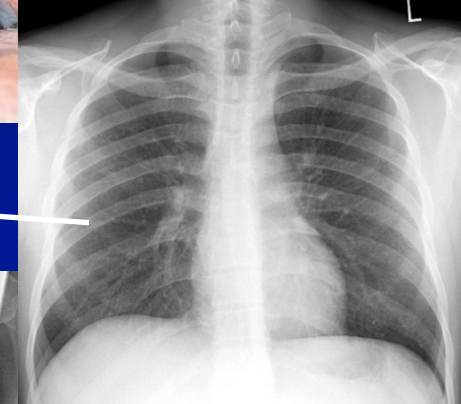
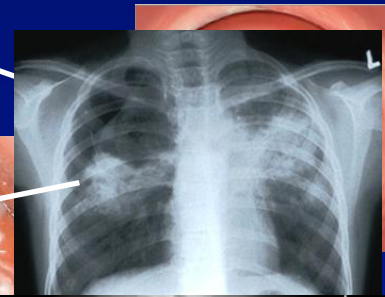
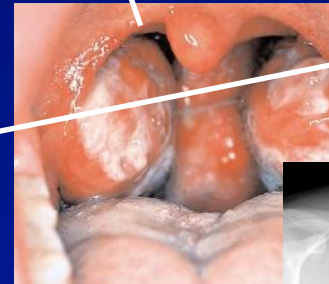
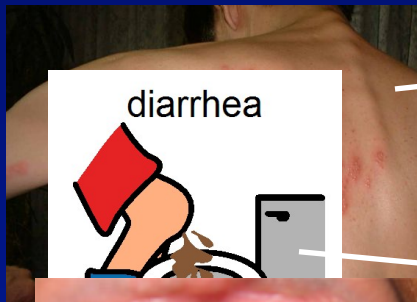
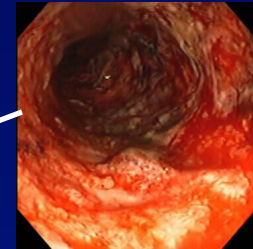
C. difficile, TB

Fungus

Candida, Histoplasmosis

Other

P. jiroveci



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What Medications are Associated with an Increased Risk of Infection?

Corticosteroids

- Prednisone
- Methylprednisolone (Solumedrol)

Immunomodulators

- 6-MP
- Azathioprine (Imuran)
- Methotrexate

Anti-TNF Agents

- Infliximab (Remicade)
- Adalimumab (Humira)
- Certolizumab (Cimzia)

Other

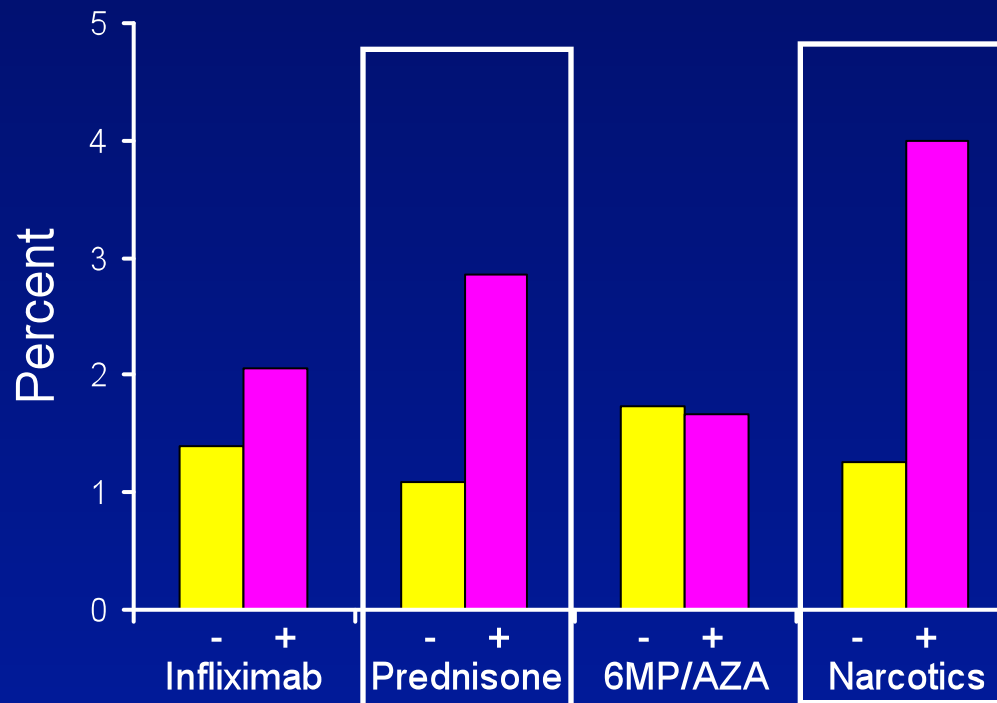
- Cyclosporine
- Natalizumab (Tysabri)



