

# Ethical Considerations for Obtaining Informed Consent: Insights from Psychology

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# Valid Consent

- Voluntary
- Competent
- Knowledgeable
  - Sufficient disclosure of risks and benefits and alternatives
  - Understand disclosed facts
- Authorize (informed consent) or decline (informed refusal)

# The Burden of Disclosure



# Effects of disclosure on patients



"Under disclosure rules, I'm required to tell you I own stock in the company whose drug I'm prescribing."

# Increased pressure to comply with decrease in trust

## Insinuation Anxiety

*Reluctance to signal distrust*

**Impropriety of insinuating bias**

Sah, S. (2021). Insinuation anxiety: Concern to signal distrust leads to greater compliance. *Working Paper*

Sah, S., et al. (2019). Insinuation anxiety: Fear of signaling distrust after conflict of interest disclosures. *Personality and Social Psychology Bulletin*, 45(7), 1099-1112.

## Panhandler Effect

*Reluctance to signal unhelpfulness*

**Implicit favor request**

Sah, S., et al. (2013). The burden of disclosure: Increased compliance with distrusted advice. *Journal of Personality and Social Psychology*, 104(2), 289-304

# The Burden of Disclosure

With disclosures of potential risk, the consumer will trust advice less



With disclosure of potential risk, the consumer feels increased pressure to act in favor of the advisor's recommendation



# Example Situation

*Imagine you are a patient suffering from early onset arthritis, and you have been seeing your rheumatologist, Dr. McLane, who you have known for the last 3 years. You are currently suffering from an acute attack which has left some of your joints aching and swollen. You decide to pay a visit to your doctor.*

*After examining you and reviewing some of your test results Dr. McLane says...*



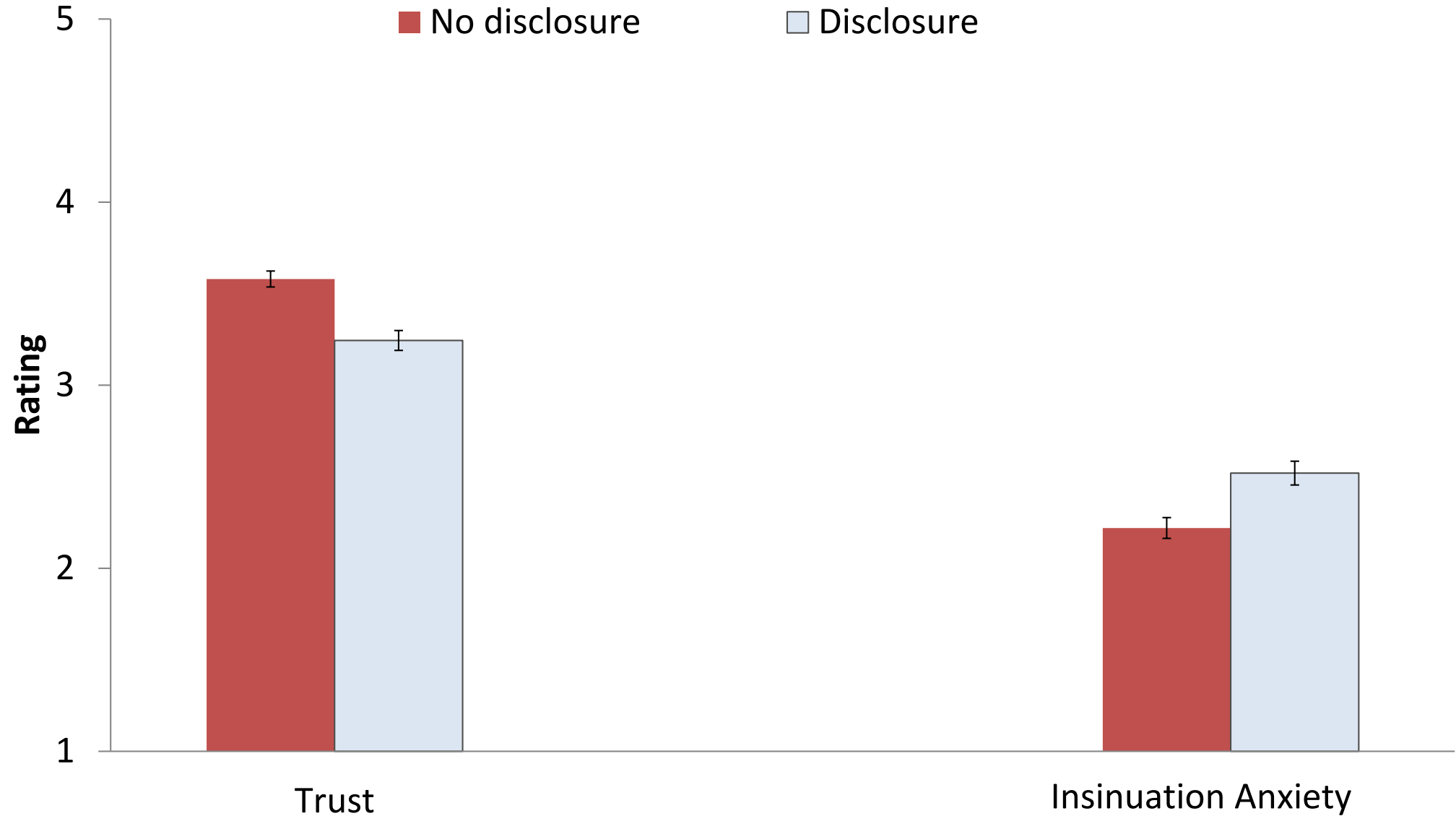
A photograph of a doctor and a patient in a clinical setting. The doctor, on the right, is wearing a white lab coat over a blue striped shirt and a dark tie. He is sitting on a stool and looking towards the patient. The patient, on the left, is a man with a beard wearing a red sweater over a white collared shirt and dark trousers. He is sitting on an examination table and looking back at the doctor. The background shows a window with blinds and medical equipment on the wall.

