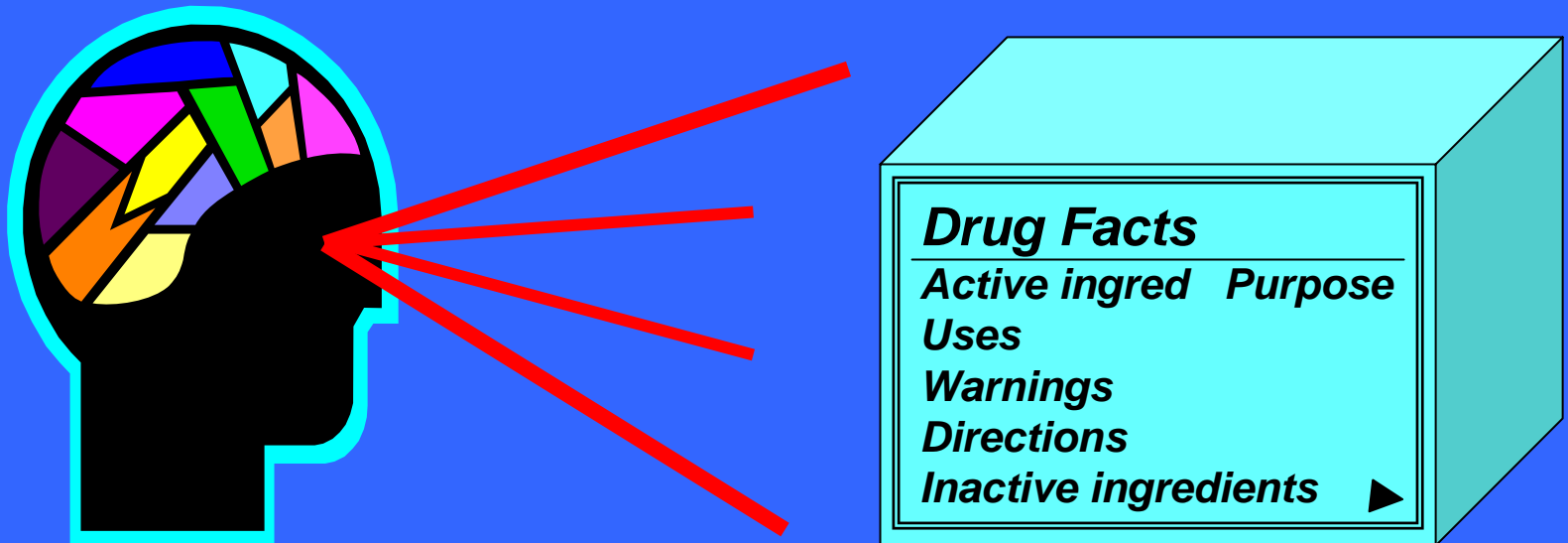


# Cognitive Accessibility of OTC Drug Information



**Ruth S. Day / Duke University**

FDA Nonprescription Drugs Advisory Committee  
(9/25/06)

# Cognitive Accessibility of OTC Drug Information

- 1) Basic Approach
- 2) Cognitive Principles
- 3) Non-OTC Examples

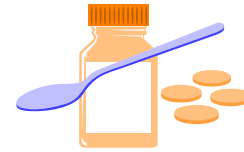
# Cognitive Accessibility of OTC Drug Information

- 1) Basic Approach
- 2) Cognitive Principles
- 3) Non-OTC Examples

- 4) OTC Examples
- 5) Generality
- 6) Conclusions

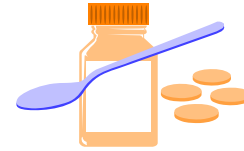
# QUESTION:

How do people understand drug information?



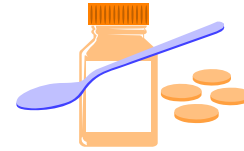
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How do people understand drug information?



ANSWER: With difficulty!

# QUESTION:



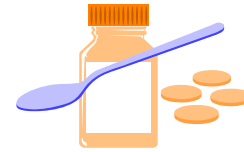
How do people understand drug information?

ANSWER: With difficulty!

# WHY:

- Heavy information load
- Complex/technical information
- etc.

# QUESTION:



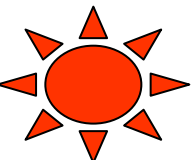
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- etc.

--**Cognitive Accessibility**



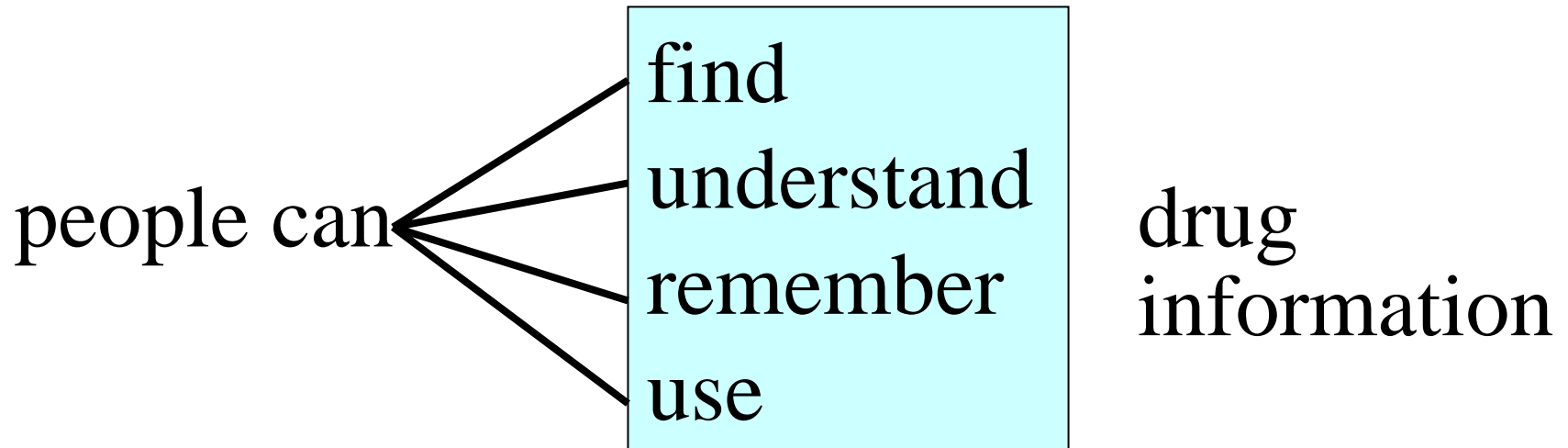
# Cognitive Accessibility

The ease with which



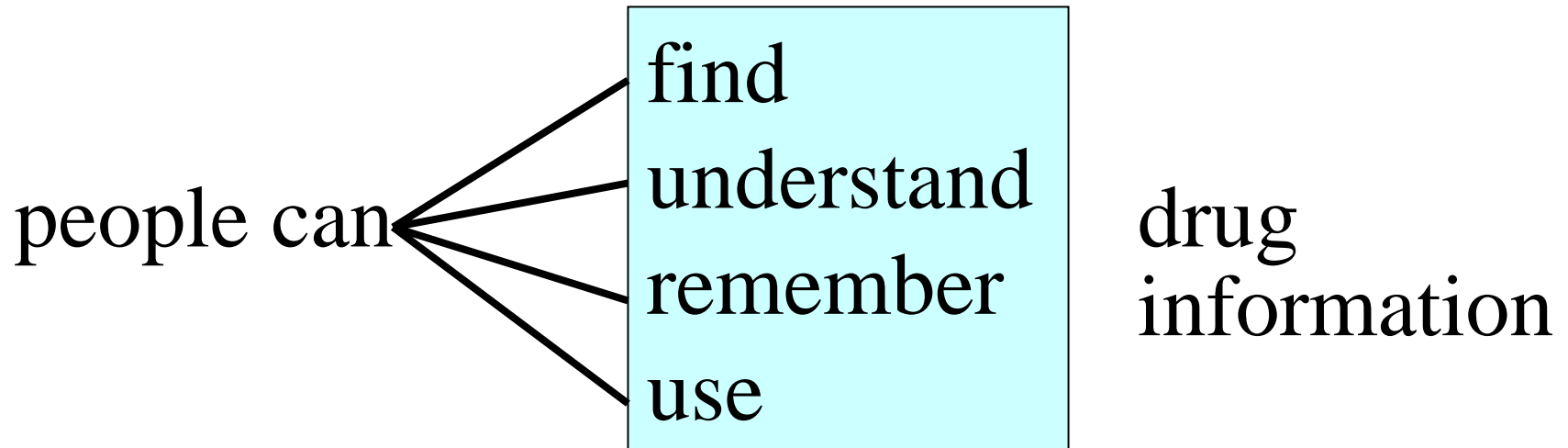
# Cognitive Accessibility

The ease with which



# Cognitive Accessibility

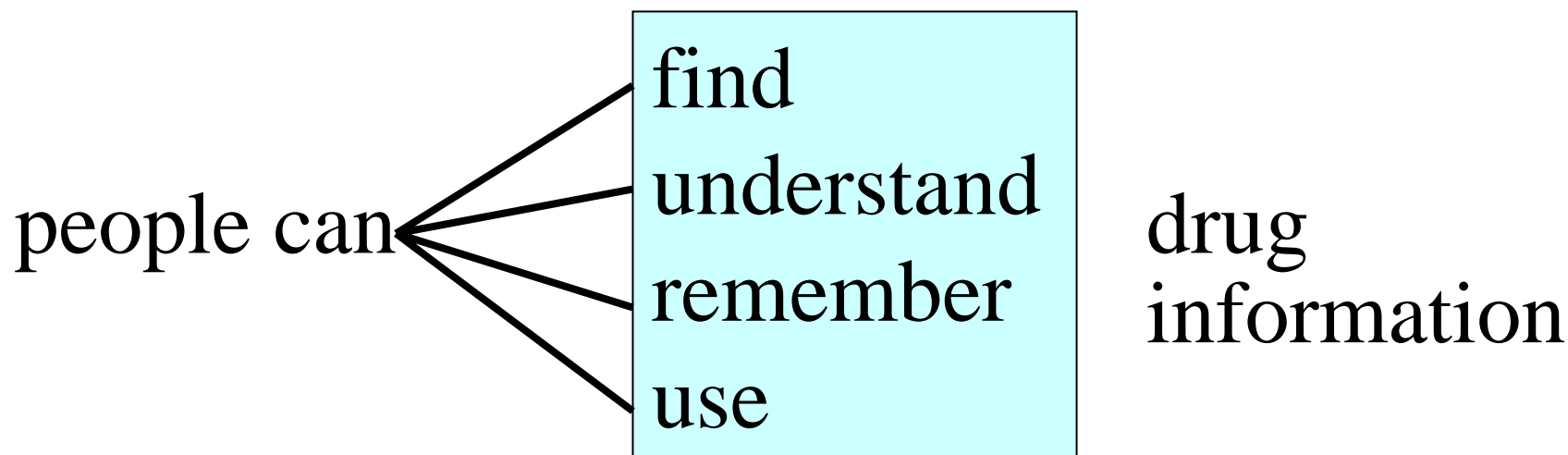
The ease with which



in a safe and effective manner.

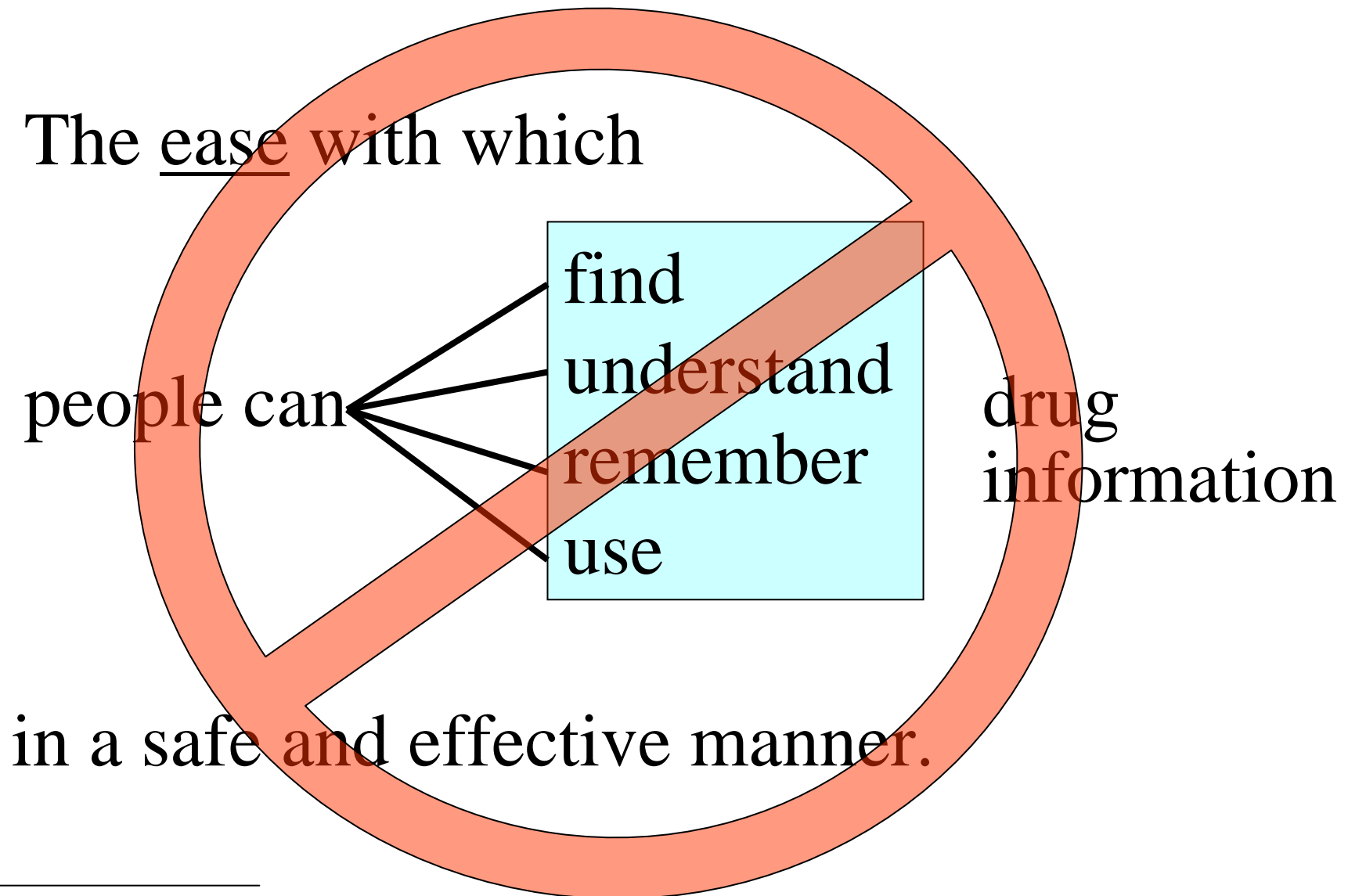
# Cognitive Accessibility\*

The ease with which



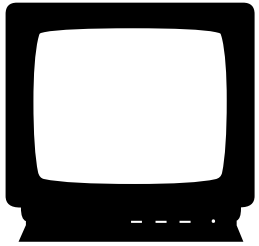
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# Cognitive IN-Accessibility

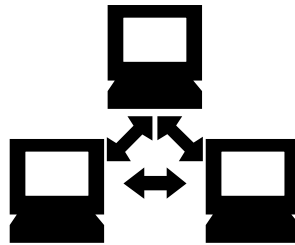


# INFORMATION SOURCES

TV Ads



Internet

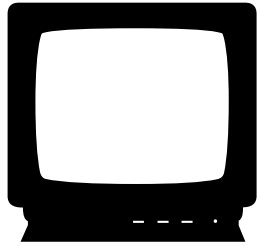


Hardcopy



# INFORMATION SOURCES

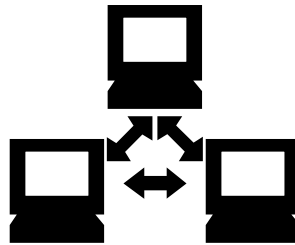
## TV Ads



Rx Ads

OTC

## Internet



Product  
Websites

## Hardcopy



Professional Label  
Patient Package Inserts  
Medication Guides  
Pharmacy Leaflets  
Print Ads  
OTC

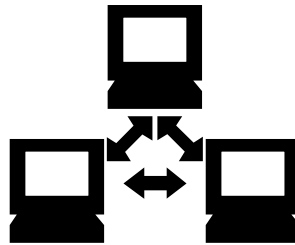
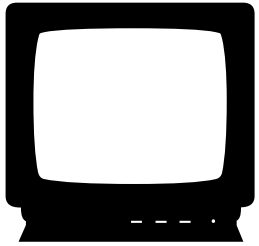
# INFORMATION SOURCES

**OTC**

**TV Ads**

**Internet**

**Hardcopy**



Rx Ads

Product  
Websites

Professional Label  
Patient Package Inserts  
Medication Guides  
Pharmacy Leaflets  
Print Ads

**OTC**

**OTC**

# BASIC APPROACH

```
graph TD; A["BASIC APPROACH"] --- B["Cognitive Analyses"]; A --- C["Enhanced Displays"]; A --- D["Cognitive Experiments"];
```

**Cognitive  
Analyses**

**Enhanced  
Displays**

**Cognitive  
Experiments**

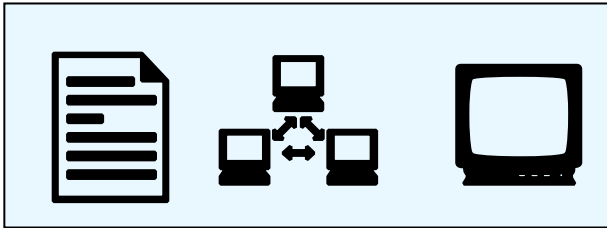


# BASIC APPROACH

**Cognitive  
Analyses**

**Enhanced  
Displays**

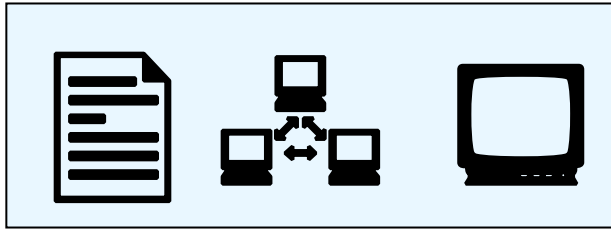
**Cognitive  
Experiments**



- Obtain quantitative measures
- Calculate “cognitive accessibility”
- Compare benefits vs. risks

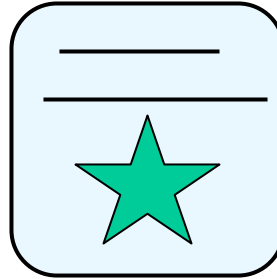
# BASIC APPROACH

## Cognitive Analyses



- Obtain quantitative measures
- Calculate “cognitive accessibility”
- Compare benefits vs. risks

## Enhanced Displays

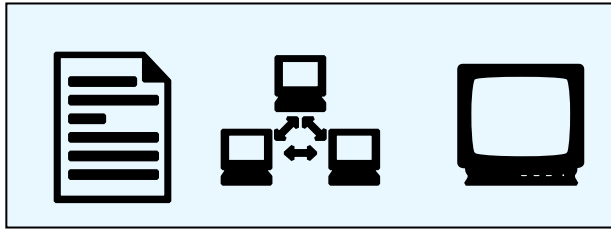


- Same info
- Based on cognitive principles

## Cognitive Experiments

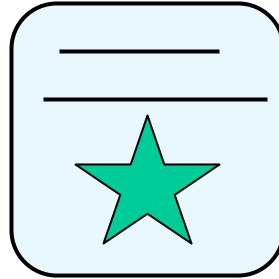
# BASIC APPROACH

## Cognitive Analyses



- Obtain quantitative measures
- Calculate “cognitive accessibility”
- Compare benefits vs. risks

## Enhanced Displays



- Same info
- Based on cognitive principles

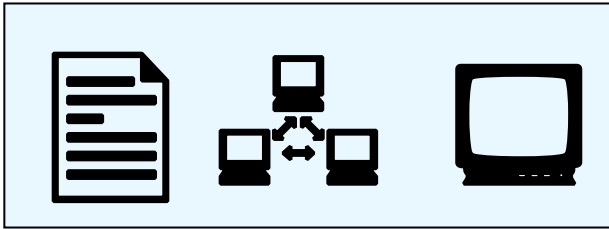
## Cognitive Experiments

Test effects on:

- Attention
- Comprehension
- Memory
- Problem Solving
- Decision Making
- Behavior

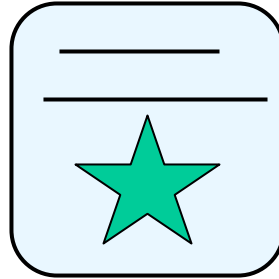
# BASIC APPROACH

## Cognitive Analyses



- Obtain quantitative measures
- Calculate “cognitive accessibility”
- Compare benefits vs. risks

## Enhanced Displays



- Same info
- Based on cognitive principles

## Cognitive Experiments

Test effects on:

- Attention
- Comprehension
- Memory
- Problem Solving
- Decision Making
- Behavior

**Health Outcomes**

# **COGNITIVE PRINCIPLES**

**Information Load**

**Chunking**

**Coding**

**Representation**

**Location**

**Speed**

**Readability**

**Comprehension**

**Prior Knowledge**

**Attention**

**Cognitive Task**

**Metacognition**

# **COGNITIVE PRINCIPLES**

## **Information Load**

**Chunking**

**Coding**

**Representation**

**Location**

**Speed**

**Readability**

**Comprehension**

**Prior Knowledge**

**Attention**

**Cognitive Task**

**Metacognition**

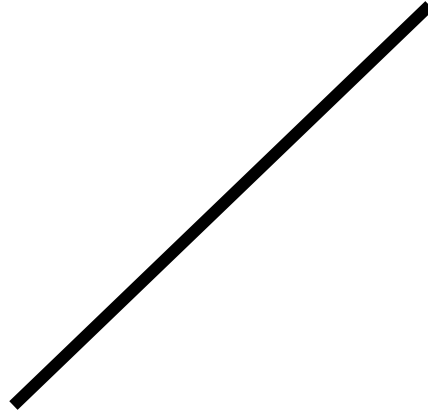
Day, R.S. (2006) Comprehension of prescription drug information: Overview of a research program. *Proceedings of the American Association for Artificial Intelligence, Argumentation for Consumer Healthcare*. <http://www.aaai.org>

**LOAD**

**How much is too much?**

**LOAD**

How much is too much?