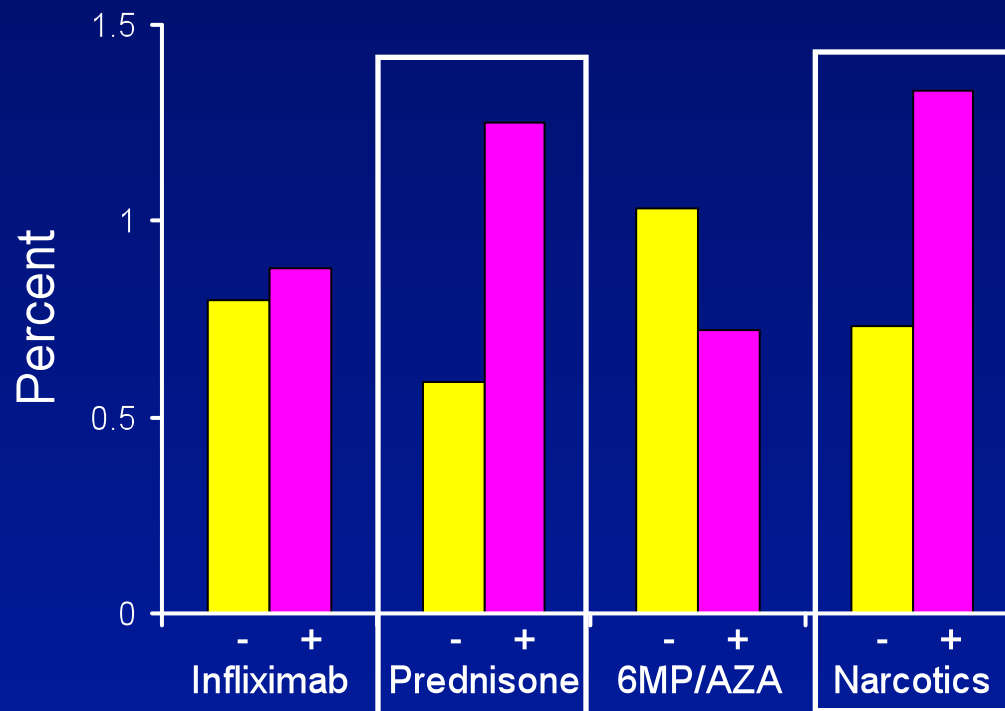
What is the Risk of Any Infection if I take these Medications?

- Hard to say exactly
- Each study has limitations and results may not apply to all IBD patients
- Definitions of “infectious complications” varied
- Most controlled clinical trials of immuno-suppressants in IBD found that the risk of developing an infection is minimally increased
- Broad range of estimates (0.5-30%)

