




Medicine & the Media
The Challenge of Reporting on Medical Research

Using What You Have Learned: Numbers

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Session objectives

Illustrate problems with how numbers are communicated using real world examples – abridged but real.

To give practical guidance about ways to understand and communicate data to avoid exaggeration and confusion.

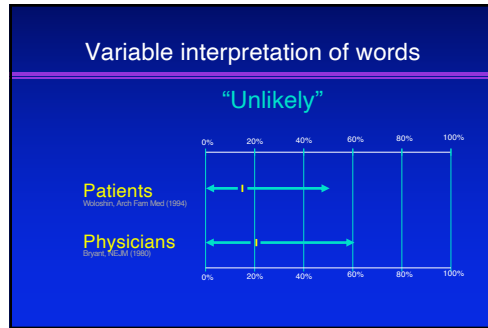
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What do you think of Dr. Jones' answer?

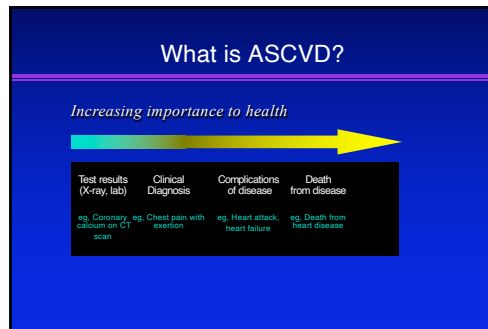
Mrs. Smith: "Doc, that Go Red for Women campaign got me thinking... what is my chance of heart disease and stroke?"

Dr. Jones: [thoughtful pause] "It is unlikely"

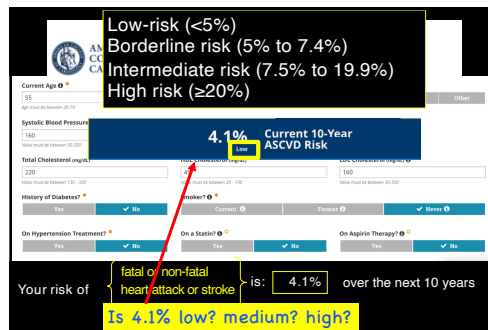
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Risk Chart

*Imagine 1000 women your age.
In the next 10 years, how many will die of....*

Age		Breast Cancer	Lung Cancer	Heart Disease	All causes
55 yrs	<i>Never smoker</i>	6	2	8	55
	<i>Current smoker</i>	5	26	20	110

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Specific Guidance on providing Risks

Use numbers if possible

Clarify outcome under consideration
What are you talking about (e.g., getting vs. dying)?
What is the time frame?

Provide context
How dangerous (lethality)?
Compare your risk to that of the "average person"
Compare this risk to other risks.

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Out of how many Americans??

This year 100,000 Americans will be found to have a brain tumor, 21,000 of which originate in the brain....

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REVIEW:
Anatomy of absolute risk statements

Proportion

The count of people who experience the outcome
21,000 Americans found to have a primary brain tumor this year

$$\frac{\text{Numerator}}{\text{Denominator}} = \frac{21,000}{275,000,000} = 0.00008 = 0.008\% \text{ in the next year}$$

The count of people who could experience the outcome
275,000,000 Americans who could get a brain tumor

Defined time frame

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Framing

How simple changes in the format of otherwise identical information can influence perceptions.

People were more likely to choose surgery over medical treatment for lung cancer when told the chance of surviving surgery was 90% than when told the chance of dying during surgery was 10%.

MacNeil, et al. NEMJ (1982)

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Saying it both ways...

Imagine 100,000 Americans

In the next year,

8 will get brain cancer
99,992 will not get brain cancer

Balanced framing
BUT...
This can get cumbersome
May lead to data overload

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Summary Guidance
Problems with numbers

Give numbers
Provide absolute risks with the other information you need to give them meaning.

Make the numbers complete
Talk about risk with both numerator (number who experienced the outcome) and denominators (out of how many).
Give readers a chance to think about the risk both ways (e.g. risk of dying and surviving).

Don't just report the numerator – give absolute risk

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Read Example 2

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What is the effect of tamoxifen?

"According to the cancer institute, the drug [tamoxifen] reduced the rate of breast cancers in women to 1 in 130 from 1 in 236 during the study."

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Some formats are easier than others

Which is the bigger chance?

a. 1 in 236
b. 1 in 130

Which is the bigger chance?

a. 4 in 1000
b. 8 in 1000

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Snively & Grimes

Asked 633 women attending university affiliated outpatient OB-Gyn clinics...

Which is bigger? 1 in 384 or 1 in 112 56% correct

Which is bigger? 2.6 per 1000 or 8.9 per 10 75% correct

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Summary Guidance
Problems with numbers

Give numbers
Provide absolute risks with the other information you need to give them meaning

Make the numbers complete & easy
Talk about risk with both numerator (count of events) and denominators (out of how many).

Give readers a chance to think about the risk both ways (e.g. risk of dying and surviving).

To facilitate comparison of absolute risks, use frequencies with constant denominator (e.g. "X in 1000" not "1 in X").

