

# Shared Decision Making

## Improving Condition Management Discussions

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# Crohn's Disease – Chronic Digestive Disorder



Gary – Age 15 in hospital

Smiling for picture, but screaming in pain when urinating

- Diagnosed at age 12
- Complications

Gary's GI Doctor is at a conference

Needs Surgery

Choose a maintenance plan



# The Options – 15 minute appointment

- Remicaid
- 6MP
- Another drug  
(I was too shocked to retain the name)
- Nutritional therapy



# Background



Not for reproduction.  
Must have written approval.



# The Players

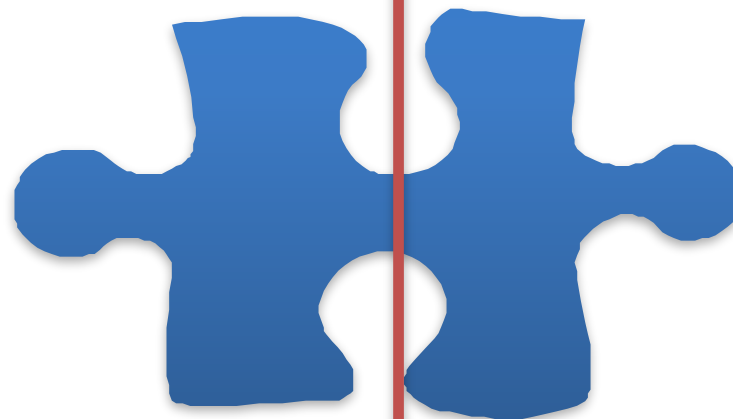
Gary



Me



Steve



Doctor



**Challenge: Choose a maintenance program**

Not for reproduction.  
Must have written approval.

# Quantitative Functional Deployment

- A big word for a simple concept
- Six Sigma Quality tool used in business to make choices
- Decisions based on customer needs and priorities
- Removes emotion from the decision
- All stakeholders have input



# Sample QFD

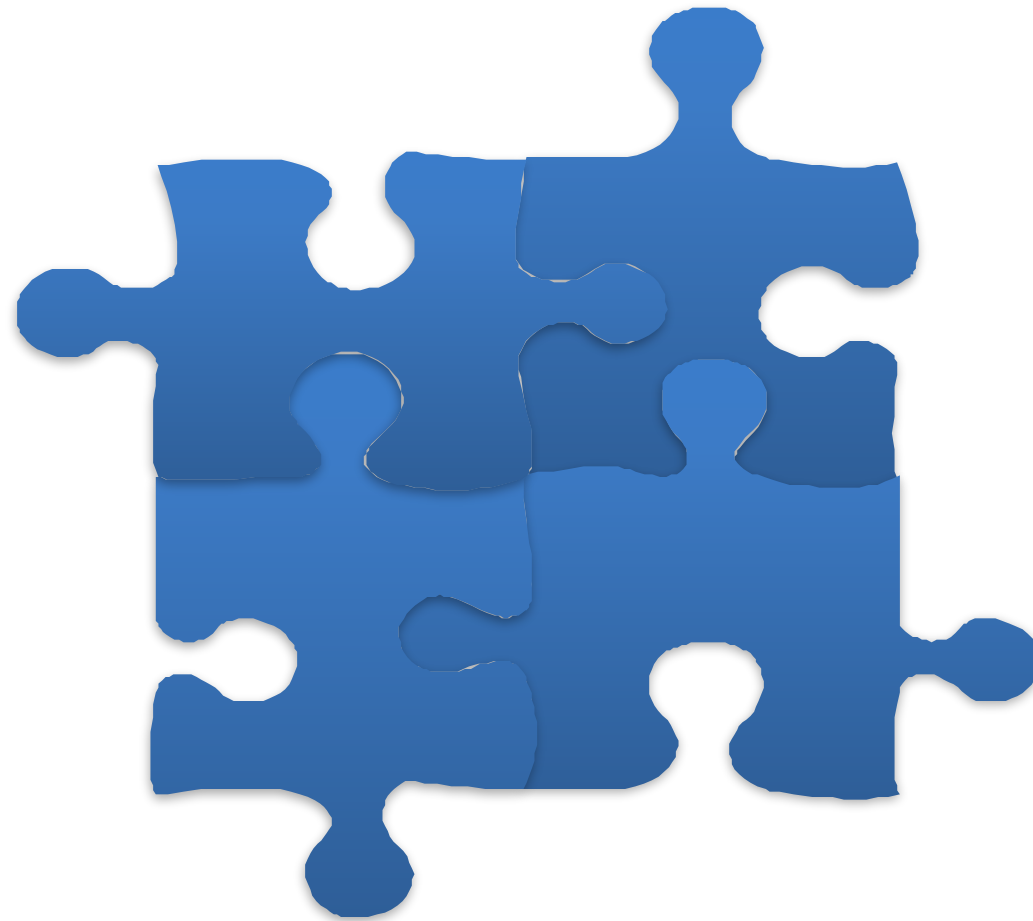
Patient Values	Gary rank	Parent rank	Average rank	Remicaid	6MP	Other drug	Nutritional Approach
<i>Ease</i>	<div>For each person:</div> <div>What matters most</div> <div>Fears</div> <div>Short term goals</div> <div>Long term goals</div>						
<i>Ability to eat foods</i>							
<i>Minimum lasting side effects</i>							
<i>Family Impact</i>							
<i>Cost</i>							
<i>Total</i>							

# Sample QFD

Patient Values	Gary rank	Parent rank	Average rank	Remicaid	6MP	Other drug	Nutritional Approach
<i>Ease</i>	<b>3</b>	<b>1</b>	<b>2</b>	<b>1</b>	<b>3</b>		<b>3</b>
<i>Ability to eat foods</i>	<b>5</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>3</b>		<b>3</b>
<i>Minimum lasting side effects</i>	<b>5</b>	<b>5</b>	<b>5</b>	<b>1</b>	<b>3</b>		<b>5</b>
<i>Family Impact</i>	<b>3</b>	<b>1</b>	<b>2</b>	<b>5</b>	<b>1</b>		<b>3</b>
<i>Cost</i>	<b>1</b>	<b>3</b>	<b>2</b>	<b>3</b>	<b>3</b>		<b>3</b>
<i>Total</i>				<b>43</b>	<b>41</b>	<b>0</b>	<b>55</b>



# Factual Methodology to discuss options





**Gary chose the nutritional approach.  
Plan B was medications.**

Not for reproduction.  
Must have written approval.



# Results



# One Data Point



- Good decision made
- Took patient & family preferences into account

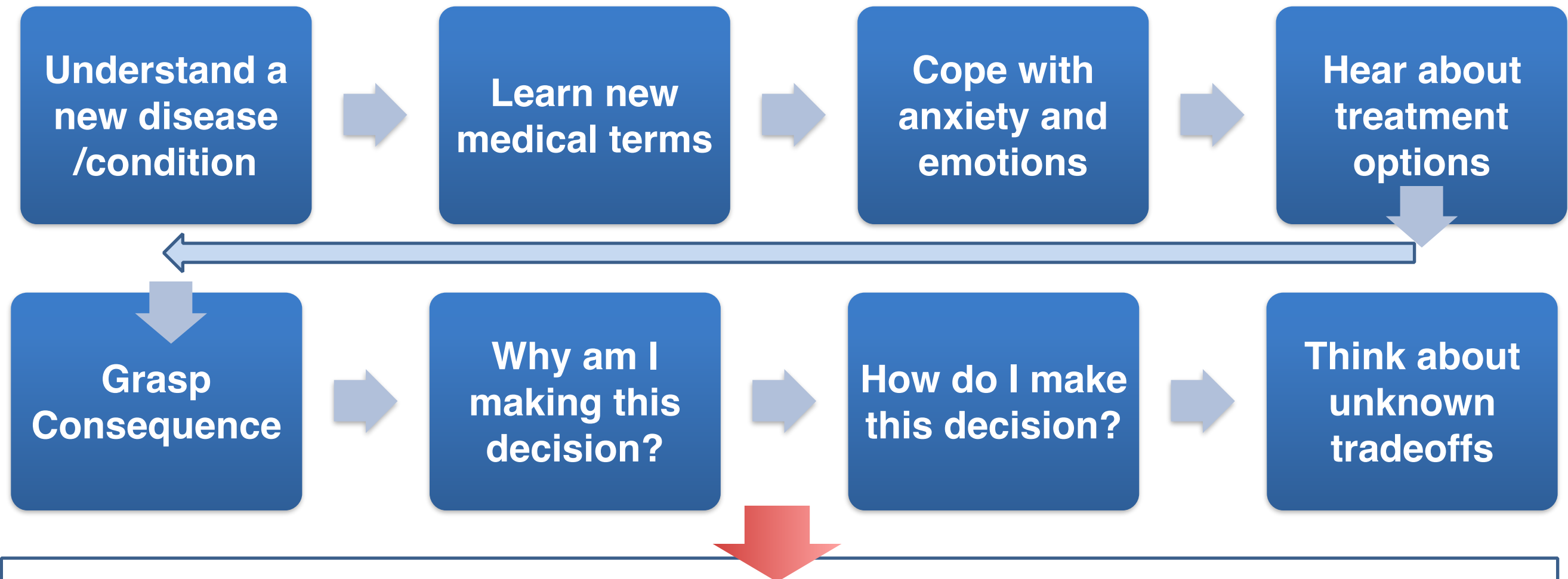


- Don't know what we don't know
  - Silent damage
  - Other risks
  - Other considerations
- Still lack understanding of Crohn's progression
- We engaged doctor

## Systematized Approach for Others



# Patients Journey:



## Patient Skills:



**Information Overload**

# How Do We Consider the Risks of Therapies in IBD?



CCEB



# Outline:

- Risks of therapies in Crohn's disease
- Benefits of therapies in Crohn's disease
- How do we put this together?
  - For ourselves
  - For our patients



# Disclaimer

All risks estimates are approximations based upon  
calculations of available data

# Outline:

- Risks of therapies in Crohn's disease
- Benefits of therapies in Crohn's disease
- How do we put this together?
  - For ourselves
  - For our patients

# Risks in Immunosuppressant Therapy

RISKS	ESTIMATE
<i>Serious/Opportunistic Infections</i>	
<i>Lymphoma</i>	
<i>Hepatosplenic T-Cell Lymphoma (HSTCL)</i>	

# Risks in Immunosuppressant Therapy

RISKS	ESTIMATE
<i>Serious/Opportunistic Infections</i>	<i>3% per year (monotherapy) 5% per year (combination therapy)</i>
<i>Lymphoma</i>	
<i>Hepatosplenic T-Cell Lymphoma (HSTCL)</i>	

# Risks in Immunosuppressant Therapy

RISKS	ESTIMATE
<i>Serious/Opportunistic Infections</i>	<i>3% per year (monotherapy) 5% per year (combination therapy)</i>
<i>Lymphoma</i>	<i>4x increased risks (monotherapy) 8x increased risk (combination therapy)</i>
<i>Hepatosplenic T-Cell Lymphoma (HSTCL)</i>	



# Risks in Immunosuppressant Therapy

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<i>Serious/Opportunistic Infections</i>	<i>3% per year (monotherapy) 5% per year (combination therapy)</i>
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<i>Hepatosplenic T-Cell Lymphoma (HSTCL)</i>	<i>160 times increased risk</i>

## Erwin Netter:

“33 1/3% of the mice used in the experiment were cured by the test drug; 33 1/3% of the test population were unaffected by the drug and remained in a moribund condition; and the third mouse got away.”

# Risks in Immunosuppressant Therapy

RISKS	ESTIMATE
<b><i>Serious/Opportunistic Infections</i></b>	<b><i>3% per year (monotherapy) 5% per year (combo therapy)</i></b>
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# Risks in Immunosuppressant Therapy

RISKS	ESTIMATE
Serious/Opportunistic Infections	30/1000 annual risk (monotherapy) 50/1000 annual risk (combo therapy)
Lymphoma	SEER annual incidence rate: 20 per 100,000; therefore: - 0.8/1000 annual incidence with monotherapy - 1.6/1000 annual incidence with combination therapy
Hepatitis (HSA)	

# Risks in Immunosuppressant Therapy

RISKS	ESTIMATE
<b>Serious/Opportunistic Infections</b>	<i>30/1000 annual incidence (monotherapy)</i> <i>50/1000 annual incidence (combo therapy)</i>
Lym Hep (HS	<div> <p><i>SEER annual incidence rate: 20 per 100,000; therefore:</i></p> <ul style="list-style-type: none"> <li><i>- T-cell lymphomas 15% of all NHL</i></li> <li><i>- HSTCL 0.07% of all T-cell lymphomas = 0.0021 per 100,000</i></li> <li><i>- Therefore, 160x increased risk = 0.34 per 100,000</i></li> </ul> </div>



# Risks in Immunosuppressant Therapy

RISKS	ESTIMATE
<b><i>Serious/Opportunistic Infections</i></b>	<b><i>30/1000 annual incidence (monotherapy) 50/1000 annual incidence (combo therapy)</i></b>
<b><i>Lymphoma</i></b>	<b><i>0.8/1000 annual incidence (monotherapy) 1.6/1000 annual incidence (combo therapy)</i></b>
<b><i>Hepatosplenic T-Cell Lymphoma (HSTCL)</i></b>	<b><i>0.0034/1000 annual incidence</i></b>

