

# Behavioral Studies

## Supporting Rx-to-OTC Switches

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# Agenda

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- Predict/evaluate consumer behavior in the OTC environment
- Consider more information on likely OTC use
- Leverage a wider array of influences on OTC use
- Expand scientific foundations of OTC switch

# The New OTC Paradigm

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- OTC switches increasingly complex
  - From acute treatment of symptomatic conditions to
  - Support of preventive lifestyle changes
  - Chronic treatment of asymptomatic conditions
- Challenges ahead

# Behavioral End-Points in OTC Switch

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- Drug pharmacology typically well-understood
  - Considered safe & effective if used properly
- Questions in OTC switch are behavioral
- Critical question:

*Will consumer behavior lead to safe and effective use?*

# Key Elements of OTC Simulation in Actual Use Studies

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- No learned intermediary
- Sample consumers with interest in treatment
- Consumer makes decisions regarding drug purchase / use / repurchase / discontinuation
  
- Data-gathering may cause “reactivity”

# Strategies to Limit Reactivity: Reactivity vs. Insight

<b>Strategy</b>	<b>Pros</b>	<b>Cons</b>
Limit frequency of data collection contacts	Reduce potential influence	Reduce detail in data Maximize use of recall

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Conduct Self-selection tests separate from AUS	Allow detailed debriefing of self-selection, without contaminating AUS	Additional research burden Do not observe purchase



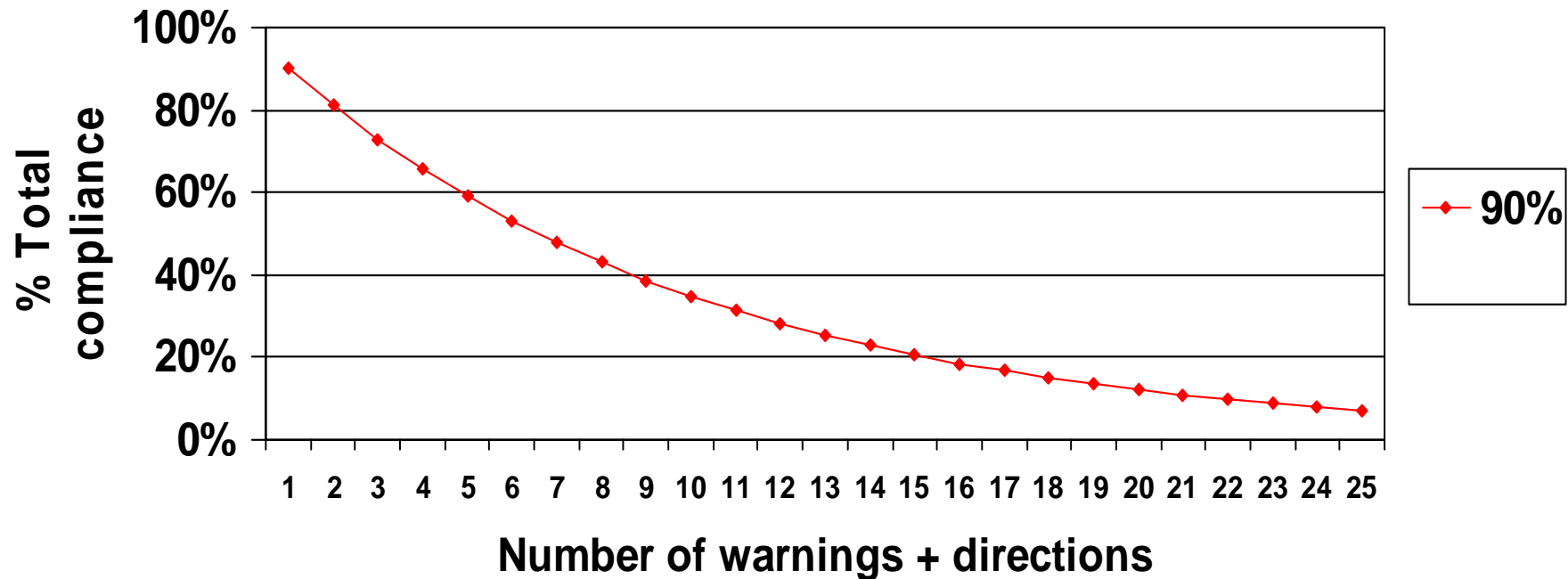
# Evaluating Study Outcomes: Focus on What's Critical to Risk / Benefit

