

The Adequacy of Class Label Communication

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Class Labeling: Implications for Treatment and Challenges to
Differentiation in Development

February 22, 2011

Overview

Two kinds of standard

An adequacy test

Application to class labels

Institutional commitments

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Two Kinds of Standard

Technical standards

specify procedures
(with implicit goals)

Performance standards

specify outcomes
(indifferent to method)

A Performance Standard for Class Labeling?

Goals

better health decisions for patients
greater credibility for industry, FDA
incentives for better science

Constraints

legal
scientifically sound

Better Health Decisions

	Should Take	Shouldn't Take
Takes		
Doesn't Take		

Better Health Decisions

	Should Take	Shouldn't Take
Takes		
Doesn't Take		

- Assess the impacts of class labels on distribution of outcomes across cells
- Assign weights to different outcomes

Greater Credibility

Warranted by

better use of science, evidence
incentives for better science

Threatened by

inconsistent, unpredictable decision
rules
poor communication with physicians,
patients

Better Science

Warranted by

- better extraction of signals
- clarification of class boundaries

Threatened by

- inconsistent decision rules
- poor communication

Signal Detection Theory

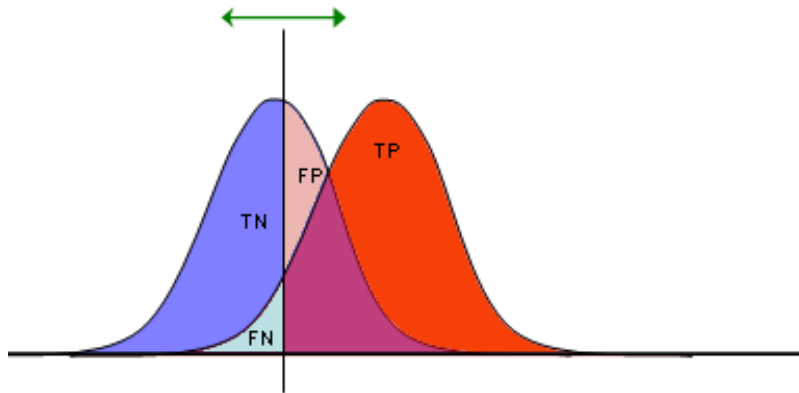
Discrimination Ability (d')

how well can we distinguish different states

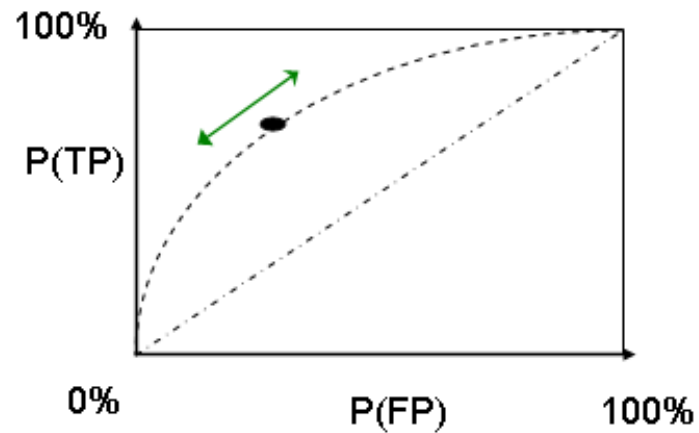
Decision Rules (β)

what weights do we assign to different outcomes

Signal Detection Theory



TP	FP
FN	TN
1	1



Useful Class Labels

- Improve discrimination ability (d')**
 - by directing science to critical issues
- Require consistent decision rules (β)**
 - to define “critical”
 - to create useful communications

Useful Class Labels

Must convey to stakeholders

conclusions

implications

d'

β

Useful Class Labels

Must convey to stakeholders

conclusions (what we found)

implications (what it means)

d' (how much we know)

β (what we value, on your behalf)