**Information  
Load**



# LOAD

How much is too much?

Information  
Load

Cognitive  
Load

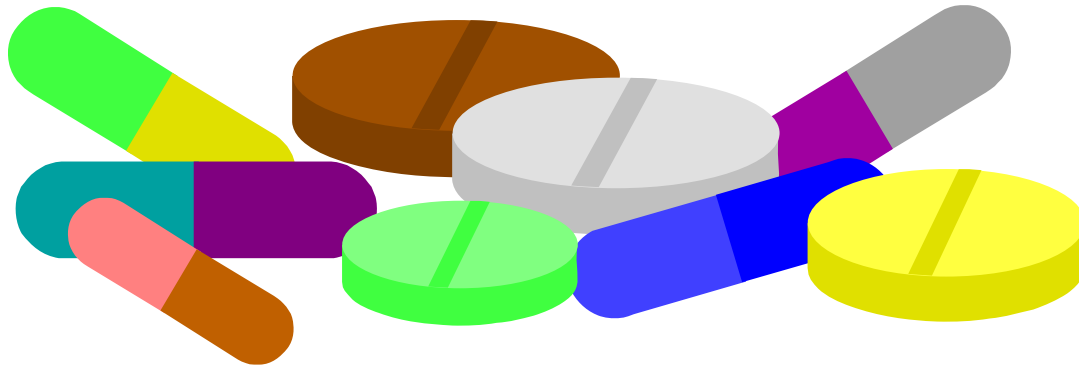
# Sample Experiment

# Medication Schedules

# Sample Experiment

# Medication Schedules

## Polypharmacy



Inderal – 1 tablet 3 times a day

Lanoxin – 1 tablet every a.m.

Carafate – 1 tablet before meals and at bedtime

Zantac – 1 tablet every 12 hours (twice a day)

Quinaglute – 1 tablet 4 times a day

Coumadin – 1 tablet a day

# List

Inderal – 1 tablet 3 times a day

Lanoxin – 1 tablet every a.m.

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# List

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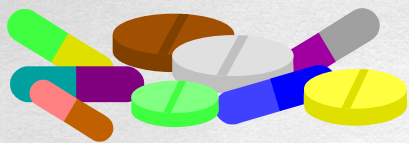
Zantac – 1 tablet every 12 hours (twice a day)

Quinaglute – 1 tablet 4 times a day

Coumadin – 1 tablet a day

# Matrix

	Break- fast	Lunch	Dinner	Bed- time
Lanoxin	✓			
Inderal	✓	✓	✓	
Quinaglute	✓	✓	✓	✓
Carafate	✓	✓	✓	✓
Zantac		✓		✓
Coumadin				✓



**F**

**O** List

**R**

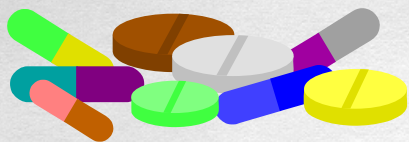
**M**

**A** Matrix

**T**



# TEST CONDITION



## Memory

Display absent  
at time of test

F

O

List

R

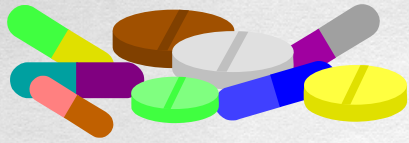
M

A

Matrix

T

# TEST CONDITION



## Memory

Display absent  
at time of test

## Comprehension

Display present  
at time of test

F

O

List

R

M

A

Matrix

T

# Procedure

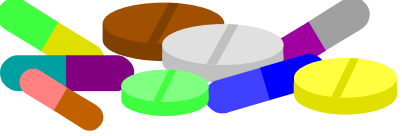
time



**Study**

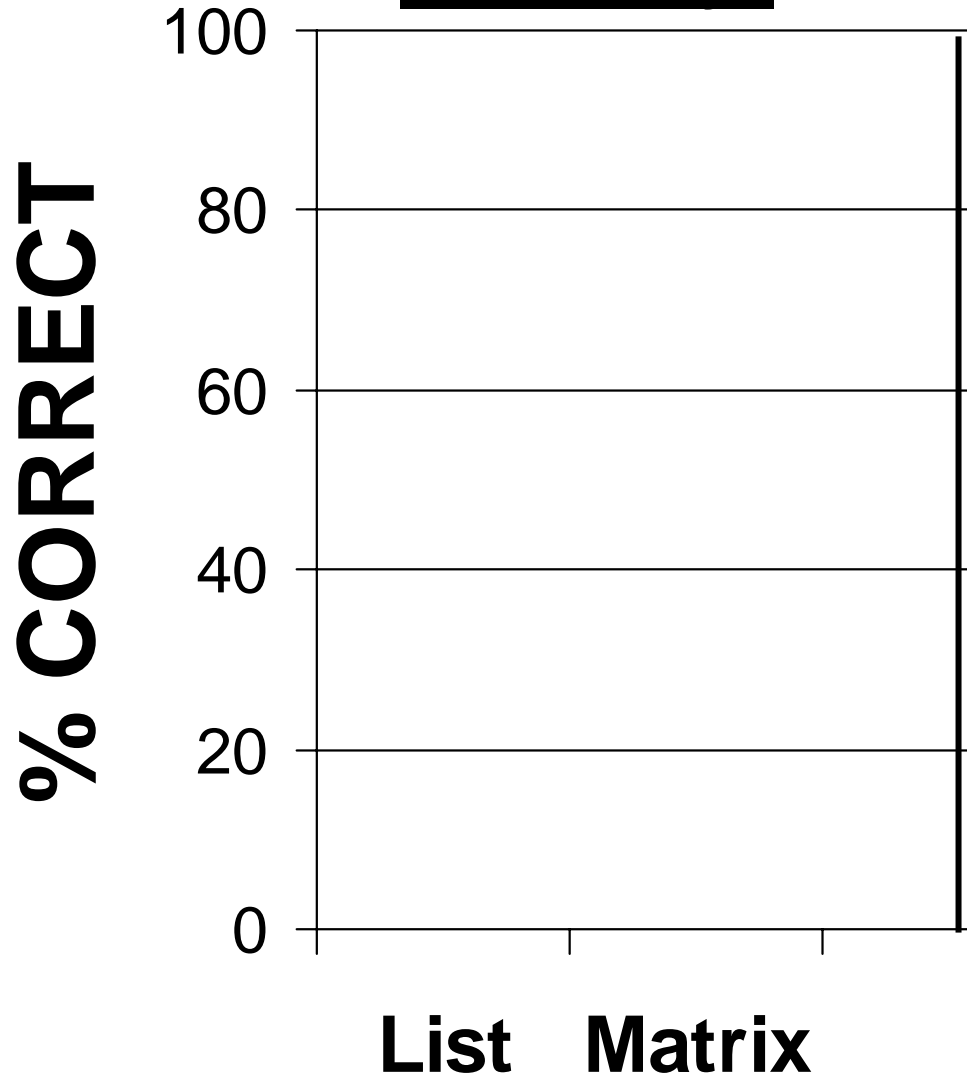
**Cognitive  
Tasks**

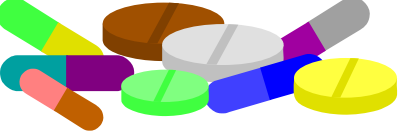
**Memory  
Comprehension  
Problem Solving**



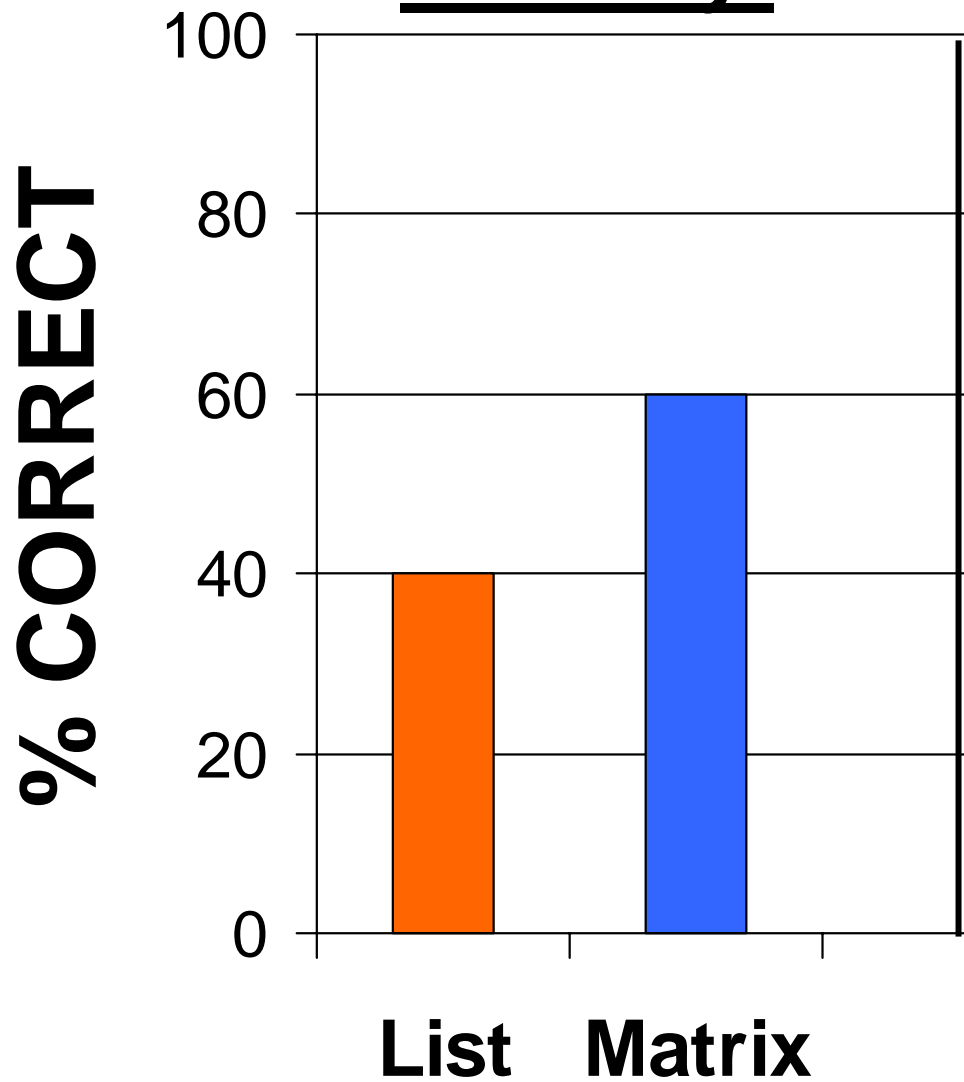
*(Display Absent)*

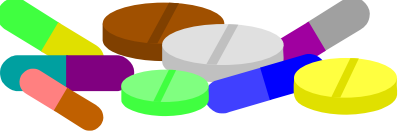
# Memory





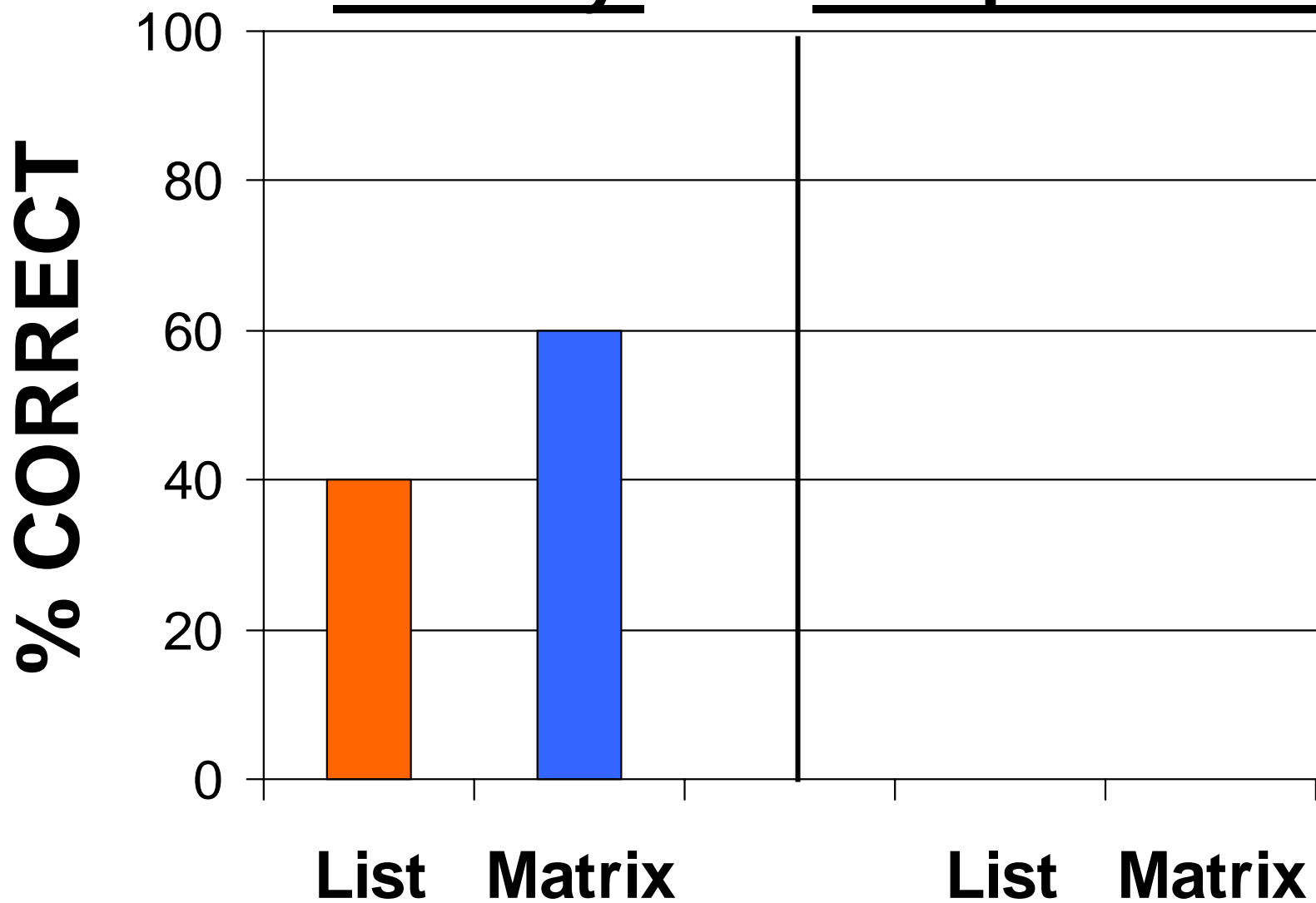
*(Display Absent)*  
**Memory**

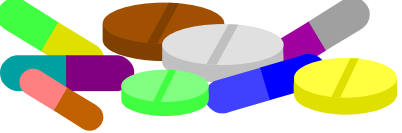




*(Display Absent)*  
**Memory**

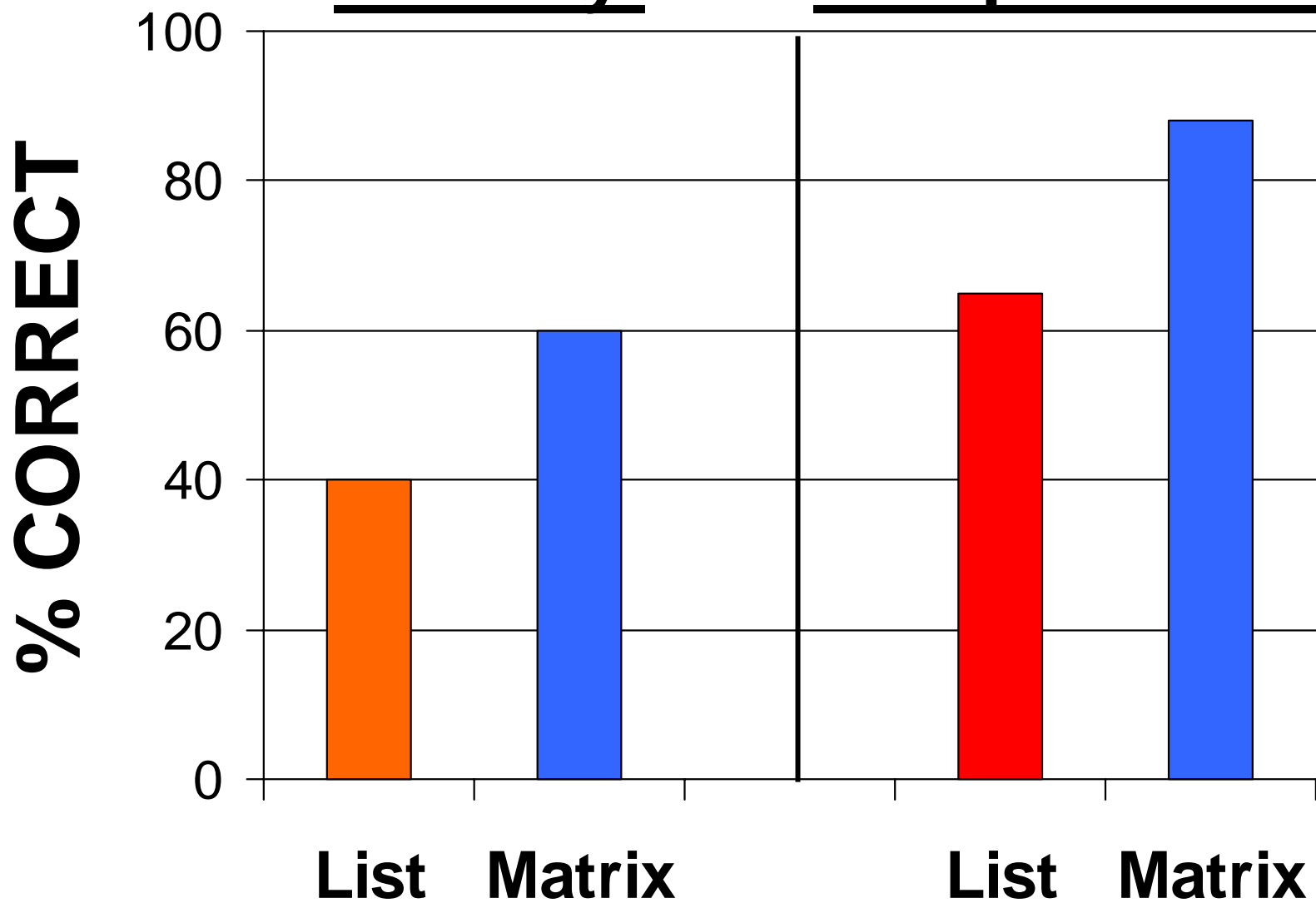
*(Display Present)*  
**Comprehension**

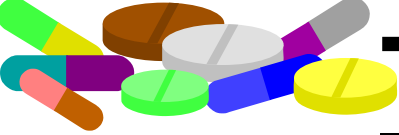




*(Display Absent)*  
**Memory**

*(Display Present)*  
**Comprehension**





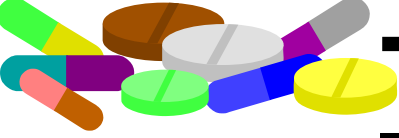
# Types of Questions

**Factual**

**Inferential**

- *“What are the names of the drugs?”*
- *“How many total pills per day?”*
- etc.





