

FDA 2017

What makes a topic preference sensitive?

2 conceptual models

<p>High Risk / High Certainty Example: Heart attack</p> <ul style="list-style-type: none">✓ Informed Consent✗ Elicit patient preferences✗ No variability	<p>High Risk / Low Certainty Example: Breast cancer</p> <ul style="list-style-type: none">✓ Informed Consent✓ Elicit patient preferences✓ Variability expected
<p>Low Risk / High Certainty Example: Change BP med</p> <ul style="list-style-type: none">✓ Informed Consent✗ Elicit patient preferences✗ No variability	<p>Low Risk / Low Certainty Example: High cholesterol</p> <ul style="list-style-type: none">✓ Informed Consent✓ Elicit patient preferences✓ Variability expected

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