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Some design issues

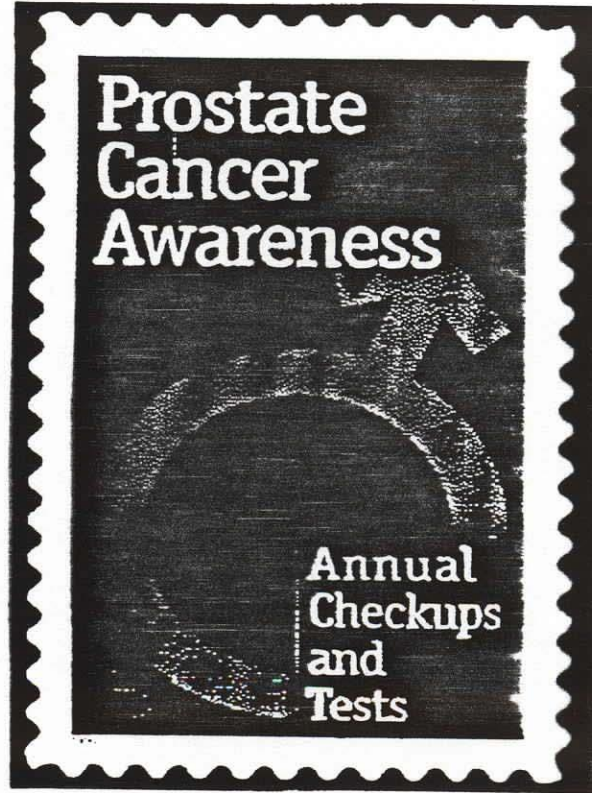
Some organizational issues

A communication is adequate, if...

- it has the information the people need
- people can understand that information
- people can access that information

Adequacy Test Scores

- needed information (B-)
- understandable information (F)
- accessible information (A-,F)



Adequacy Test Scores

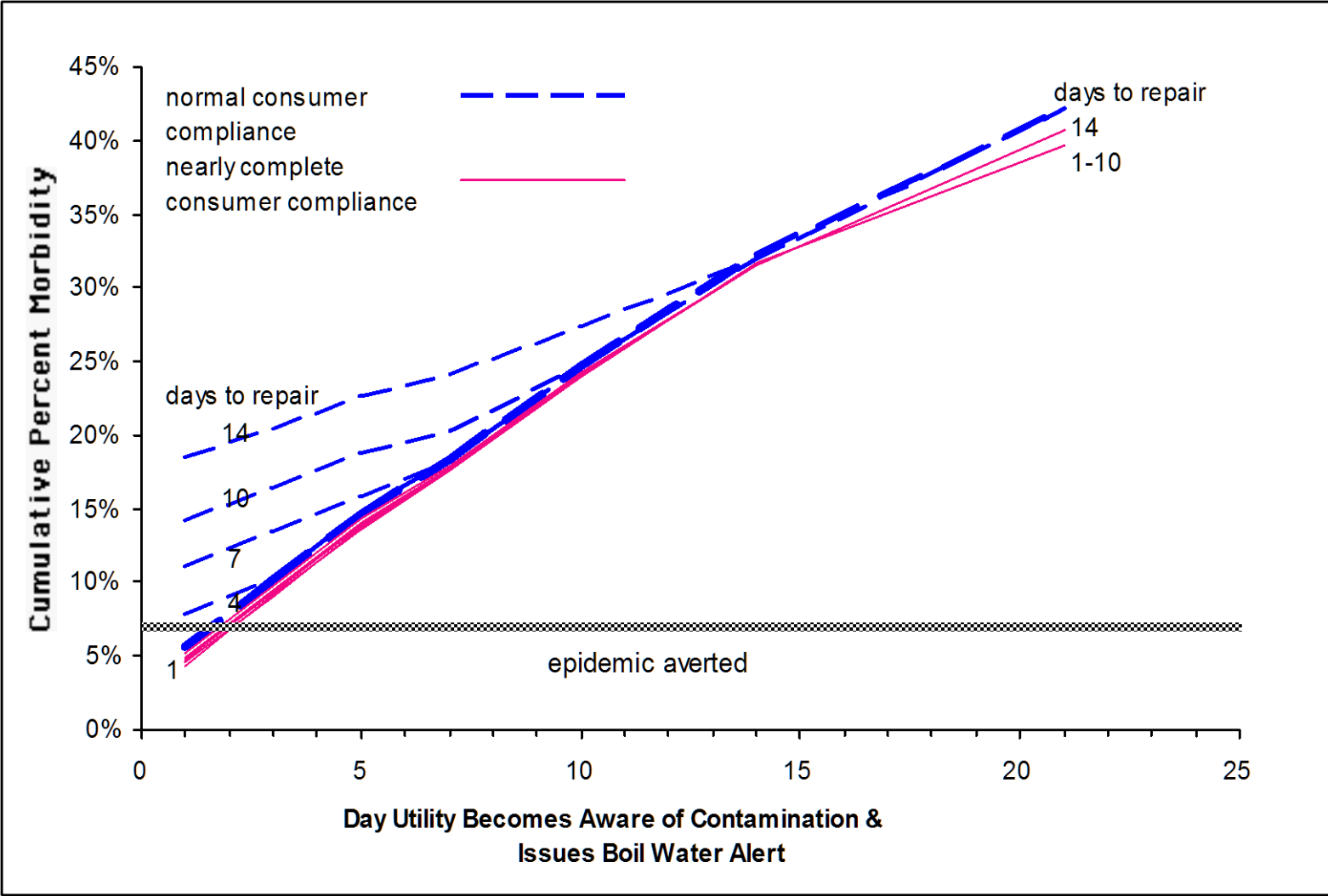
- needed information (D)
- understandable information (B)
- accessible information (B?)