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- Focus on issues that matter most for consumer health
- Identify and agree on core issues for particular switch
- Design: Study & end-points to address key questions
- Evaluation: Focus on key end-points for risk

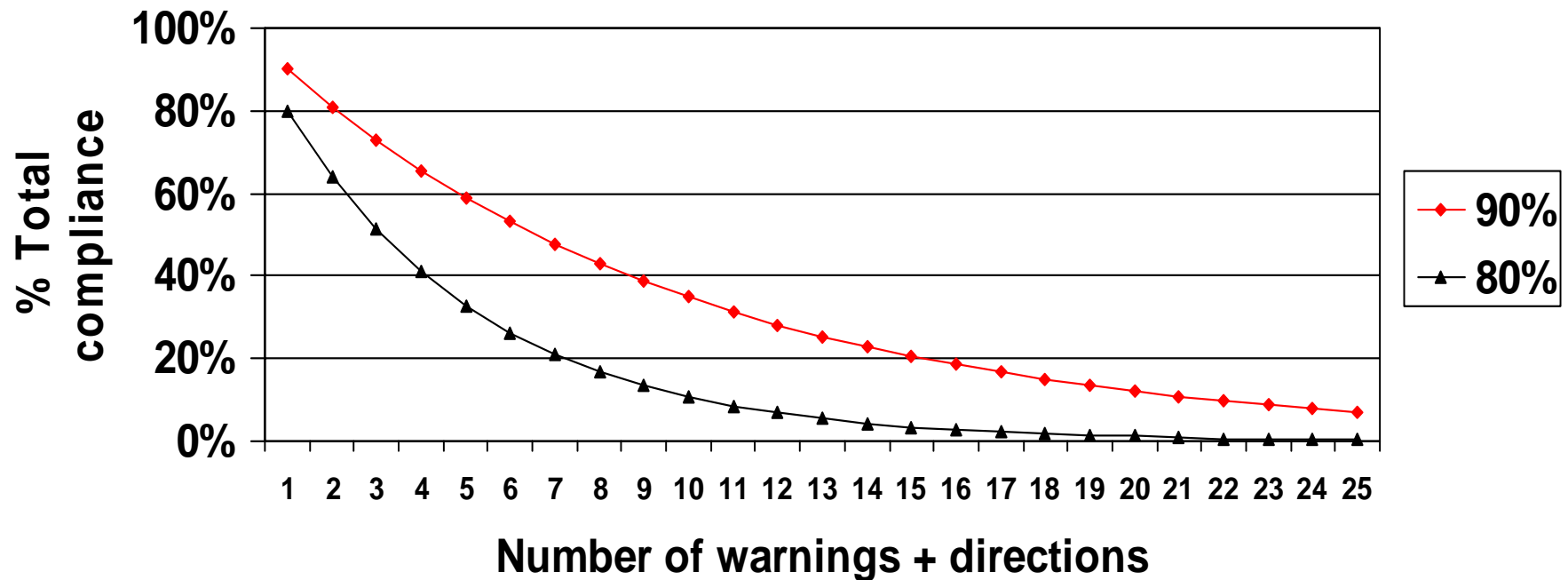
# Total Compliance Measures Highly Sensitive to Number of Warnings + Directions