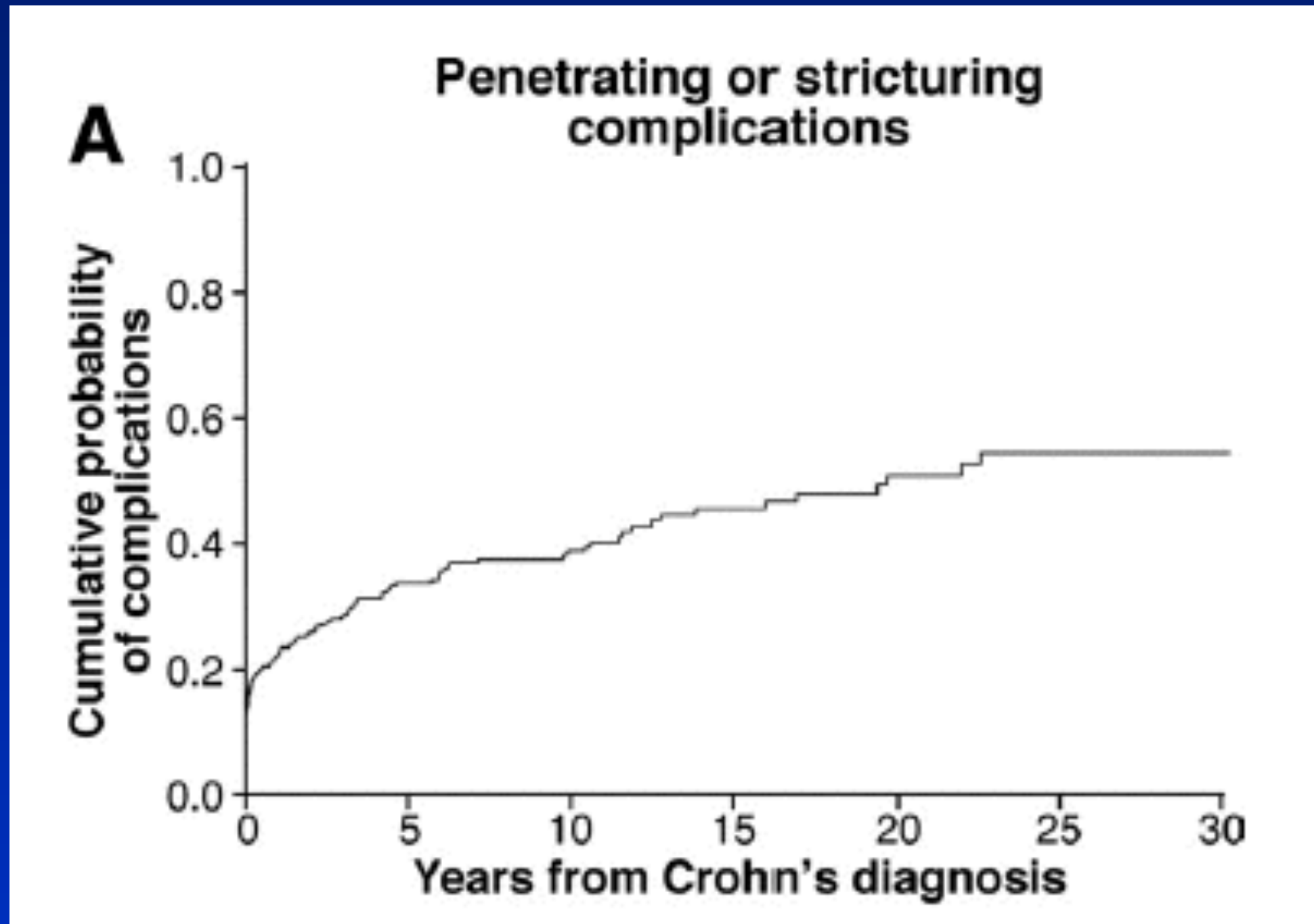
# Outline:

- Risks of immunosuppressant therapy
- Benefits of immunosuppressant therapy

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

- For ourselves
- For our patients

# Untreated IBD: Risk of surgery

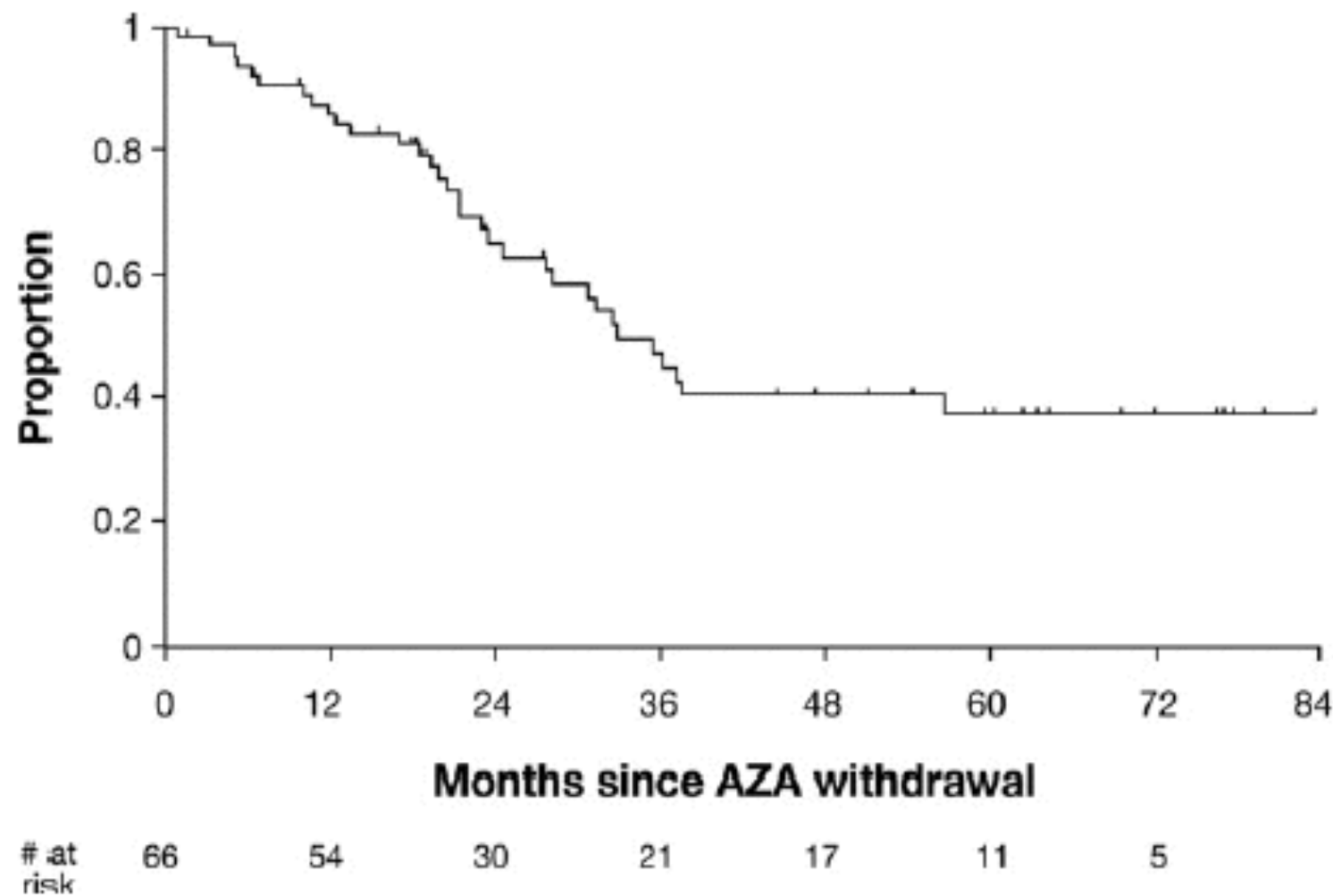


# Untreated IBD: Risk of mortality

STUDY	MORTALITY RISK
<i>Lewis et al. Am J Gastro 2008 (GPRD Database)</i>	<i>CD: HR 2.44 (1.84-3.25) UC: HR 1.67 (1.34-2.09)</i>

# Risk of medication cessation:

- Azathioprine



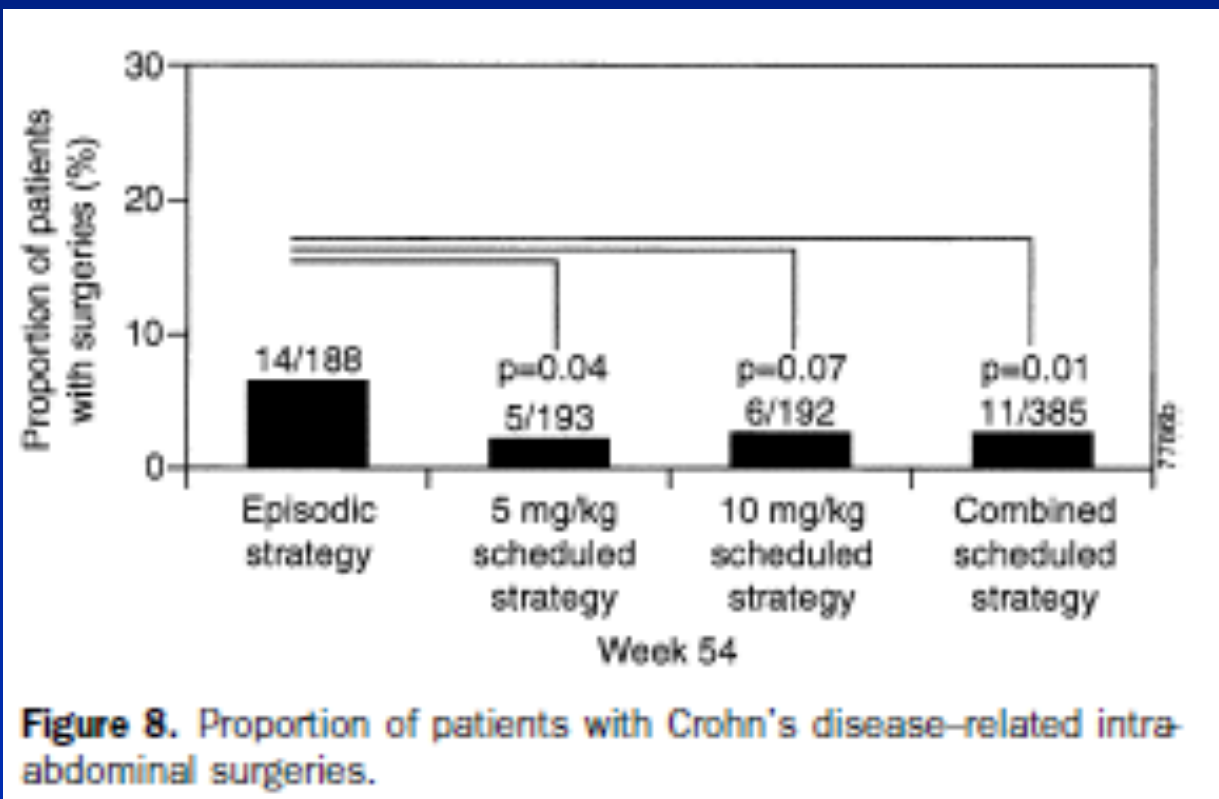
**Figure 2.** Cumulative probability of remaining in remission after AZA withdrawal in 66 patients.



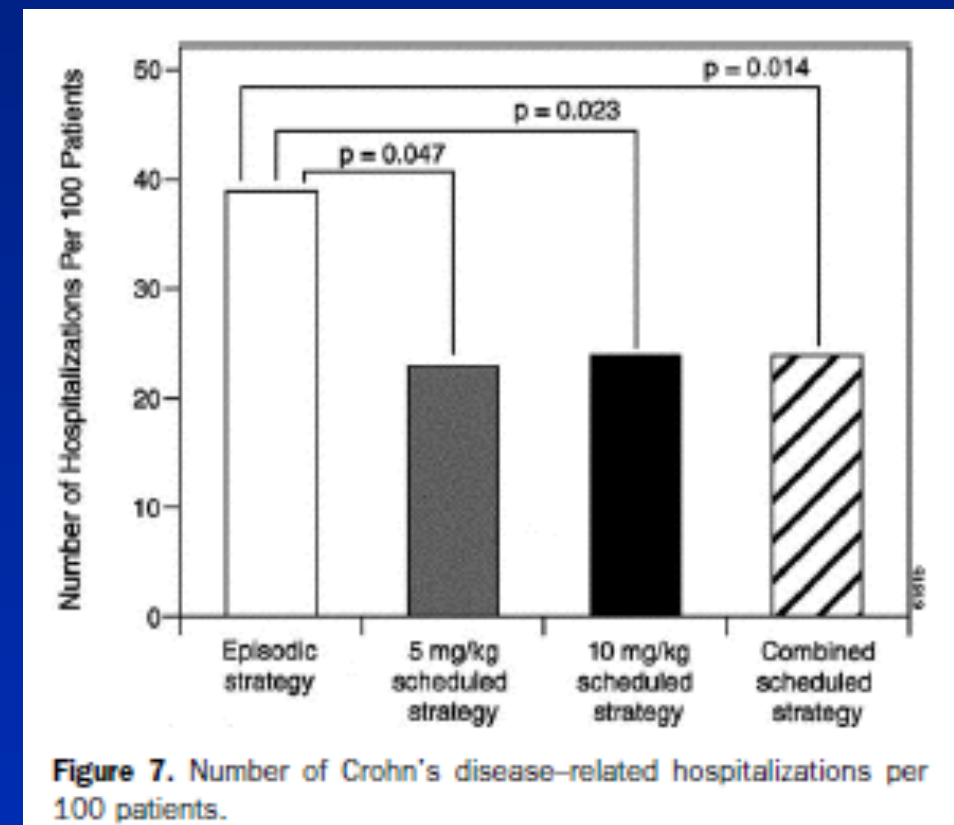
# Risk of medication cessation:

- Infliximab

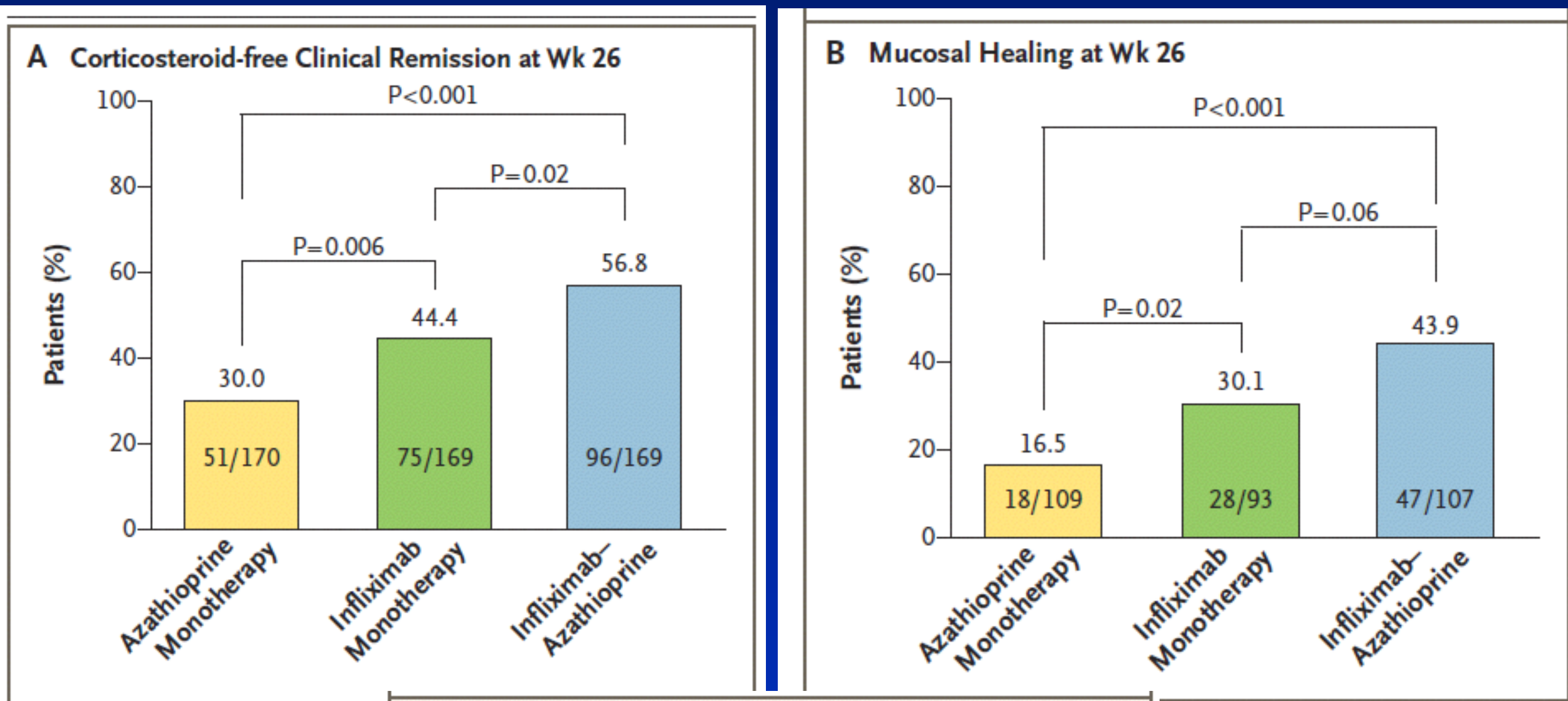
Intra-abdominal surgeries



CD-related hospitalizations



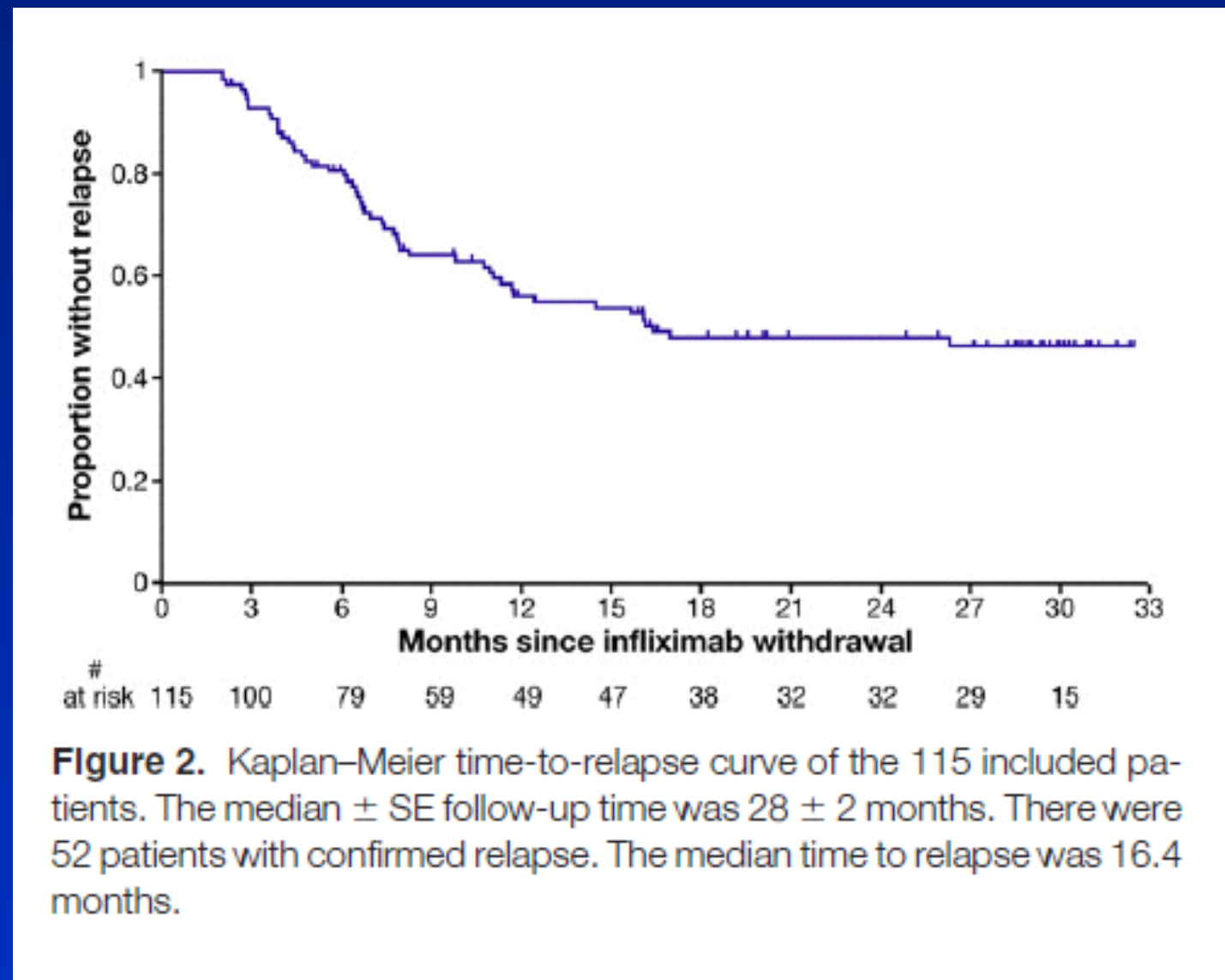
# Monotherapy vs. Combination Therapy



**Figure 2.** Patients with Corticosteroid-free Clinical Remission (Panel A) and Mucosal Healing (Panel B) at Week 26.

# Risk of medication cessation:

- Cessation of anti-TNF therapy when on combination therapy



# Corticosteroids: are bad

- Fluid retention
- CHF
- Metabolic abnormalities
- Hypertension
- Muscle weakness
- Loss of muscle mass
- Osteoporosis
- Compression fractures (spine)
- Aseptic necrosis (femoral/humeral head)
- Pathologic fractures
- Tendon rupture
- Hyperglycemia
- cataracts
- Gastric ulcers
- Pancreatitis
- Impaired wound healing
- Bruising
- Pseudotumor cerebri
- Emotional disturbances
- Menstrual irregularities
- Cushingoid features
- Growth suppression (children)
- Secondary adrenocortical / pituitary unresponsiveness
- Diabetes mellitus
- Glaucoma
- Weight gain

# Corticosteroids: Risks

STUDY	REPORTED INFECTION RISK
<i>Lichtenstein et al Clin Gastro Hep 2006</i>	<b>Serious Infections</b> <i>Adj OR 2.2 (1.5-3.3), p=0.001</i>
<i>Toruner et al. Gastro 2008</i>	<b>Opportunistic Infections</b> <i>OR 3.3 (1.8-6.1), p&lt;0.001</i>
<i>Aberra et al. Gastro 2003</i>	<b>Post-operative infections:</b> <i>Any infection: OR 3.7 (1.2-11.0)</i> <i>Major infection: OR 5.5 (1.1-27.3)</i>
STUDY	MORTALITY RISK
<i>Lichtenstein et al. Clin Gastro Hep 2006 (TREAT registry)</i>	<i>OR 2.1 (1.1–3.8) p=.016</i>
<i>Lewis et al. Am J Gastro 2008 (GPRD Database)</i>	<i>CD: HR 2.48 (1.85-3.31)</i> <i>UC: HR 2.81 (2.26-3.50)</i>

# Outline:

- Risks of immunosuppressant therapy
- Benefits of immunosuppressant therapy
- **Putting it all together**
  - For ourselves
  - For our patients



# How do these risks stack up?

	Immunosuppressant therapy	Corticosteroids /Active Disease
Number needed to treat to cause one additional Serious infection per year with therapy	483 (monotherapy) 276 (combo therapy)	483 (steroids)
Number needed to treat to cause one additional lymphoma per year with therapy	4357 (mono therapy) 714 (combo therapy)	
Number needed to treat to cause one additional HSTCL per year with therapy	20,964	
Number needed to cause one additional relapse per year without treatment	3	
Number needed to cause one additional hospitalization per year without treatment	7	
Number needed to cause one additional abdominal surgery per year without treatment	21	
Number needed to treat to cause one additional death		146 (steroids)
Number needed not to treat to cause one additional death		21 (active disease)

*Adapted from:*  
 Kandiel A et al. Gut 2005  
 Trenton X et al. CGH 2009  
 Toruner M et al, Gastro 2008

Lewis JD et al, Am J Gastro 2008  
 Siegel C. et al. CGH 2006  
 Rutgeerts P et al. Gastro 2004  
 Grijalva CG et al, JAMA 2011

Lichtenstein G et al. CGH 2006  
 Herrinton L et al Pharm Drug Safe 2012  
 Singh S et al, IBD 2012  
 Bloomgren G et al NEJM 2012

# Why is changing the way we practice so hard?

- How one perceives risk:
  - Epidemiologist: risk is a measured property of a group of people
  - Physician/patient: risk is a specific property of ME
- Perception becomes reality:
  - Reject statistical reasoning in favor of anecdotal reasoning
  - Accept common risks we “know” in favor of uncommon risks we “fear”

# Outline:

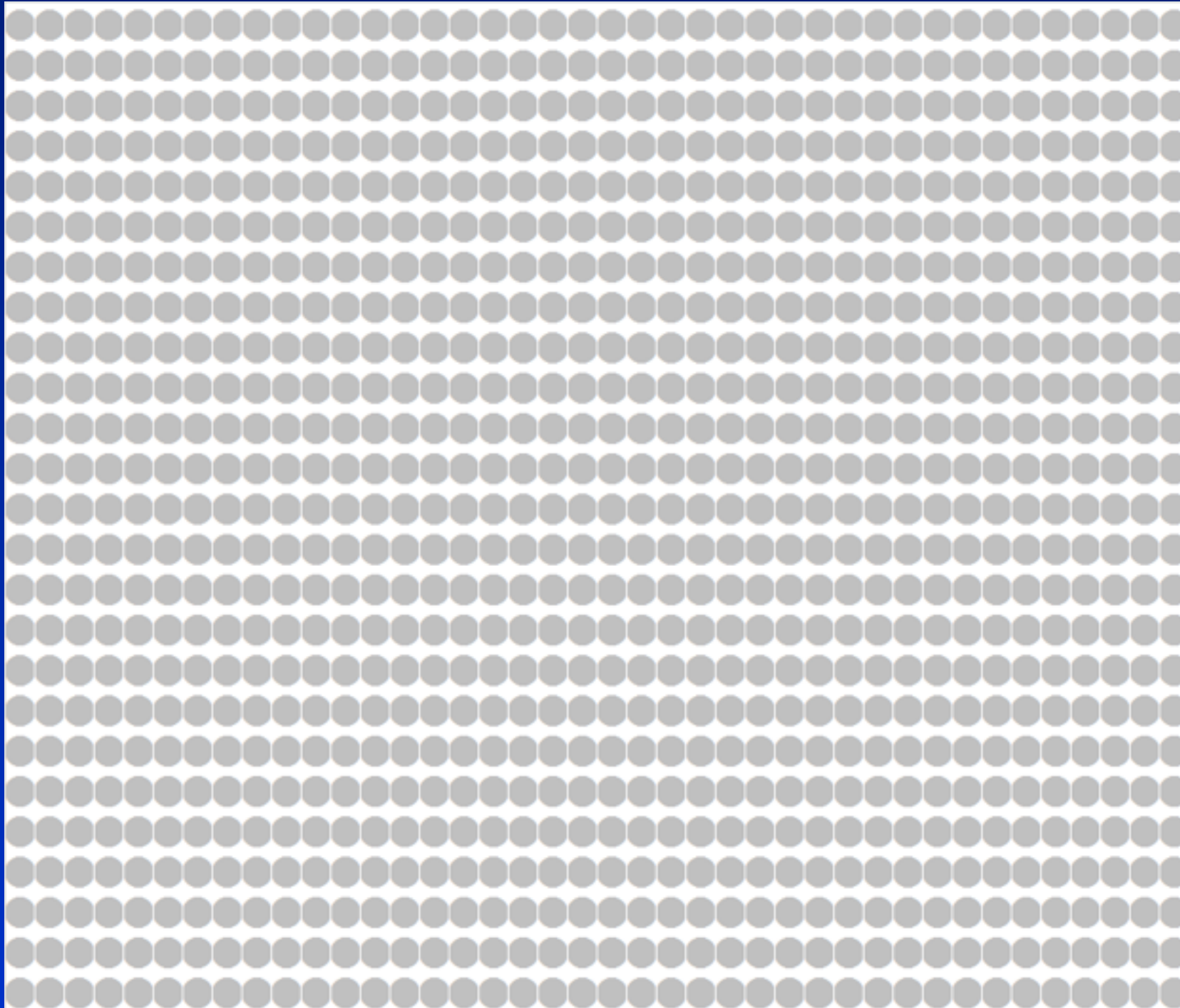
- Risks of immunosuppressant therapy
- Benefits of immunosuppressant therapy
- **Putting it all together**
  - For ourselves
  - For our patients