Boil Water Advisory

February 5, 2008



The Hoboken Office of Emergency Management is recommending that any water used for drinking and/ or cooking be boiled, prior to use.



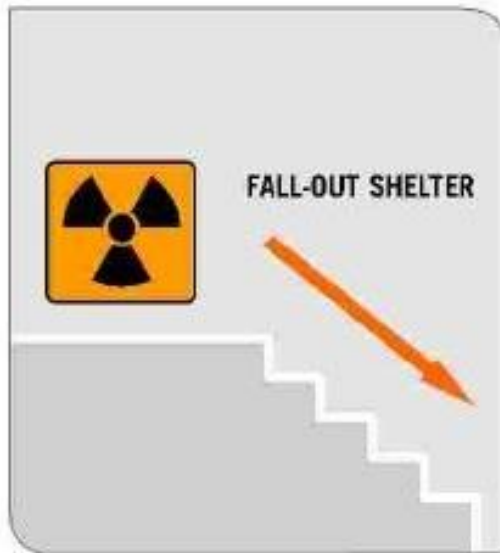
Adequacy Test Scores

(Cryptosporidium, E. coli)

- needed information (B, B)
- understandable information (B, B)
- accessible information (F, B)

BE INFORMED

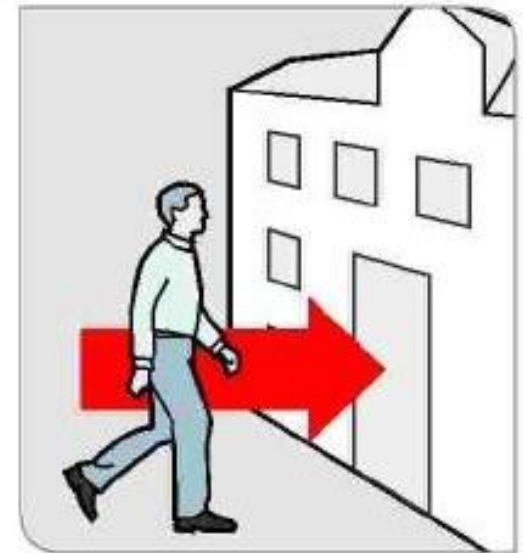
NUCLEAR BLAST



1. Take cover immediately, below ground if possible, though any shield or shelter will help protect you from the immediate effects of the blast and the pressure wave.