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Percentages better

Annals of Internal Medicine ORIGINAL RESEARCH

Communicating Data About the Benefits and Harms of Treatment
A Randomized Trial

Tested comprehension of data presented in different formats

- Percents best
- X in 1000 format a close second
- Frequencies with changing denominators much worse.
- Combination - "6% or 60 in 1000" - adds little but clutter

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Read Example 3

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EVISTA Significantly Reduces Clinical Vertebral Fracture Risk

at **One Year** **68%** reduction vs. placebo

EVISTA risedronate HCl

1. How would you describe the benefit of EVISTA? (check one)

- Very big
- Big
- Moderate
- Small
- Very small

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It's like a sale

Extremely Fancy Store

Would you go if selected items were..

Things like flat screen TVs?
Save \$1,000's

Things like a pack of gum?
Save pennies

"68% of what" matters!
Know the REGULAR price!

68% OFF
On selected items!

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What is the effect of Evista?
How good is the sale?

PLACEBO	EVISTA
0.83%	0.27%

How much do you save?

Absolute risk reduction: $0.83\% - 0.27\% = 0.56\%$

If 1000 women took EVISTA instead of placebo for 1 year, about 6 fewer women would have a vertebral fracture.

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A less **clunky** way to describe the effect of EVISTA

PLACEBO	EVISTA
0.83%	0.27%

So finally...this is how you get to the **68% off sale!**

Relative Risk = $\frac{0.27\%}{0.83\%} = 0.32$

Relative risk reduction = $1 - .32 = .68 = 68\%$

Over 1 year, EVISTA lowered the risk of vertebral fracture by 68 percent compared to placebo: 0.83% vs. 0.27%.

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Shopping	Medicine
REGULAR price	Absolute risk (control group)
SALES price	Absolute risk (intervention group)
SALES price REGULAR price	Relative risk times the risk
The SALE: % off	Relative risk reduction % lower
SAVINGS REGULAR price - SALES price	Absolute risk reduction percentage points lower

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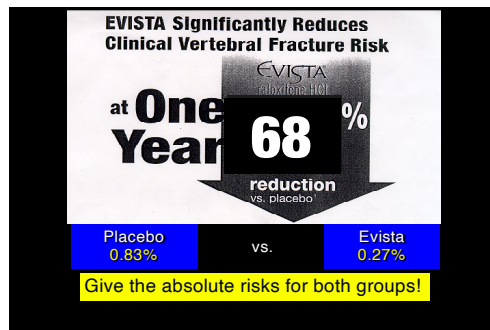
Lots of different ways of saying the same thing
Another kind of framing

The same information feels very different when you see the chances for each group (absolute risks).

Well-described finding that relative risk reduction appears more impressive than corresponding absolute risk reduction.

The EVISTA ad agency knew what they were doing....

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In patients with multiple risk factors for heart disease,

Lipitor
reduces risk of heart attack by **36%***

3% of patients taking a sugar pill had heart attack compared to 2% of patients taking Lipitor.

*Not seen in a large clinical study. 3% of patients taking a sugar pill or placebo had a heart attack compared to 2% of patients taking Lipitor.

LIPITOR
atorvastatin calcium

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Relative vs. absolute risk reductions

"% off" **"savings"**

Chance of death at 1 year		Risk reduction	
Placebo	DRUG	Relative (1-DRUG/Placebo)	Absolute (Placebo-DRUG)
30%	10%	67%	20%
3%	1%	67%	2%
0.003%	0.001%	67%	0.002%

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Number needed to treat

$$\frac{1}{20\%} = \frac{1}{0.20} = 5$$

Risk of death at 1 year		Absolute risk reduction	NNT
Placebo	DRUG	Absolute Risk Reduction	
30%	10%	20%	5
3%	1%	2%	50
0.003%	0.001%	0.002%	50,000

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Evista: 0.27% vs. 0.83%

Use it in a sentence

Study: Absolute risks with outcome & time frame
The EVISTA group had about one-third the risk of a painful spine fracture compared to placebo: 0.3% vs. 0.8% women had a spine fracture over 1 year.

Relative risk reduction (RRR) = 0.68 = 68%
EVISTA reduced the risk of a painful spine fracture by 68 percent compared to placebo: 0.3% vs. 0.8% women had a spine fracture over 1 year

Absolute risk reduction (ARR) = 0.56%
EVISTA lowered the risk of a painful spine fracture by 0.56 percentage points compared to placebo: 0.3% vs. 0.8% women had a spine fracture over 1 year

Number needed to treat (NNT) = 178
178 women would have to take EVISTA for a year to prevent 1 painful spine fracture.

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Specific Guidance on Effect Sizes

Relative risk reductions (or relative risks) are not meaningful unless you provide the "regular price".
68% less...need to know 68% of What

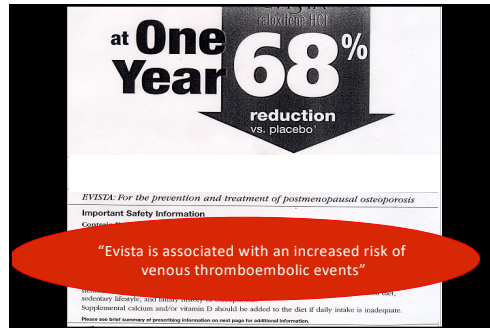
Comparing absolute risks is most helpful.
0.8% (placebo) vs. 0.3% (EVISTA)

Relative risks are helpful to compare effect sizes of different exposures.

