



RTI HEALTH SOLUTIONS®

Improving the Effectiveness of Risk Communication

Prepared for

FDA Hearing on Risk Communication

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LEADING RESEARCH...
MEASURES THAT COUNT

Overview

- Two examples:
 - Risk communication in Alosetron risk-management program
 - Effect of risk communication format on patient risk-benefit tradeoffs for hormone replacement therapy
- Lessons:
 - Patients and physicians can understand quantitative risk information and make informed choices
 - Risk perceptions and risk attitudes can depend on presentation method

Example of Effective Communication: Alosetron

- Patient-oriented messages on benefits, risks, and what action patients should take
 - Physician-patient agreement form (PPA)
 - Medication guide provided by physician and pharmacist
- Evaluation of communication process and knowledge using patient survey
 - Voluntary follow-up survey (mail and phone)
 - Recruitment card from physicians and in product packaging
 - Data collected at initiation, 5 weeks, 10 weeks, and quarterly for one year
 - Enroll 35% of users

Results of Alosetron Patient Follow-up Survey through December 31, 2003 (n=3,219)

Indicators of Compliance with RMP	%
Signed a Physician-Patient Agreement form	93
Discussed possible risks of Lotronex with doctor	96
Discussed with doctor how Lotronex can help	97
Discussed with doctor reasons to stop taking Lotronex	95
Discussed when to call the doctor	94
Received medication guide from doctor	91
Received medication guide from pharmacist	90
Read the medication guide (of those receiving it)	98
Received prescription with blue sticker	87

Knowledge Questions 1-3 (added based on cognitive testing)

New or worsening pain in the bowels is a sign that a patient could be experiencing a serious problem related to Lotronex

- True
- False
- Don't Know

If a patient experiences new or worsening pain in the bowels, which is the best action to take?

- Continue taking Lotronex as prescribed
- Lower the dose for a few days
- Stop taking Lotronex, and call the Doctor
- Don't Know

Blood in the stool is a sign that a patient could be experiencing a serious problem related to Lotronex

- True
- False
- Don't Know

Knowledge Questions 3-6 (added based on cognitive testing)

If there is blood in the stool, which is the best action to take?

- Continue taking Lotronex as prescribed
- Lower the dose for a few days
- Stop taking Lotronex, and call the Doctor
- Don't Know

Constipation is a sign that a patient could be experiencing a serious problem related to Lotronex

- True
- False
- Don't Know

If a patient becomes constipated, which is the best action to take?

- Continue taking Lotronex as prescribed
- Lower the dose for a few days
- Stop taking Lotronex, and call the Doctor
- Don't Know

Potential Reasons for Success of Alosetron Medication Guide and PPA

- Motivated population receiving treatment
 - Most severely affected by IBS symptoms
 - Many had received Alosetron prior to product withdrawal
- Good physician compliance
 - Enrolling in prescribing program
 - Prescribing only to patients meeting clinical criteria
 - Counseling patients
 - Signing physician-patient agreement form
 - Reporting adverse events
- Effective communication using multiple approaches
 - Physician-patient agreement form
 - Medication guide
- **Lesson - Importance of careful development and testing of**
 - **Communication instrument**
 - **Measurement instrument**

Effect of Risk Communication on Hormone Replacement Therapy (HRT) Preferences

- Women's Health Initiative Study: benefits of HRT not greater than health risks
 - Decreased risk of hip fracture
 - Increased risk of myocardial infarction and breast cancer
- Did not consider benefits of relief from vasomotor symptoms of menopause

Effect of Risk Communication on HRT Stated Preferences

- Risk-benefit tradeoff study
- Objectives
 - Estimate stated willingness to trade risk for vasomotor symptom control
 - Test effect on stated preferences of absolute-risk versus relative-risk measures
- Maximum Acceptable Risk measured by Conjoint-analysis methods
 - Rigorous conceptual framework
 - Ordinal utility theory
 - Choice-based preferences
 - Advanced statistical modeling

HRT Study Design

- Web-enabled survey
- Choices between realistic treatment alternatives
 - Efficacy features: symptom severity, frequency, and duration
 - Risk features: infarct, cancer, and fracture
 - Risks presented either as absolute risks or relative risks
- Internal validity tests incorporated in design
- 523 women aged 46-60