**Doctor gives two options**

# With disclosure doctor reveals a financial COI:

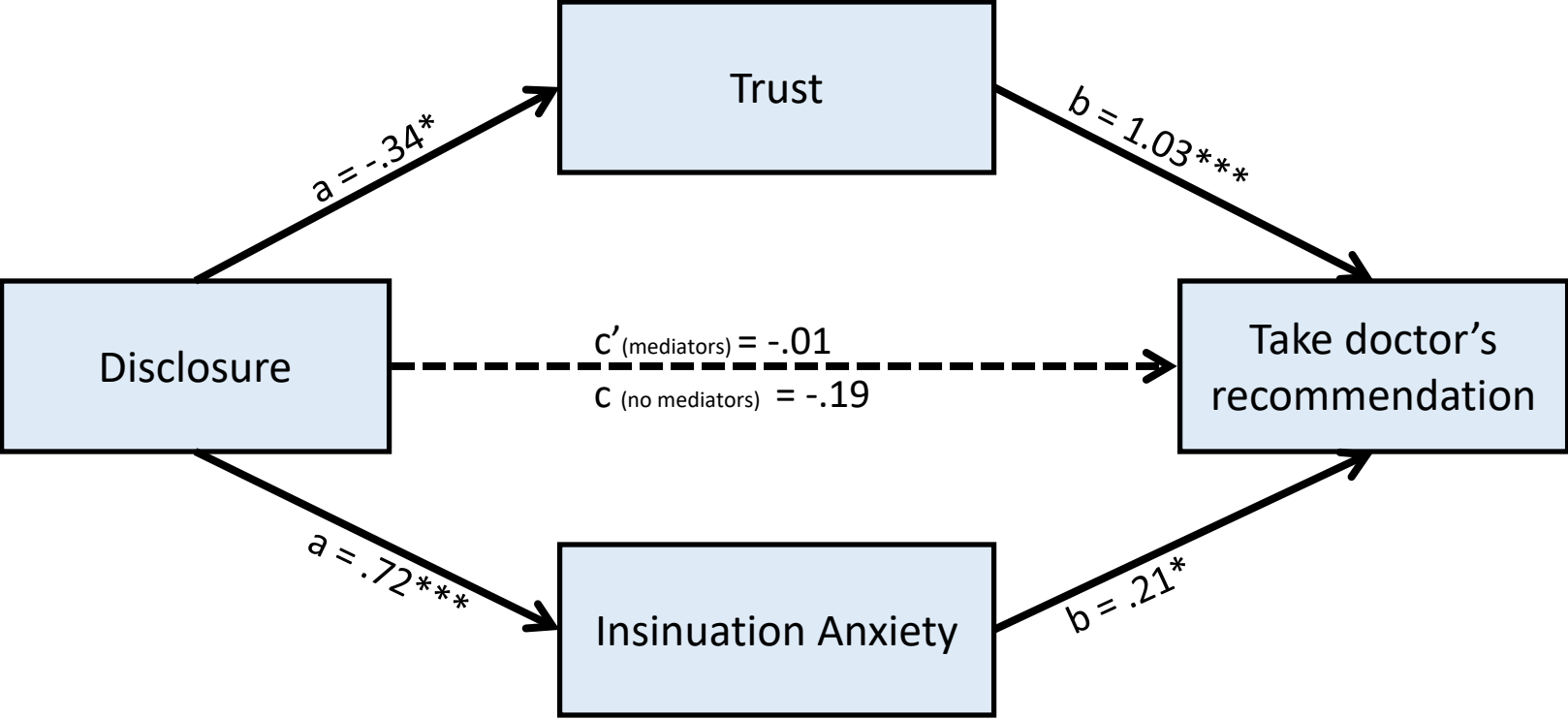
*“I do think it is important, however, to let you know I will receive a referral fee from the manufacturer of the drug if I refer you for the clinical trial”*