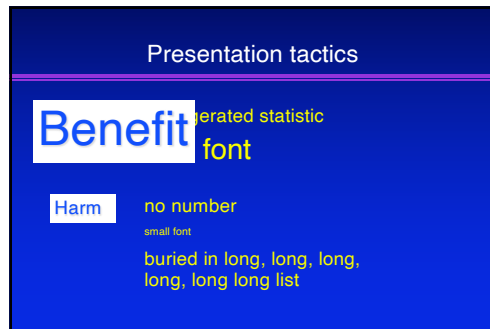
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What about harms?

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Understanding harm ALSO means comparing the absolute risks

Risk of venous thromboembolic event over 3 years

PLACEBO	EVISTA
0.35% (3.5 in 1000)	1.1% (11 in 1000)

Relative Risk = $\frac{1.1\%}{0.35\%} = 3.1$

% higher = $3.1 - 1 = 2.1$ **210%**

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Over 3 years, what happened to postmenopausal women with osteoporosis who were given.....

	PLACEBO	EVISTA
Benefit		
EVISTA reduced the chance of a painful spine fracture	3.5% 35 out of 1000	2.1% 21 out of 1000
Harm		
EVISTA increased the chance of a serious blood clot	0.35% 3.5 out of 1000	1.1% 11 out of 1000

Net effect of EVISTA per 1000 women:
14 fewer fractures
7.5 more serious blood clots

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Lunesta
(compared to regular pill) to reduce current symptoms for adults with insomnia

What else drug is for?
To treat a seizure in some epilepsy cases

Who might consider taking this?
Adults age 18 and over who are prescribed to take at least 1 month

Recommended monitoring:
No known drug, alcohol, or food interactions

Other things to consider:
Other things to consider:
Sedation, dizziness, headache, constipation, dry mouth, blurred vision, back pain, weight gain, changes in cholesterol and triglyceride levels

How long has the drug been in use?
Lunesta was approved in 2001. An animal study shows no drug-drug interactions. Safety studies will be up over time. In general, if there are unknown, serious drug side effects, they emerge after the drug is in the market for a long enough number of people have used the drug.


Lunesta Study Findings
The results of the study are shown in the table below. Lunesta was compared to a regular pill (placebo) in a study of 1,000 people with insomnia. The study was conducted over 4 weeks. The results are shown in the table below.

What difference did Lunesta make?	People given Lunesta (20% of people)	People given placebo (80% of people)
Did Lunesta help?	68%	58%
Did Lunesta help with sleep?	72%	62%
Did Lunesta help with staying asleep?	75%	65%
Did Lunesta help with waking up?	78%	68%
Did Lunesta have side effects?		
Did Lunesta cause drowsiness?	15%	10%
Did Lunesta cause dizziness?	12%	8%
Did Lunesta cause headache?	10%	7%
Did Lunesta cause constipation?	8%	5%
Did Lunesta cause dry mouth?	6%	4%
Did Lunesta cause blurred vision?	5%	3%
Did Lunesta cause back pain?	4%	2%
Did Lunesta cause weight gain?	3%	2%
Did Lunesta cause changes in cholesterol?	2%	1%
Did Lunesta cause changes in triglyceride levels?	2%	1%

Simple tabular display of benefit and side effects data

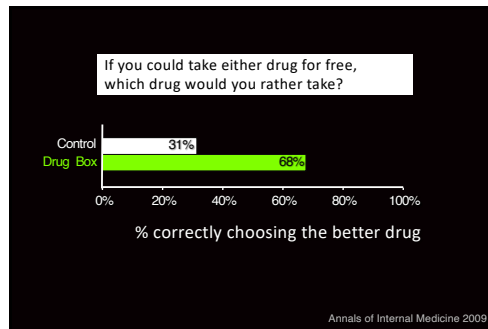
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Drug Box: National Randomized Trial



Study Features (n=231)
Real world challenge: Show people ads for 2 drugs treating the same condition.
The drugs have similar side effects but one is substantially more effective.
Can people choose the objectively *better* drug?

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FDA Risk Communication Advisory Committee
Recommendations
FDA should adopt a single standard document for communicating essential information about pharmaceuticals which provides quantitative summaries of risks and benefits.
FDA should adopt the **Drugs Facts Box format** as its standard.


Advisory committee recommendations are non-binding: FDA usually follows them but doesn't have to.

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An Act of Congress

Sec. 3.507. Presentation of prescription drug benefit and risk information.
If the addition of quantitative summaries of the benefits and risks of prescription drug such as a **drug facts box** would improve healthcare decisionmaking, shall promulgate regulations as needed to implement"

The drug box is my favorite part!



President Obama Signs Health Reform Into Law -- March 23, 2010

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Summary Guidance

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Presenting effect sizes
Relative risks should be accompanied by absolute risks for both benefit and harm.

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