# Discussing risk with patients

- Numeracy: basic math skills for health-related activities
  - Over 50% of Americans lack minimum basic skills to apply to arithmetic operations of numbers in print materials

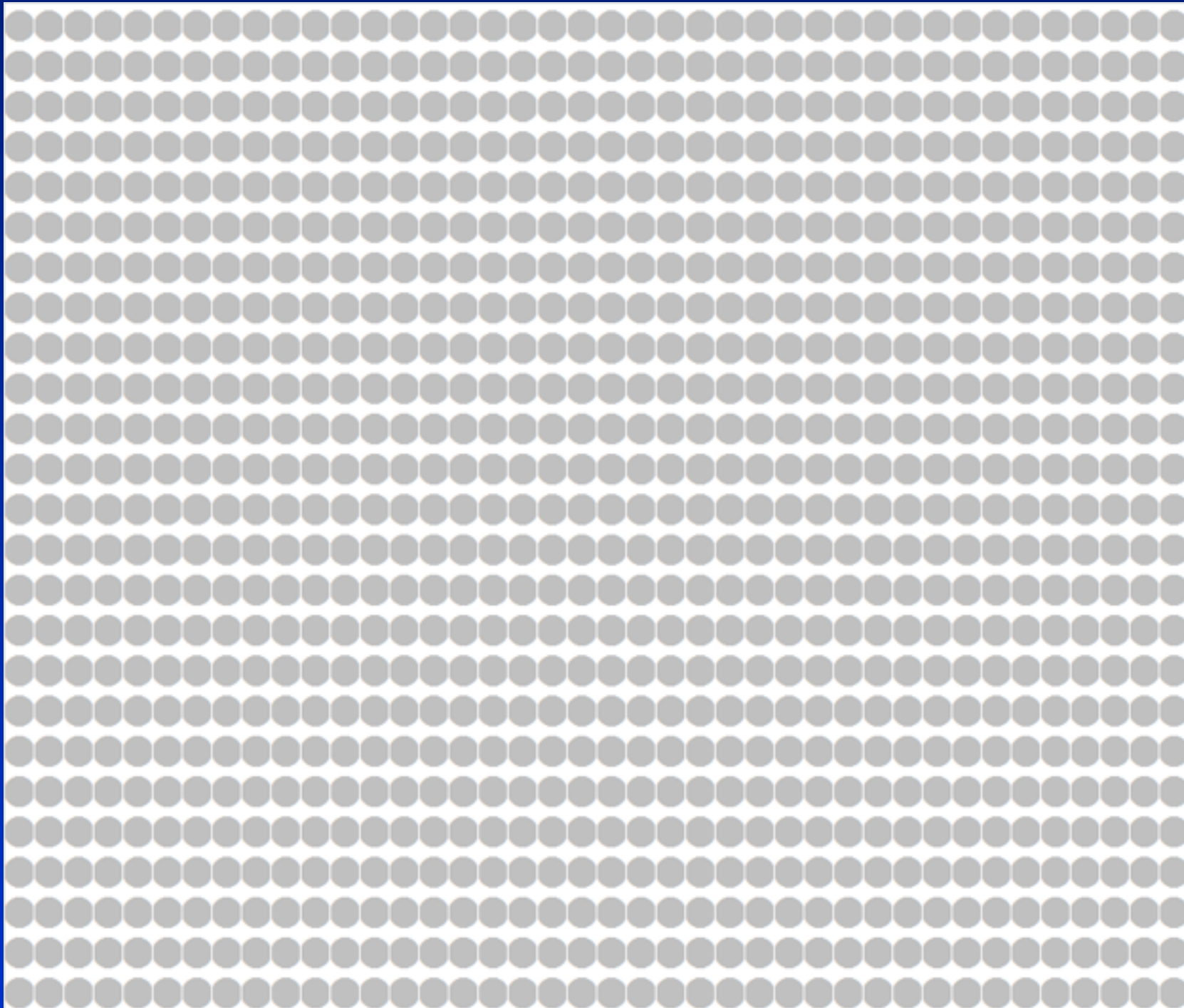
# Discussing risk with patients

- Use visual aids!



# Discussing risk with patients

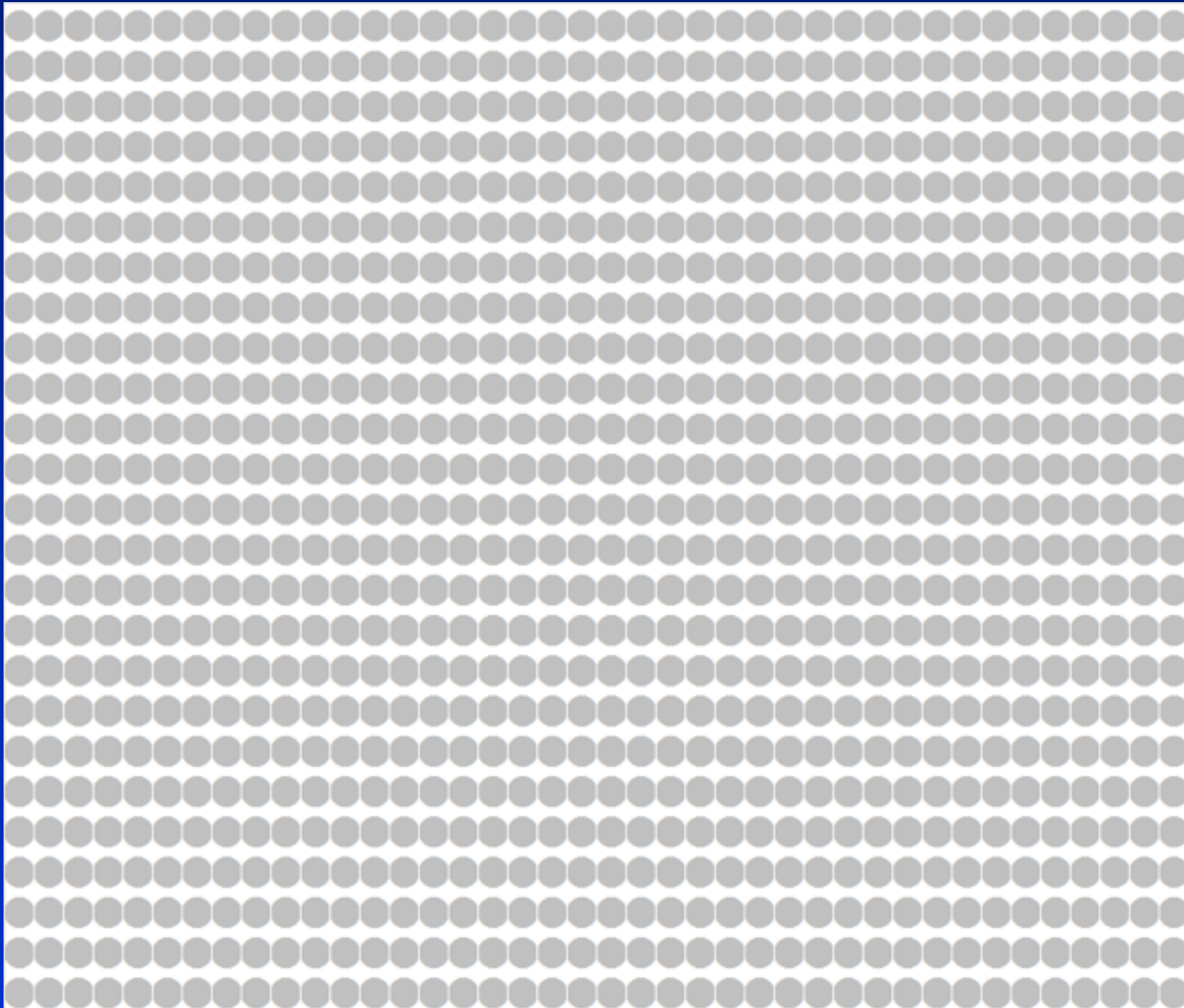
- 1000 people treated with IS therapy
  - Number of people developing HSTCL





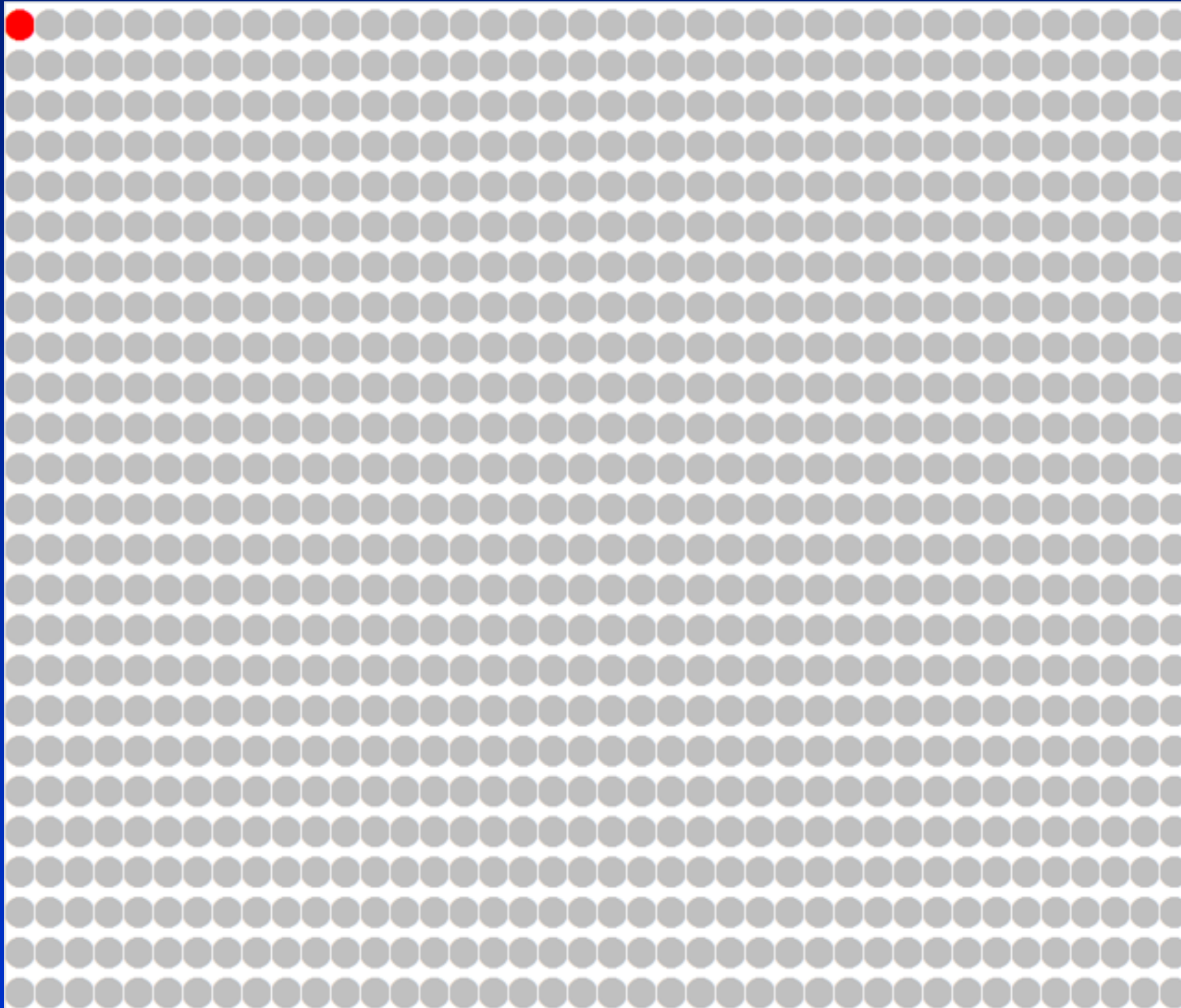
# Discussing risk with patients

- 1000 people treated with IS monotherapy
  - Number of people developing lymphoma



# Discussing risk with patients

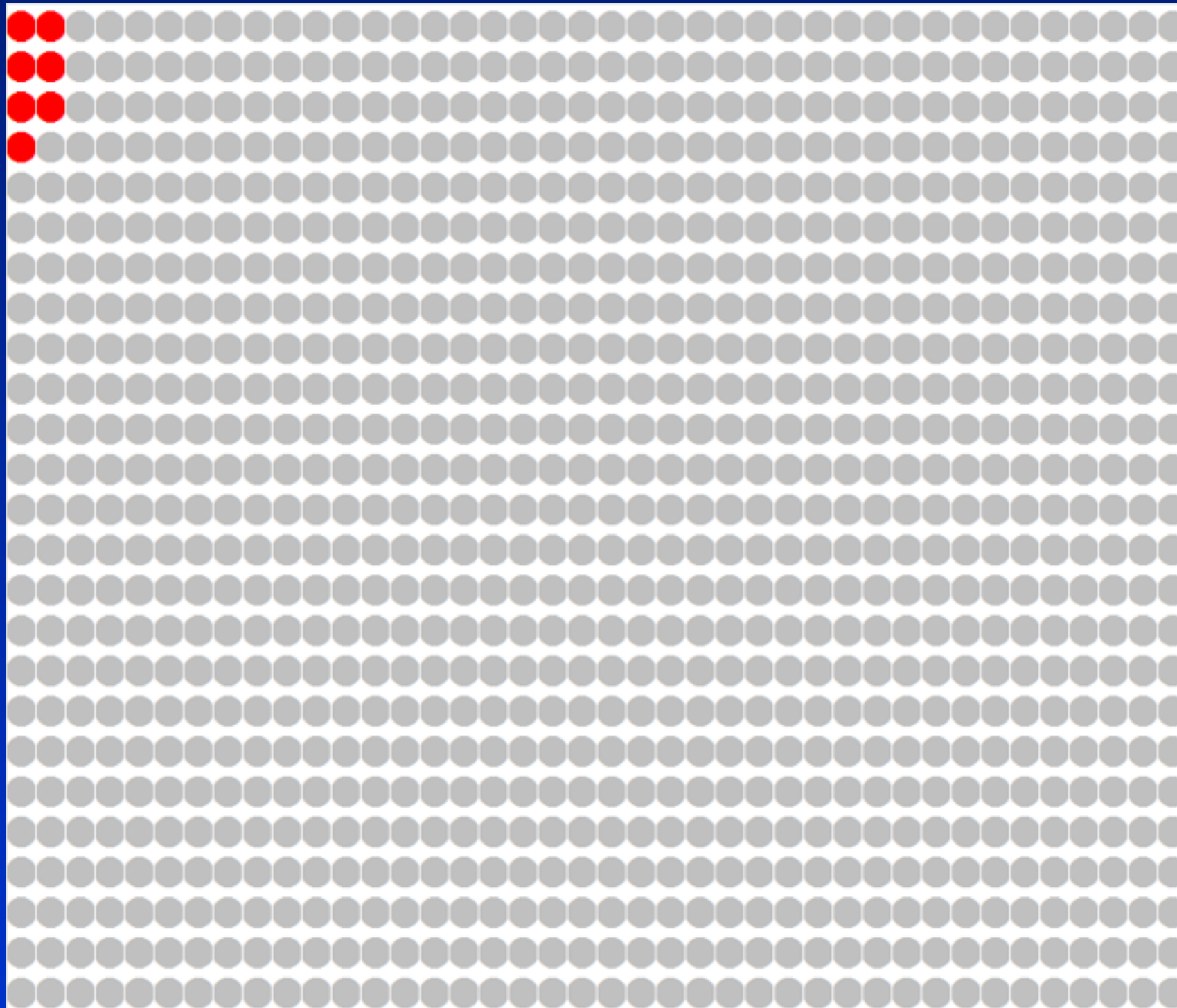
- 1000 people treated with IS combination therapy
  - Number of people developing lymphoma