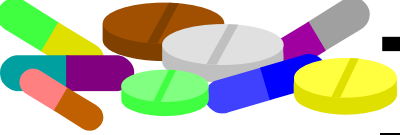
# Types of Questions

## Factual

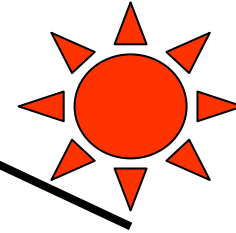
- *“What are the names of the drugs?”*
- *“How many total pills per day?”*
- etc.

## Inferential

- Scenarios
- Go beyond the information given



# Types of Questions



## Factual

## Inferential

- *“What are the names of the drugs?”*
- *“How many total pills per day?”*
- etc.

Scenarios

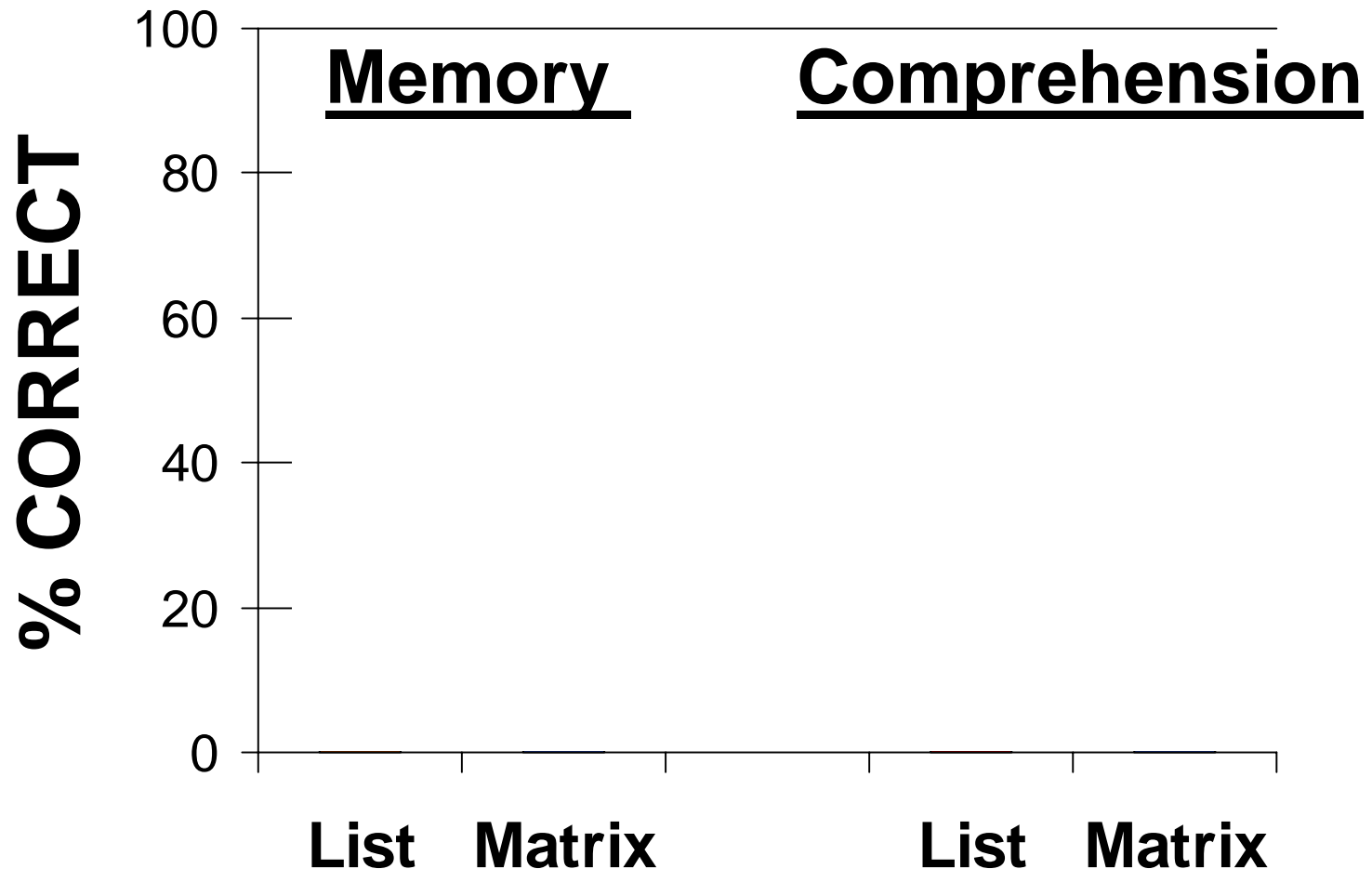
Go beyond the information given

## Scenario Question:

“If you leave home in the afternoon and will not be back until breakfast time the next day, how many Inderal should you take along?”

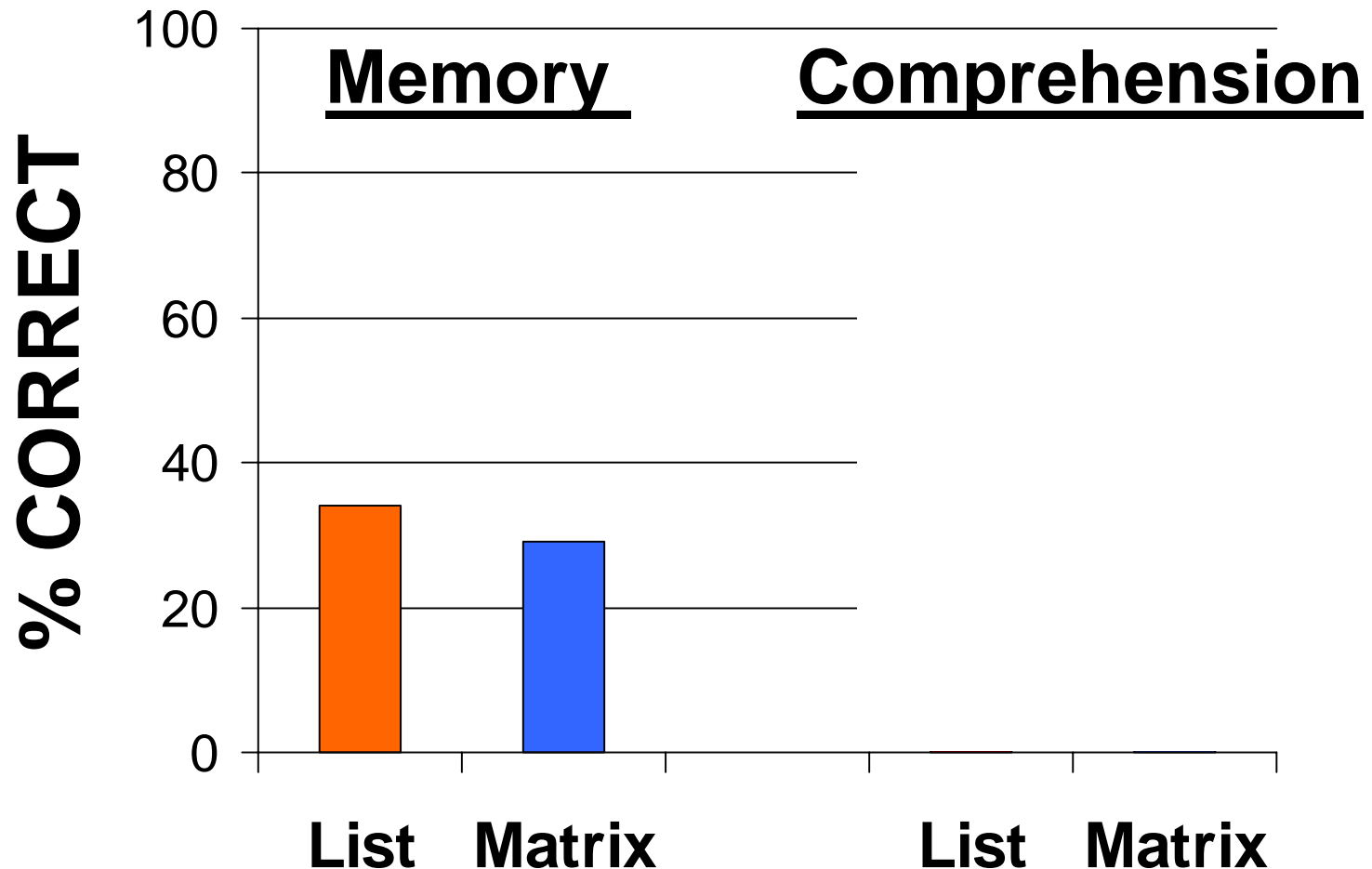
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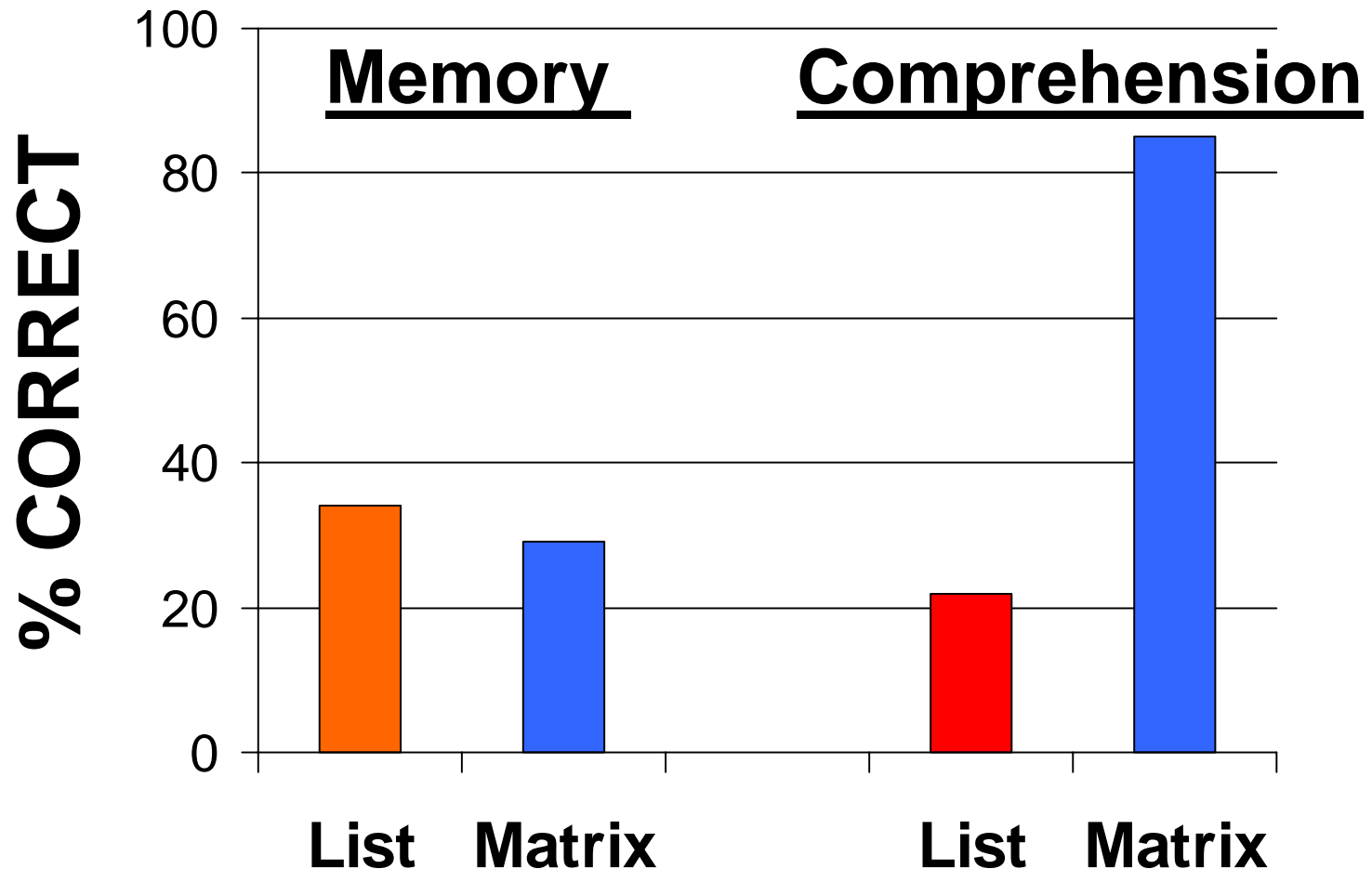
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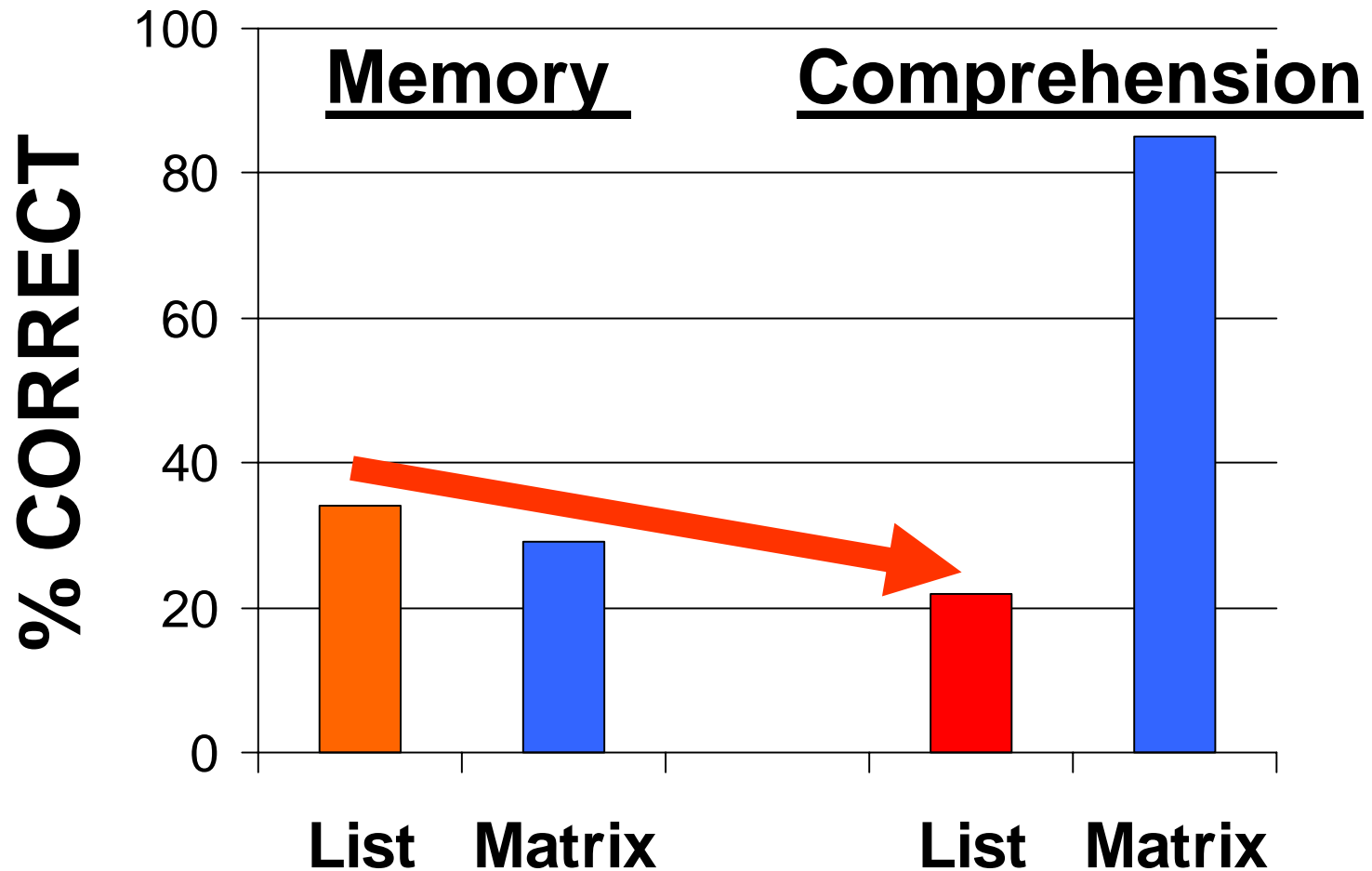
# Scenario Question:

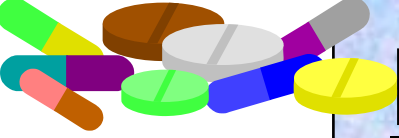
“If you leave home in the afternoon and will not be back until breakfast time the next day, how many Inderal should you take along?”



# Scenario Question:

“If you leave home in the afternoon and will not be back until breakfast time the next day, how many Inderal should you take along?”





# Medication Schedules

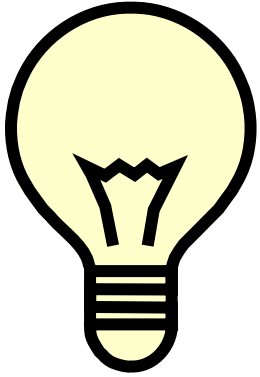
## Principles

- Alternative Representations
- Multiple Cognitive Tasks



# CHUNKING

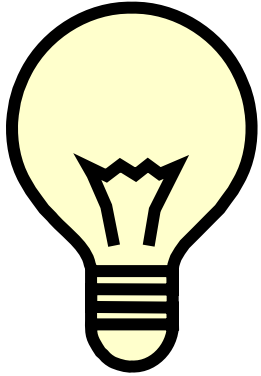
# CHUNKING



Basic idea ....