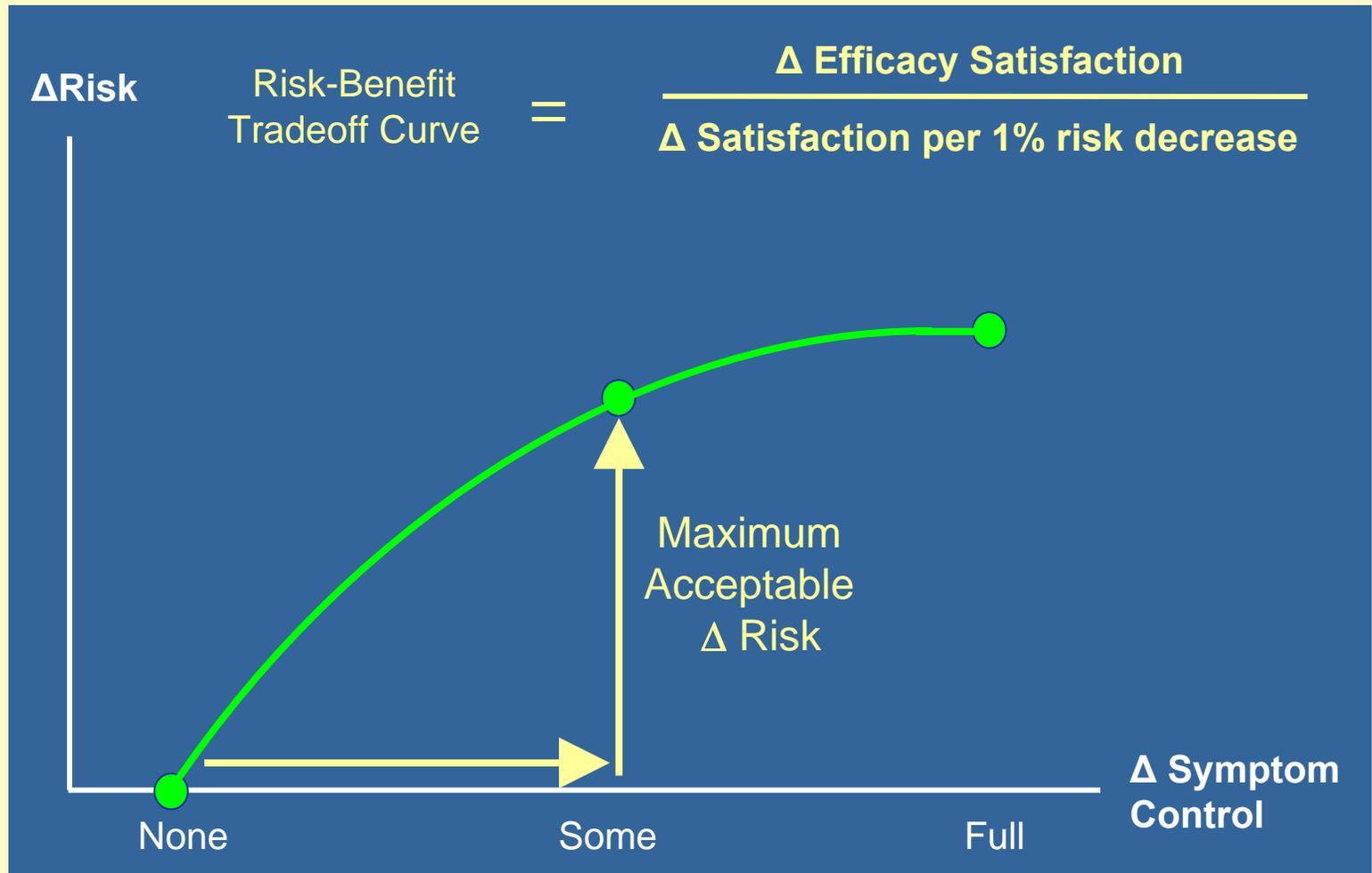
Example Conjoint Task

	Results of Treatment A	Results of Treatment B
Intensity of daytime hot flashes	Mild	Severe
Frequency of daytime hot flashes	1 – 2 times a day	More than 6 times a day
Frequency of night sweats	None	1 – 3 times a night
Duration of hot flashes and night sweats	7 years	1 year
Risk of hip or back fractures within 10 years	↓ 50% decrease in risk	↓ 50% decrease in risk
Risk of heart attack within 10 years	↓ 25% decrease in risk	↑ 30% increase in risk
Risk of breast cancer within 10 years	No change in risk	↓ 25% decrease in risk

