

# Patient Preference

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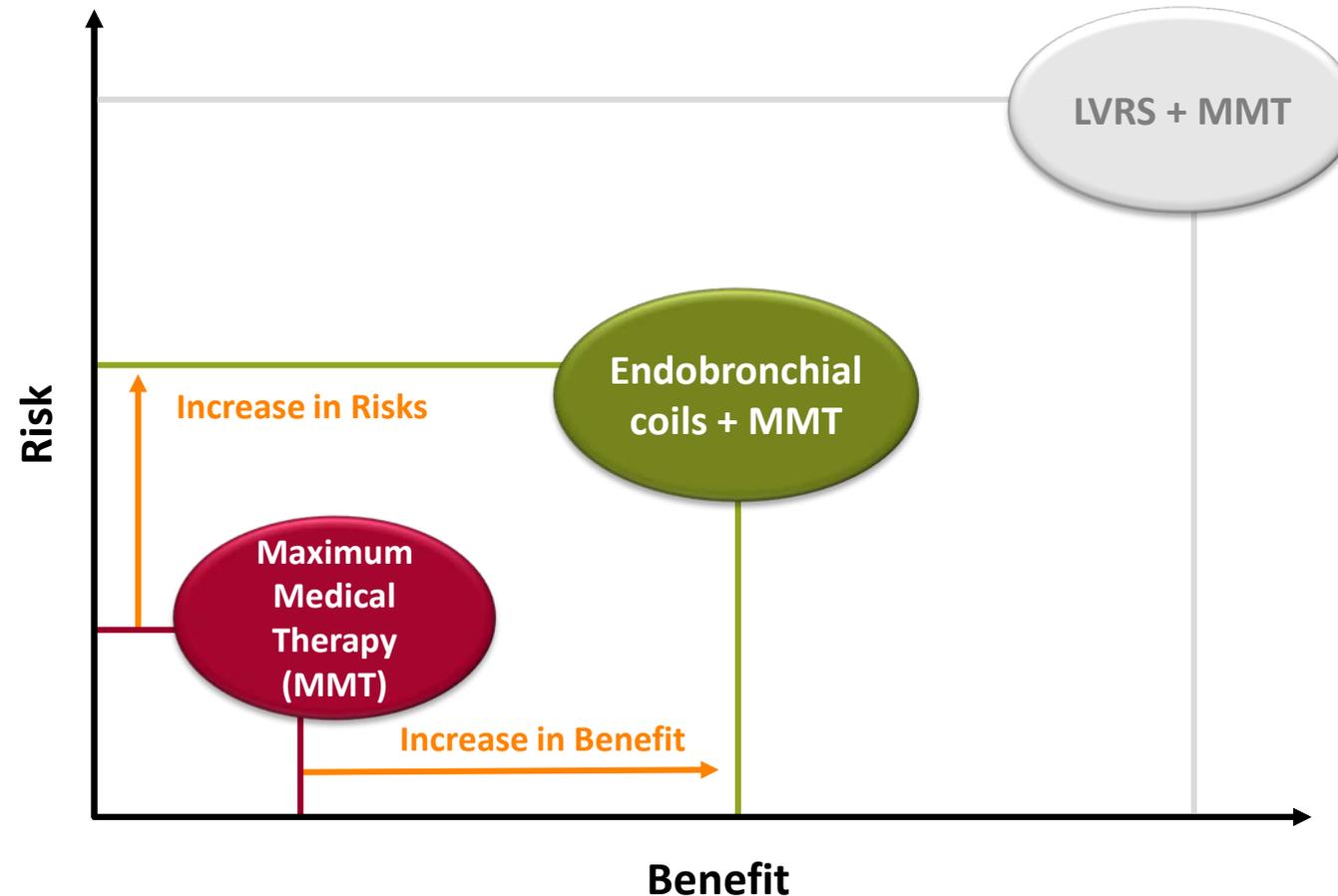
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# Patient Preference Testing

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- Uses established methods to quantify patients' perspectives on benefits and risks
- Expands upon what may be heard from individual patients in an open public hearing
- CDRH issued patient preference testing guidance in 2016
- **The study suggests that there is a group of patients in the target population for whom the benefit of a coil treatment likely outweighs the risks when compared to the outcomes of maximum medical therapy**

# The Patient Benefit-Risk Continuum for Emphysema Interventions



Adapted from Irony T, Ho M. Incorporating Patient Preferences into Regulatory Decision Making. Society for Medical Decision Making. St. Louis, MO 2015.

# Patient Preference Study Design

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## Objective

- Quantify preferences for benefits and risks of emphysema treatments from the patient perspective

## Endpoint

- Proportion of patients who perceive that the benefit of endobronchial coils outweighs the risks

## Study participants

- Recruited through US clinical centers that treat patients for severe emphysema
- 202 Coil-naïve participants not enrolled in RENEW
- Eligibility criteria similar to RENEW's
- 7 RENEW sites and 1 non-RENEW site

# Improving Breathlessness With Activity is the Primary Treatment Goal for Patients With Severe Emphysema

“Everything else is related to shortness of breath.”