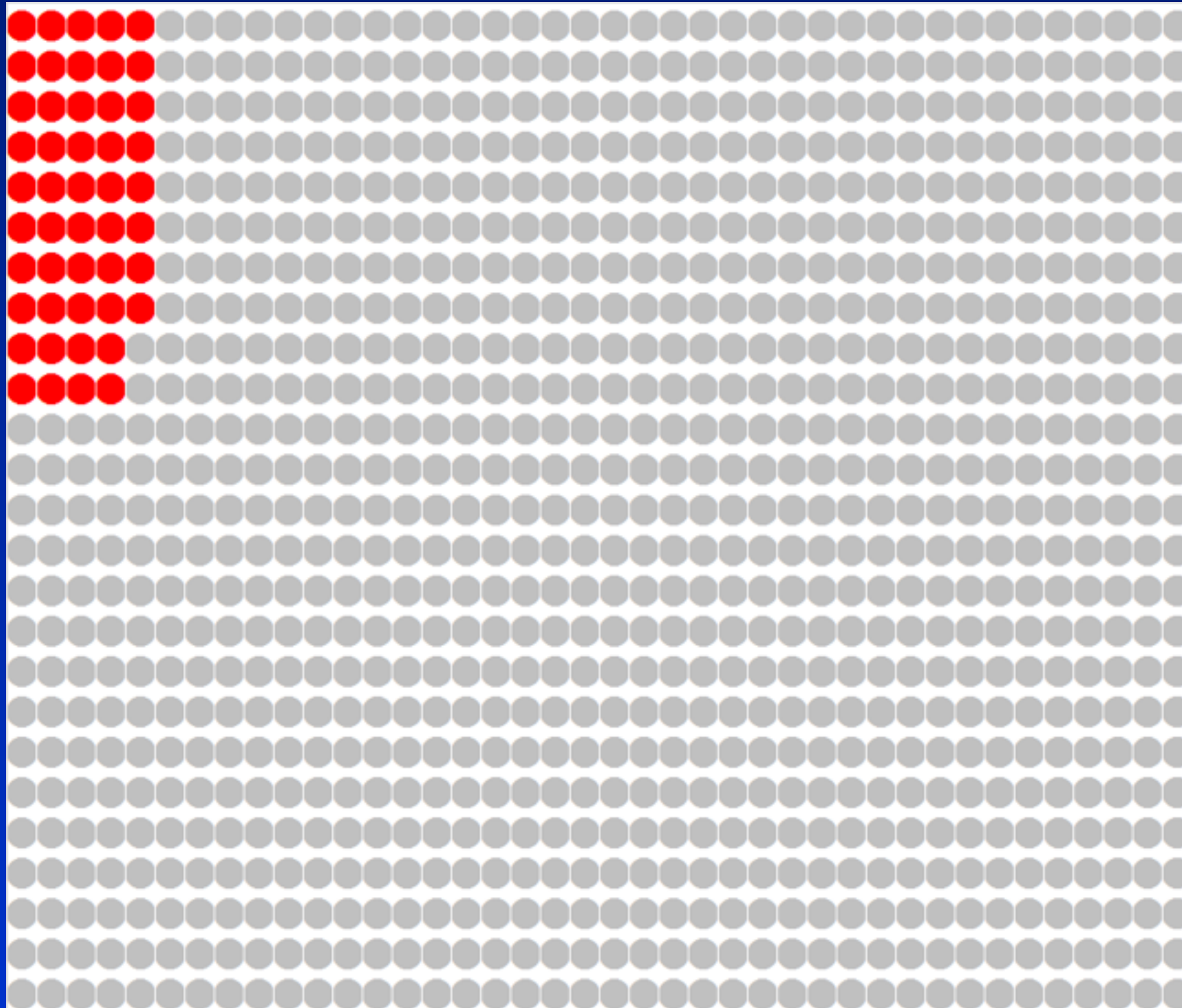
# Discussing risk with patients

- 1000 people treated with corticosteroids
  - Number of people developing dying



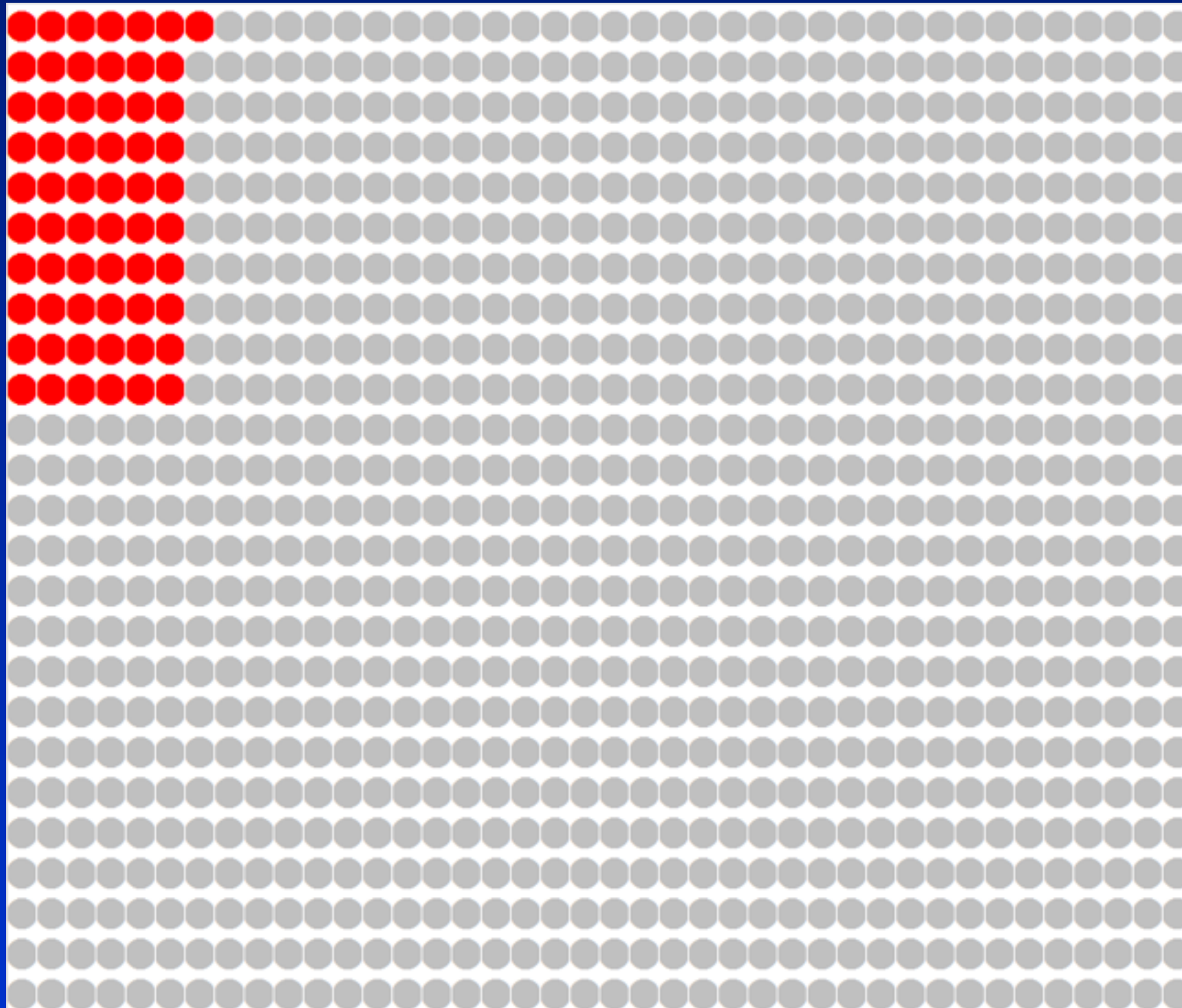
# Discussing risk with patients

- 1000 people with untreated active disease
  - Number of people dying



# Discussing risk with patients

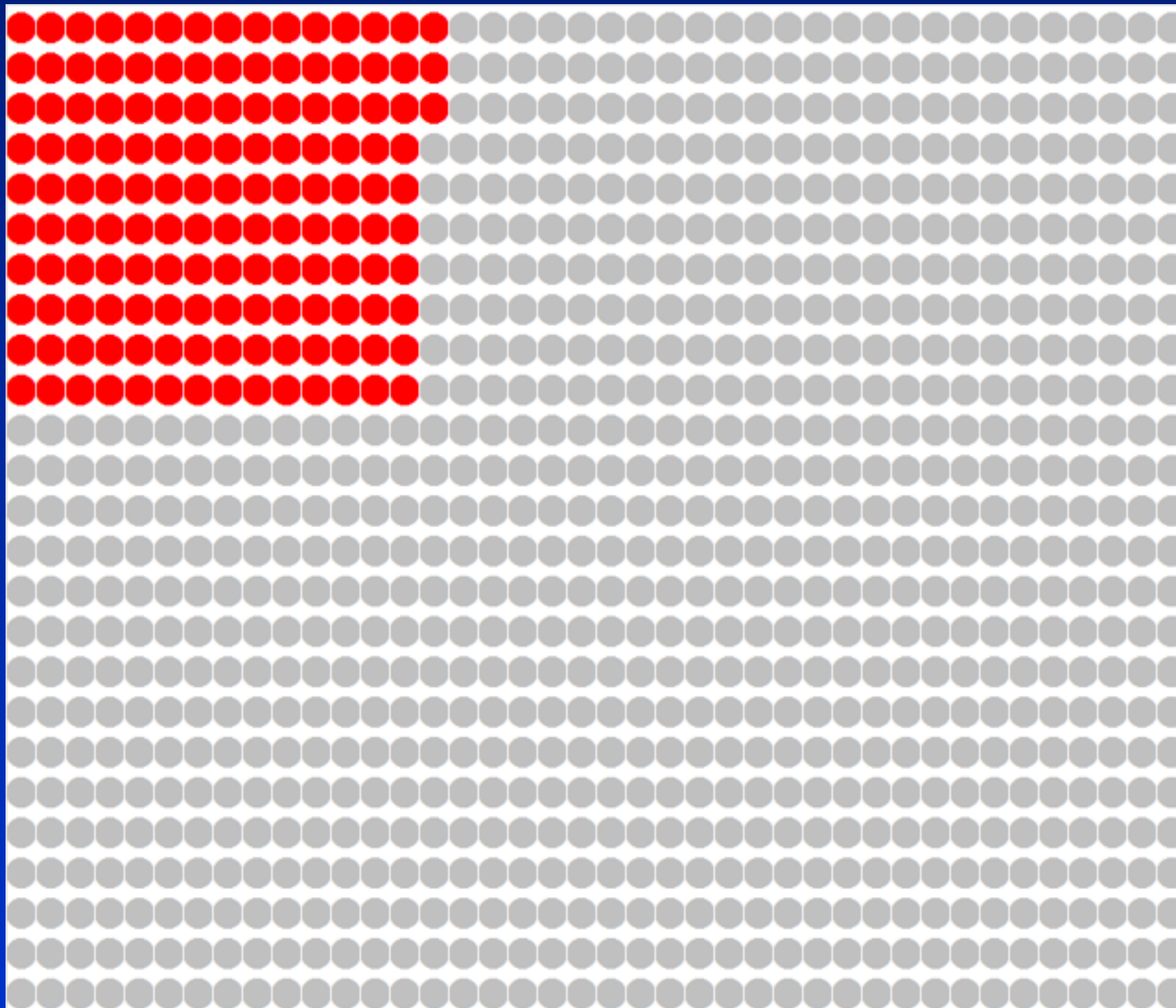
- 1000 people stopping effective IS therapy
  - Number of people requiring surgery