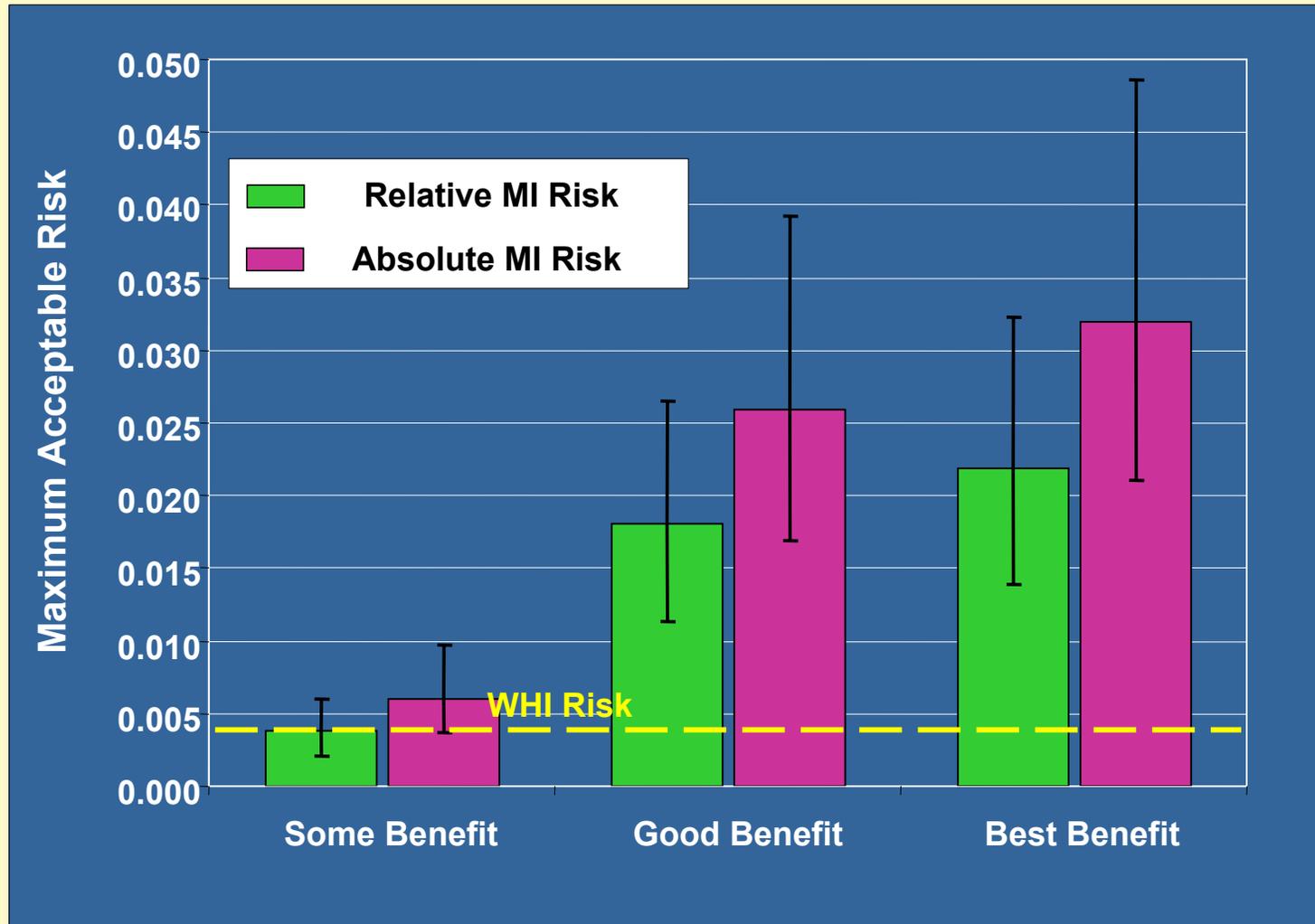
Check the box that best describes your opinion