# CHUNKING



Basic idea ....



# CHUNKING

## Print Ads







## PATIENT SUMMARY OF INFORMATION

Please read this information before you start taking RELPAX and each time you renew your prescription. Remember, this summary does not take the place of discussions with your doctor. You and your doctor should discuss RELPAX when you start taking your medication and at regular checkups.

### What is RELPAX?

RELPAX is a prescription medicine used to treat migraine headaches in adults. RELPAX is not for other types of headaches.

### What is a Migraine Headache?

Migraine is an intense, throbbing headache. You may have pain on one or both sides of your head. You may have nausea and vomiting, and be sensitive to light and noise. The pain and symptoms of a migraine headache can be worse than a common headache. Some women get migraines around the time of their menstrual period. Some people have visual symptoms before the headache, such as flashing lights or wavy lines, called an aura.

### How Does RELPAX Work?

Treatment with RELPAX reduces swelling of blood vessels surrounding the brain. This swelling is associated with the headache pain of a migraine attack. RELPAX blocks the release of substances from nerve endings that cause more pain and other symptoms like nausea, and sensitivity to light and sound.

It is thought that these actions contribute to relief of your symptoms by RELPAX.

### Who should not take RELPAX?

#### Do **not** take RELPAX if you:

- have uncontrolled high blood pressure.
- have heart disease or a history of heart disease.
- have hemiplegic or basilar migraine (if you are not sure about this, ask your doctor).
- have or had a stroke or problems with your blood circulation.
- have serious liver problems.
- have taken any of the following medicines in the last 24 hours: other "triptans" like almotriptan (Axert®), frovatriptan (Frova™), naratriptan (Amerge®), rizatriptan (Maxalt®), sumatriptan (Imitrex®), zolmitriptan (Zomig®); ergotamines like Bellerгал-S®, Cafergot®, Ergomar®, Wigraine®; dihydroergotamine like D.H.E. 45® or Migranal®; or methysergide (Sansert®). These medicines have side effects similar to RELPAX.\*
- have taken the following medicines within at least 72 hours: ketoconazole (Nizoral®), itraconazole (Sporanox®), nefazodone (Serzone®), troleandomycin (TAO®), clarithromycin (Biaxin®), ritonavir (Norvir®), and nelfinavir (Viracept®). These medicines may cause an increase in the amount of RELPAX in the blood.\*
- are allergic to RELPAX or any of its ingredients. The active ingredient is eletriptan. The inactive ingredients are listed at the end of this leaflet.

Tell your doctor about all the medicines you take or plan to take, including prescription and non-prescription medicines, supplements, and herbal remedies. Your doctor will decide if you can take RELPAX with your other medicines.

Tell your doctor if you know that you have any of the following: risk factors for heart disease like high cholesterol, diabetes, smoking, obesity, menopause, or a family history of heart disease or stroke.

### How should I take RELPAX?

RELPAX comes in 20 mg and 40 mg tablets. When you have a migraine headache, take your medicine as directed by your doctor.

- Take one RELPAX tablet as soon as you feel a migraine coming on.

- If your headache improves and then comes back after 2 hours, you can take a second tablet.
- If the first tablet did not help your headache at all, do not take a second tablet without talking with your doctor.
- Do not take more than two RELPAX tablets in any 24-hour period.

### What are the possible side effects of RELPAX?

RELPAX is generally well tolerated. As with any medicine, people taking RELPAX may have side effects. The side effects are usually mild and do not last long.

The most common side effects of RELPAX are:

- dizziness
- nausea
- weakness
- tiredness
- pain or pressure sensation (e.g., in the chest or throat)

In very rare cases, patients taking triptans may experience serious side effects, including heart attacks. **Call your doctor right away** if you have:

- severe chest pains
- shortness of breath

This is not a complete list of side effects. Talk to your doctor if you develop any symptoms that concern you.

### What to do in case of an overdose?

Call your doctor or poison control center or go to the ER.

### General advice about RELPAX

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use RELPAX for a condition for which it was not prescribed. Do not give RELPAX to other people, even if they have the same symptoms you have.

This leaflet summarizes the most important information about RELPAX. If you would like more information about RELPAX, talk with your doctor. You can ask your doctor or pharmacist for information on RELPAX that is written for health professionals. You can also call 1-866-4RELPAX (1-866-473-5729) or visit our web site at [www.RELPAX.com](http://www.RELPAX.com).

### What are the ingredients in RELPAX?

Active ingredient: eletriptan hydrobromide

Inactive ingredients: microcrystalline cellulose, lactose, croscarmellose sodium, magnesium stearate, titanium dioxide, hypromellose, triacetin, and FD&C Yellow No. 6 aluminum lake.

Store RELPAX Tablets at room temperature 15-30°C (59-86°F).

\*The brands listed are the trademarks of their respective owners and are not trademarks of Pfizer Inc.

## IMPORTANT SAFETY INFORMATION ABOUT LYRICA

LYRICA may make you feel dizzy or sleepy.

- Do not drive a car, work with machines, or do other dangerous things until you are sure you will be alert. Ask your doctor when it is okay to do these things.

LYRICA may cause problems with your eyesight, including blurry vision. Call your doctor if you have any changes in your eyesight.

## ABOUT LYRICA

LYRICA is a prescription medicine used to treat:

- Nerve pain from diabetes
- Nerve pain that continues after the rash from shingles heals

This pain can be sharp or burning. It can feel like tingling, shooting, or numbness. Some people taking LYRICA had less pain by the end of the first week. LYRICA may not work for everyone.

## WHO IS LYRICA FOR?

Who can take LYRICA:

- Adults 18 years or older with nerve pain from diabetes or after shingles

Who should NOT take LYRICA:

- Anyone who is allergic to anything in LYRICA

LYRICA has not been studied for nerve pain in children under 18 years of age.

## BEFORE STARTING LYRICA

Tell your doctor about all your medical conditions.

Tell your doctor if you:

- Have or had kidney problems or dialysis
- Have heart problems, including heart failure
- Have a bleeding problem or a low blood platelet count
- Have abused drugs or alcohol. LYRICA may cause some people to feel "high."
- Are either a man or woman planning to have children or a woman who is breast-feeding, pregnant, or may become pregnant. It is not known if LYRICA may decrease male fertility, cause birth defects, or pass into breast milk.

Tell your doctor about all your medicines. Include over-the-counter medicines, vitamins, and herbal products. Tell your doctor if you take:

- Rosiglitazone (Avandia®)\* or pioglitazone (Actos®)\*\* for diabetes
- Narcotic pain medicines such as oxycodone, tranquilizers, or medicines for anxiety such as lorazepam
- Any medicines that make you sleepy

## POSSIBLE SIDE EFFECTS OF LYRICA

LYRICA may cause serious side effects, including:

- Dizziness and sleepiness
- Eyesight problems
- Weight gain and swelling of hands and feet. Weight gain may affect control of diabetes. Weight gain and swelling can be serious for people with heart problems.
- Unexplained muscle pain, soreness, or weakness along with a fever or tired feeling. If you have these symptoms, tell your doctor right away.
- Skin sores. In LYRICA studies, skin sores were seen in animals but not in humans. If you have diabetes, pay extra attention to your skin. Tell your doctor about any skin problems.

The most common side effects of LYRICA are:

- Dizziness
- Sleepiness
- Swelling of hands and feet
- Blurry vision
- Weight gain
- Trouble concentrating
- Dry mouth

You may have a higher chance of swelling or gaining weight if you are taking certain diabetes medicines with LYRICA. Medicines that already make you sleepy or dizzy may make you feel more sleepy or dizzy with LYRICA.

## HOW TO TAKE LYRICA

Do:

- Take LYRICA exactly as your doctor tells you. Your doctor may tell you to take it 2 or 3 times a day.
- Take LYRICA with or without food.

Don't:

- Do not drive a car or use machines if you feel sleepy while taking LYRICA.
- Do not drink alcohol or use other medicines that make you sleepy while taking LYRICA.
- Do not change the dose or stop LYRICA suddenly. You may have headaches, nausea, diarrhea, or trouble sleeping if you stop taking LYRICA suddenly.
- Do not start any new medicines without first talking to your doctor.

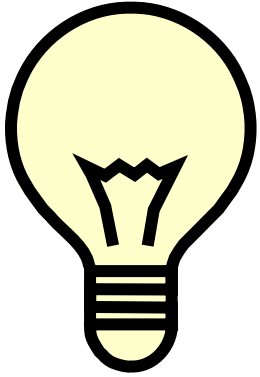
## NEED MORE INFORMATION?

- Ask your doctor or pharmacist. This is only a brief summary of important information.
- Go to [www.lyrica.com](http://www.lyrica.com) or call 1-888-9-LYRICA (1-888-959-7422).



# CODING

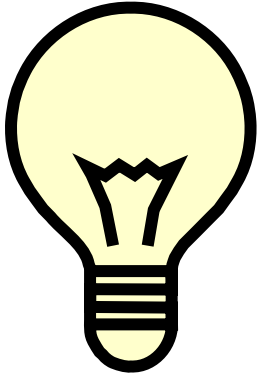
# CODING



Basic idea ....



# CODING



Basic idea ....

Name A




Name B



# CHUNKING & CODING

## Pharmacy Leaflet

(CMI)

ABOUT YOUR MEDICINE	
<p>Tiopronin (tye-oh-PRO-nin) is used to prevent kidney stones, which may develop due to too much cystine in the urine (cystinuria).</p> <p>If any of the information in this leaflet causes you special concern or if you want additional information about your medicine and its use, check with your doctor, nurse, or pharmacist. Remember, keep this and all other medicines out of the reach of children and never share your medicines with others.</p>	<p>medicine and then restarting it may increase the chance of side effects.</p> <p>If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.</p>
BEFORE USING THIS MEDICINE	
	
<p>Discuss with your doctor the possible side effects of this medicine. Some of them may be serious or last a long time. Tell your doctor, nurse, and pharmacist if you . . .</p> <ul style="list-style-type: none"><li>• are allergic to any medicine, either prescription or nonprescription (OTC);</li><li>• are pregnant or intend to become pregnant while using this medicine;</li><li>• are breast-feeding;</li><li>• are taking any other prescription or nonprescription (OTC) medicine;</li><li>• have any other medical problems, especially blood problems (or history of).</li></ul>	
PROPER USE OF THIS MEDICINE	
<p>Take this medicine on an empty stomach (at least 30 minutes before meals or 2 hours after meals).</p> <p>You should drink 2 full glasses (8 ounces each) of water with each meal and at bedtime. You should also drink another 2 full glasses during the night.</p> <p>It is important that you follow any special instructions from your doctor, such as following a low-methionine diet. Methionine is found in animal proteins such as milk, eggs, cheese, and fish. If you have any questions about this, check with your doctor.</p> <p>Take this medicine regularly as directed. Do not stop taking it without first checking with your doctor, since stopping the</p>	<p><b>PRECAUTIONS WHILE USING THIS MEDICINE</b></p> <p>Your doctor should check your progress at regular visits to make sure that this medicine is working properly and to check for unwanted effects.</p> <p><b>POSSIBLE SIDE EFFECTS OF THIS MEDICINE</b></p> <p><i>Side Effects That Should Be Reported To Your Doctor Immediately</i></p> <p><i>More common</i> - Yellow eyes or skin</p> <p><i>Less common</i> - Fever or sore throat; muscle pain; unusual bleeding or bruising</p> <p><i>Other Side Effects That Should Be Reported To Your Doctor</i></p> <p><i>More common</i> - Pain, swelling, or tenderness of the skin; skin rash, hives, or itching; ulcers or sores in mouth</p> <p><i>Less common</i> - Chills; cloudy or bloody urine; high blood pressure; hoarseness; joint pain; swelling of feet or lower legs; tenderness of glands; trouble in breathing; unusual bleeding</p> <p><i>Rare</i> - Chest pain; cough; double vision; general feeling of discomfort, illness, or weakness; muscle weakness; spitting up blood; swelling of lymph glands; trouble in chewing, talking, or swallowing</p> <p><i>Side Effects That Usually Do Not Require Medical Attention</i></p> <p>These possible side effects may go away during treatment; however, if they continue or are bothersome, check with your doctor, nurse, or pharmacist.</p> <p><i>More common</i> - Abdominal or stomach pain; bloating or gas; diarrhea or soft stools; loss of appetite; nausea or vomiting; warts; wrinkling or peeling or unusually dry skin</p> <p><i>Less common</i> - Changes in taste or smell</p> <p>Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor, nurse, or pharmacist.</p>
<small>The information on this leaflet has been selectively abstracted from USP DI for use as an educational aid and does not cover all possible uses, actions, precautions, side effects, or interactions of the medicine. It is not intended as medical advice for individual problems. © 1997 USPDC, Inc.</small>	

# EXAMPLE (Original)

Tell your doctor, nurse, and pharmacist if you ...

- are allergic to any medicine, either prescription or nonprescription (OTC);
- **are pregnant or intend to become pregnant while using this medicine**
- are breast-feeding;
- are using any other prescription or nonprescription (OTC) medicine, especially diuretics (water pills) or potassium-containing medicines or supplements;
- have any other medical problems, especially heart or blood vessel disease or kidney disease;
- are on a strict low-sodium diet or dialysis, or use low-salt milk or salt substitutes;
- have had a kidney transplant

**Source:** Day, R. S. (1999) Optimizing patient comprehension through medicine information leaflets: Cognition experiments. In A.G. Hartzema, S.Tolleson-Rinehart, B.L. Sleath, and R.S. Day, *Optimizing Patient Comprehension through Medicine Leaflets*. Rockville, MD: U.S. Pharmacopeia. Pp. 60-176.

**How many?**

# EXAMPLE (Original)

Tell your doctor, nurse, and pharmacist if you ...

- are allergic to any medicine, either prescription or nonprescription (OTC);
- **are pregnant or intend to become pregnant while using this medicine**
- are breast-feeding;
- are using any other prescription or nonprescription medicine, especially diuretics (water pills), potassium-containing medicines or supplements;
- have any other medical problems, especially heart disease, blood vessel disease or kidney disease;
- are on a strict low-sodium diet or dialysis treatment; milk or salt substitutes;
- have had a kidney transplant

A rectangular form with a red border on a light orange background. It contains several horizontal lines of wavy lines, resembling a handwriting practice sheet or a form for capturing user input. The lines are arranged in a list-like structure, with some lines starting with a small black dot, similar to the bullet points in the adjacent text box.

**Source:** Day, R. S. (1999) Optimizing patient comprehension of medicine information leaflets: Cognition experiments. In Tolleson-Rinehart, B.L. Sleath, and R.S. Day, *Optimizing Patient Comprehension through Medicine Leaflets*. Rockville, MD: U.S. Pharmacopeia. Pp. 60-176.

# Chunked & Coded

Tell your doctor, nurse, and pharmacist if you have:

## **Allergic to Medicines**

- prescription medicine
- nonprescription medicine (OTC)

## **Pregnancy**

- are pregnant
- intend to become pregnant
- are breast-feeding

## **Other Medicines**

- prescription medicine
- nonprescription medicine (OTC)
- especially: --diuretics (water pills)
  - potassium-containing medicines
  - potassium-containing supplements

## **Medical Conditions**

- any other medical problems
- especially: --heart disease
  - blood vessel disease
  - kidney disease
  - kidney transplant
  - on dialysis

## **Diet**

- on a strict low-sodium diet
- use low-salt milk
- use salt substitutes



# CHUNKING & CODING

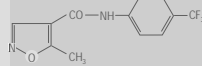
## Professional Label

### CONTRAINDICATIONS AND WARNINGS

PREGNANCY MUST BE EXCLUDED BEFORE THE START OF TREATMENT WITH ARAVA. ARAVA IS CONTRAINDICATED IN PREGNANT WOMEN, OR WOMEN OF CHILDBEARING POTENTIAL WHO ARE NOT USING RELIABLE CONTRACEPTION. (SEE CONTRAINDICATIONS AND WARNINGS.) PREGNANCY MUST BE AVOIDED DURING ARAVA TREATMENT OR PRIOR TO THE COMPLETION OF THE DRUG ELIMINATION PROCEDURE AFTER ARAVA TREATMENT.

### DESCRIPTION

ARAVA™ (leflunomide) is a pyrimidine synthesis inhibitor. The chemical name for leflunomide is N-(4-(trifluoromethyl)phenyl)-5-methylisoxazole-4-carboxamide. It has an empirical formula  $C_{12}H_8F_3N_2O_2$ , a molecular weight of 270.2 and the following structural formula:



ARAVA is available for oral administration as tablets containing 10, 20, or 100 mg of active drug. Combined with leflunomide are the following inactive ingredients: colloidal silicon dioxide, croscopvidone, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, starch, talc, titanium dioxide, and yellow ferric oxide (20 mg tablet only).

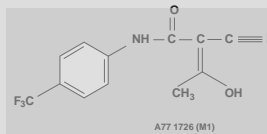
### CLINICAL PHARMACOLOGY

#### Mechanism of Action

Leflunomide is an isoxazole immunomodulatory agent which inhibits dihydroorotate dehydrogenase (an enzyme involved in de novo pyrimidine synthesis) and has antiproliferative activity. Several *in vivo* and *in vitro* experimental models have demonstrated an anti-inflammatory effect.

#### Pharmacokinetics

Following oral administration, leflunomide is metabolized to an active metabolite A77 1726 (hereafter referred to as M1) which is responsible for essentially all of its activity *in vivo*. Plasma levels of leflunomide are occasionally seen, at very low levels. Studies of the pharmacokinetics of leflunomide have primarily examined the plasma concentrations of this active metabolite.



A77 1726 (M1)

#### Absorption

Following oral administration, peak levels of the active metabolite, M1, occurred between 6 - 12 hours after dosing. Due to the very long half-life of M1 (~2 weeks), a loading dose of 100 mg for 3 days was used in clinical studies to facilitate the rapid attainment of steady-state levels of M1.

## CONTRAINDICATIONS AND WARNINGS

PREGNANCY MUST BE EXCLUDED BEFORE THE START OF TREATMENT WITH DRUG-X. DRUG-X IS CONTRAINDICATED IN PREGNANT WOMEN, OR WOMEN OF CHILDBEARING POTENTIAL WHO ARE NOT USING RELIABLE CONTRACEPTION. (SEE CONTRAINDICATIONS AND WARNINGS.) PREGNANCY MUST BE AVOIDED DURING DRUG-X TREATMENT OR PRIOR TO THE COMPLETION OF THE DRUG ELIMINATION PROCEDURE AFTER DRUG-X TREATMENT.

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**Addition**

RARE BUT LIFE-THREATENING LIVER TOXICITY HAS BEEN REPORTED, INCLUDING ACUTE LIVER FAILURE.

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RARE BUT LIFE-THREATENING LIVER TOXICITY HAS BEEN REPORTED, INCLUDING ACUTE LIVER FAILURE.

Chunked

# CHUNKING & CODING

## CONTRAINDICATIONS AND WARNINGS

### PREGNANCY

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### LIVER TOXICITY

RARE BUT LIFE-THREATENING LIVER TOXICITY HAS BEEN REPORTED, INCLUDING ACUTE LIVER FAILURE.

Chunked & Coded



# Visual Contrast

## **CONTRAINDICATIONS AND WARNINGS**

### **PREGNANCY**

Pregnancy must be excluded before the start of treatment with Drug-X. Drug-X is contraindicated in pregnant women, or women of childbearing potential who are not using reliable contraception. (See “Contraindications and Warnings.”)

Pregnancy must be avoided during Drug-X treatment or prior to the completion of the drug elimination procedure after Drug-X treatment.

### **LIVER TOXICITY**

Rare but life-threatening liver toxicity has been reported, including acute liver failure.