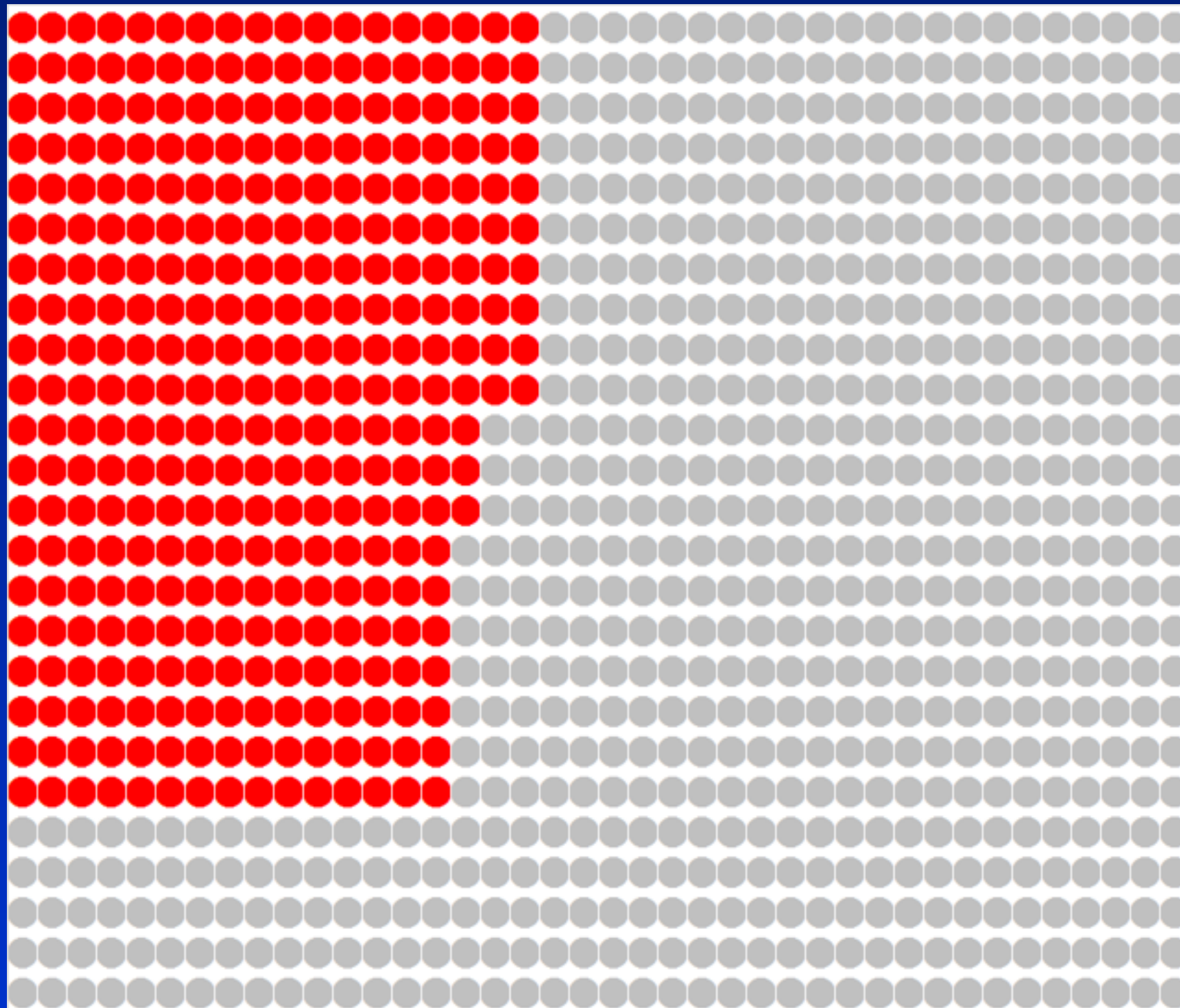
# Discussing risk with patients

- 1000 people stopping effective IS therapy
  - Number of people requiring hospitalization



# Discussing risk with patients

- 1000 people stopping effective IS therapy
  - Number of people suffering disease relapse





Are we asking a lot?

## What matters most...

### Sciatica from a Slipped (herniated) Disc

This grid is designed to help you and your healthcare provider select the treatment option that is best for you. It is for people diagnosed with a herniated disc who have experienced sciatica pain for at least six weeks and is not for people with bowel and urine problems due to the disc pressing on their nerves. Ask your healthcare provider if there are other treatment options available to you. Use the back of this page to write down any other questions you have.

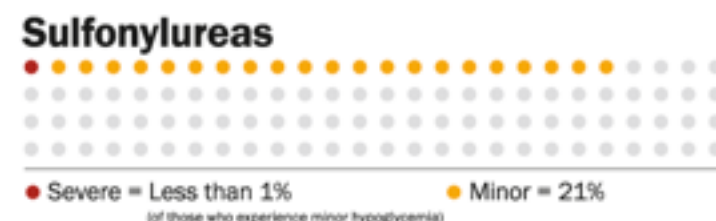
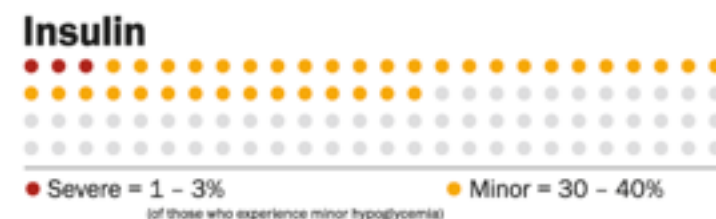
Frequently asked questions	Managing without Injections or Surgery	Injections (epidural steroids)	Surgery
<b>What does the treatment involve?</b>	<p>Taking pain relievers that reduce inflammation around the nerve and attempting to be as active as possible.</p> <p>Physical therapy may also help.</p>	<p>A needle is used to inject local anaesthetic and steroid where the nerve is under pressure near the spine.</p> <p>An injection is normally performed at a special clinic and takes around 20 minutes.</p>	<p>The slipped disc that puts pressure on the nerve is removed during an operation on the back.</p> <p>The operation takes approximately 2 hours. Most people stay in hospital for a night or two but some go home the day of the surgery.</p>
<b>How soon will I feel better?</b>	6 weeks after diagnosis, roughly 20 in 100 people say they are very or somewhat satisfied with their symptoms.	Most people who experience relief feel better within the first week or so after the injection.	6 weeks after surgery, roughly 60 in 100 people say they are very or somewhat satisfied with their symptoms.
<b>Which treatment gives the best long term results?</b>	1 year after diagnosis, around 45 people who manage without surgery or injections say they are very or somewhat satisfied with their symptoms.	It is hard to say: some studies have shown benefits from steroid injections but others have not.	1 year after surgery, around 70 in 100 people say they are very or somewhat satisfied with their symptoms.
<b>What are the main risks/side effects associated with this treatment?</b>	All medications have some side effects. Being active is unlikely to make your sciatica harder to treat in the future.	Fewer than 1 in 100 people have complications, which could potentially include bleeding, headache, and infection.	The main risks associated with this surgery are infection (2 in 100), blood clots (1 in 100) and damage to the nerves (less than 1 in 100).
<b>How will this treatment impact my ability to work?</b>	You should return to your daily activities and return to work as soon as you are able to do so.	Most people return to work and normal activities the day after the injection.	Most people are off work for 6-8 weeks following this operation.



## Weight Change



## Low Blood Sugar (Hypoglycemia)



## Blood Sugar (A1c Reduction)

**Metformin** 1 - 2%

**Insulin** Unlimited %

**Glitazones** 1%

**Exenatide** ½ - 1%

**Sulfonylureas** 1 - 2%

## Daily Routine

### Metformin

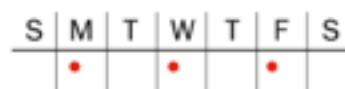


### Insulin



## Daily Sugar Testing (Monitoring)

### Metformin



Monitor 2 - 5 times weekly,  
less often once stable.

### Insulin



## Side Effects

### Metformin

In the first few weeks after starting Metformin, patients may have some **nausea, indigestion** or **diarrhea**.

### Insulin

There are no other side effects associated with Insulin.



# VIDEO & MULTIMEDIA PROGRAMS

## Interactive:

Ask Questions at any time  
for follow up with a nurse

## Intuitive navigation:

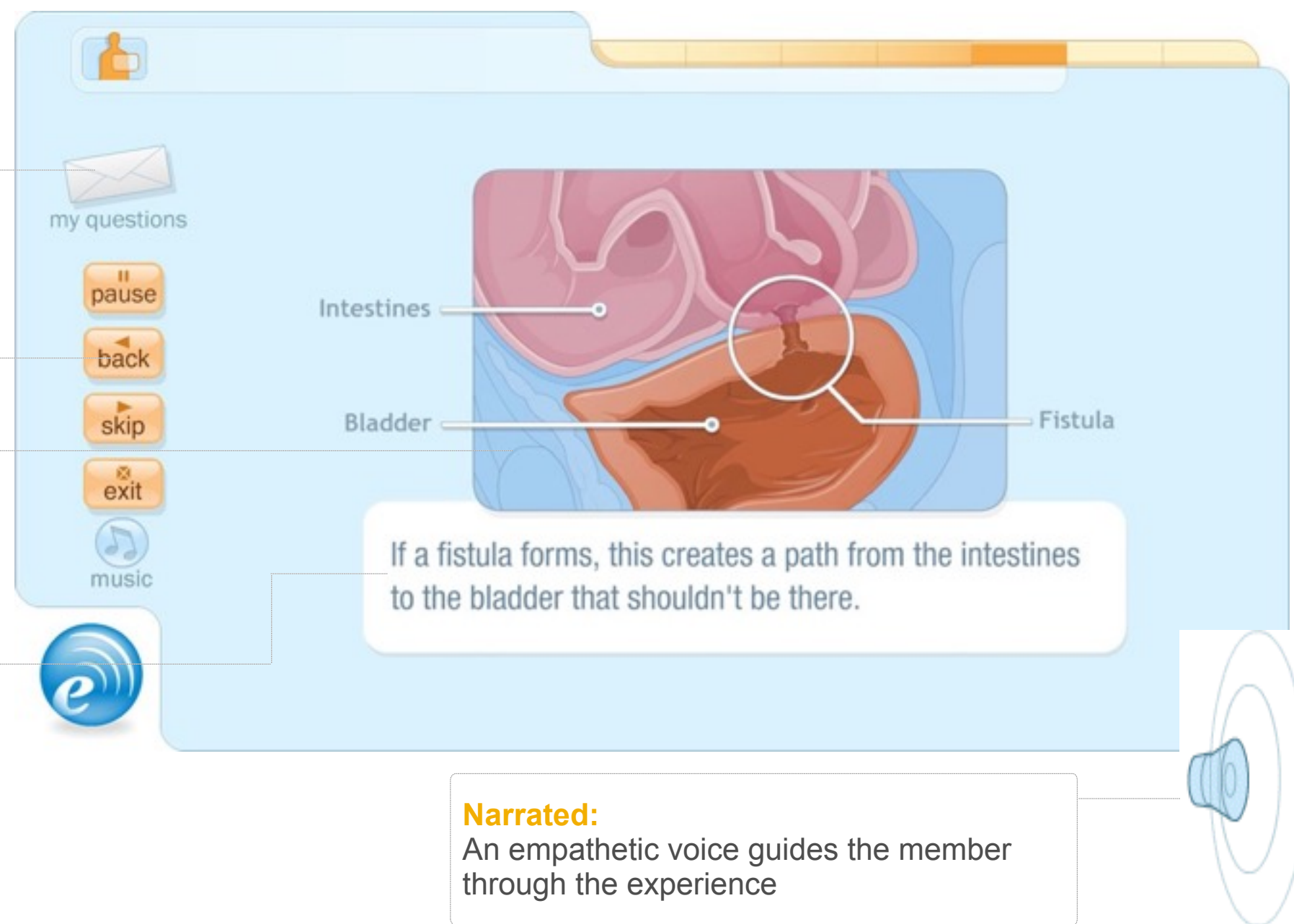
Simple to use for all  
levels of computer  
experience

## Visual learning:

Preferred by all patients,  
critical for those with low  
health literacy

## Plain language:

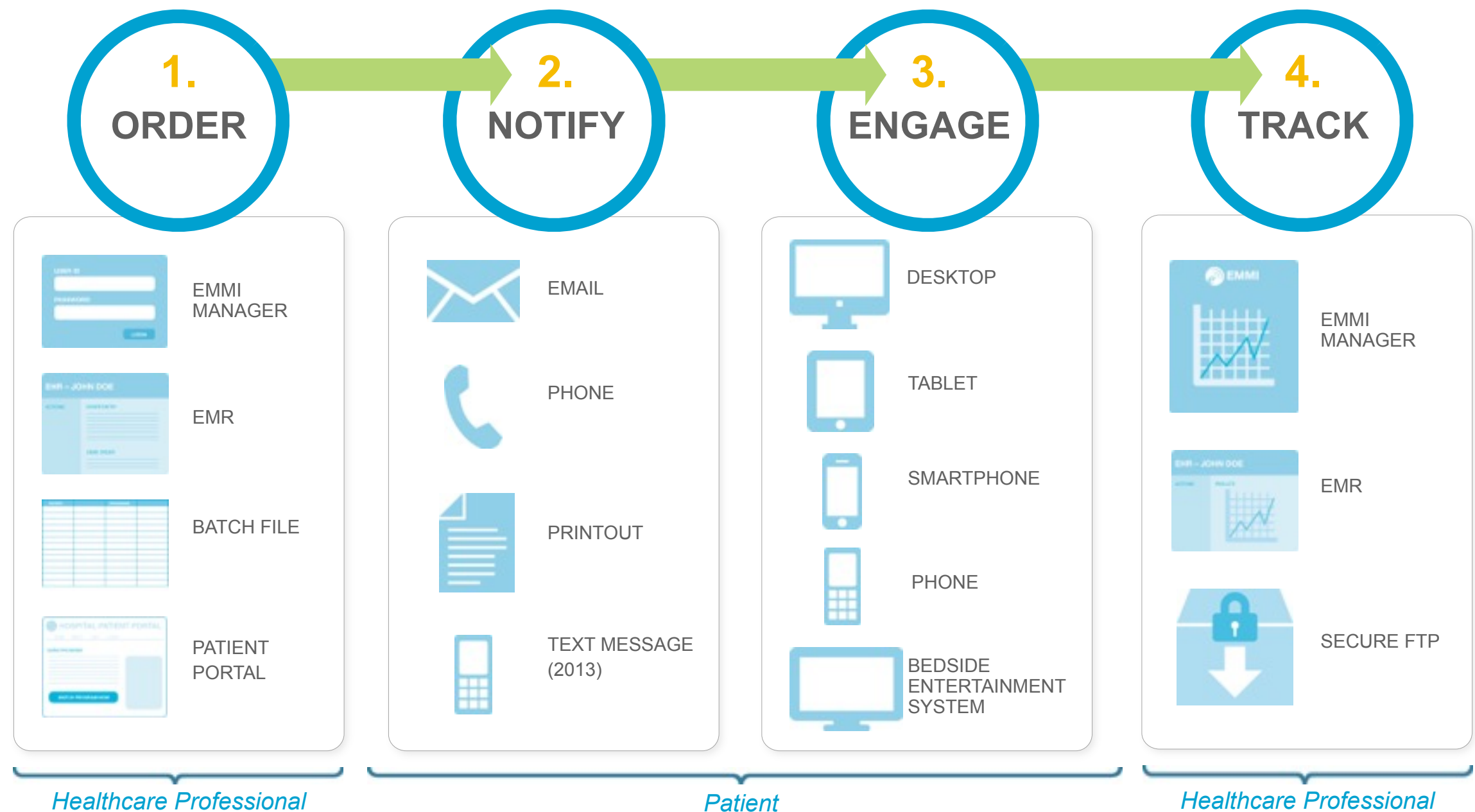
Targeting a 4th to 5th  
grade reading level

