

Some Suggestions for FDA's Risk Communication Strategies

A Different Perspective

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FDA's Drug Safety Information

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To increase the transparency of the agency's decision making process . . .

The increased openness will enable patients and their healthcare professionals to make better-informed decisions about individual treatment options

Paling's Perspectives

“Better-informed decisions . . .” will only come if FDA provides more data and context than at present

IMHO Nothing is more important than that FDA leads an effort to develop good risk communication practices for the agency and industry and starts to model that in its own communications.

Inside A Bee Hive



*Bees represent perfection - especially when it comes to effective communication
And TEAMWORK*

Paling's Perspectives

Perceptions not based on realities are only revealed when the routine explanation is challenged

Avoid sources of *misunderstanding* and skepticism- e.g. not qualifying “Safe and effective” ; not countering the impression that listing risks is primarily a legal CYA

Paling's Perspectives

**FDA must accept the challenge
to communicate the numbers**

Lesson from EPA = Dose makes the poison

**Communicating probability is the essential first
step to making an informed decision about
risks and benefits**

Provisions in FDAAA re adverse effects in clinical trials

**Secretary shall publish “a table of adverse effects . . .
With number and frequency of such events . . .**

**Shall post with the tables . . . information to enhance
patient understanding and to ensure that such risk
tables do not mislead patients or the public.”**

Section 801 (a), Section 402(j)(3)(I)

Patient Information Sheets A to Z

Aleve (Naproxen)

1. May increase the risk of cardiovascular and cerebrovascular events
2. Can cause stomach ulcers that bleed -
the chance increases the longer you take naproxen
3. Can cause allergic reactions . .
4. Can cause liver damage . . .
5. Can cause kidney damage . . .
6. Can cause fluid retention . . .
7. May cause problems in unborn child . . .

See Joel Davis in Health Affairs 26 2007, 863-870

Patient Information Sheets A to Z

Zonegran (and antiepileptic medications)

In FDA's analysis, patients receiving antiepileptic drugs have approximately *twice the risk* of suicidal behavior (0.43%) compared to patients that received Placebo (0.22%)

Communicating Probabilities

Using estimates of numbers

1. Relative risks - do not give “information”

E.g. Increased risks from Hormone Therapy

26% of breast cancer

41% of stroke and

29% of heart attack and cardiac death

Communicating Probabilities

Using estimates of numbers

2. Confusion comparing probabilities in 1 in x format

Instead of this

Risk of Mother having a Child with Down Syndrome

- 20 year ... 1 in 1667
- 25 year ... 1 in 1250
- 30 year ... 1 in 953
- 35 year ... 1 in 378
- 40 year ... 1 in 106
- 45 year ... 1 in 30
- 49 year ... 1 in 11

Rephrase using common denominator

- 20 year ... fewer than 1 in 1000
- 25 year ... fewer than 1 in 1000
- 30 year ... approx 1 in 1000
- 35 year ... approx 3 in 1000
- 40 year ... approx 9 in 1000
- 45 year ... approx 33 in 1000
- 49 year ... approx 91 in 1000

Communicating Probabilities

Using estimates of numbers

3. Positive & Negative framing

Negative Vs Positive Framing

Breast cancer risks from HT

Over a 5-year period, *4 women out of 1000* will get breast cancer as result of taking HT

IN OTHER WORDS:

996 women out of 1000 will stand to get the benefits of HT and will not get breast cancer as a result of treatment

Suggestions

Try to Use

**Absolute numbers with a common denominator,
Show positive framing and negative framing.**

Patient Information Sheets A to Z

Zonegran (and antiepileptic medications)

In FDA's analysis, patients receiving antiepileptic drugs has approximately *twice the risk* of suicidal behavior (0.43%) compared to patients that received Placebo (0.22%)

The evidence showed that on average, 2 extra people out of 1000 showed suicidal behavior (while 998 out of 1000 took the drugs and did not report suicidal behavior)

Risk Communication Provisions in FDAAA

**Within one year, Commissioner of FDA
shall submit to congress a report on how best to
communicate to the public the risks and benefits of
new drugs ...**