# Disclosure increases burden



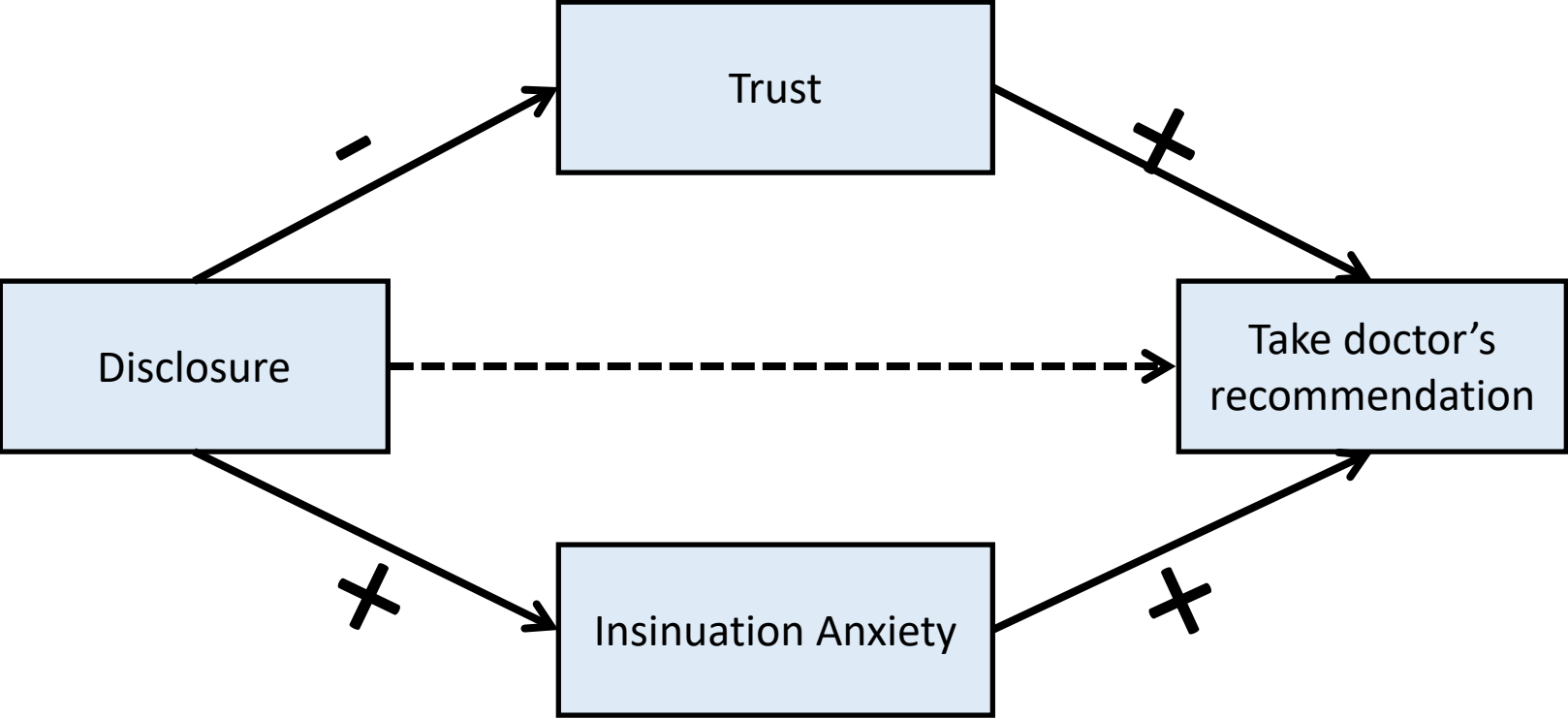
*N* = 112, All *p* < .05,  
Error bars: +/- 1 SE

