FDA 2017

What makes a topic preference sensitive?

2 conceptual models

High Risk / **High Certainty** Example: Heart attack ✓ Informed Consent × Elicit patient preferences × No variability	High Risk / **Low Certainty** Example: Breast cancer ✓ Informed Consent ✓ Elicit patient preferences ✓ Variability expected
Low Risk / **High Certainty** Example: Change BP med ✓ Informed Consent × Elicit patient preferences × No variability	Low Risk / **Low Certainty** Example: High cholesterol ✓ 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?

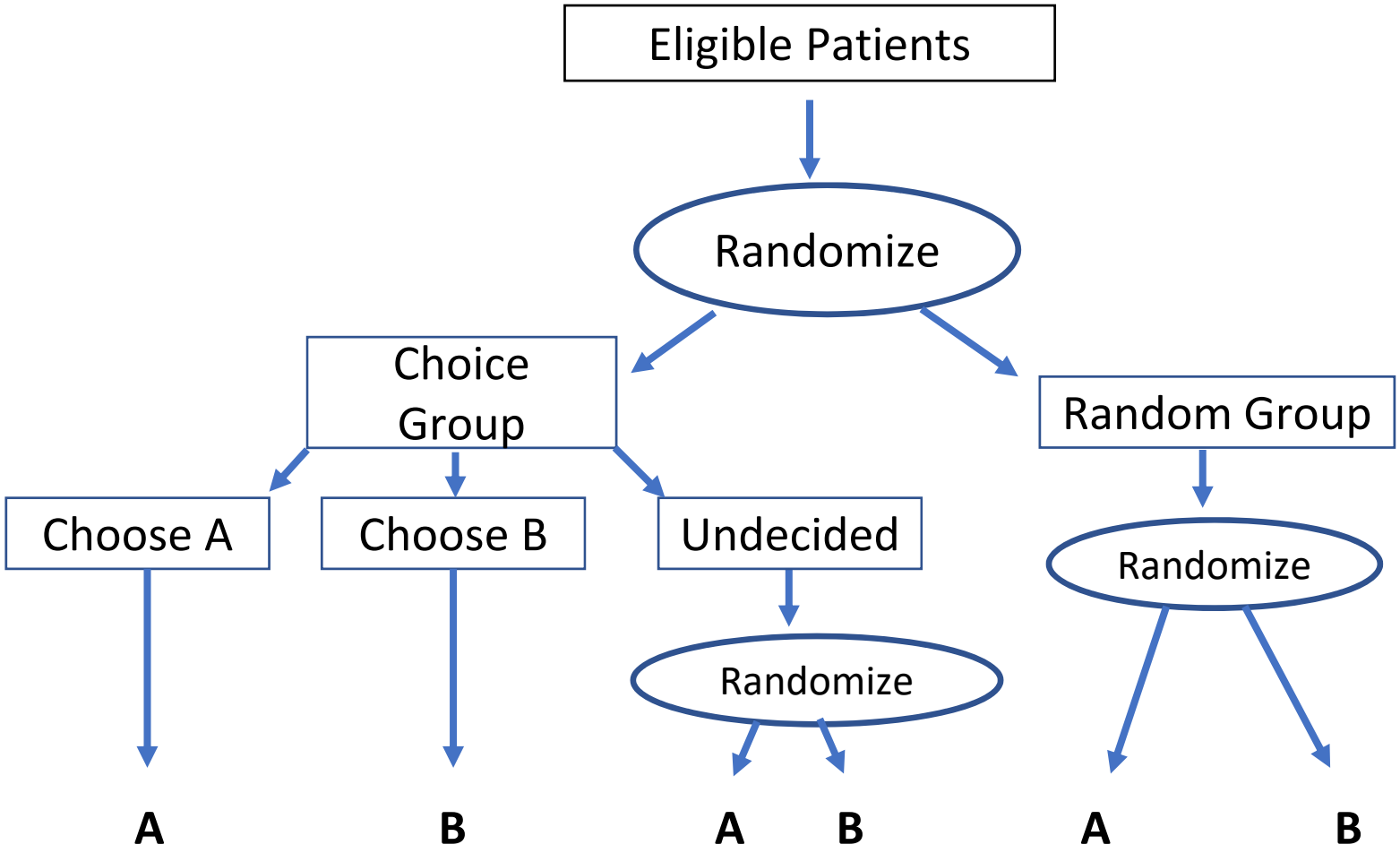
Conditions are not preference sensitive…..

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


Eligible Patients
Randomize
Choice Group
Random Group
Choose A
Choose B
Undecided
Randomize
Randomize
A
B
A
B
A
B