# CHUNKING & CODING

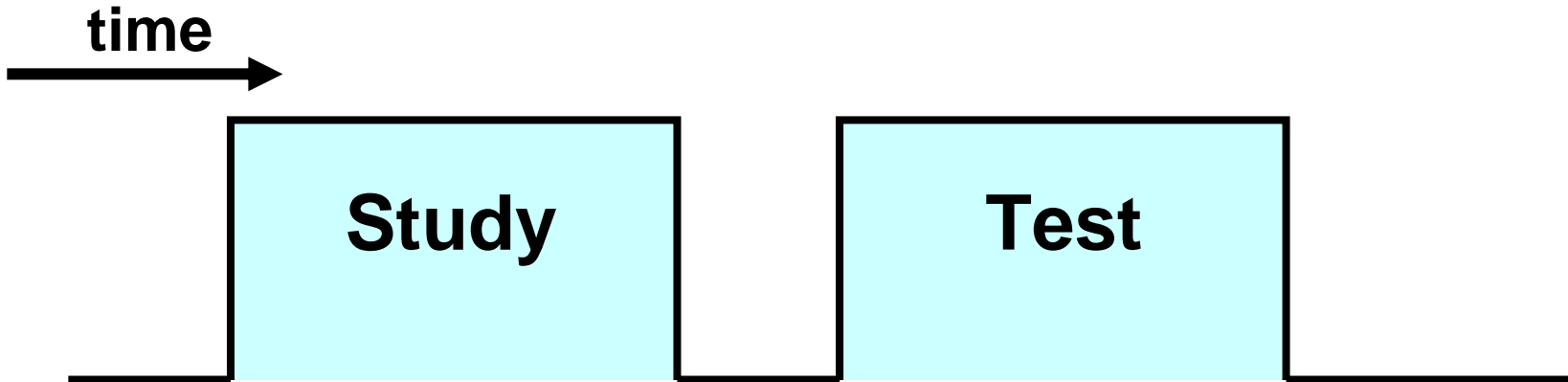
time



**Study**

**Test**

# CHUNKING & CODING



**--Chunked > UnChunked**

**--Coded > UnCoded**

# READABILITY

# READABILITY

Pregnancy must be excluded before the start of treatment with Drug-X. Drug-X is contraindicated in pregnant women, or women of childbearing potential who are not using reliable contraception. (See “Contraindications and Warnings.”)  
Pregnancy must be avoided during Drug-X treatment or prior to the completion of the drug elimination procedure after Drug-X treatment.

# Words = 48

# Sentences = 3

# READABILITY

Pregnancy must be excluded before the start of treatment with Drug-X. Drug-X is contraindicated in pregnant women, or women of childbearing potential who are not using reliable contraception. (See “Contraindications and Warnings.”)  
Pregnancy must be avoided during Drug-X treatment or prior to the completion of the drug elimination procedure after Drug-X treatment.

# Words = 48

**Grade level = 12**

# Sentences = 3

**Passives = 66%**

# LINGUISTIC STRUCTURE

Pregnancy must be excluded  
before the start  
of treatment  
with Drug-X.

Drug-X is contraindicated  
in pregnant women,  
or women  
of childbearing potential  
who are not using reliable contraception.

Pregnancy must be avoided  
during Drug-X treatment  
or prior  
to the completion  
of the drug elimination procedure  
after Drug-X treatment.

# LINGUISTIC STRUCTURE

Pregnancy must be excluded  
**before** the start  
**of** treatment  
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Drug-X is contraindicated  
**in** pregnant women,  
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Pregnancy must be avoided  
**during** Drug-X treatment  
or prior  
**to** the completion  
**of** the drug elimination procedure  
**after** Drug-X treatment.



# LARD FACTOR

# LARD FACTOR

Original  
High LF

Pregnancy must be excluded before the start of treatment with Drug-X. Drug-X is contraindicated in pregnant women, or women of childbearing potential who are not using reliable contraception. Pregnancy must be avoided during Drug-X treatment or prior to the completion of the drug elimination procedure after Drug-X treatment.

# LARD FACTOR

Original  
High LF

Pregnancy must be excluded before the start of treatment with Drug-X. Drug-X is contraindicated in pregnant women, or women of childbearing potential who are not using reliable contraception. Pregnancy must be avoided during Drug-X treatment or prior to the completion of the drug elimination procedure after Drug-X treatment.

Revised  
Lower LF

Exclude pregnancy before starting Drug-X treatment. Drug-X is contraindicated in pregnant women or women of childbearing potential who are not using reliable contraception. Avoid pregnancy during Drug-X treatment and after treatment (until completing the drug elimination procedure).

**Patient Information Sheet for Adderall - Mozilla**

File Edit View Go Bookmarks Tools Window Help

Back Forward Reload Stop <http://www.fda.gov/cder/drug/infosheets/patient/adderallpt.htr> Search Print

Home Bookmarks

### What Are The Risks?

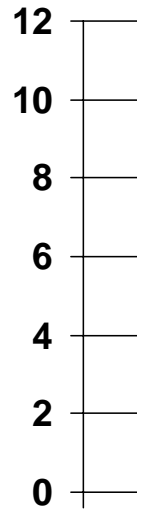
- **Sudden deaths:** See FDA Alert.
- **Abuse potential:** See Warning.
- **Worsening mental illness (psychosis):** Adderall may make symptoms of existing mental illness worse.
- **Possible decreased growth and weight loss:** Adderall may decrease growth and cause weight loss. Children who take it for a long time should have their growth and body weight measured regularly.
- **Increased tics:** Adderall may worsen tics and Tourette's disorder.
- **Pregnancy:** Tell your healthcare professional if you are or may be pregnant because your baby may be premature or have a low birth weight. Also, your baby may show withdrawal symptoms, such as agitation and drowsiness.
- **Breast feeding:** Do not breast feed while taking Adderall because it can pass into your breast milk.
- **Other side effects** include loss of appetite, difficulty sleeping, dry mouth, headaches, and mood changes.
- **Tell your healthcare professional** about any medical conditions you have in addition to

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# Readability

Grade Level



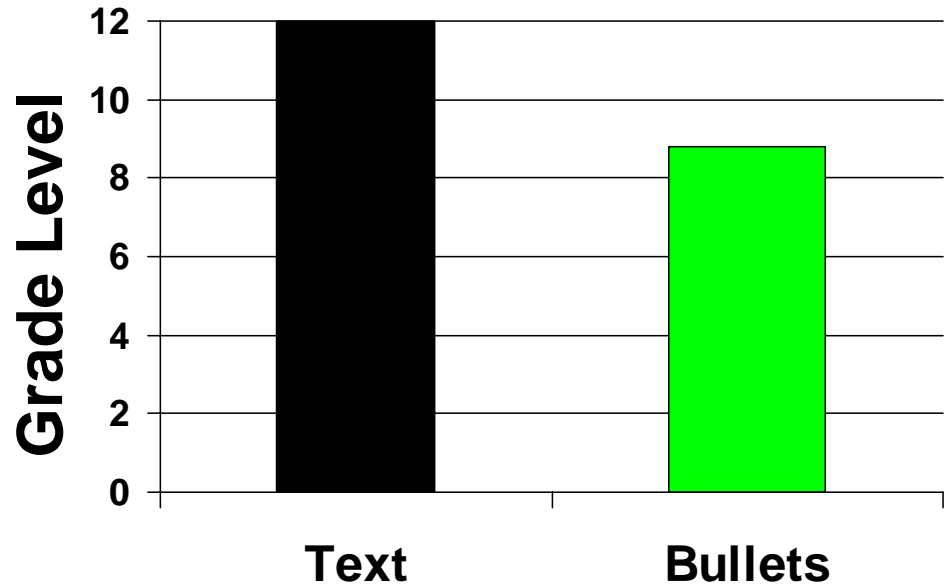
Text

Bullets

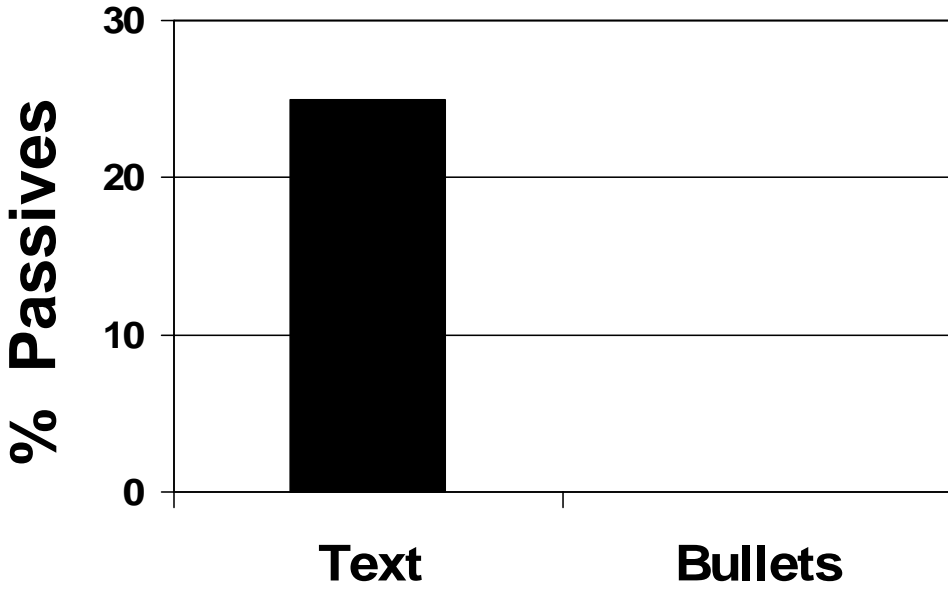
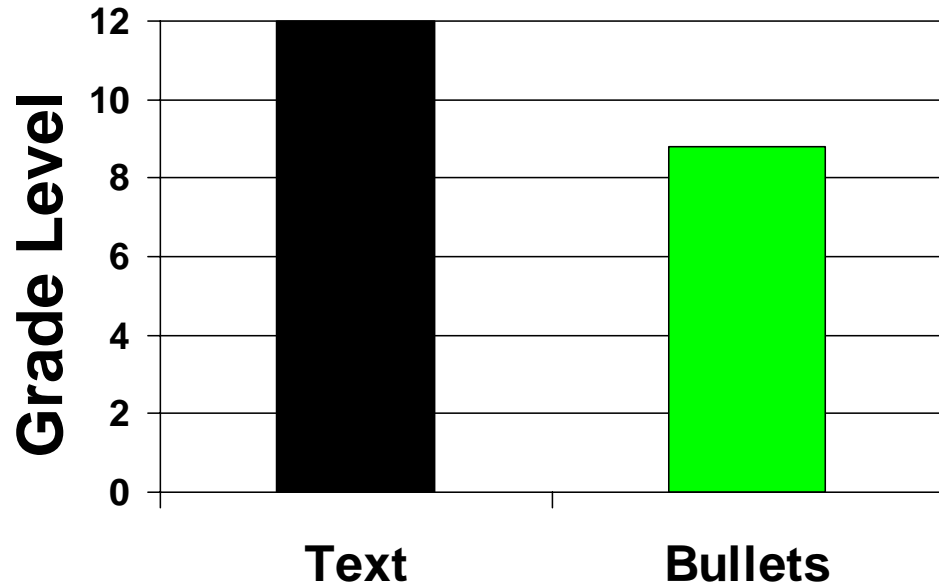




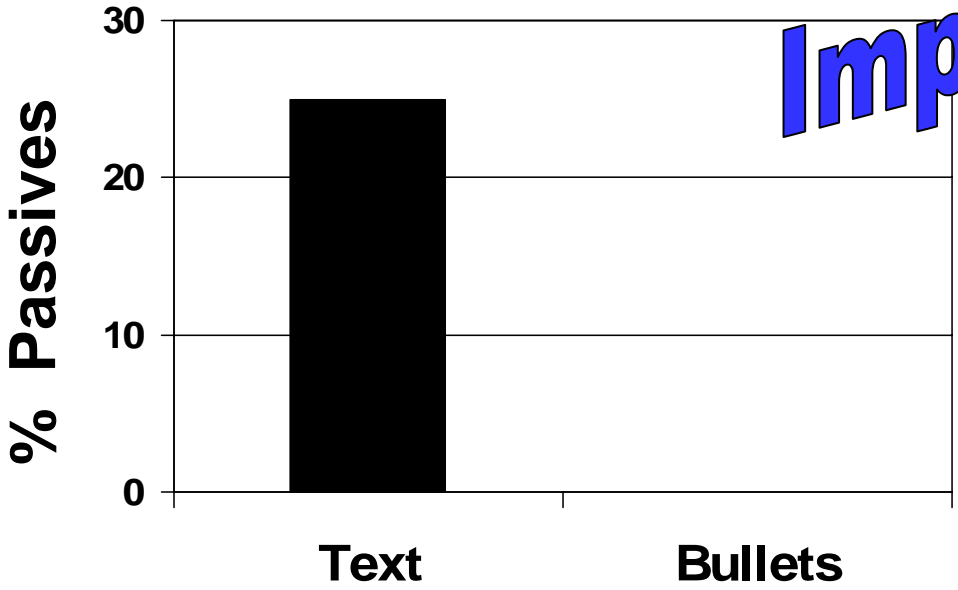
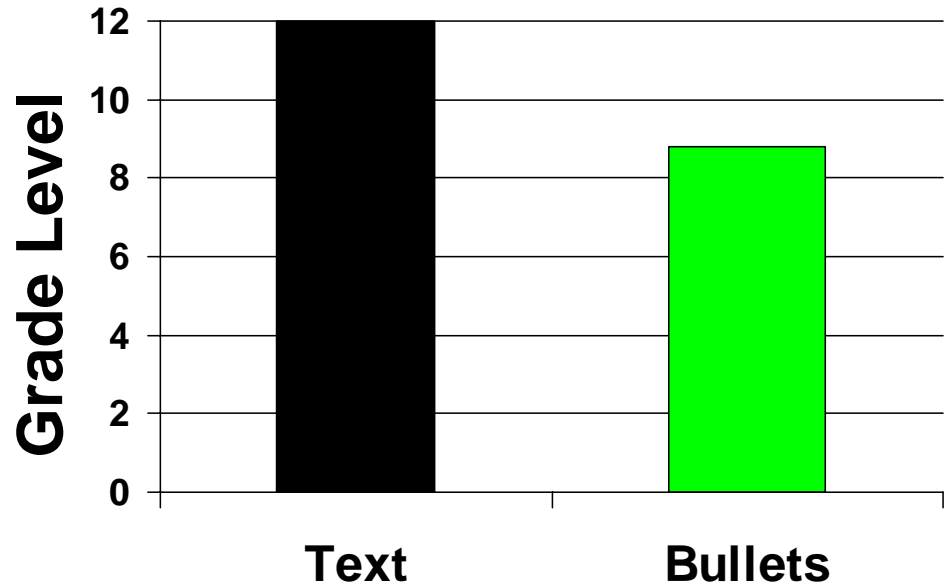
# Readability



# Readability



# Readability



**Implications**  
Comprehension  
Memory  
Behavior



# LOCATION of INFORMATION

# COGNITIVE PRINCIPLE

# **COGNITIVE PRINCIPLE:**

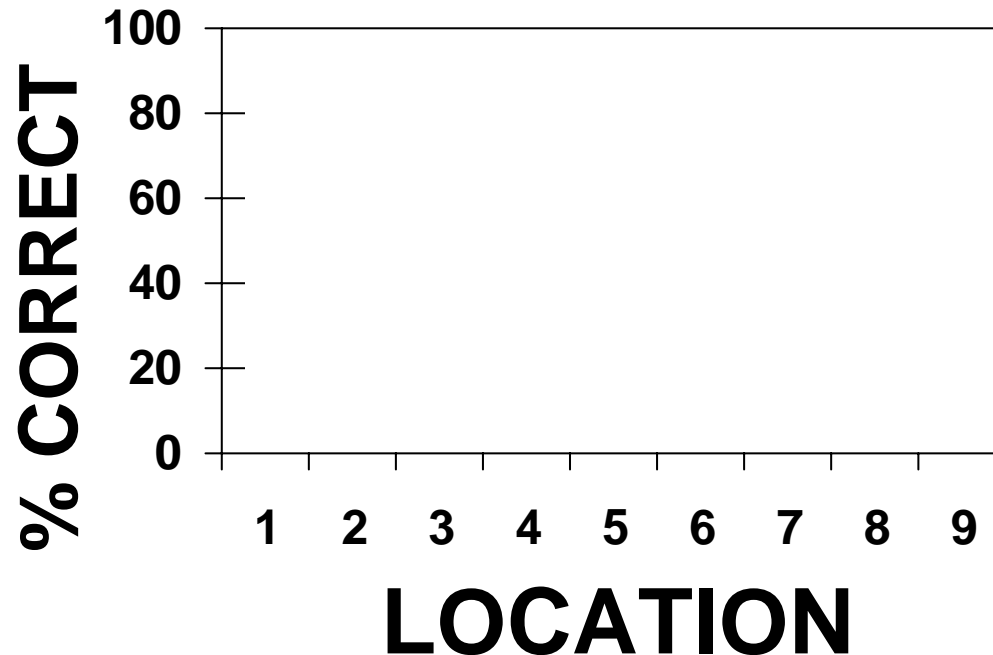
## **Serial Position Effect**

**Task:** --see/hear list of items  
--report them

# COGNITIVE PRINCIPLE: Serial Position Effect

**Task:** --see/hear list of items  
--report them

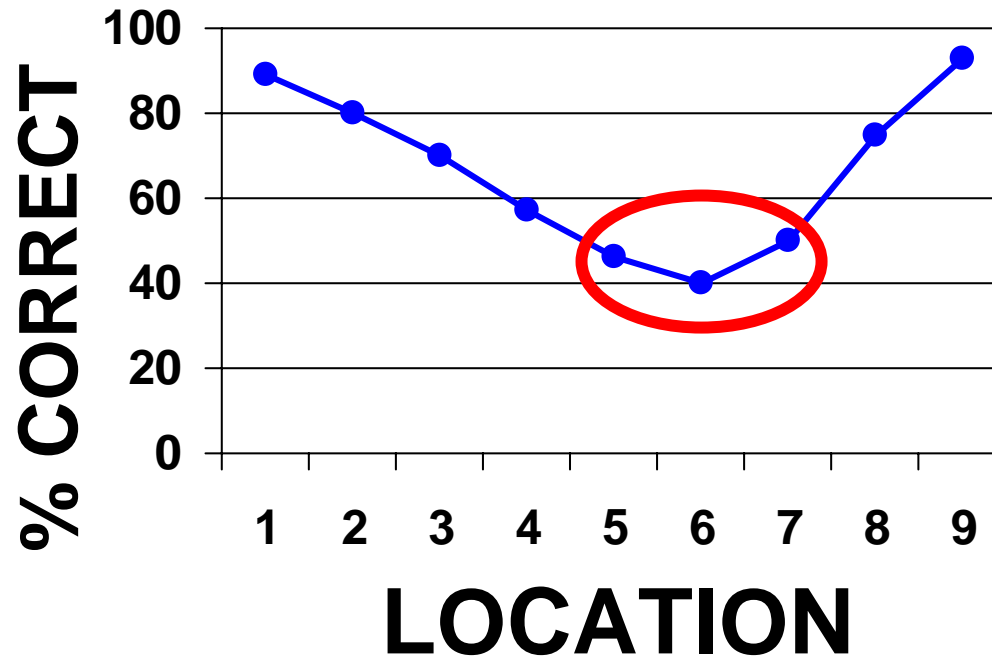
**Typical Results:**



# COGNITIVE PRINCIPLE: Serial Position Effect


**Task:** --see/hear list of items  
--report them

**Typical Results:**

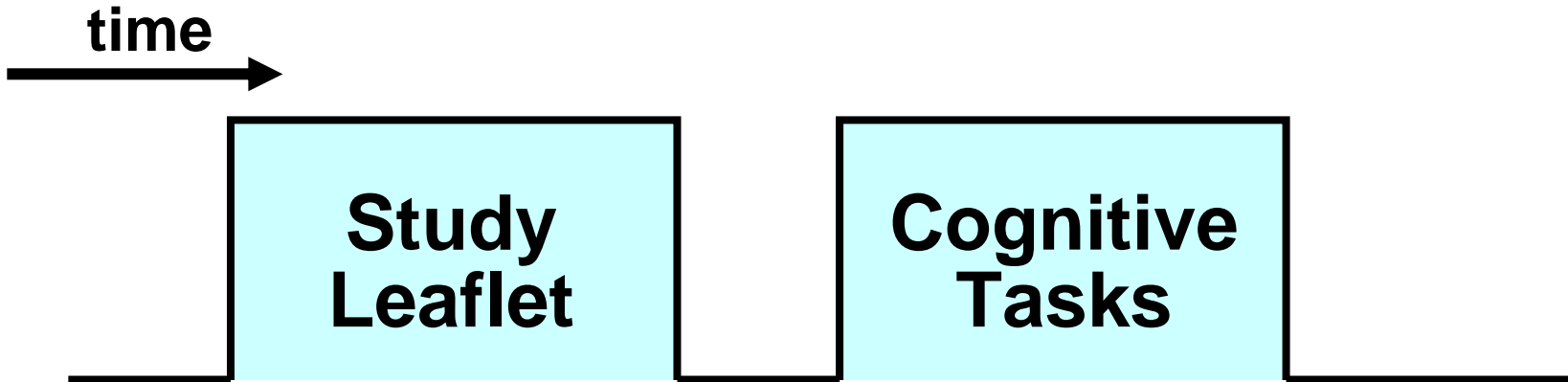


# LOCATION of INFORMATION

CMI

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<small>The information in this leaflet has been selectively abstracted from USP DI for use as an educational aid and does not cover all possible uses, actions, precautions, side effects, or interactions of the medicine. It is not intended as medical advice for individual problems. © 1997 USPC, Inc.</small>	