# Opposing forces fully mediate taking advice



\*  $p < .05$   
\*\*  $p < .01$   
\*\*\*  $p < .001$

# Opposing forces fully mediate taking advice



# Implications

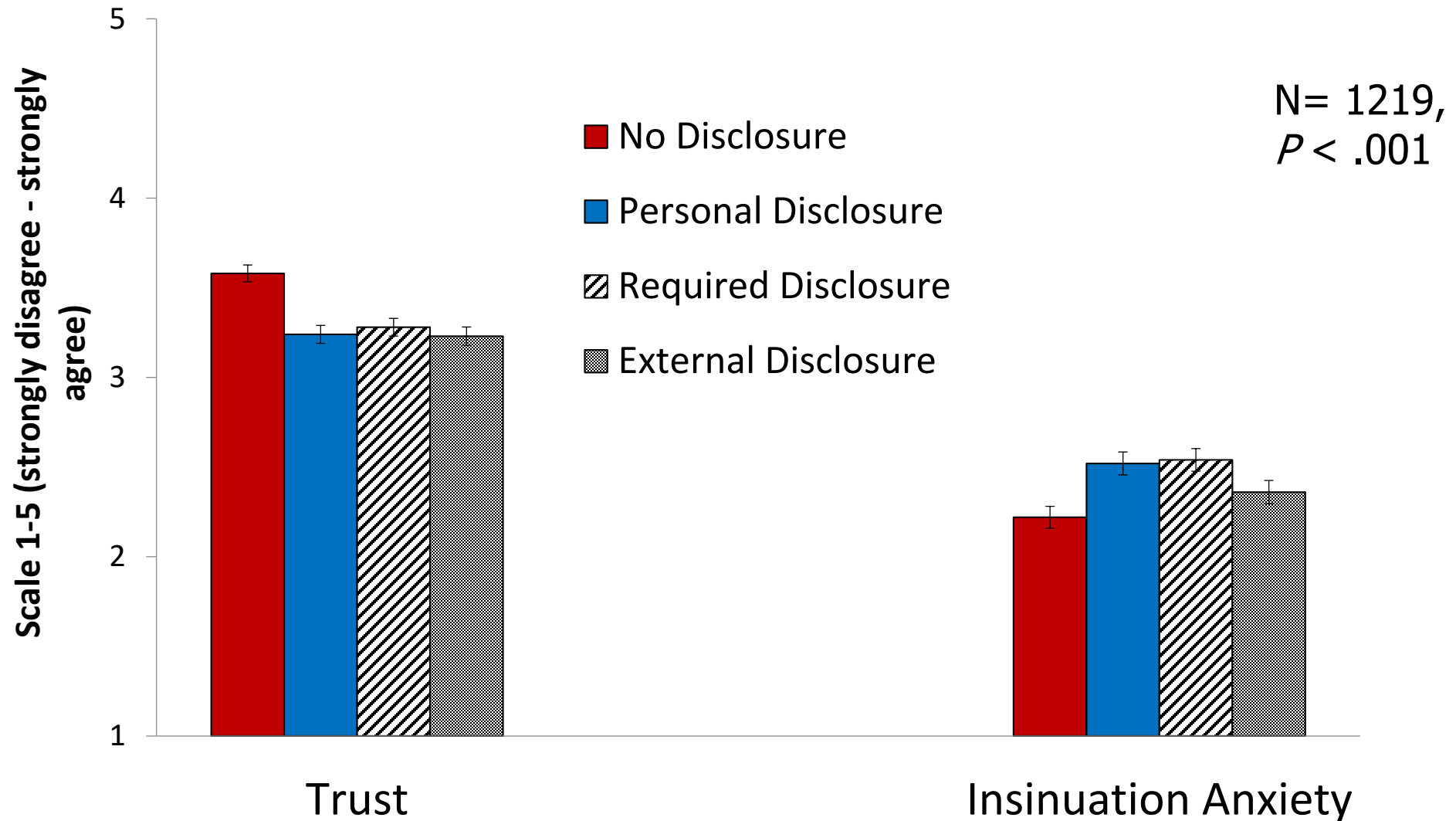
- Insinuation Anxiety increases compliance... but not consent
  - Unreliable
  - Short lived
  - Element of feeling coerced (decreasing “voluntary” element)
- Ethically problematic