Section 904, 121 stat944

Patient Information Sheets A to Z

Communication by descriptive words

While most patients prescribed Cipro tolerate the medicine, *rarely* patients develop serious adverse reactions which may include:

(6 items-no indication of levels of probabilities)

Communicating Probabilities

Using descriptive words

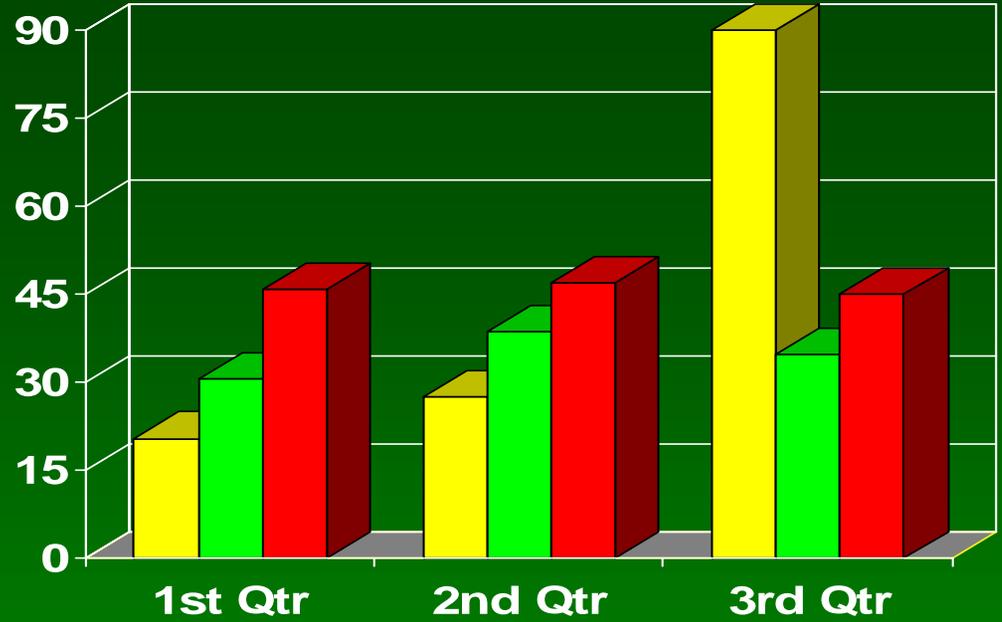
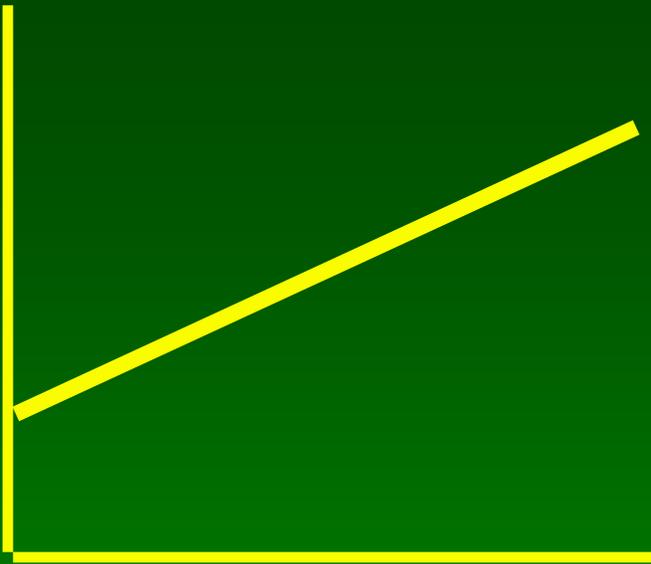
Risk frequency and various verbal descriptors

Frequency range (1 in)	EU descriptors	Calman verbal scale	Calman descriptive scale	Paling perspective scale
1–9	Very common			Very high
10–99	Common	High	Frequent, significant	High
100–999	Uncommon	Moderate		Moderate
1,000–9,999	Rare	Low	Tolerable, reasonable	Low
10,000–99,999	Very rare	Very low		Very low
100,000–999,999		Minimal	Acceptable	Minimal
1,000,000–9,999,999		Negligible	Insignificant, safe	Negligible