2. Consider if you can get out of the area;



3. Or if it would be better to go inside a building and follow your plan to "shelter-in-place".

(http://www.ready.gov/america/_downloads/nuclear.pdf)

Adequacy Test Scores

- needed information (C)
- understandable information (B)
- accessible information (B)

A Disclaimer

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<http://www.ready.gov/america/other/notices.html>

DHS to Scrap Color Code Terror Alerts by April

Homeland Security Advisory System criticized for "scaring, not preparing"

By PIERRE THOMAS and JASON RYAN

January 26, 2011



Russia Adopts Color-Coded Terror Alert System

By ELLEN BARRY

Published: January 28, 2011

The New York Times

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Behavioral Research Finds That

Decision making follows simple principles.

Some Principles of Judgment

People are good at tracking what they see,
but not at detecting sample bias.

People have difficulty projecting non-
linear trends.

People have limited ability to evaluate the
extent of their own knowledge.

People have difficulty imagining themselves
in other visceral states.

Transient emotions can affect perceptions,
perhaps enough to tip close decisions.

Some Principles of Choice

People consider the return on their investment in making decisions.

People dislike uncertainty.

People confuse ignorance and stupidity.

People are insensitive to opportunity costs.

People are prisoners to sunk costs, hating to recognize losses.

People may not know what they want, especially with novel questions.

Behavioral Research Finds That

Decision making follows simple principles.

However,

- the set of principles is large,
- the triggers are subtle, and
- the interactions complex

As a result, research is needed on each communication.

Dietary Supplements

Court-mandated disclaimer

(Pearson v. Shalala, 1999)

Example: saw palmetto for benign prostatic hyperplasia (BPH)

Eggers, S.L., & Fischhoff, B. (2004). A defensible claim? Behaviorally realistic evaluation standards. *Journal of Public Policy and Marketing*, 23, 14-27

Court-Mandated Disclaimer

Recently, a review of the efficacy and safety of saw palmetto supplementation in men treated with saw palmetto in 18 randomized clinical studies showed a positive correlation between saw palmetto and prostate health.*

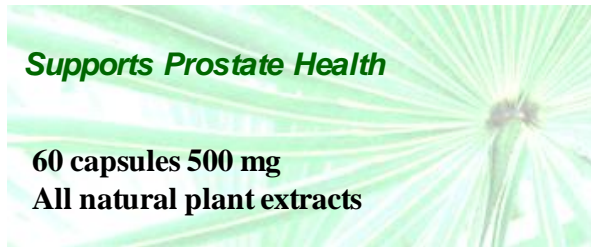
*This statement has not been evaluated by the Food and Drug Administration.

This product is not intended to diagnose, treat, cure or prevent any disease.

Structure/function claim

Herbal Good[®]

Concentrated Saw Palmetto



60 capsules 500 mg
All natural plant extracts

Recently, a review of the efficacy and safety of saw palmetto supplementation in men with prostate problems revealed that about 80 -90 percent of men treated with saw palmetto in 18 randomized clinical studies showed a positive correlation between saw palmetto and prostate health*.

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Concentrated Saw Palmetto

Directions: As a dietary supplement, take one to three capsules daily.

Supplement Facts

Serving Size: 1 soft gel capsules
Servings Per Container 30

Amount Per Serving	% DV
Saw Palmetto Berries (Serenoa repens) 500 mg	**

** Daily Value (DV) not established.

Other Ingredients: Soybean Oil, Gelatin, Glycerin, Caramel Color, Titanium Dioxide

No Sugar, No Starch, No Artificial Colors, No Artificial Flavors, No Preservatives, Sodium Free, No Wheat, No Gluten, No Corn, No Dairy, Yeast Free

Storage Instructions: Store in a cool, dry place.

Warning: Keep out of reach of children.

Prescription Drug Facts: Lunesta (Eszopiclone)

What is this drug for?	To make it easier to fall or to stay asleep
Who might consider taking it?	Adults age 18 and older with insomnia for at least 1 month
Who should NOT take it?	People under age 18
Recommended testing	No blood tests, watch out for abnormal behavior
Other things to consider doing	Reducing caffeine (especially at night), exercise, regular bedtime, avoid daytime naps

LUNESTA STUDY FINDINGS

788 healthy adults with insomnia for at least 1 month -- sleeping less than 6.5 hours per night and/or taking more than 30 minutes to fall asleep-- were given LUNESTA or a sugar pill nightly for 6 months. Here's what happened:

What difference did LUNESTA make?	People given a sugar pill	People given LUNESTA (3 mg each night)
Did LUNESTA help? LUNESTA users fell asleep faster (15 minutes faster)	45 minutes to fall asleep	30 minutes to fall asleep
LUNESTA users slept longer (37 minutes longer)	5 hours 45 minutes	6 hours 22 minutes
Did LUNESTA have side effects? <i>Life threatening side effects</i> No difference between LUNESTA and a sugar pill	None observed	
<i>Symptom side effects</i>		
More had unpleasant taste in their mouth (additional 20% due to drug)	6% 6 in 100	26% 26 in 100
More had dizziness (additional 7% due to drug)	3% 3 in 100	10% 10 in 100
More had drowsiness (additional 6% due to drug)	3% 3 in 100	9% 9 in 100
More had dry mouth (additional 5% due to drug)	2% 2 in 100	7% 7 in 100
More had nausea (additional 5% due to drug)	6% 6 in 100	11% 11 in 100

How long has the drug been in use?

Lunesta was approved by FDA in 2005. As with all new drugs we simply don't know how its safety record will hold up over time. In general, if there are unforeseen, serious drug side effects, they emerge after the drug is on the market (when a large enough number of people have used the drug).

Design Principles

Columns show choice

Quantitative risk and benefit information

Useful units (e.g., minutes to fall asleep)

Alternative expressions (% , frequency)

Do the math

Quality of evidence

Saw Palmetto Review Facts

Who was studied?

A total of 2939 men between the ages of 40 and 90 participated in the 18 studies. On average, participants experienced moderate urinary tract symptoms associated with BPH