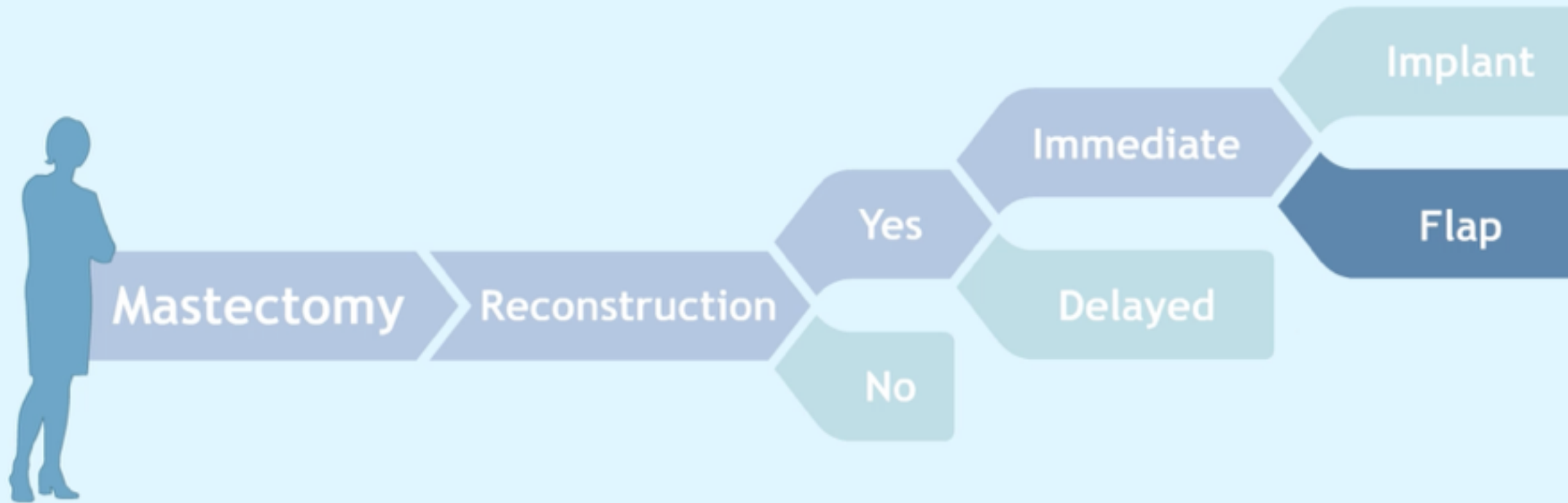


## Narrated:

An empathetic voice guides the member  
through the experience

# HOW DOES IT WORK?





Because both treatments are equally effective at extending your life, it's about deciding which risks you're willing to accept and which

Doctors believe mastectomy and lumpectomy with radiation have the SAME ability to

They know that, even though they have different risks, lumpectomy and mastectomy are both equally good at treating breast cancer.



Lumpectomy or Mastectomy

## Addressing Misconceptions



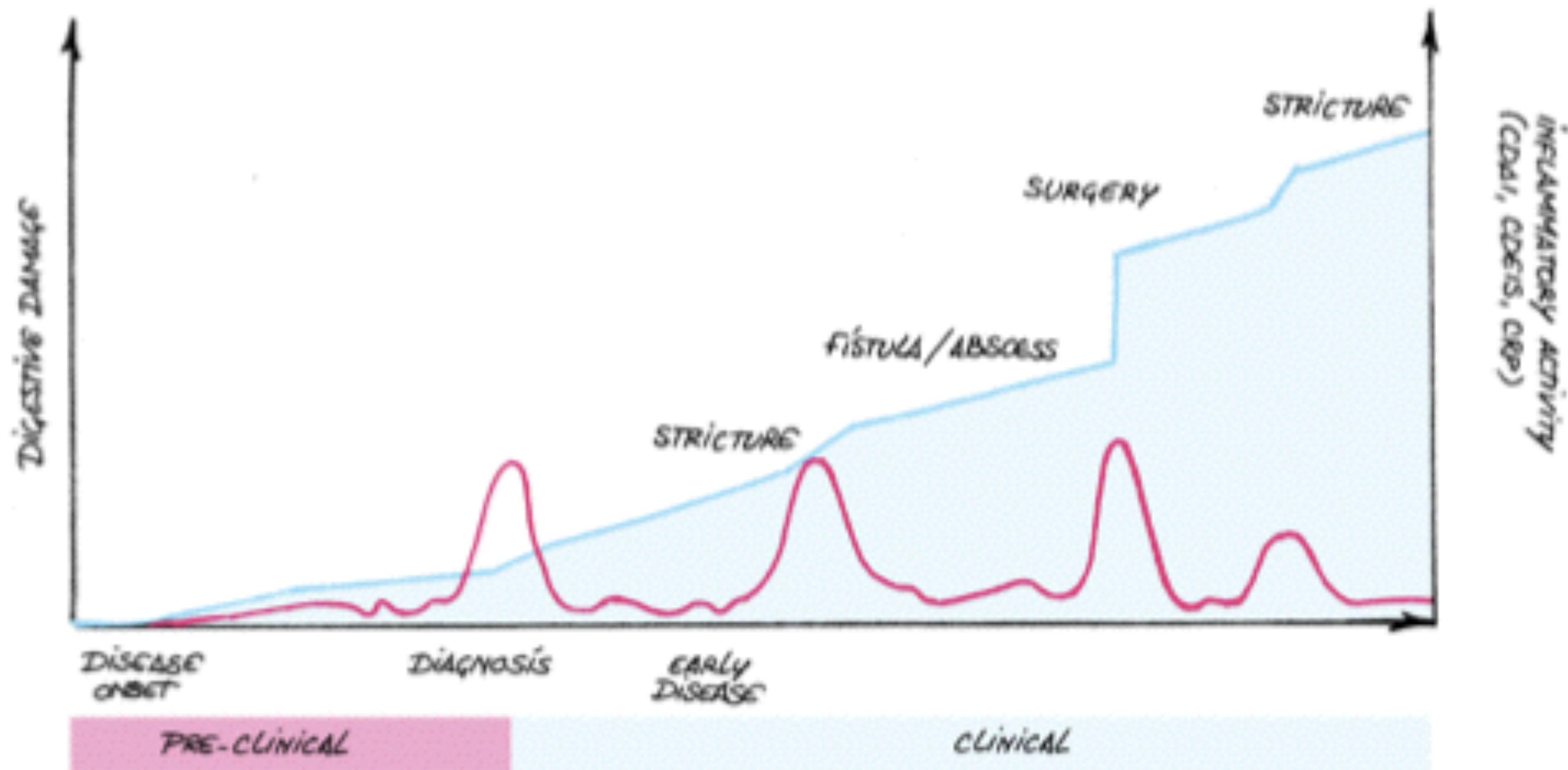
# Which of these do you agree with?

- ☐ Having some kind of breast is important to me
- ☐ Keeping my original breast is important to me
- ☐ I'm OK with the idea of having one breast gone
- ☐ I'm comfortable with the idea of wearing a prosthesis
- ☐ Sensation (feeling) in my breasts is important to me
- ☐ I'm still not sure how I feel