# External and Mandatory Disclosure

## Examined four conditions:

- No disclosure
- Voluntary personal disclosure
- Legally required disclosure
- External disclosure – from a third party

# External and Required Disclosure





# Implications

- Legally required disclosure was similar to voluntary personal disclosure
- External disclosure → less insinuation anxiety → less compliance
- Disclosure from a third party decreases pressure



# Large randomized pre- registered field study

Disclosure of  
conflicts of interest  
> \$20,000

Rose, S., **Sah, S.**, Dweik, R., et al,  
(2019). A randomized field  
experiment of patient responses to  
physician disclosures of industry  
conflicts of interest.  
*Organizational Behavior & Human  
Decision Processes.*

Disclosure: Study funded by The Greenwall Foundation



<Date>

<FirstName> <LastName>

<Street Address>

<City>, <State> <ZIPCODE>

Dear <FirstName> <LastName>,

You are scheduled for an appointment with Dr. <PhysicianName> on <date> at <time>, in <building name> of Cleveland Clinic, located at <address>. If you have questions about your appointment, including transportation or parking, please call 1-800-223-2273 or visit our website <http://my.clevelandclinic.org/patients-visitors/>.

Cleveland Clinic wants you to know that your physician, Dr. <PhysicianName>, has a financial relationship with a company that makes products that may be prescribed or used in your care. These relationships are shown on the following page, and the Innovation Management and Conflict of Interest Program has reviewed Dr. <PhysicianName>'s relationships with drug and medical device companies. Physicians interact with the makers of drugs and devices in a number of ways. For example, a physician might receive compensation for inventing a drug or device, consulting, advising, providing education or other services.

Some research suggests that physicians who have financial relationships with companies may tend to favor products of those companies. The research suggests that physicians with such financial relationships may overestimate the benefits or underestimate the risks of the companies' products. The policy of the Cleveland Clinic permits physicians to engage in these financial relationships, because we believe that these collaborations are an important way to advance scientific and medical knowledge to develop life-saving technologies. Companies draw expertise from our physicians because they are leaders in their fields.

We believe that it is important for patients to have this information, so that you can make fully-informed choices regarding which physician you see and your treatment options. Dr. <PhysicianName> would be happy to respond to any questions or concerns you may have, or you may contact the Cleveland Clinic's Conflict of Interest Office, at [IM\\_COIOffice@ccf.org](mailto:IM_COIOffice@ccf.org).

Please contact us if you have any questions.

Sincerely,

Susannah L. Rose, PhD  
Professional Staff, Cleveland Clinic  
Assistant Professor, Cleveland Clinic Lerner College of Medicine  
Case Western Reserve University, 216-444-0849

Appointment reminder  
(control)

Disclosure Information

Risk Manipulation

Benefit Manipulation



# Dependent variables

Medical records (N = 1903)