# Experiments

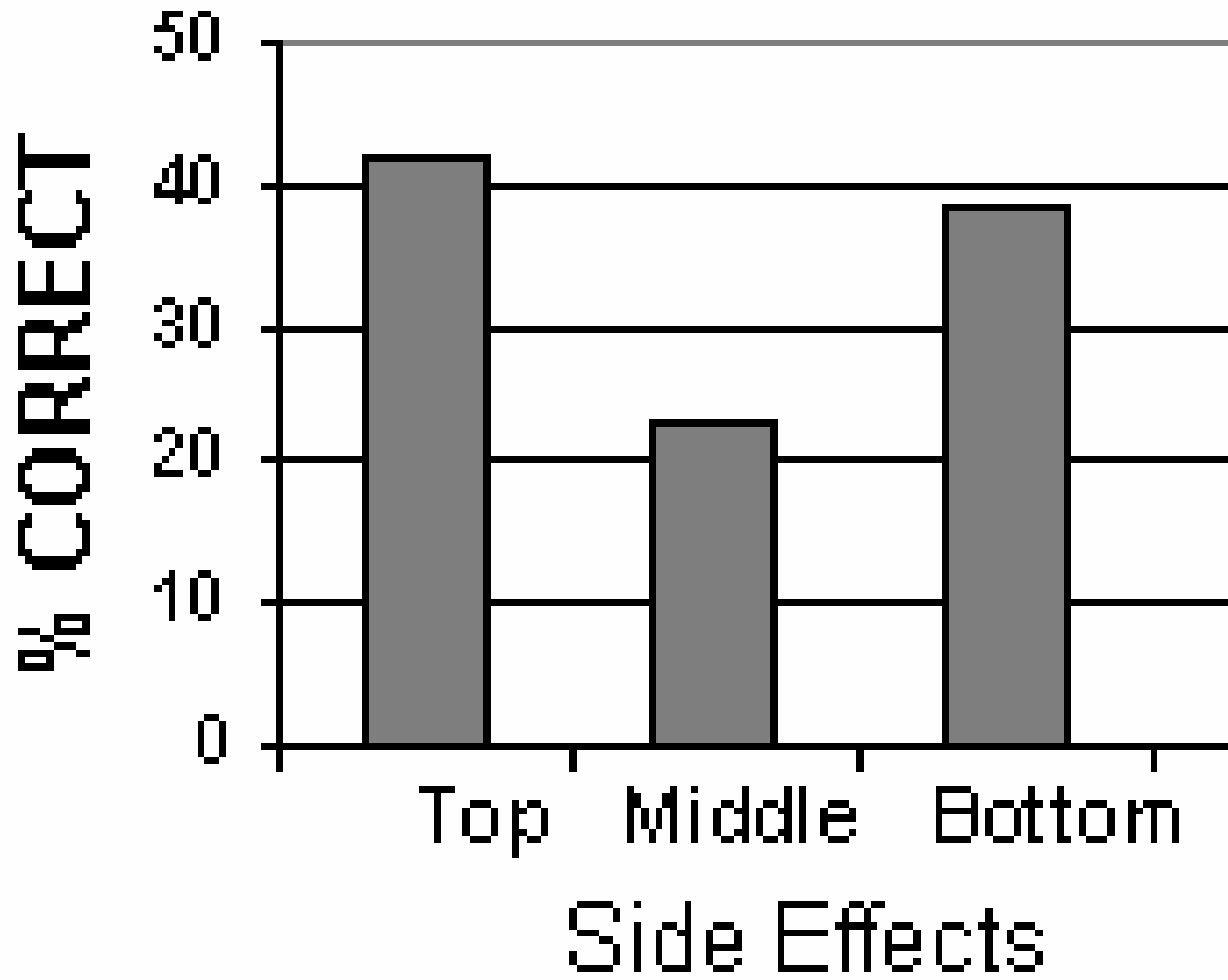


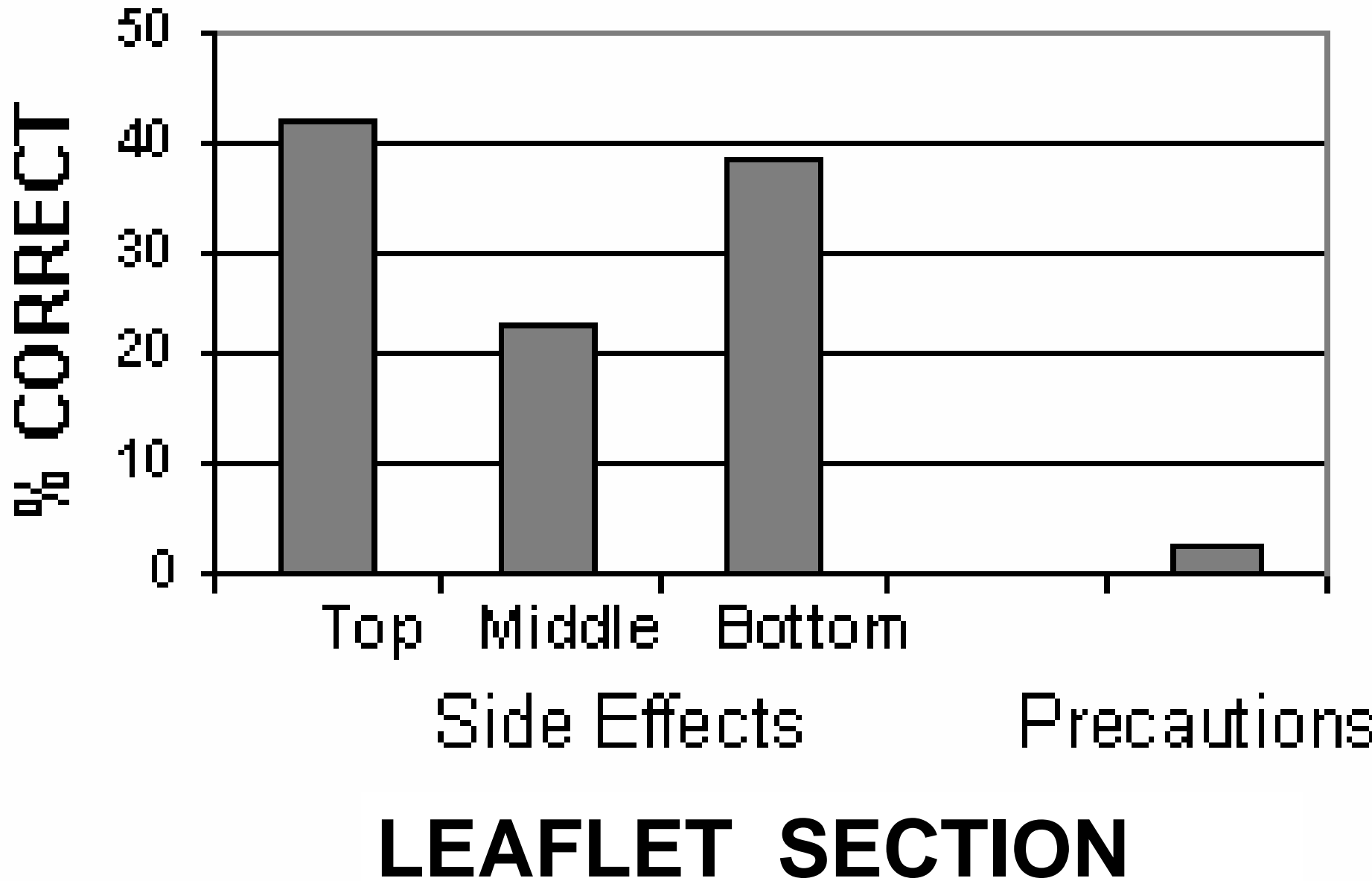
## Example

*“What are possible side effects?”*





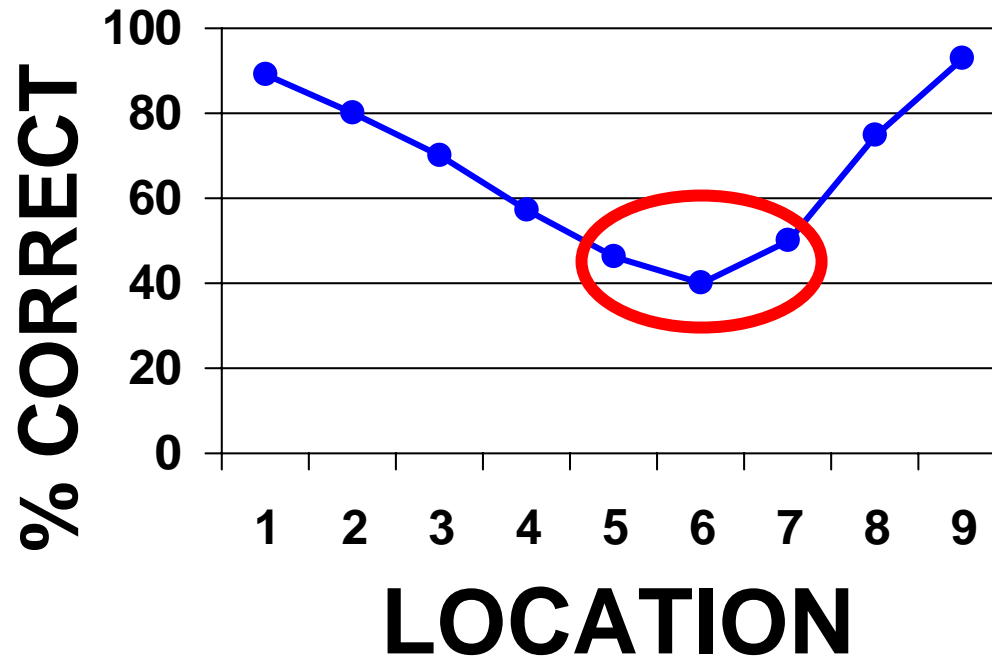




# COGNITIVE PRINCIPLE: Serial Position Effect

**Task:** --see/hear list of items  
--report them

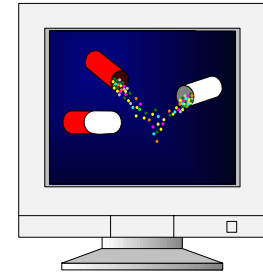
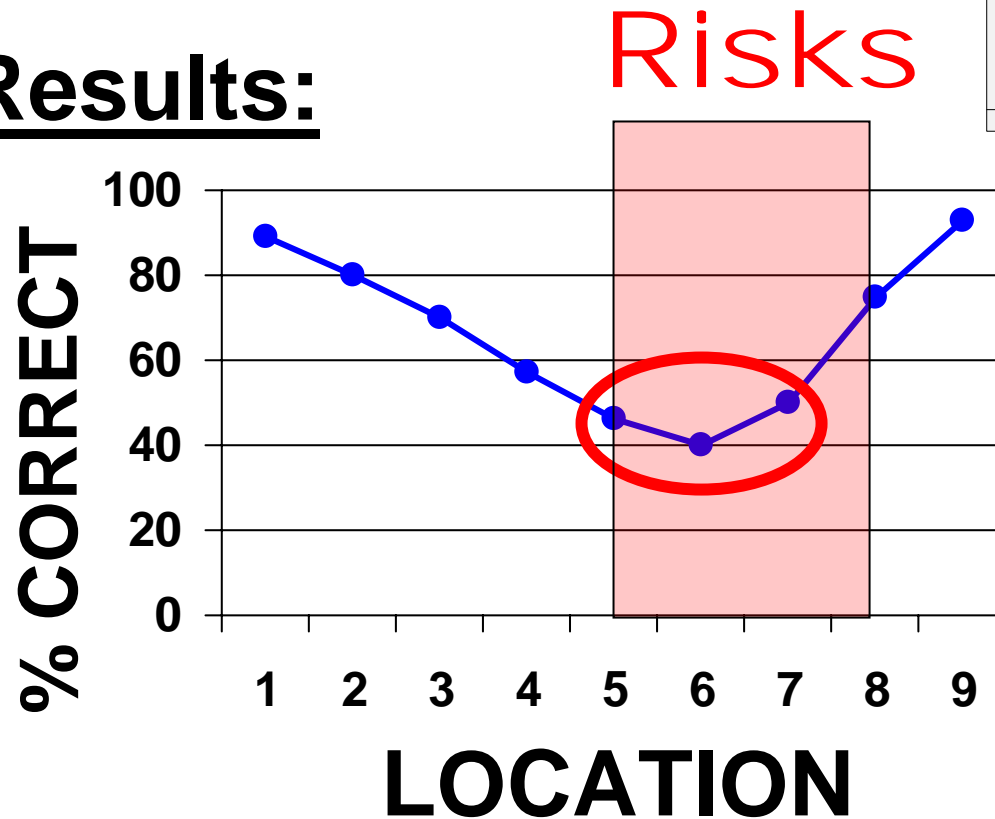
**Typical Results:**



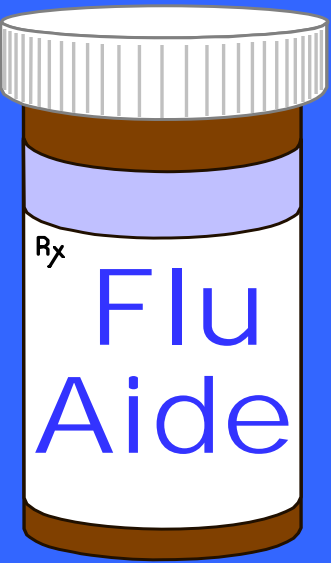
# COGNITIVE PRINCIPLE: Serial Position Effect

**Task:** --see/hear list of items  
--report them

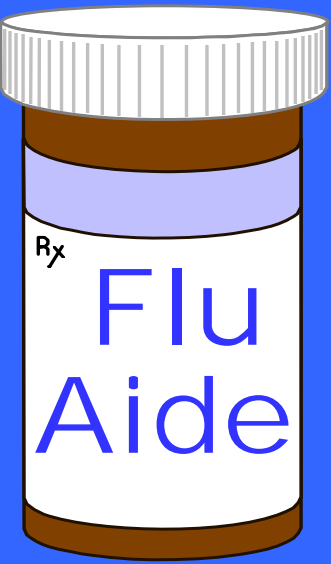
**Typical Results:**



# Produced New TV Ad Hypothetical Drug

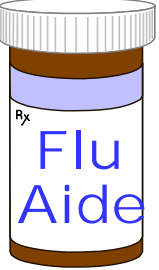


# Produced New TV Ad Hypothetical Drug

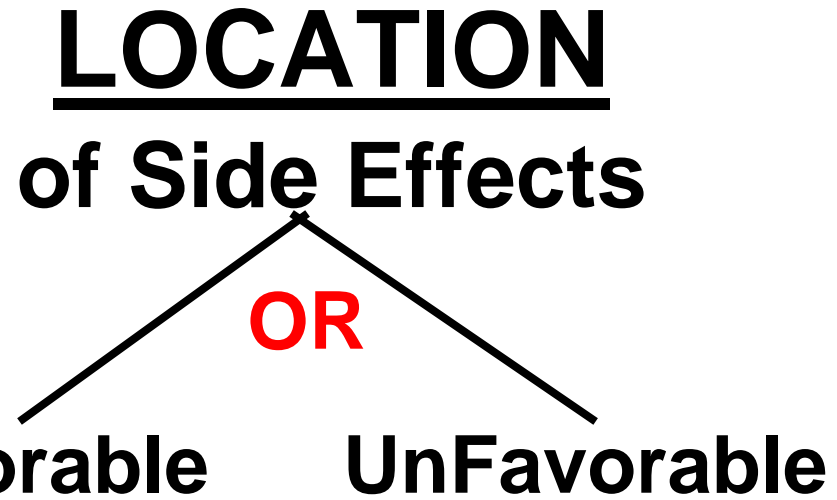
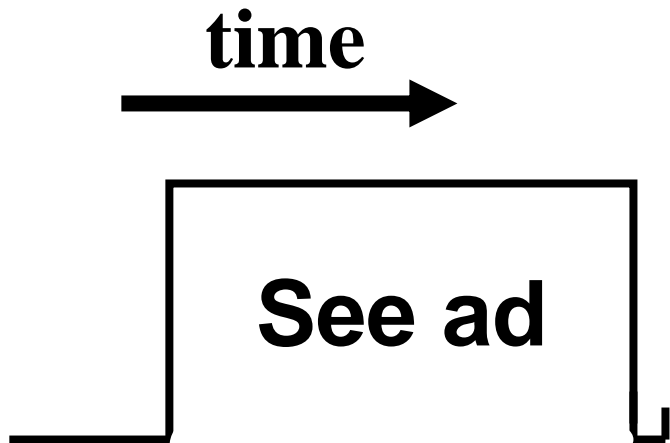


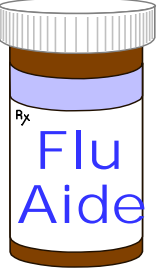
## Structure & content

- Like typical ads
- Purpose
  - vary specific factors
  - observe effects on cognition