Feelings / Thought Exercises

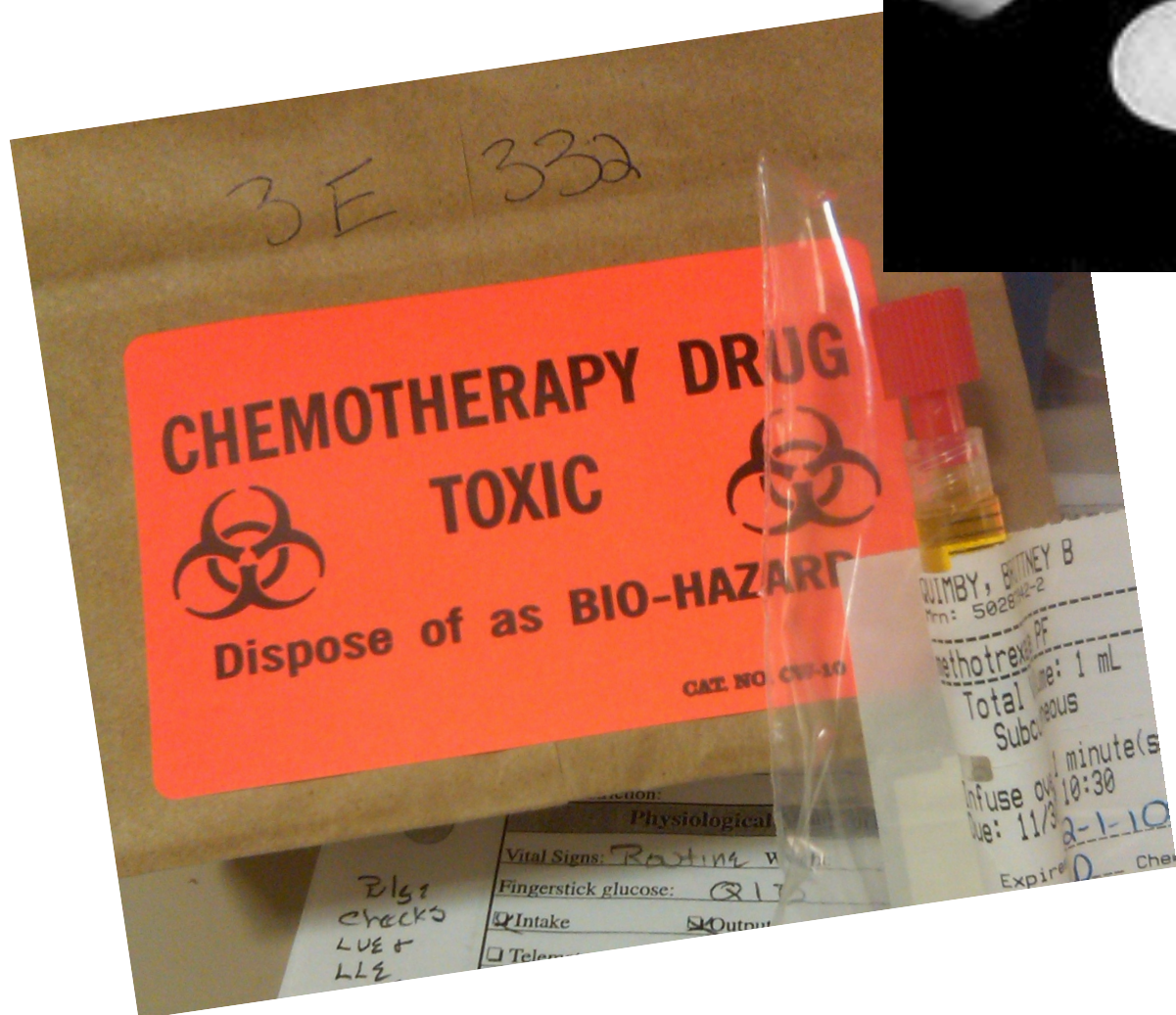
# CONSIDER CROHN'S DISEASE

ACTIVITY IN A THEORETICAL PATIENT WITH CROHN'S DISEASE



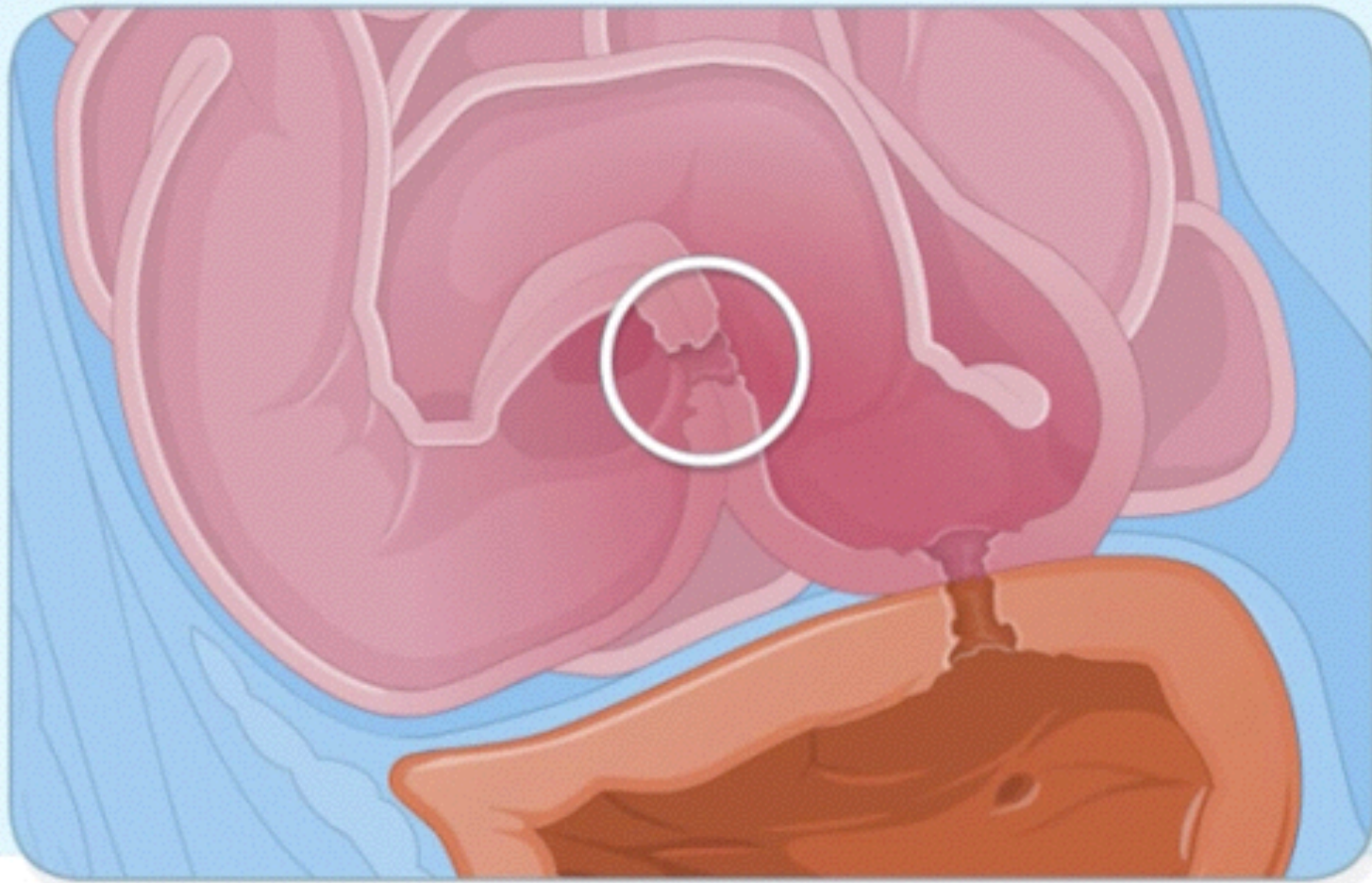


# TERRIFYING RISKS



HSTCL  
HEPATOSPLENIC  
T-CELL LYMPHOMA





Fistulas can also form between 2 different parts of the intestines.

COMPETENCY  
& CANDOR

Even when people can't see or feel fistulas, they can be causing problems.

TOO SCARY OR NOT CANDID ENOUGH?



How many get relief from their problems  
and can stop taking steroids (prednisone)?

Immunomodulators



Clarifying Risk Info



Treatments for Crohn's Disease v1.1  
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# Understanding Risk

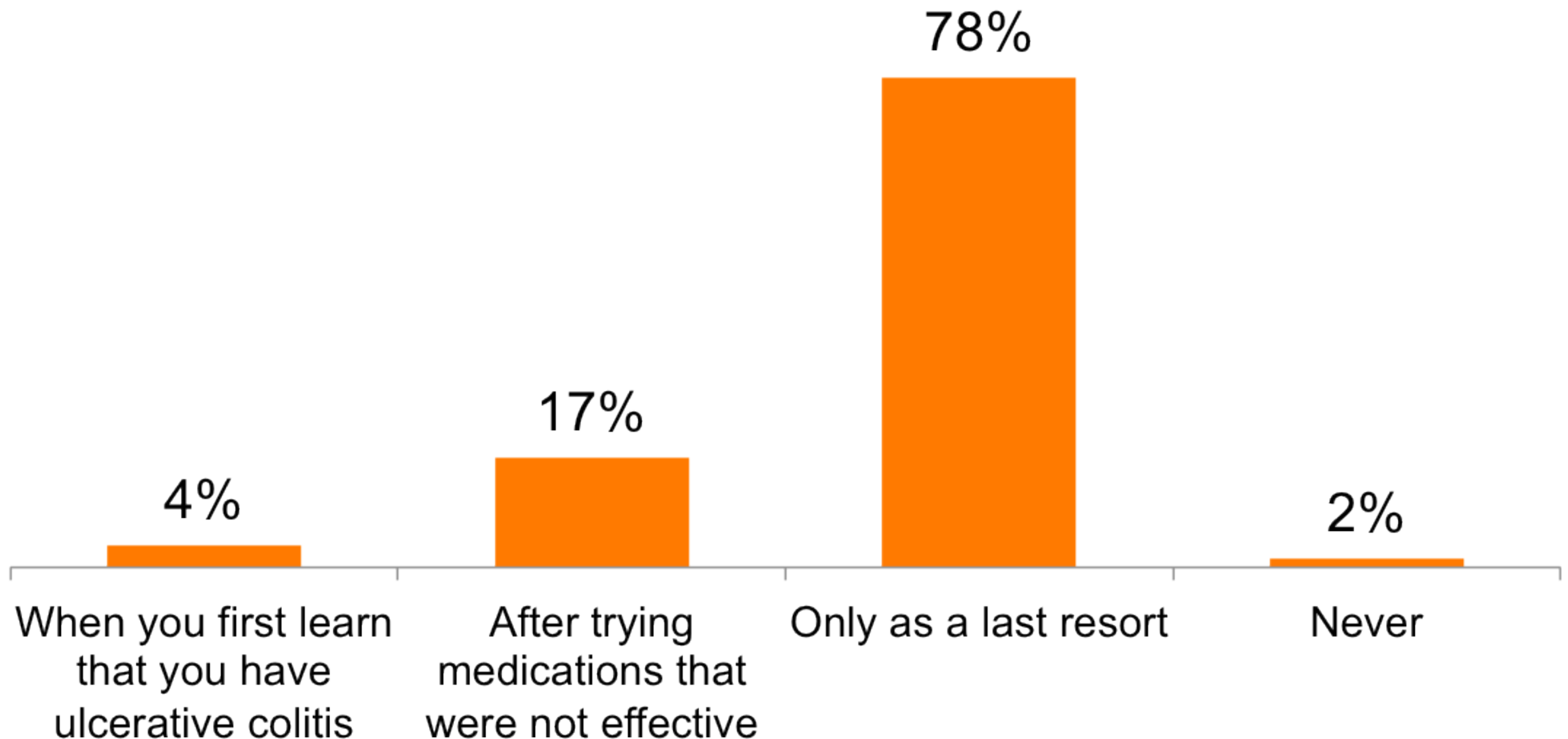


# ULCERATIVE COLITIS: CREATING COMPETENCY WHEN PATIENTS DON'T WANT TO KNOW



# 460 PATIENTS

*At what point do you believe surgery is a reasonable treatment option for ulcerative colitis?*





La la la la la...

I can't hear you!

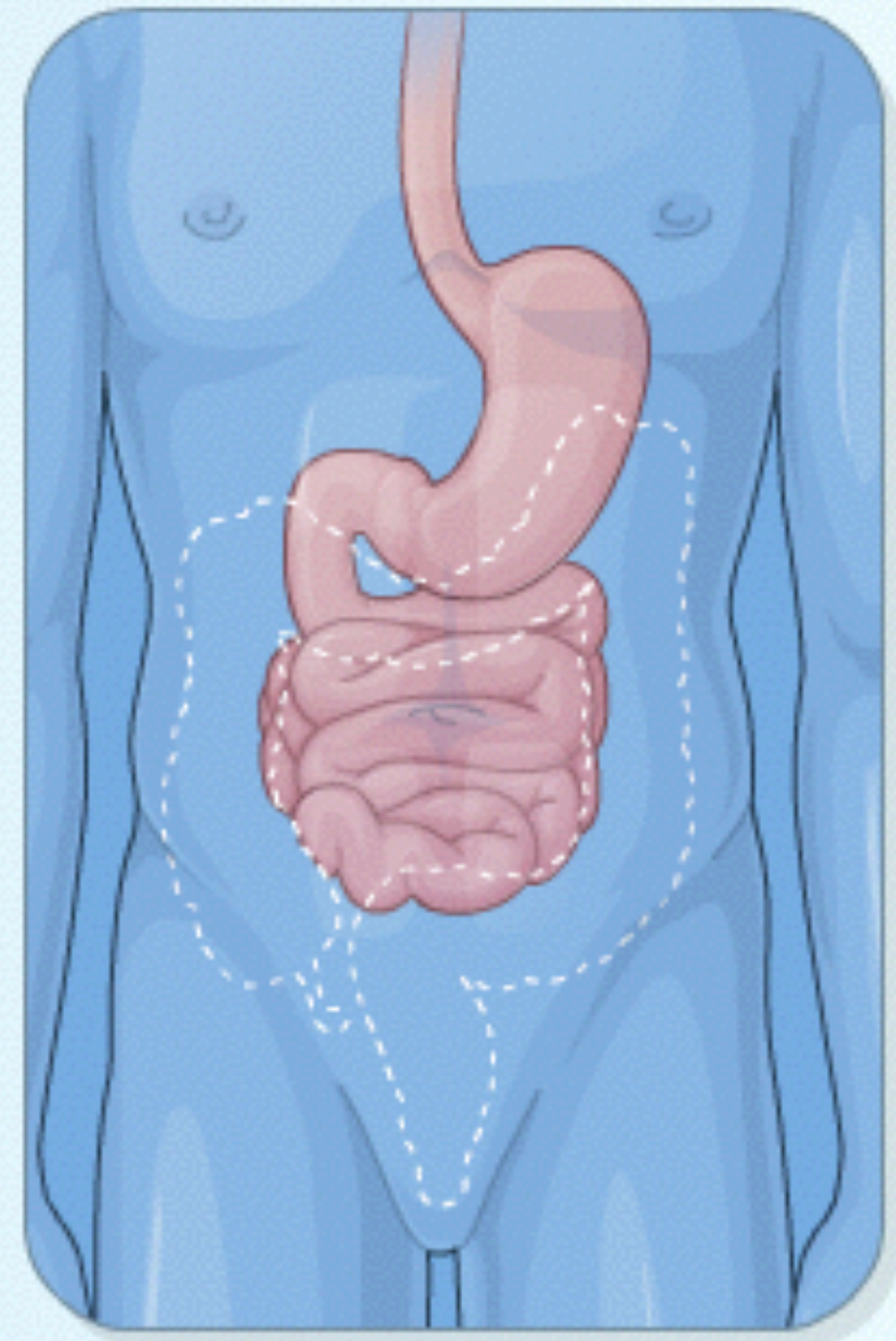




# CREATE COMPETENCE

## Why consider surgery?

- Gets rid of UC digestive problems
- Colon cancer risk very low or zero
- No regular colonoscopies
- Can eat and drink almost anything
- Stop or avoid steroids and prescription medications





# AUTONOMY

## RISKS OF COLECTOMY WITH ILEOSTOMY

The main risks are the chance of a bulge (hernia) around the ostomy, or if the ostomy becomes longer (prolapse). Or the skin in the area can become irritated.

Would you like to hear more about these risks now?

more info

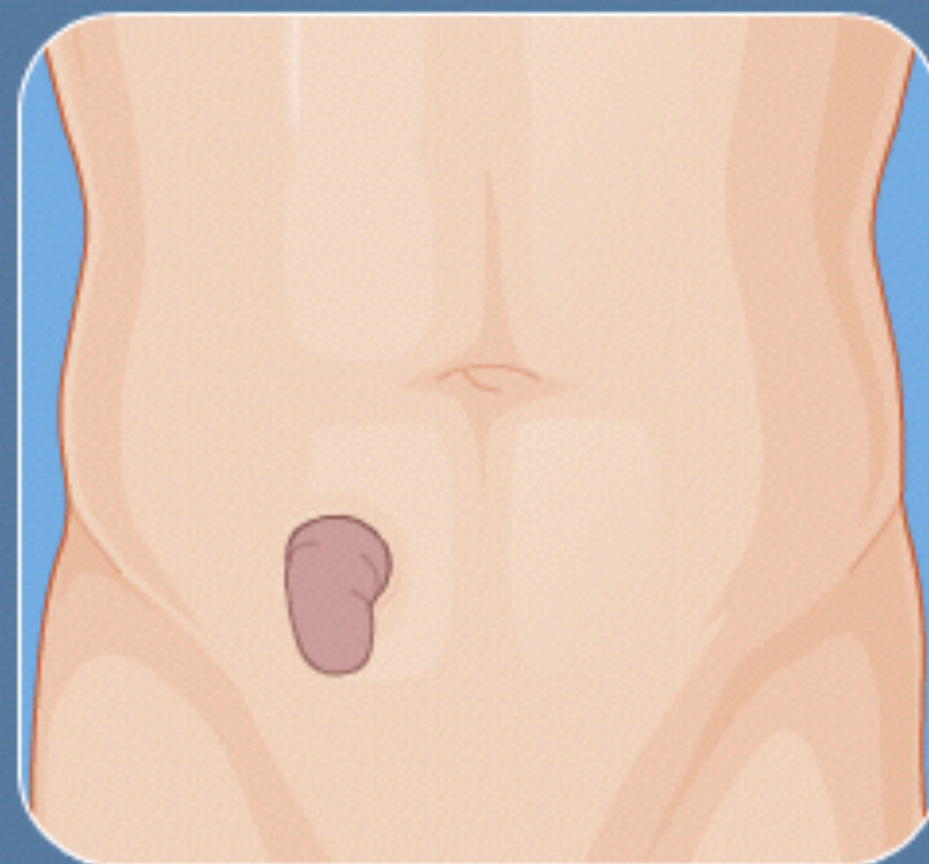
skip





### Intestines poke out

It's less common, but other times the ostomy becomes longer and a little section of the intestines can sort of bulge or poke out through the stoma (prolapse).





COMPETENCE CREATES “RELIEF”

I watched the Crohn's program. ... I really liked the voice and tone. The information was easy to follow. In fact, my 10 year old could easily follow it. I agree with the previous feedback about the information not being scary.



*How one mom dispensed equal doses of humor, humility,  
and corporate smarts to help her family navigate  
their health care crisis*

# QUESTIONING PROTOCOL



by  
RANDI REDMOND OSTER

COSTS  
of CARE



**JAMA** Internal Medicine

*Formerly Archives of Internal Medicine*

[www.RandiRedmondOster.com](http://www.RandiRedmondOster.com)

# THANK YOU

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