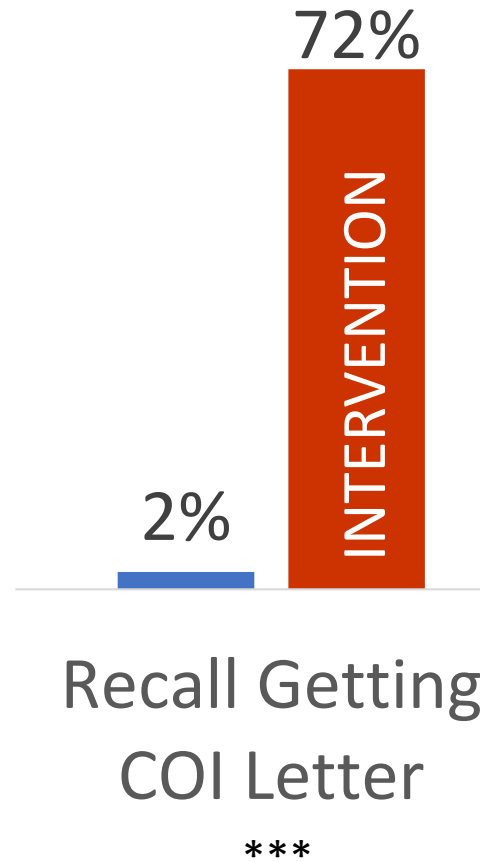
— **Cancelled/missed appointments**

Survey to eligible patients who saw their physician within a week of physician appointment: 68% response rate (N = 868/1276)

— **Patients' knowledge** of their physicians' industry relationships

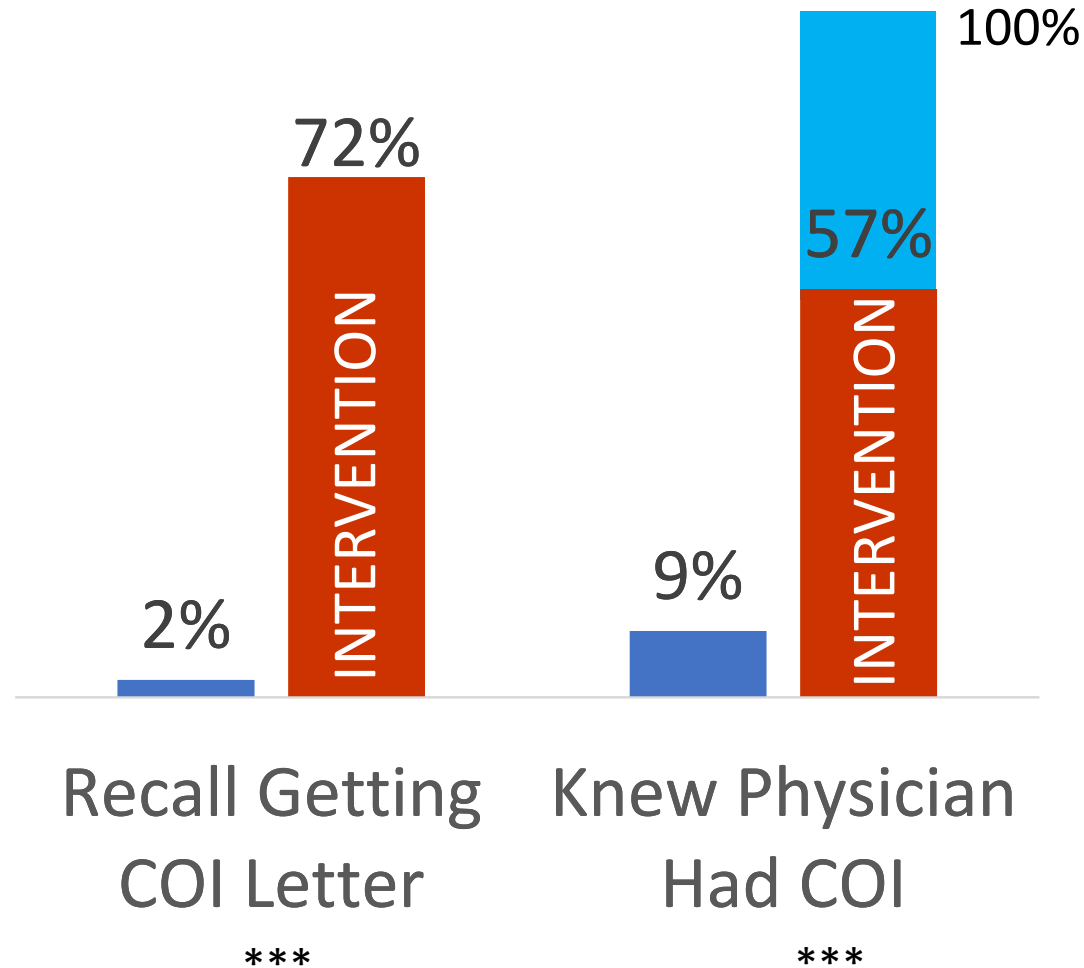
— **Trust in the physician** (3 dimensions – integrity, benevolence and expertise) and **trust in the hospital**