**% Total Compliance,  
When 90% Comply with Each Element**



# Total Compliance Measures Highly Sensitive to Number of Warnings + Directions

**% Total Compliance,  
When 80-90% Comply with Each Element**



# Interpreting Outcomes: How Good is Good Enough?

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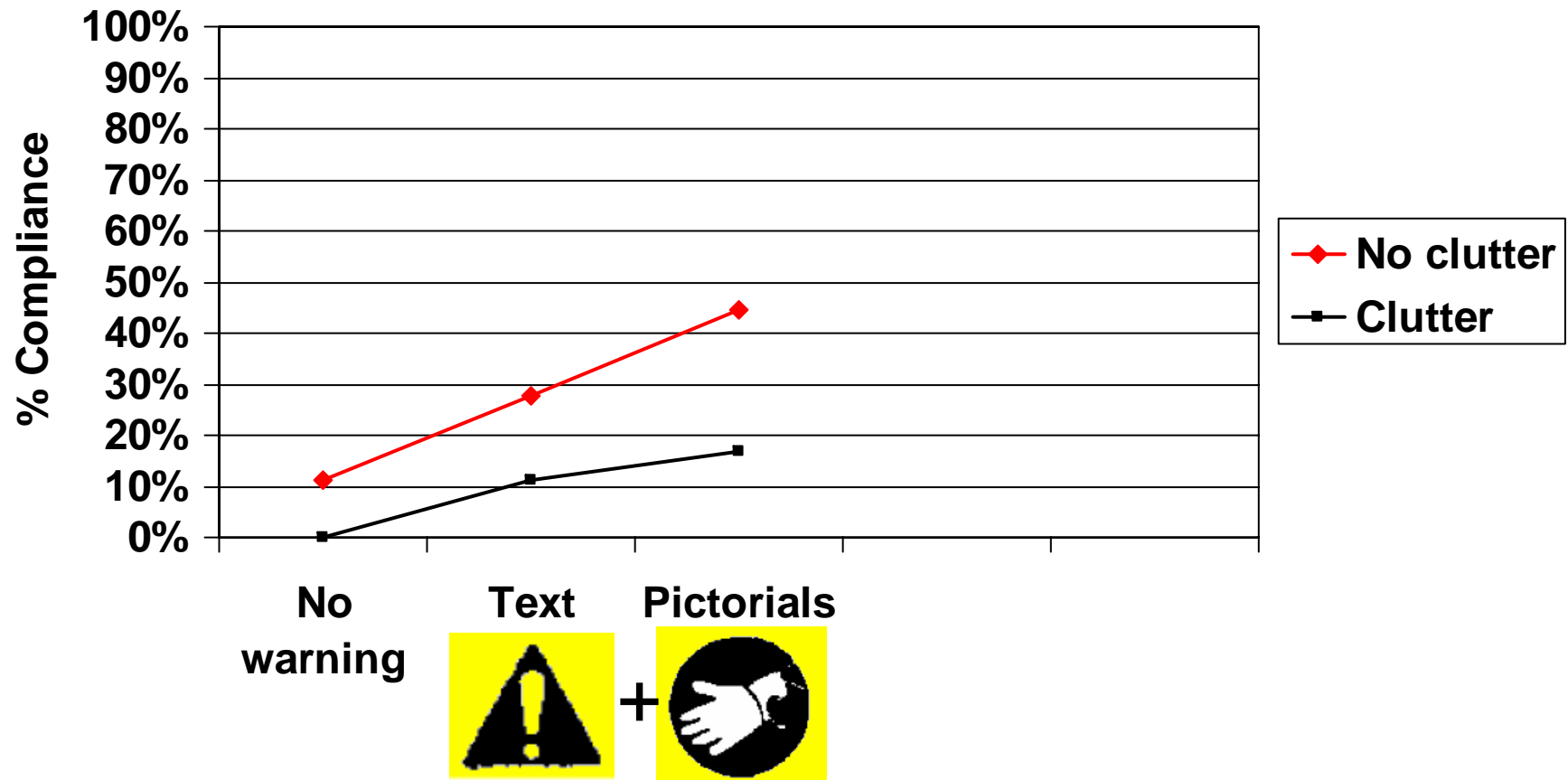
- No single standard; weigh by risk
- Benchmarks:
  - Compliance with warnings in other domains
  - Behavior under Rx