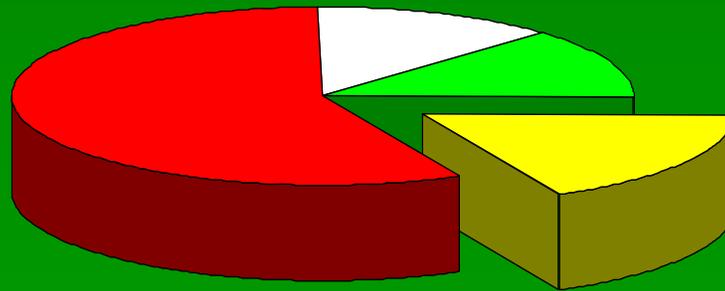
Data are taken from [41] and other sources. EU, European Union.

Analogous process worked for nutrition

A consistently applied communication standard might even educate consumers, expanding their range of effective decision making (as the FDA's Nutrition Facts Panel may have done (Moorman 1996))



Visual Aids To Improve Understanding



Suggestions

Consider Using Simple Visual Aids

To avoid the deceptive impressions of relative risks

AND

**To enable the Benefits Framing to be shown
side by side with the Risks Framing**

Paling's Wife's Perspectives

All Risks Must be Seen in Perspective

Daughter's letter home from college

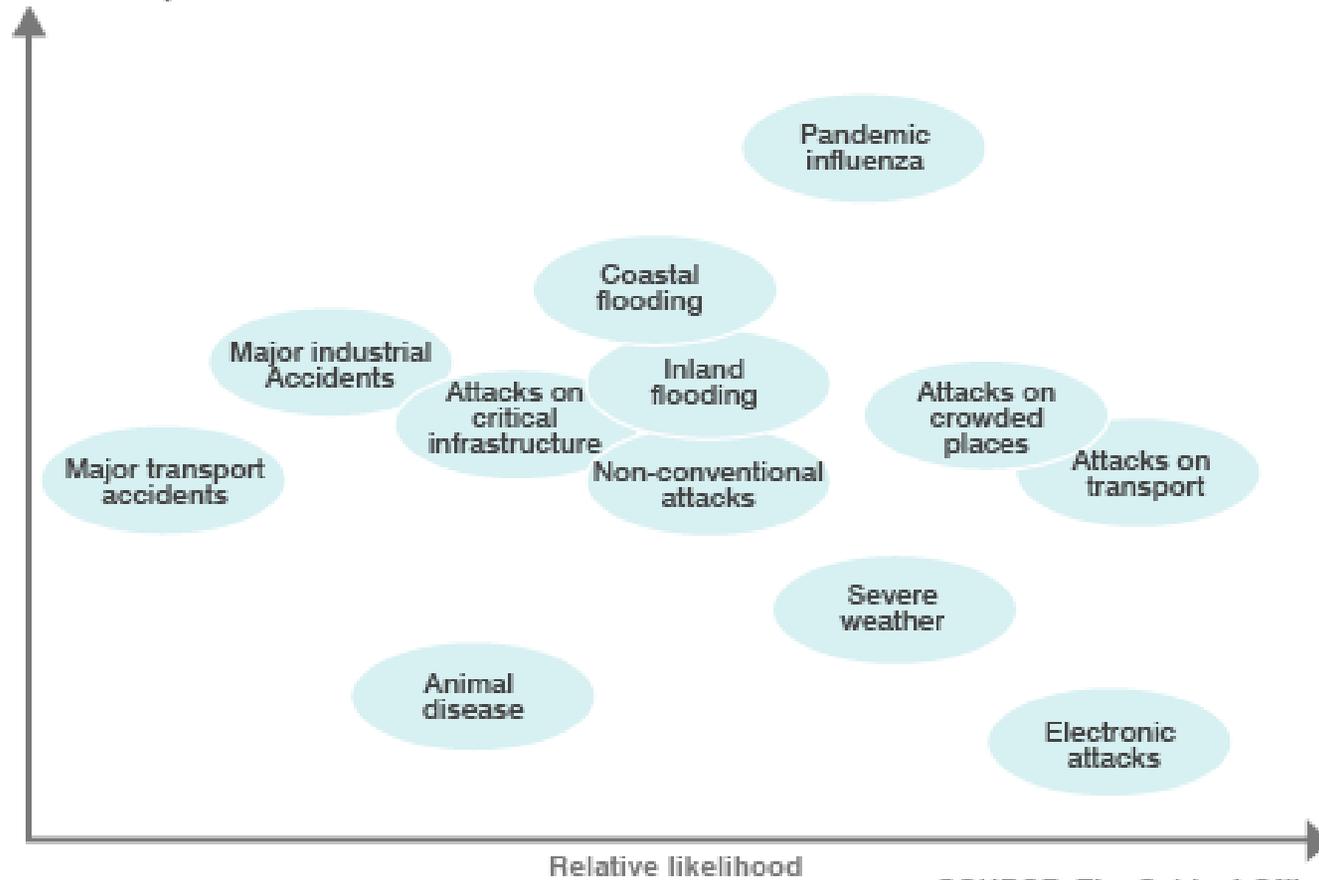
Paling's Perspectives

**A BIG RISK
involves**

RESILIENCY – (ODDS X CONSEQUENCES)

UK's Public Risk Register

HIGH CONSEQUENCE RISKS FACING THE UK



While communicating risks, can FDA also
Promote Healthy Behaviors?

**Four simple behaviors can have a major
positive effect on your health**

*Combined Impact of Health Behaviors and Mortality in Men and Women:
The EPIC-Norfolk Prospective Population Study. Khaw et al Jan 8, 2008
PLoS Med 5 (1):e12.doi:10.1371/journal.Pmed.0050012*

Four health behaviors combined predict . . . An estimated equivalent to 14 yr in chronological age

Methods and Findings

We examined the prospective relationship between lifestyle and mortality in a prospective population study of 20,244 men and women aged 45–79 y with no known cardiovascular disease or cancer at baseline survey in 1993–1997, living in the general community in the United Kingdom, and followed up to 2006. Participants scored one point for each health behaviour: current non-smoking, not physically inactive, moderate alcohol intake (1–14 units a week) and plasma vitamin C >50 mmol/l indicating fruit and vegetable intake of at least five servings a day, for a total score ranging from zero to four. After an average 11 y follow-up, the age-, sex-, body mass-, and social class-adjusted relative risks (95% confidence intervals) for all-cause mortality (1,987 deaths) for men and women who had three, two, one, and zero compared to four health behaviours were respectively, 1.39 (1.21–1.60), 1.95 (1.70–2.25), 2.52 (2.13–3.00), and 4.04 (2.95–5.54) $p < 0.001$ trend. The relationships were consistent in subgroups stratified by sex, age, body mass index, and social class, and after excluding deaths within 2 y. The trends were strongest for cardiovascular causes. The mortality risk for those with four compared to zero health behaviours was equivalent to being 14 y younger in chronological age.

Conclusions

Four health behaviours combined predict a 4-fold difference in total mortality in men and women, with an estimated impact equivalent to 14 y in chronological age.

Suggestion

Now FDA is being asked to improve its communications, needs to provide a riskcomm primer

Produce an overarching one page summary of basic risk communication perspectives

Overarching Perspectives

- 1. FDA is committed to give best efforts to protect the health and safety of American families.**
- 2. When used as directed, most FDA- approved treatments offer far more benefits than risks for most people.**
- 3. Yet all drugs have risks and patients should always consult their healthcare professionals when making decisions about their medical choices**

Overarching Perspectives

- 4. Different people have different responses to different treatments and so patients need to be alert and report if their treatment seems to be having no effect or an adverse effect on them**
- 5. Estimates of risks from a population of people may not apply to any particular individual - but it is the best doctors have to go on in predicting your best options**
- 6. Some decisions that FDA has to make when it approves treatments are very complex and so it is always willing to make changes in the light of new knowledge**

Overarching Perspectives for Dealing with Uncertainties

- 7. Talk to your doctor about your the risks and benefits of your treatment options and make sure you know if there any warning signs you should look out for**
- 8. Learn more about your treatment /condition by reading the relevant information provided by (new and improved) FDA website**
- 9. Remember, you can greatly increase your chances of a good outcome by keeping yourself as healthy as possible by your personal choices about what you eat and drink, and whether you exercise and don't smoke.**