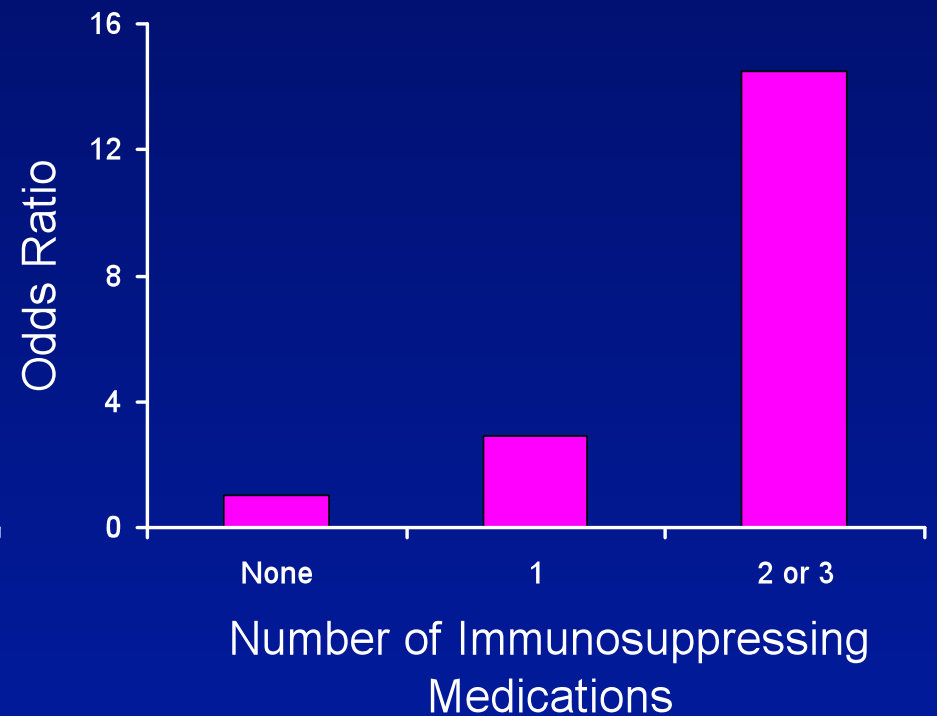
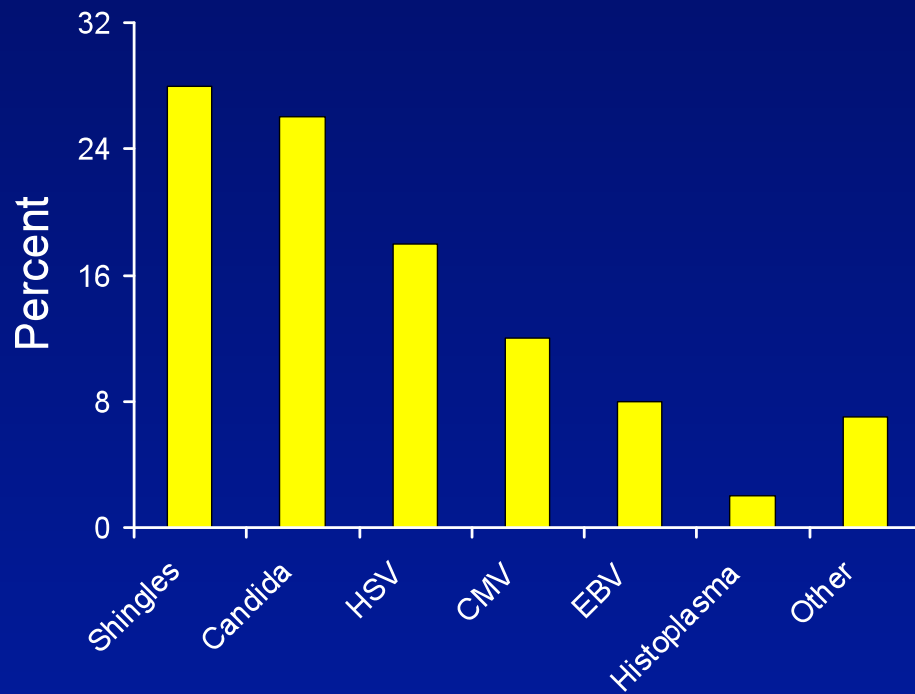
What is the Risk of Serious Infections if I take these Medications?



What is the Risk of Death if I take these Medications?



What is the Risk of Opportunistic Infections if I take these Medications?



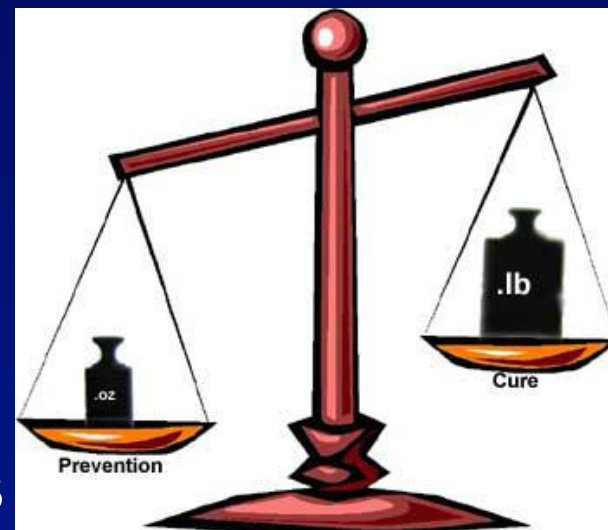
What can I do?

- Be reassured that therapy-related infectious complications are quite rare
- Discuss the risk/benefit balance with your doctor
- Notify your doctor if you develop unusual or prolonged symptoms (e.g. unexplained fevers, chronic cough, weight loss, odd skin rashes, non-healing mouth ulcers)
- Prevention



An Ounce of Prevention

- Adequate nutritional intake
- Wash hands, avoid close contact with sick individuals
- Obtain recommended vaccines (preferably before starting immunosuppressive therapy)
 - Annual influenza & H1N1 vaccines
 - Pneumococcal vaccine every 5 years
 - Hepatitis B vaccine series
 - ? {
 - Varicella Virus vaccine series
 - Human Papilloma Virus vaccine



Summary

- Certain infections can be a complication of Crohn's disease regardless of therapy
- Therapy-related (opportunistic) infections are relatively rare and can occur in Crohn's or UC
- Increased numbers of immunosuppressive medications correlate with increased risk of opportunistic infections
- If immunosuppressive medications are needed, prevention of infections is key

Risks



"We've considered every potential risk except the risks of avoiding all risks."

Benefits