# Realistic Expectations of Warning Compliance

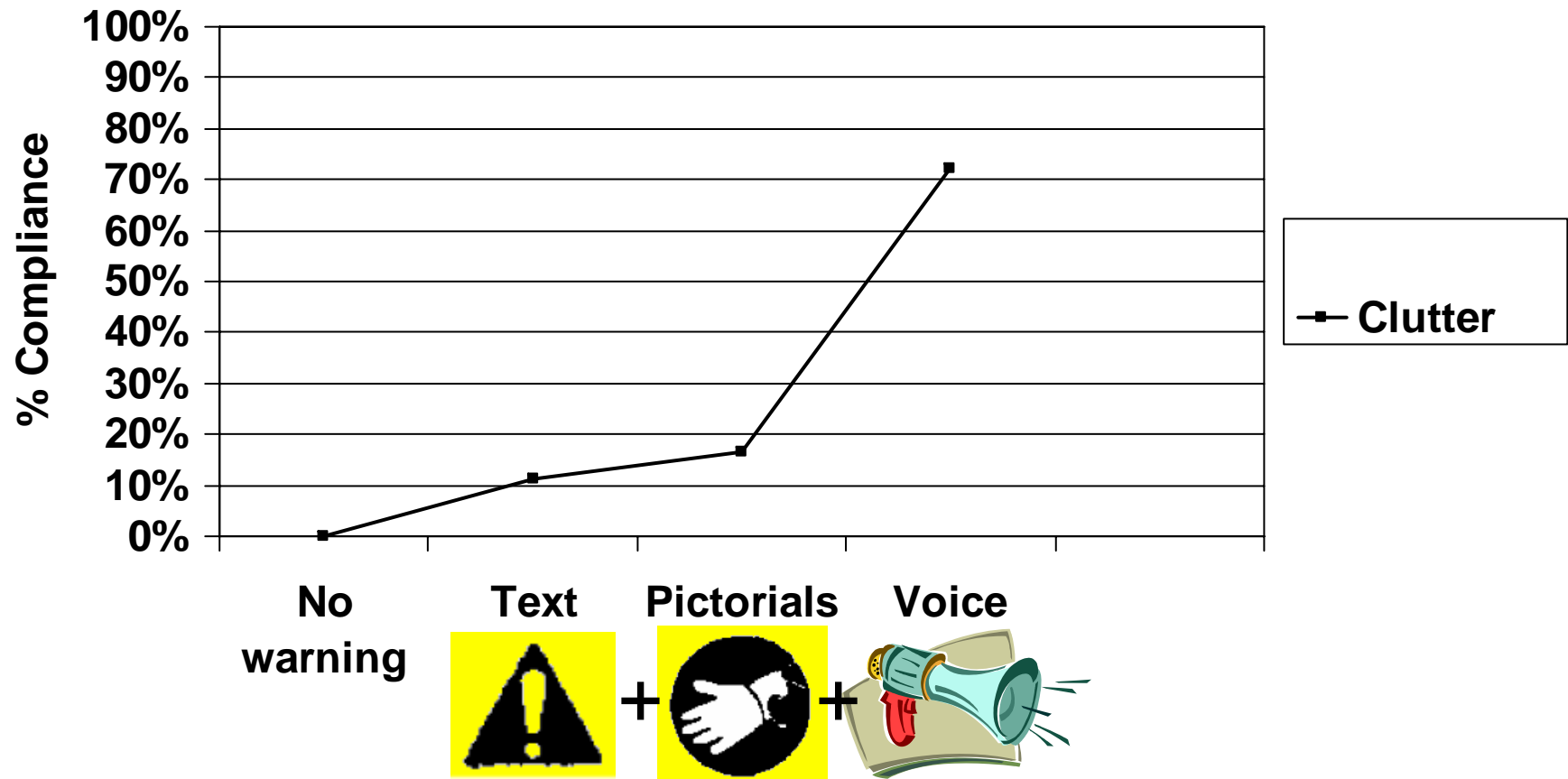
- Experimental example:  
Warning to wear gloves/mask
- Randomized to:
  - Range of different warnings
  - Cluttered vs. uncluttered setting
- Evaluate compliance