“If I didn’t have shortness of breath, I’d be OK.”

“The shortness of breath thing for me is the whole thing.”

“If I could get my breath, I could do whatever.”

“[breathlessness] is the manifestation of the disease that most concerns me.”

# SGRQ Item 11 Measures Breathlessness and was Used as the Measure of Benefit in the Patient Preference Study

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Improvement in  
breathlessness  
reflects how  
patients think  
about the benefits  
of treatment



RENEW measured  
quality-of-life  
improvements  
using the SGRQ



SGRQ Item 11  
measures patient-  
reported  
breathlessness  
with activity

# Benefit: Improvement in Breathlessness With Activity (SGRQ Item 11)

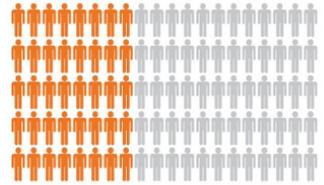
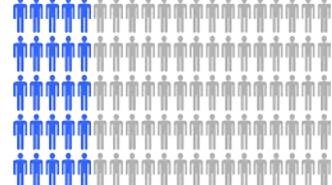
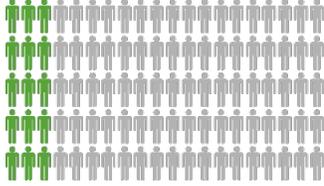
## Baseline

I don't feel out of breath doing these activities	I do feel out of breath doing these activities					
						
Sitting or lying still	Washing or dressing yourself	Walking around the house	Walking outside on level ground	Walking up a flight of stairs	Walking up hills	Playing sports or other physical activities

## With improvement

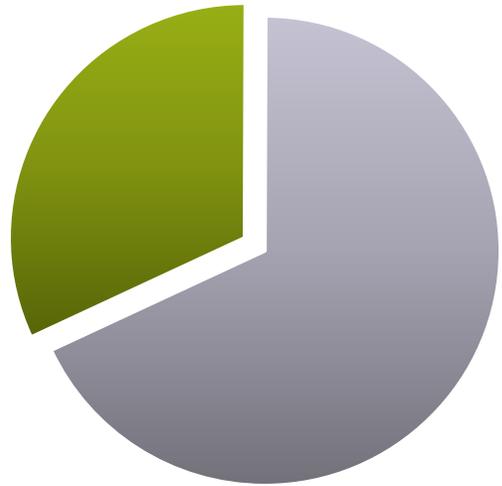
I don't feel out of breath doing these activities	I do feel out of breath doing these activities					
						
Sitting or lying still	Washing or dressing yourself	Walking around the house	Walking outside on level ground	Walking up a flight of stairs	Walking up hills	Playing sports or other physical activities

# Example Survey Question

TX TYPE	Treatment A	Treatment B	
	Implantable lung device	Medicines	
BENEFIT	<p>Chance of <u>improvement in shortness of breath</u> in the next year</p>  <p>40 out of 100 people (40%) have improved shortness of breath</p>	 <p>25 out of 100 people (25%) have improved shortness of breath</p>	
	<p>Difference in <u>flare-ups</u> in the next year</p> <p>1-2 more flare-ups</p>	<p>No change in flare-ups</p>	
	<p>Additional risk of <u>collapsed lung</u> in the next year</p> <p>Small chance (10%)</p>	<p>No chance</p>	
	RISK	<p>Additional risk of <u>pneumonia</u> requiring hospitalization in the next year</p>  <p>15 additional cases in 100 people (15%)</p>	<p>None</p>
		<p>Additional risk of <u>dying</u> in the next year</p> <p>None</p>	<p>None</p>
	<p>Which treatment would you choose?</p> <p><input checked="" type="checkbox"/></p>	<p><input type="checkbox"/></p>	

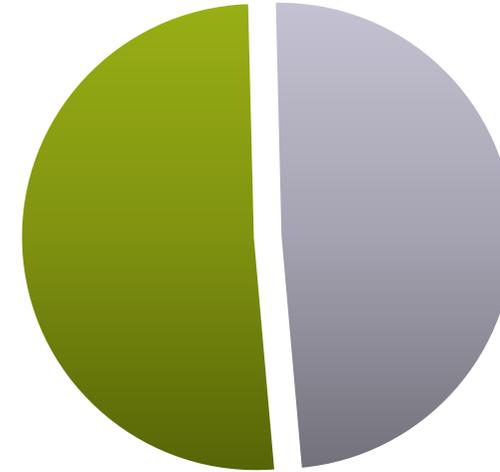
# The Study Suggests There is a Group of Patients in the Target Population for Whom the Benefit of a Coil Treatment Likely Outweighs the Risk when Compared to Maximum Medical Therapy

## Full Survey Sample



- Benefit > Risks (32%)
- Risks > Benefits (68%)

## Survey Sample With RV $\geq$ 225%



- Benefit > Risks (51%)
- Risks > Benefits (49%)

Patient preference for the additional risk of pneumonia requiring hospitalization was extrapolated from 15% to 17.5% (full sample) or 17.3% (RV  $\geq$ 225% predicted).