Summary of Review

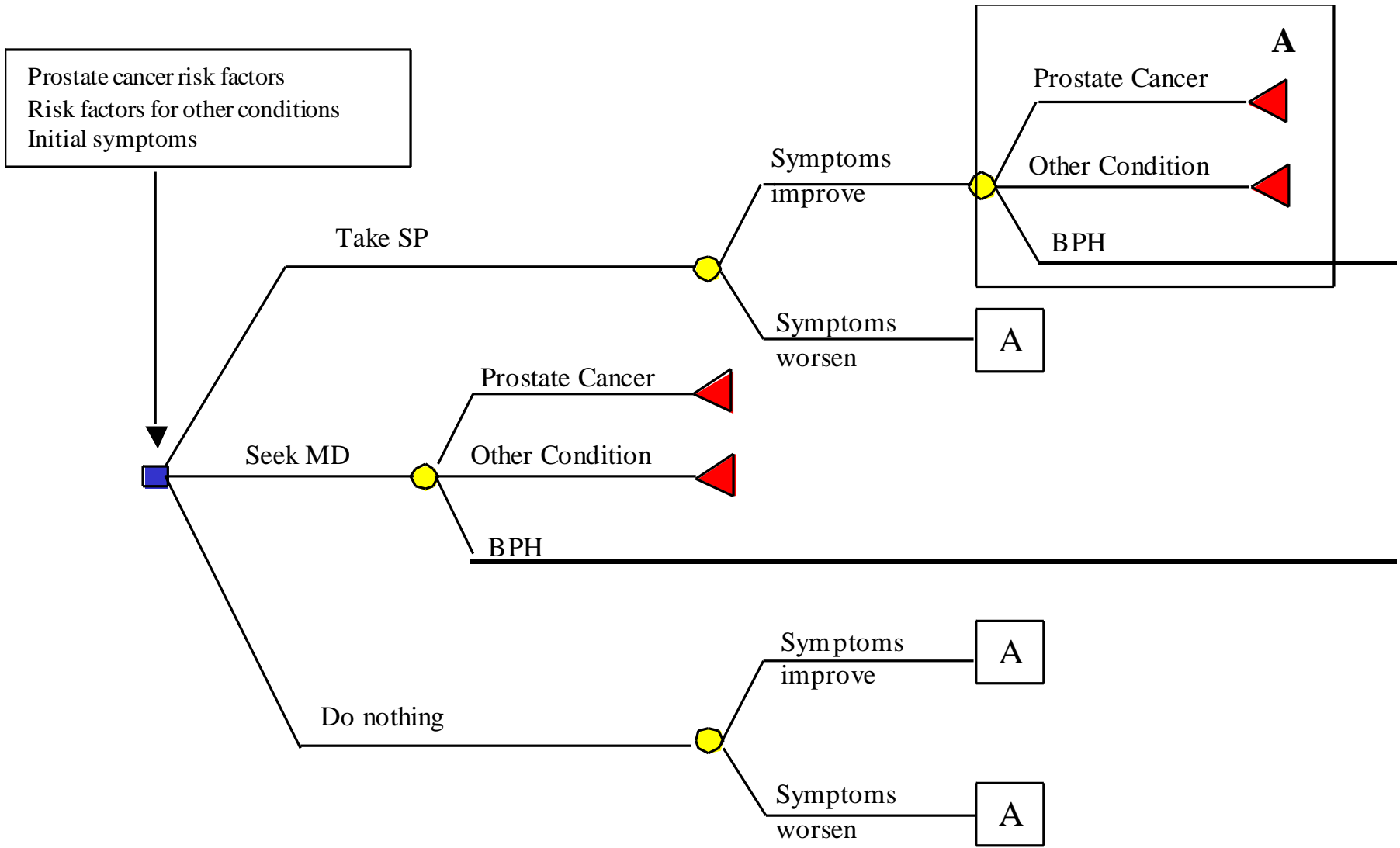
Studies of treatments*

	Men who took placebo	Men who took Saw Palmetto	Alpha Blocker** (drug)	Finasteride (drug)	TURP (surgery)
How drug might help					
Number of men out of 100 who report relief	51	74	74	67	88
Average degree of relief	29%	37%	48%	32%	85%
Percentage of men who stopped treatment	7%	9%	15%	11%	N/A
Side effects due to treatment					
Death	0%	0%	?	?	Less than 1%
Infection	0%	0%	?	?	16%
Incontinence	0%	0%	?	?	3%
Erectile Dysfunction	0.7	1.1	0%	3%	14%
Other sexual problems	?	?	6%	?	73%
Other side effects***	?	?	?	?	?

†This review was published in the Journal of the American Medical Association, Vol 280. No. 18, 1604-9.

* Information from the Foundation of Informed Medical Decision Making and Health Dialog, Inc. (<http://www.healthdialog.com/>)

**Alpha blockers include Tamsulosin, Doxazosin, Terazosin



Optimality of Uncertain Choices

No Claim	Should Consume	Should Not Consume
Does Consume	3%	2%
Does Not Consume	30%	65%

Health Claim	Should Consume	Should Not Consume
Does Consume	20%	45%
Does Not Consume	13%	22%

Health Claim 1 + Disclaimer	Should Consume	Should Not Consume
Does Consume	19%	40%
Does Not Consume	14%	27%

Health Claim 2 + Disclaimer	Should Consume	Should Not Consume
Does Consume	32%	2%
Does Not Consume	1%	65%

Useful Class Labels

Basic Applied Research Questions

Conveying

conclusions (what we found)

implications (what it means)

d' (how much we know)

β (what we value, on your behalf)

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Useful class labels require the right