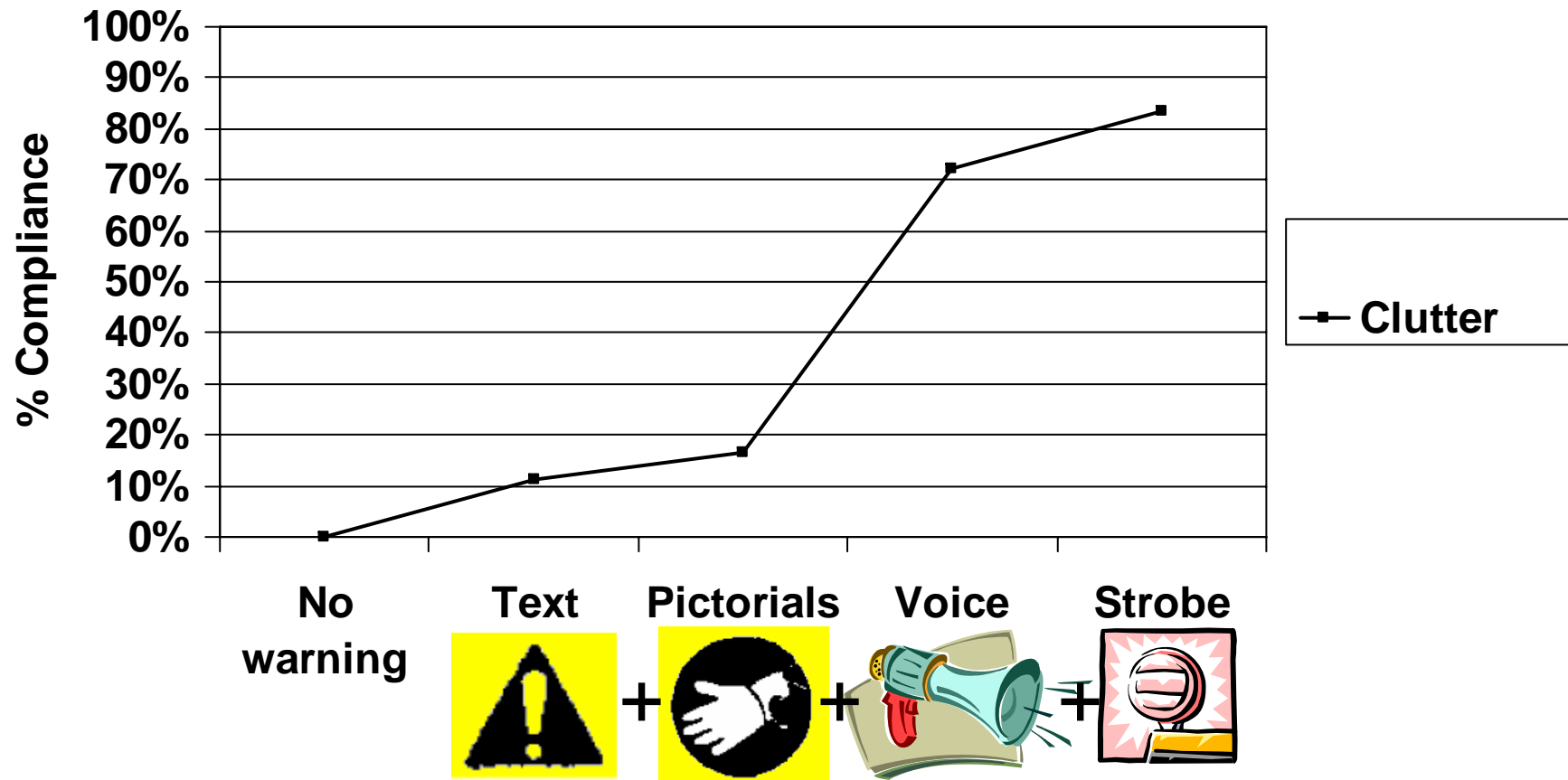
# Compliance with Warning/Direction for Chemical Protection