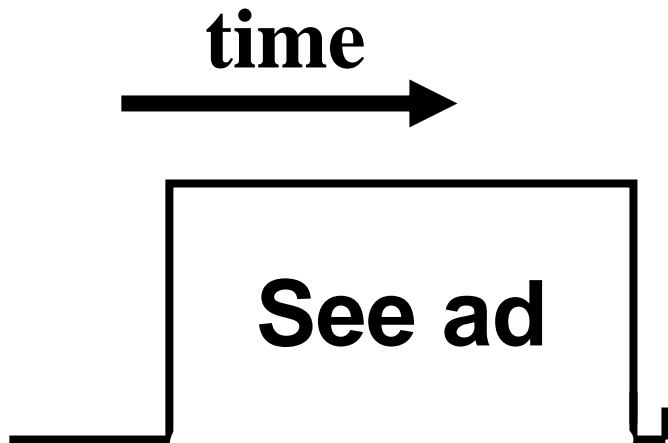


# Experiment





# Experiment



## LOCATION of Side Effects

OR

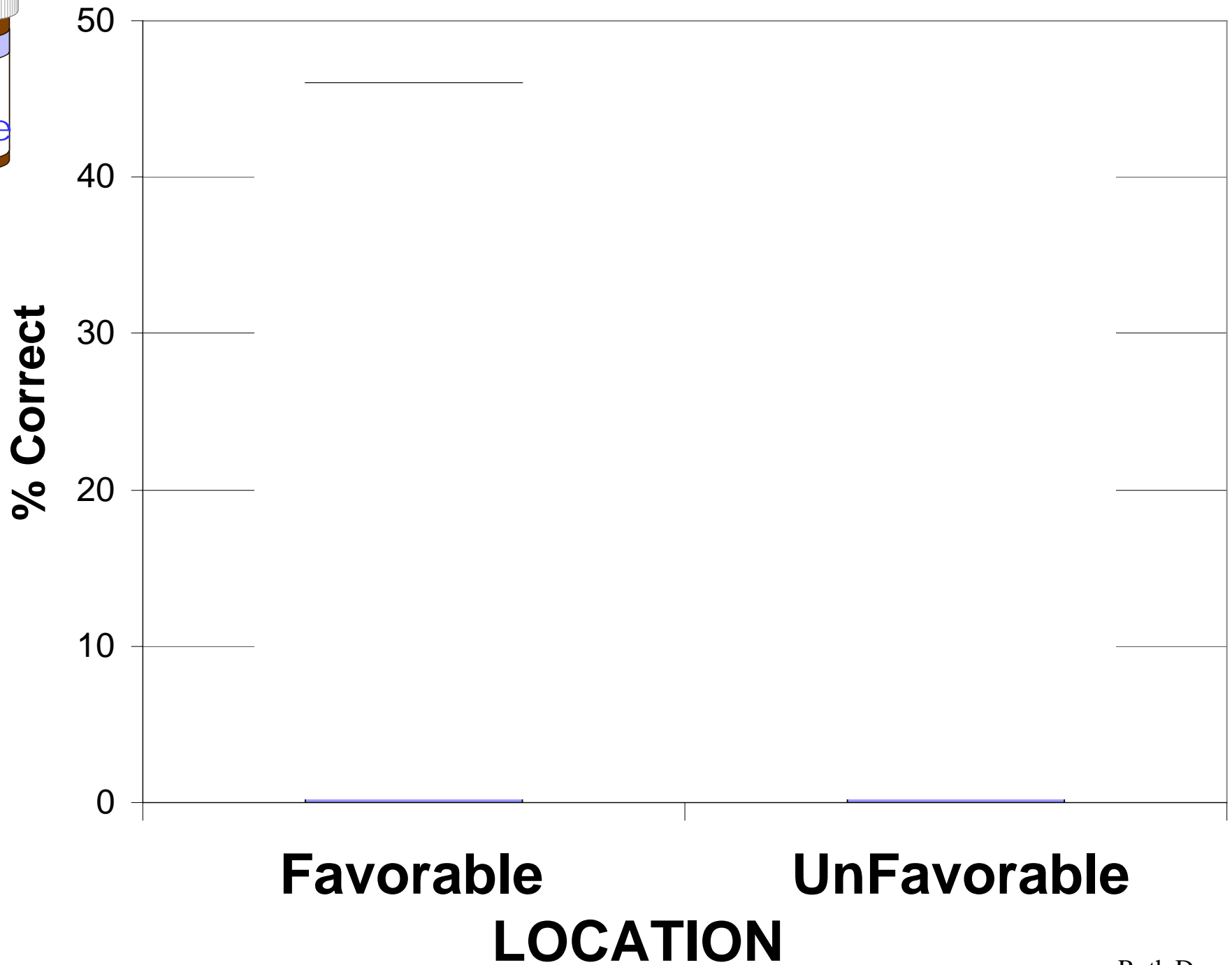
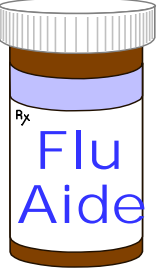
Favorable

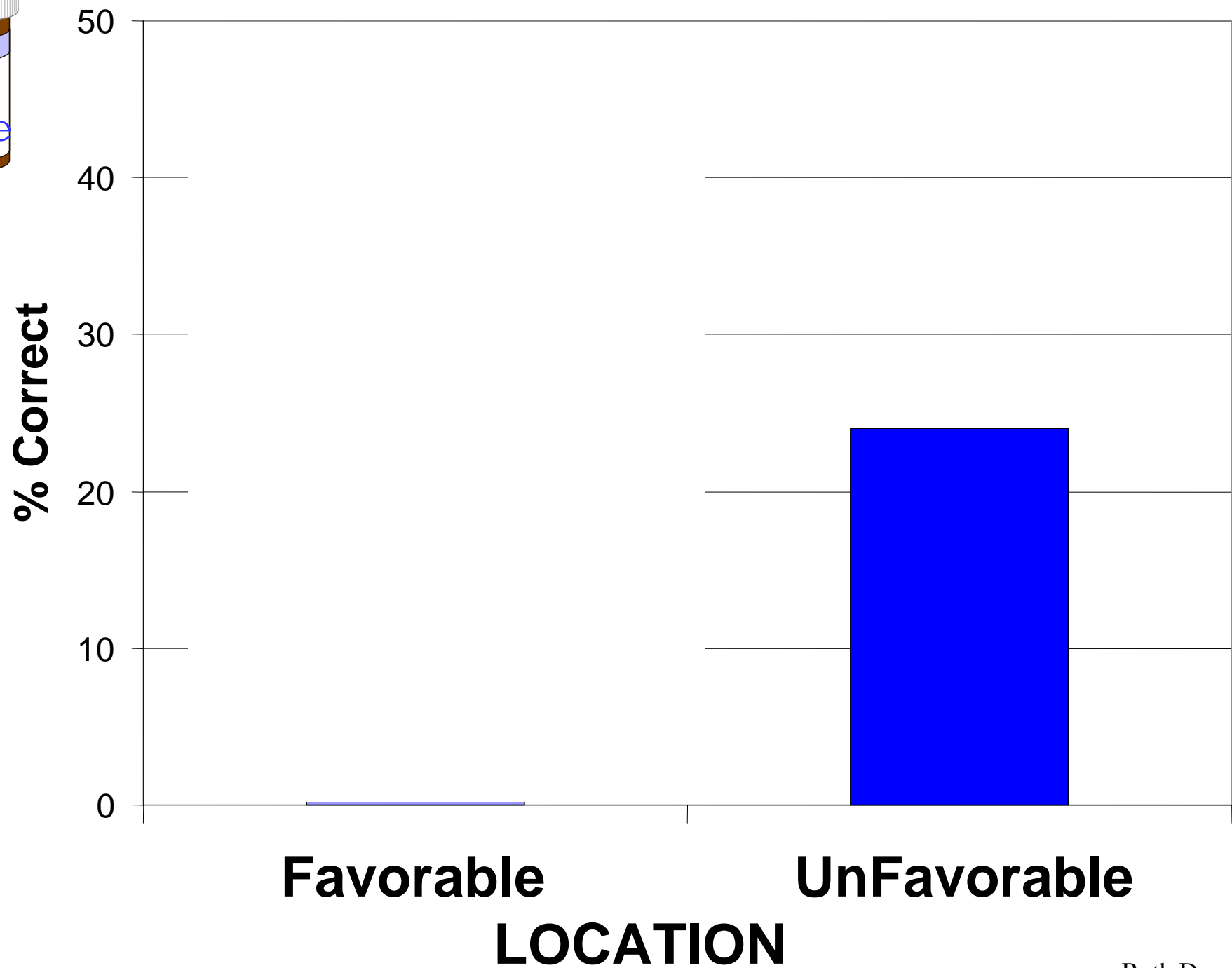
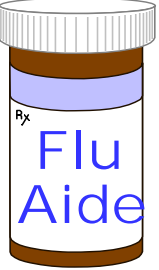
UnFavorable

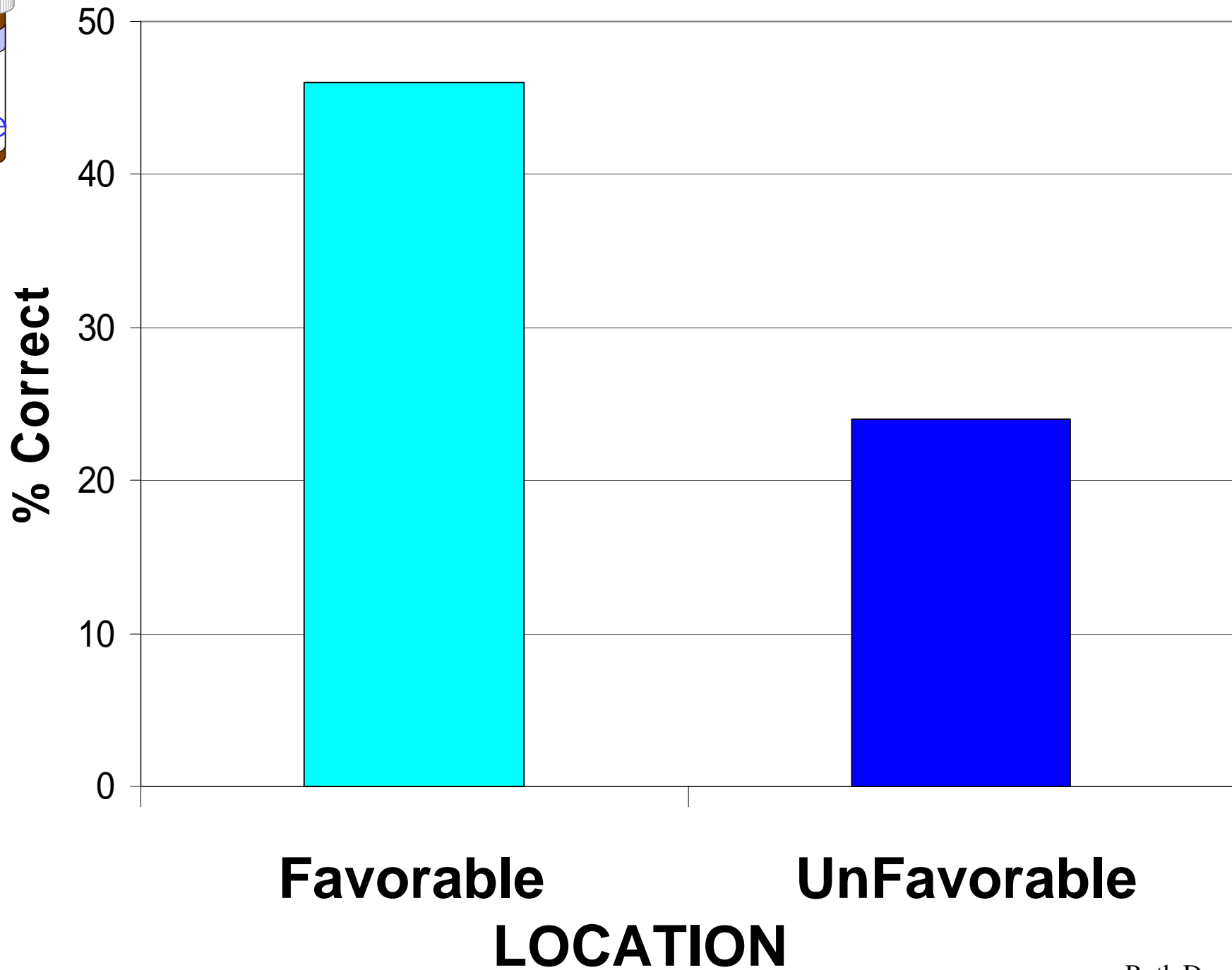
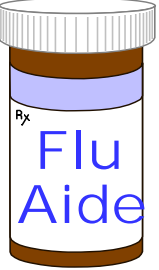
Same visual  
Same auditory

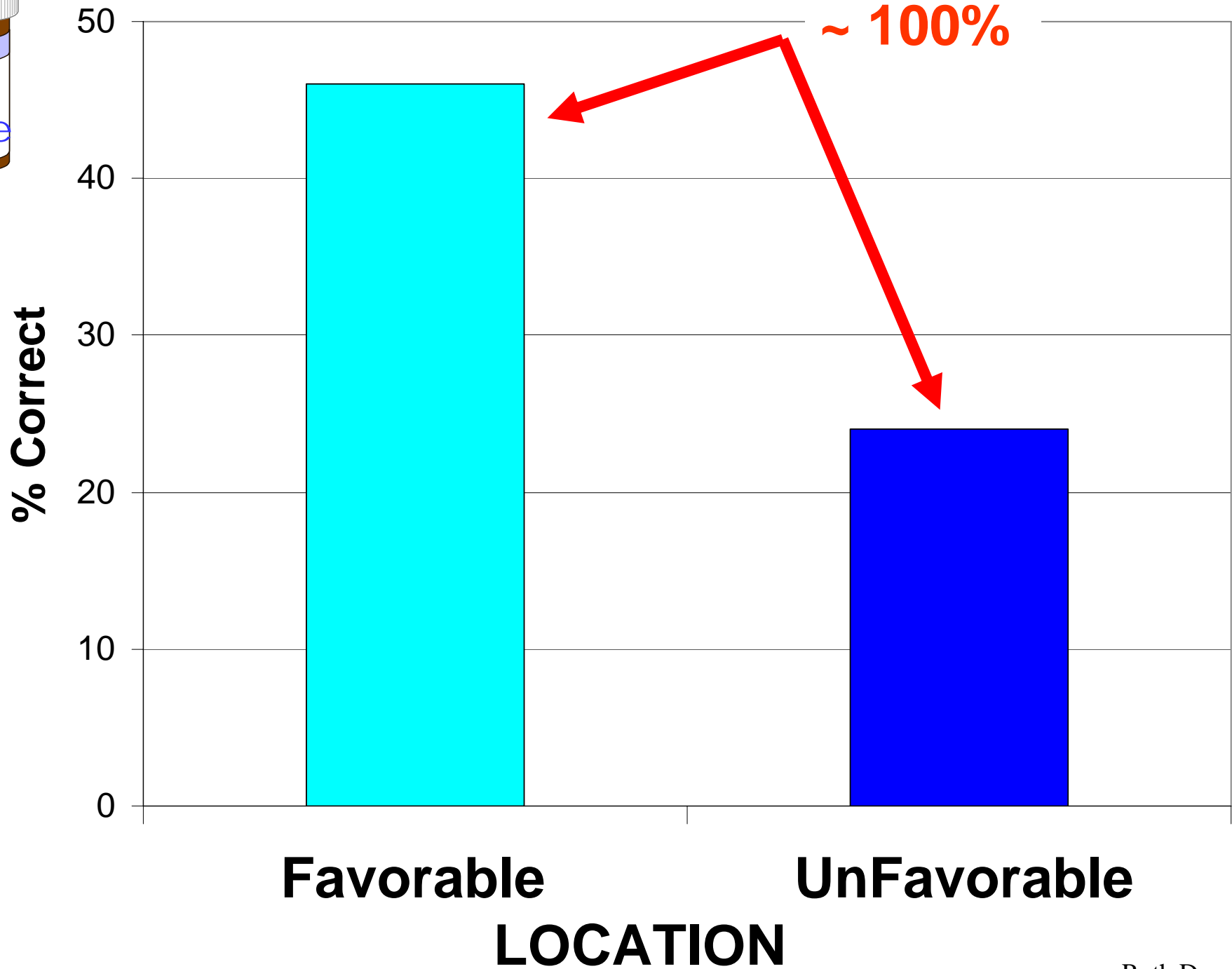
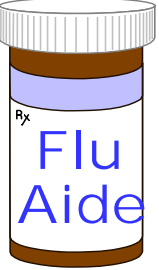
Differ only in location of side effects







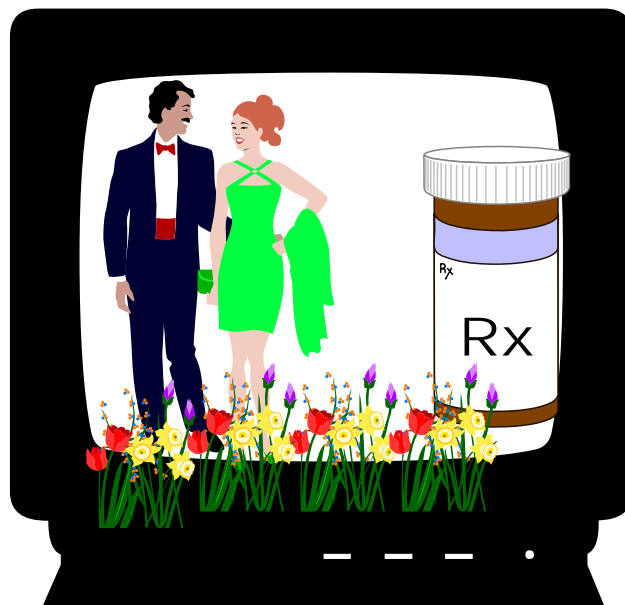




# READABILITY

# READABILITY

Rx TV Ads



# READABILITY

**Readability  $\neq$  Comprehensibility**

# READABILITY

**Readability  $\neq$  Comprehensibility**

However,

- easy to measure
- has predictive value
- therefore = quick “proxy” for  
comprehensibility



