FDA 2017
What makes a topic preference sensitive?

2 conceptual models
<table>
<thead>
<tr>
<th>High Risk / <strong>High Certainty</strong></th>
<th>High Risk / <strong>Low Certainty</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Example: Heart attack</td>
<td>Example: Breast cancer</td>
</tr>
<tr>
<td>✓ Informed Consent</td>
<td>✓ Informed Consent</td>
</tr>
<tr>
<td>✗ Elicit patient preferences</td>
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</tr>
<tr>
<td>✗ No variability</td>
<td>✓ Variability expected</td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td>Low Risk / <strong>High Certainty</strong></td>
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</tr>
<tr>
<td>Example: Change BP med</td>
<td>Example: High cholesterol</td>
</tr>
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Strength of Recommendation

• High quality evidence (*usually*) that intervention’s desirable effects are clearly greater than undesirable effects
  → Strong recommendation

• Uncertainty about trade-offs (low quality evidence or desirable and undesirable effects closely balanced)
  → Weak recommendation
For which conditions might decision-making be enhanced by data from a patient preference study?
Conditions are not preference sensitive.....

Decisions are + need to be preference sensitive from patients’ point-of-view:

• OA vs RA
• Lung CA vs PSA screening
• TJA
When does a patient preference study add value?

- Drug/device development
- Drug/device approval
- Drug/device recall
- Treatment heterogeneity
Eligible Patients

Randomize

Choice Group

Choose A
Choose B

Undecided

Random Group

Randomize

Randomize

A

A

B

B