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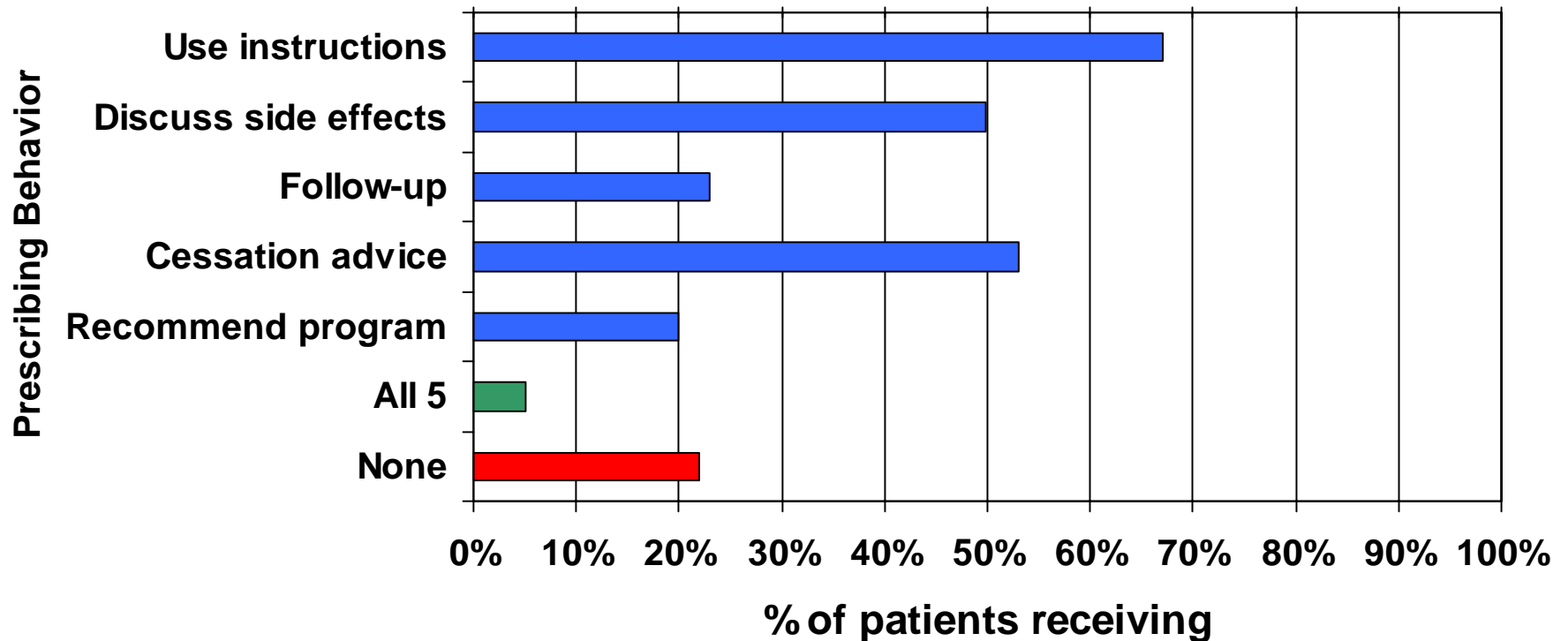
# Context for OTC Switch: Rx Use Patterns

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- Evaluate change: existing Rx context vs. OTC
- Real-world Rx use as benchmark
- Example:  
OTC Switch of Nicotine Replacement Therapy (NRT): Nicotine gum and patch