# Recall of letter and Knowledge of physicians' financial relationships



# Recall of letter and Knowledge of physicians' financial relationships

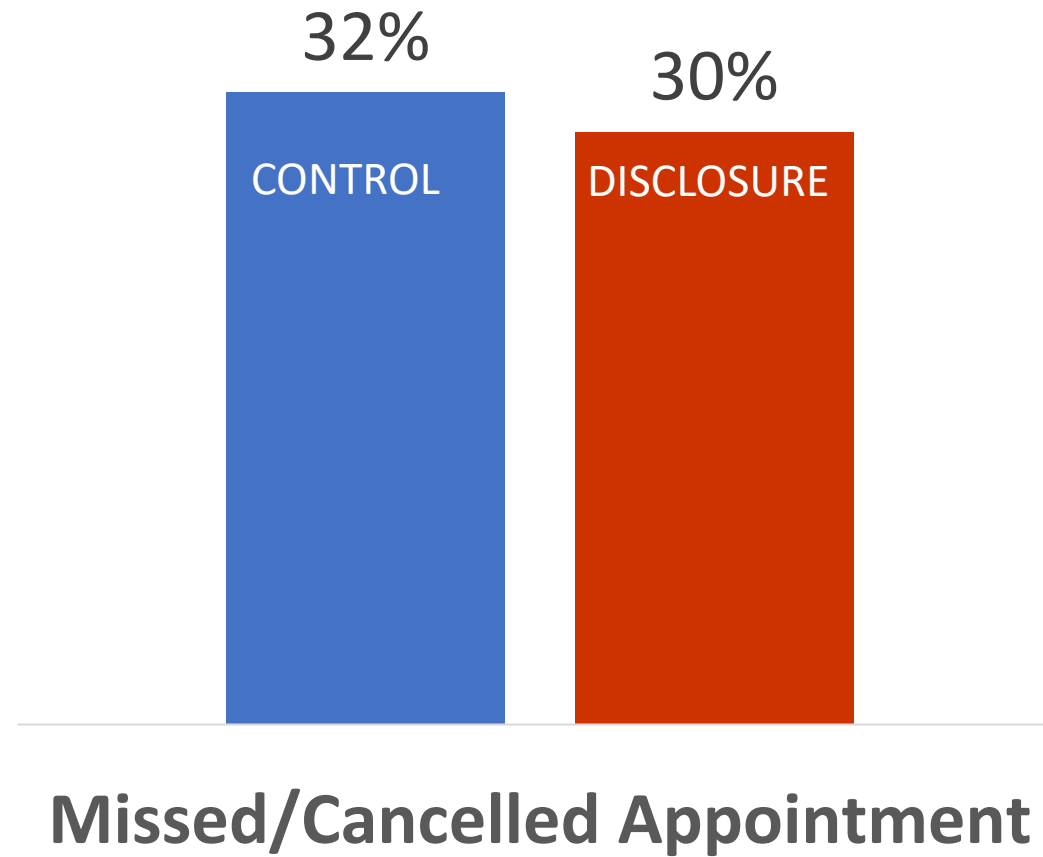
—So, letter had an effect.



# Patient Trust in Physician and Hospital

***NON-SIGNIFICANT***

# Appointment attendance (non significant)





A large, smooth, rounded rock formation, likely a boulder or a small rock formation, is the central focus of the image. It is light brown or tan in color and has a slightly textured surface. The rock is positioned on a flat, sandy or rocky ground. In the background, there are other smaller rock formations and a clear, bright blue sky. The overall scene is a desert landscape. The word "Robustness" is overlaid in white text on the rock.

Robustness

# Bottom line

Mailed disclosure letter improved patients' **knowledge** of their physicians' financial relationships with industry, but left some patients uninformed.

Even for physicians with very **large** relationships, and among patients successfully **informed**, and with the **risks** highlighted, the disclosure did **not** affect **trust** in physicians or the hospital or the likelihood of **missing** their appointments.

# Improving consent response and retention: To reduce insinuation anxiety

## Decrease Social Pressure

External disclosure  
Private, cooling off periods

## Increase Deliberation

Disclosure ahead of time  
Salience, understanding,  
deliberation

# Contact information

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