Process

People

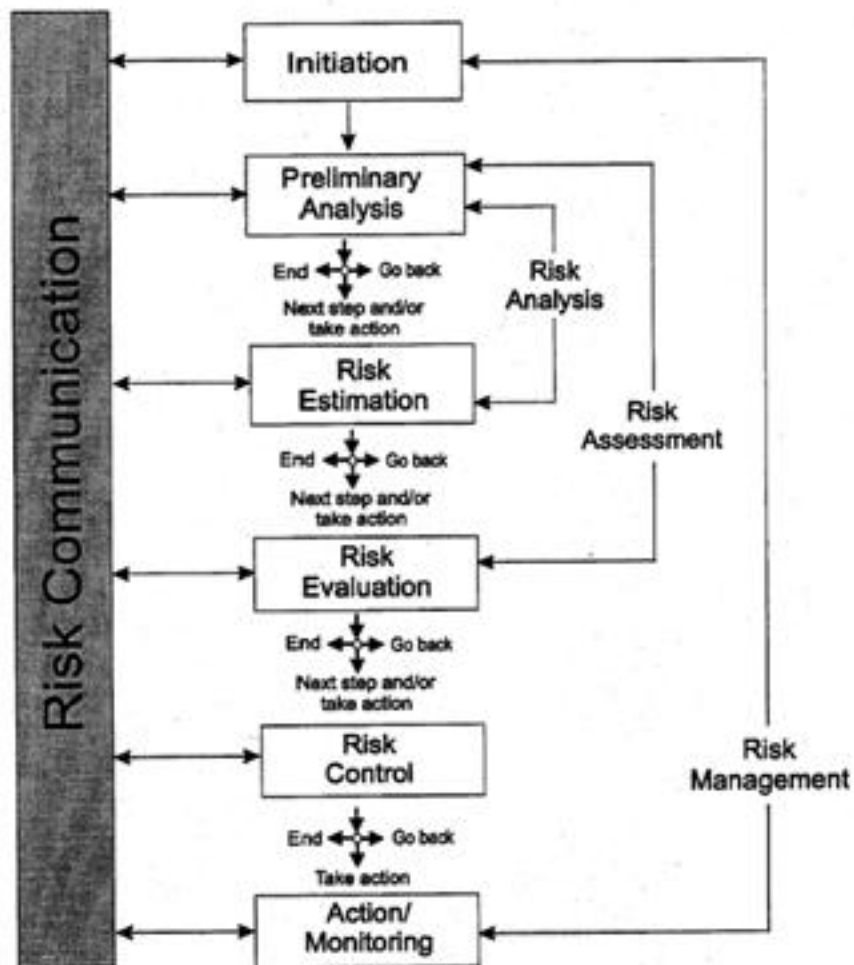
Leadership



CAN/CSA-Q850-97
***Risk Management:
Guideline for
Decision-Makers***

*A National Standard of
Canada*





Note: Risk communication with stakeholders is an important part of each step in the decision process.

Figure 2
Steps in the Q850 Risk Management Decision-Making
Process — Simple Model

The Right People

Who know the science

Who can extract the needed information

Who can make it comprehensible

Who can make it accessible

**FDA'S
STRATEGIC PLAN
FOR
RISK COMMUNICATION**

Fall, 2009

Recommendations

1. FDA should adopt a single standard document for communicating essential information about pharmaceuticals, which would replace the current set (PPI, CMI, and MG), through an appropriate consultative process.
2. That standard document should include quantitative summaries of risks and benefits, along with use and precaution information.
3. FDA should adopt the Drug Facts Box format as its standard. It should engage in a process for creating a standard for elaborating information. This adoption should be supported by a rigorous evaluation process, building on existing research.
4. FDA should rely on its existing review processes to derive the authoritative information that the standard document requires, including pharmaceutical company submissions and expert panel summaries. It should create a process for ensuring up-to-date information on all drugs.
5. FDA-approved and required communications should be subject to rigorous empirical evaluation of their effectiveness.
6. FDA should establish performance standards for the effectiveness of the standard document(s), defined in terms of individuals who have received it.
7. FDA should conduct a systems analysis of the dissemination processes by which the standard document(s) reach consumers at times relevant to their decision making about a product's adoption and use.
8. FDA should identify populations for which the standard document or the dissemination system is inadequate. It should address their needs, where that is within its capabilities, and partner with other organizations, where it is not.
9. FDA should continue to strengthen its practice of relying on the best available social and behavioral science for designing and evaluating communications, including research on textual, numerical, and visual displays. It should foster research relevant to improving the effectiveness and dissemination of its standard document(s). It should include analytical research for identifying the information most critical to the decision making of target audiences.

A Complex Working Hypothesis

People usually do sensible things if they

- get relevant information in a concise, credible, comprehensible form
- are judged by their own goals.
- have control over their environment
- have basic decision-making competence

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Center for Risk Perception and Communication: <http://sds.hss.cmu.edu/risk/>

Center for Behavioral Decision Research <http://cbdr.cmu.edu/>