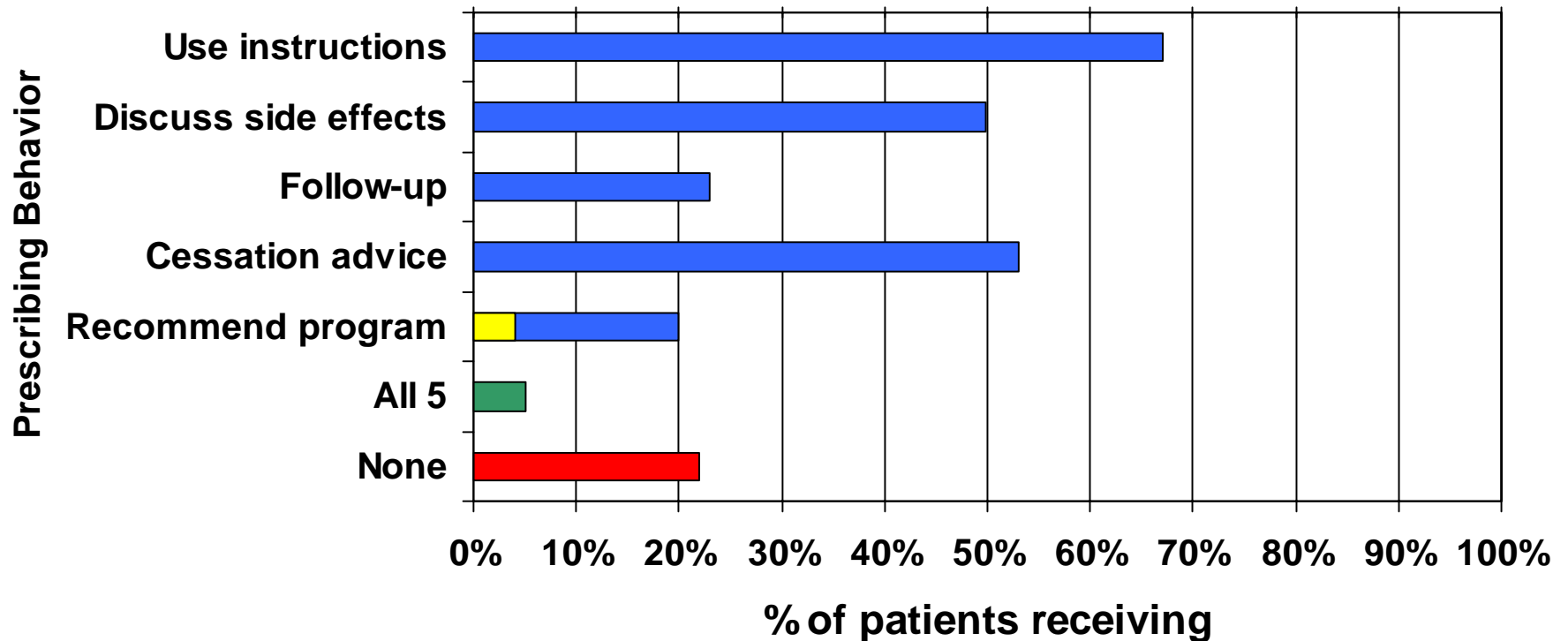
# Prescribing Practices for NRT

(Pre-OTC Switch, Patient Reports)



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# Expanding Sources of Information for Predicting OTC Behavior

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- Actual patterns of Rx use
- Actual patterns of OTC (BTC) use ex-US
- Actual patterns of use of similar OTCs
- Post-marketing surveillance

# Expand Sources of Influence on OTC Behavior

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- Label is primary source of OTC information
- Expand other points of influence
  - In-pack materials: Print, CDs (still considered 'labeling')
  - Consumer educational materials/programs
  - Behavioral programs
  - Outreach to physicians and other influencers
- Risk Management Programs
  - Especially important for small at-risk populations

# Evaluating Supplementary Programs

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- Evaluation based on importance for safe OTC use
- Demonstrate the drug is OTC-able **with** the program
- Some programs can't be implemented/evaluated before approval

# More Research Is Needed

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e.g.,

- How do wording, format, order of warnings affect attention, priority, & compliance?
- How much does assessment lead to reactivity? How best to minimize reactivity?

# Advancing the Scientific Foundations of OTC Switch

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- Assess “State of the Science”
  - Analyze past switches
  - Review behavioral research relevant to OTC
- Collect new data on key OTC issues
- Develop behavioral science of OTC Switch



# Questions?

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