A is much better	A is somewhat better	A and B are the same	B is somewhat better	B is much better
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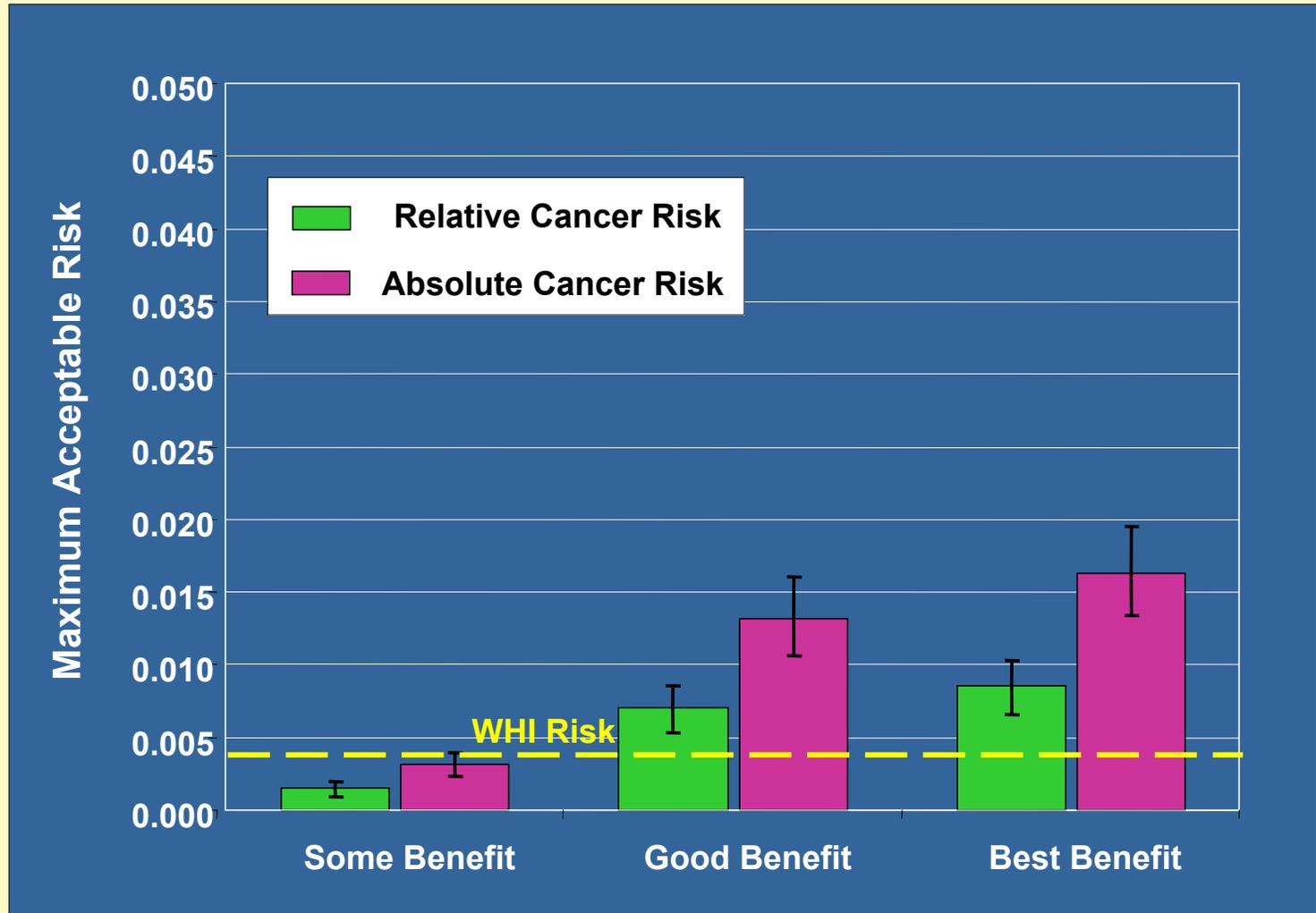
Risk-Benefit Tradeoffs



HRT Maximum Acceptable Myocardial Infarction Risk



HRT Maximum Acceptable Breast Cancer Risk



Conclusions

- Women had a higher tolerance for risk when the risk was presented as absolute risk
- Women were willing to accept risks greater than WHI risk estimates to obtain good symptom control

Conclusions

- Patients and physicians can understand risk information and make informed choices
- Careful design and testing is needed for both the communication and evaluation instruments
- The type of risk to be communicated (relative, absolute, or both) is important
- The patient perspective on trade-offs between risks and benefits can be evaluated in a scientifically robust manner and inform policy decisions

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