



QUESTIONS TO GUIDE REPORTING

WHAT IS THE FINDING?

What is the distinct exposure - or treatment - in each group?

If it is a lifestyle exposure (diet or exercise), how does it translate into what you have to eat or do?

What is the outcome under consideration?

If the outcome is a surrogate (e.g. cholesterol test), is it strongly linked to patient outcomes (e.g. heart attack)?

If the outcome is a composite (e.g. combining multiple components such as heart attack, stroke, or death), can you learn about the role of each component?

If the outcome is a score (e.g., Hamilton Rating Scale for Depression), can you learn what constitutes a clinically important difference (that patients can notice) and what proportion in each group experienced it?

How big is the finding?

What is the chance of the outcome (over what time period) in each group?

Just knowing the relative risk ("0.75 times the risk") or the relative risk reduction ("25% lower") without knowing the absolute risk is insufficient. Remember that a relative risk of 0.75 can represent an infinite number of combinations (e.g. 0.003% vs. 0.004%, 3% vs. 4%, 30% vs. 40%)

Guidelines for presenting absolute risks

- Present an absolute risk – both the numerator (how many outcomes) and the denominator (how many could have had the outcome) – for each exposure group.
- Consider using percents (10%) rather than frequencies (10 in 100) even for events <1% – if using frequencies, keep the denominator constant throughout.
- Avoid "1 in x" - which makes comparisons harder (e.g. use 2% or 20 in 1000 not 1 in 50)
- Provide context for the absolute risk

How dangerous is the disease (compare chances of getting and dying from disease)?

How does this risk compare to other risks (e.g., chance of dying from cancer vs. heart disease)?

What are the downsides of intervention: life threatening harms, bothersome side effects, inconvenience, cost?

When reporting on a beneficial treatment, make sure you look for associated harms. And report the absolute risks for these harms in the same format, for the same time frame, and the same dose.

Special case: Odds ratio overstate effects when outcomes are common (>20%).

Always ask: What are the absolute risks in each exposure group?

WHAT DOES THE FINDING MEAN?

How does the finding fit in with what is already known about this topic?

Is the finding clinically important or just "statistically significant" (i.e., $p < 0.05$)?

Is the outcome something people directly experience or really care about? Are the findings big or small?

Try avoiding the word "significant". Refer to clinical significance as "important", and statistical significance as "unlikely to be due to chance".

COULD THE FINDING BE WRONG?

If an observational study, consider how likely it is that confounding -- differences between the people in the exposure groups—might explain the finding?

How different are the exposure groups in terms of age, sex, income, illness level, behaviors like smoking?

Did the investigators attempt to deal with confounding? How much did adjustment change the finding?

If it is a negative study (i.e. findings are not statistically significant), ask whether the confidence interval includes a clinically important effect?

Special case: 5- (10-) year survival rates of patients diagnosed by different methods tell you nothing about the benefits of early detection. Don't take higher 5-year survival as evidence that early detection saves lives.

BOTTOM LINE If you can't get answers, consider skipping the story.
Use numbers (and put them in tables) and highlight cautions

HOW TO HIGHLIGHT STUDY CAUTIONS

SETTING	SUGGESTED LANGUAGE
Preliminary research (e.g., unpublished scientific meeting presentations)	"The findings presented are preliminary. Because the findings have not undergone final peer review, they have yet to be independently verified, and may change."
Inherently weak designs	
Animal or lab study	"Because the study was based on animals, researchers cannot be certain whether the findings will apply to people."
Cross sectional studies	"Because all information was collected simultaneously, you cannot know if the exposure caused the outcome, or visa versa."
Ecologic studies (e.g., International comparison of dietary fat consumption vs. colon cancer mortality rate)	"The study compared the average level of [exposure] in [different groups] and [outcome] in these [groups] - there is no way to know if the people [with exposure] actually had [had outcome]."
Models (e.g., decision analysis)	"The findings are based on hypothetical relationships which may not exist."
No control group	"Because there was no control group (i.e., a group not [taking drug]), it is impossible to know if [drug] accounts for the findings."
Small study (e.g., less than 30 people)	"These findings are based on a small study; larger studies are needed to really understand how much the intervention works."
Surrogate outcomes	"We cannot know whether [surrogate outcome] will translate into a clinically meaningful outcome such as [patient outcome]." (e.g. cholesterol lowering vs. heart attack death)
Classic designs	
Randomized trial	
Extrapolation	"The findings may not apply to people who differ from those in the study (e.g., people with less severe disease or at lower risk for bad outcomes)"
New interventions	"The findings are based on short-term data. Short-term benefits may diminish and side effects may emerge over time. Longer term studies are needed."
New drugs	<p>"[Drug] is a new drug (approved in [200x]). As with all new drugs, we don't know how its safety record will hold up over time. In general, if there are unforeseen, serious side effects, they emerge after the drug is on the market when a large enough number of people have used the drug."</p> <p>If this is the first drug in its class, consider adding: "since this is the first drug of its kind to receive FDA approval, experience is particularly limited."</p>
Observational studies (with a control group)	
Trial <u>not</u> possible (e.g., harmful exposure)	"Because the study was not true experiment, there may be something else about the people who happened to be exposed to [exposure] that explains the findings."
Trial possible (e.g., beneficial exposure)	"Because the study was not a true experiment, it is not known if changing [the exposure] will alter the outcome. There may be something else about the people who happened to be exposed to [exposure] that explains the findings. A randomized trial is needed before widespread adoption of [intervention]."
All studies	"The benefit of [any action/intervention] should be weighed against the [side effects, inconveniences, costs, etc.]."

BOTTOM LINE Use cautions – all studies have them.
 Consider not reporting preliminary or inherently weak research.