# READABILITY

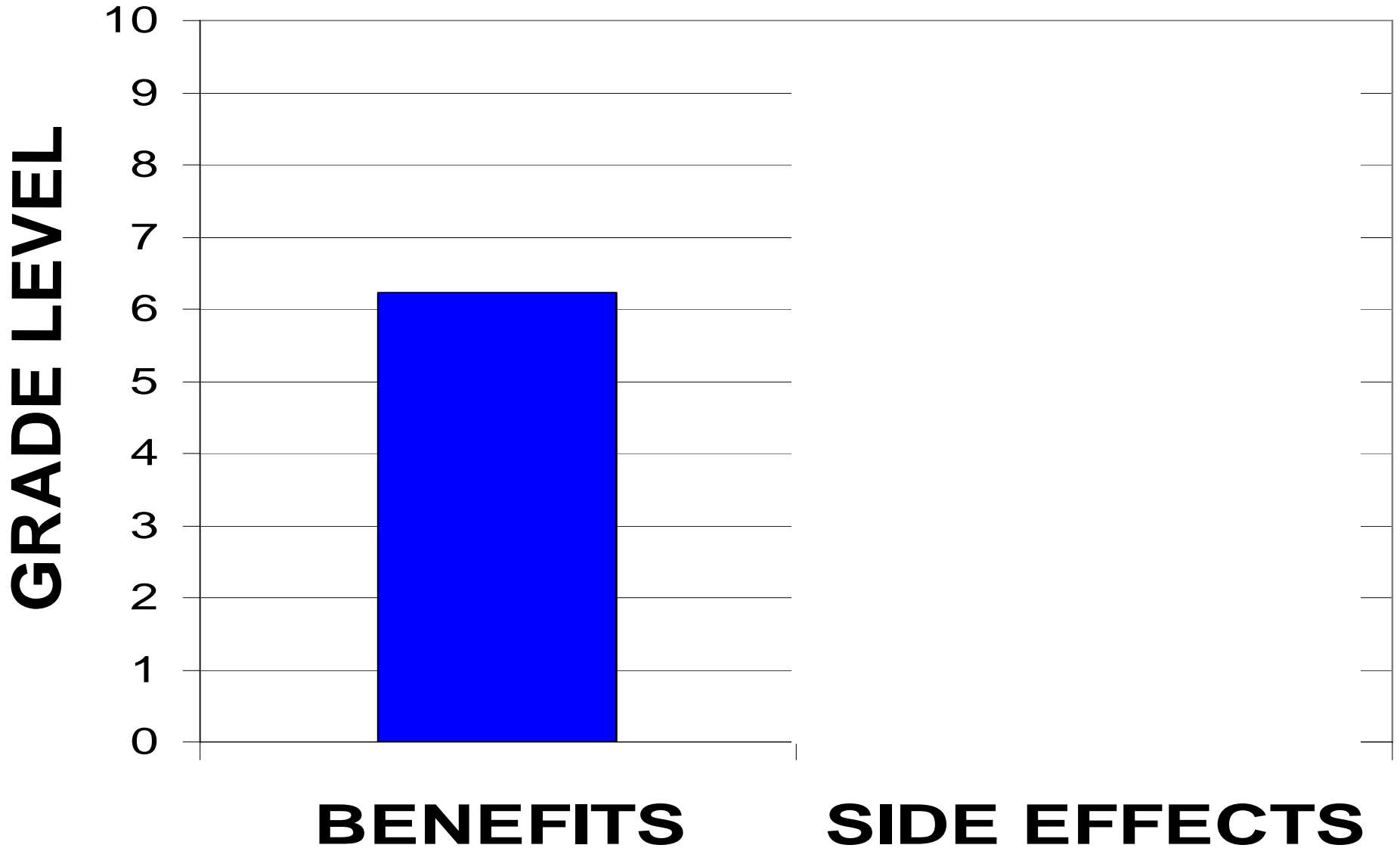
**GRADE LEVEL**

10  
9  
8  
7  
6  
5  
4  
3  
2  
1  
0

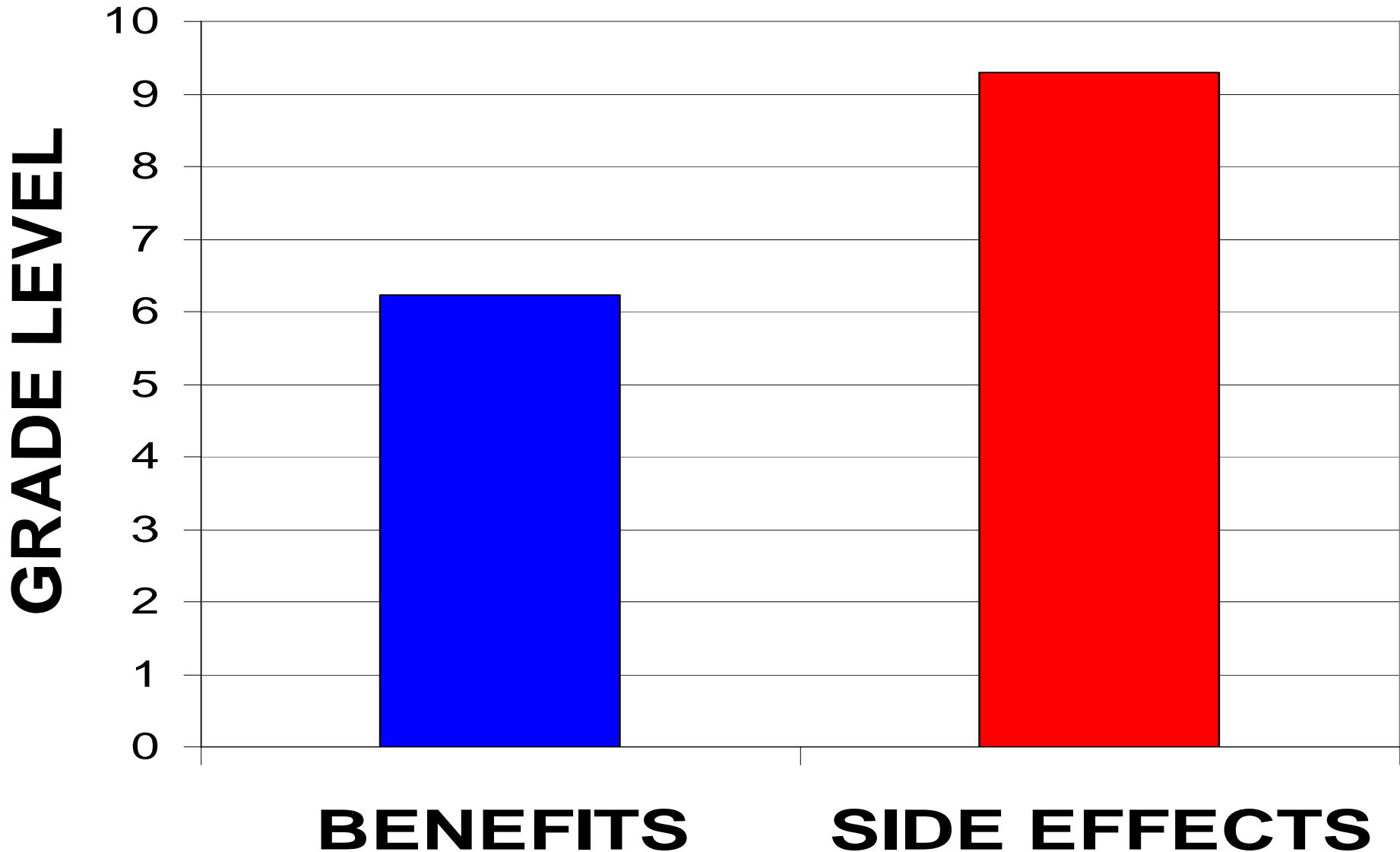
**BENEFITS**

**SIDE EFFECTS**

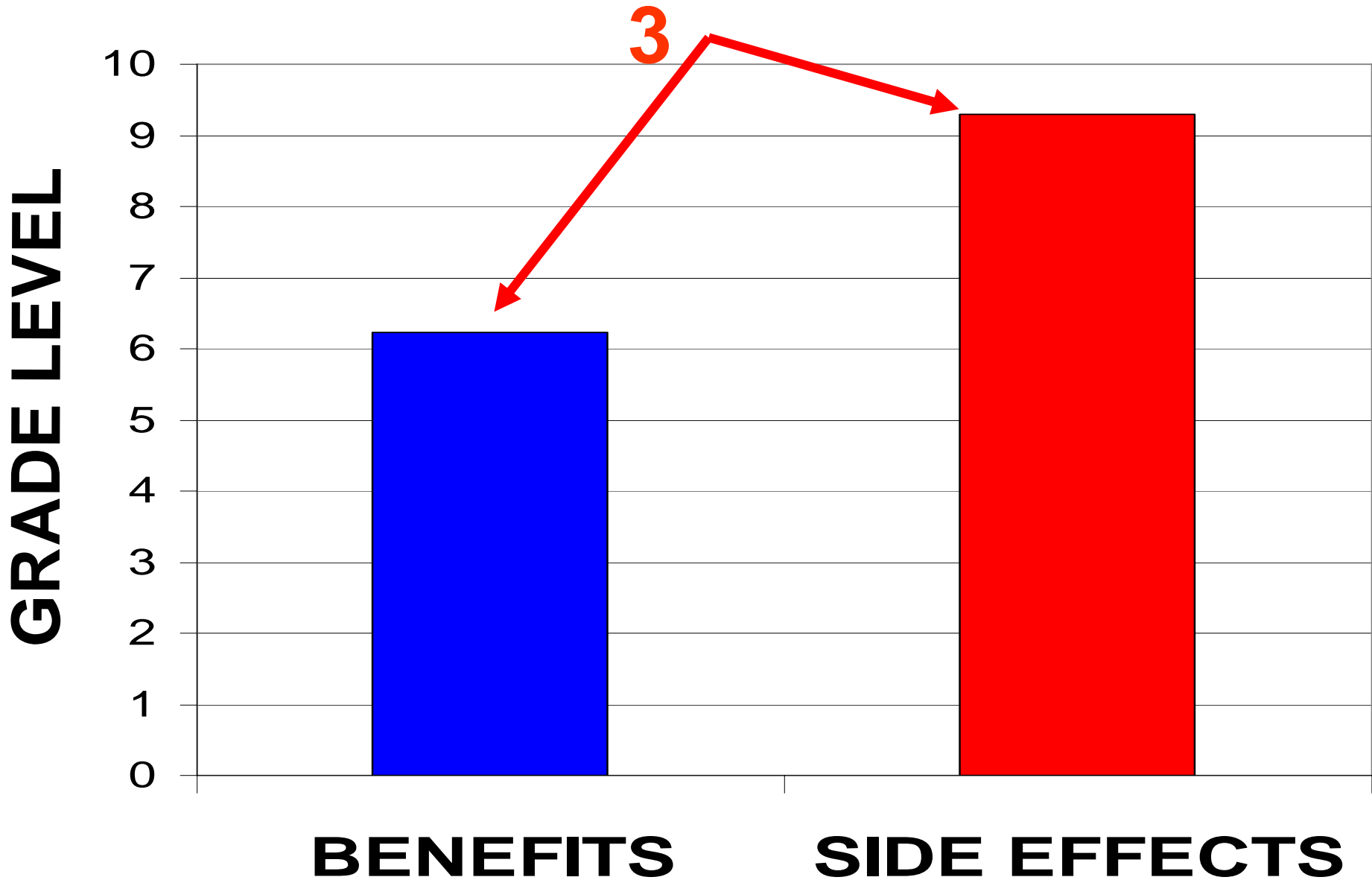
# READABILITY



# READABILITY



# READABILITY



# Experiments

time



See ad

(N = 1-3)

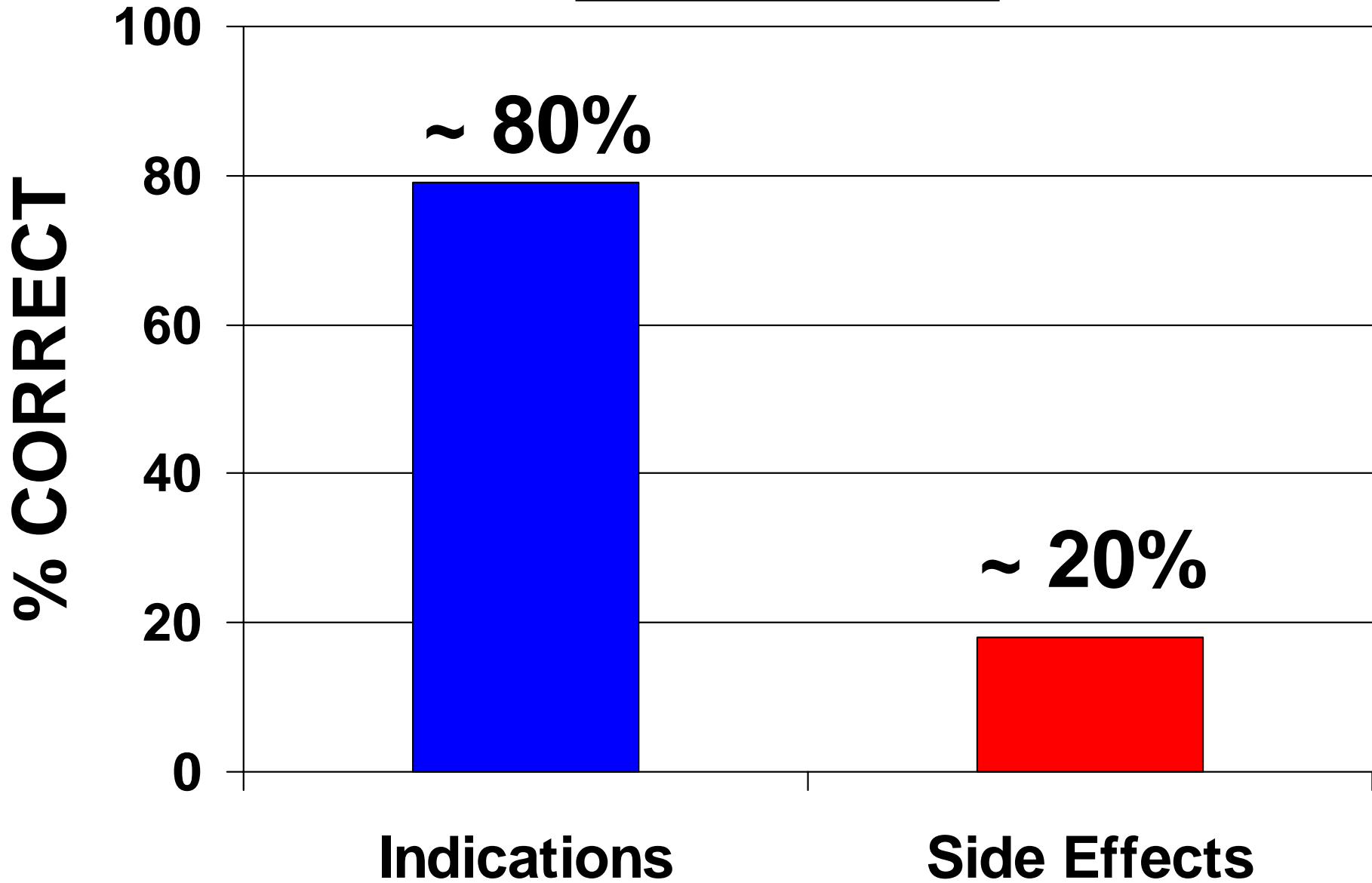
Test

Benefits

Risks

Other

# Overall



# Alternative Representations

# Alternative Representations

```
graph TD; A[Alternative Representations] --> B[SAME Information]; A --> C[DIFFERENT Displays]
```

**SAME**

**Information**

**DIFFERENT**

**Displays**



# Alternative Representations

# Side Effects

# Alternative Representations

## Linear Orderings



# Alternative Representations

Severity



# Alternative Representations

Severity



Frequency



# Alternative Representations

Severity



Frequency



Health State



# Alternative Representations

## Linear Orderings



# Alternative Representations

## Linear Orderings



### Mild

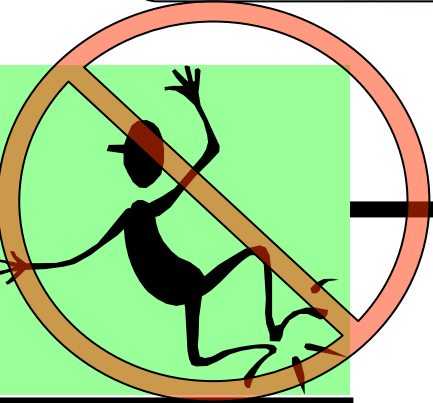
Diarrhea  
Drowsiness  
Nausea

### Life-Threatening

Chest pain  
Shortness of breath  
Slurred speech

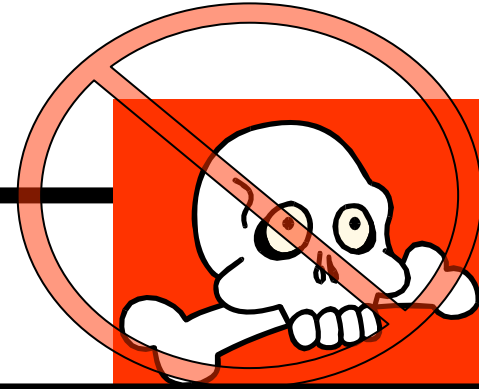
# Alternative Representations

## Linear Orderings



### Mild

Diarrhea  
Drowsiness  
Nausea



### Life-Threatening

Chest pain  
Shortness of breath  
Slurred speech



# Alternative Representations

## Linear Orderings



### Mild

Diarrhea  
Drowsiness  
Nausea

### Life-Threatening

Chest pain  
Shortness of breath  
Slurred speech

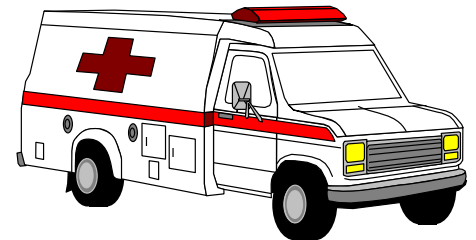
# Drug X



Diarrhea  
Drowsiness  
Nausea



Chest pain  
Shortness of breath  
Slurred speech



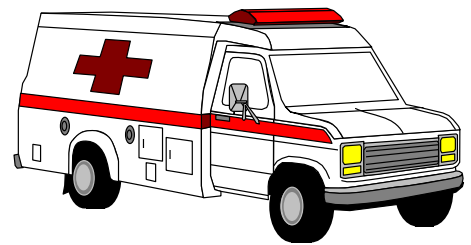
# Drug X



Diarrhea  
Drowsiness  
Nausea

Chest pain  
Shortness of breath  
Slurred speech

**Low Health Literacy**  
**Limited English**



# Alternative Representations

```
graph TD; A[Alternative Representations] --> B[SAME Information]; A --> C[DIFFERENT Displays]
```

**SAME**

**Information**

**DIFFERENT**

**Displays**

# PARAGRAPH

## Plain

Possible side effects include chest pain, slurred speech, seizure, anxiety, joint pain, weakness, dry mouth, headache, and nausea.

# PARAGRAPH

## Plain

Possible side effects include chest pain, slurred speech, seizure, anxiety, joint pain, weakness, dry mouth, headache, and nausea.

## Categorized

Possible dangerous side effects include chest pain, slurred speech, and seizure. Some are worrisome such as anxiety, joint pain, and weakness. Others are mild such as dry mouth, headache, and nausea.

# PARAGRAPH

## Plain

Possible side effects include chest pain, slurred speech, seizure, anxiety, joint pain, weakness, dry mouth, headache, and nausea.

## Categorized

Possible **dangerous** side effects include chest pain, slurred speech, and seizure. Some are **worrisome** such as anxiety, joint pain, and weakness. Others are **mild** such as dry mouth, headache, and nausea.

# LIST

## Plain

- chest pain
- slurred speech
- seizure
- anxiety
- joint pain
- weakness
- dry mouth
- headache
- nausea



# LIST

## Plain

- chest pain
- slurred speech
- seizure
- anxiety
- joint pain
- weakness
- dry mouth
- headache
- nausea

## Chunked +

### Dangerous

- chest pain
- slurred speech
- seizure

### Worrisome

- anxiety
- joint pain
- weakness

### Mild

- dry mouth
- headache
- nausea

# LINE

## Mild

## Dangerous

---

dry mouth  
headache  
nausea

anxiety  
joint pain  
weakness

chest pain  
slurred speech  
seizure

# LINE

**Mild**

**Dangerous**

---

dry mouth  
headache  
nausea

anxiety  
joint pain  
weakness

chest pain  
slurred speech  
seizure

# ARROW

---

dry mouth  
headache  
nausea

anxiety  
joint pain  
weakness

chest pain  
slurred speech  
seizure

# LINE

**Mild**

**Dangerous**

dry mouth  
headache  
nausea

anxiety  
joint pain  
weakness

chest pain  
slurred speech  
seizure

# ARROW

dry mouth  
headache  
nausea

anxiety  
joint pain  
weakness

chest pain  
slurred speech  
seizure

# ARROW +



dry mouth  
headache  
nausea

anxiety  
joint pain  
weakness

**chest pain  
slurred speech  
seizure**



# MATRIX

	<u>Dangerous</u>	<u>Worrisome</u>	<u>Mild</u>
<b>More Common</b>			dry mouth headache nausea
<b>Less Common</b>		anxiety joint pain weakness	
<b>Rare</b>	chest pain slurred speech seizure		

# MATRIX

	<u>Dangerous</u>	<u>Worrisome</u>	<u>Mild</u>
<b>More Common</b>		anxiety	dry mouth headache
<b>Less Common</b>		joint pain	nausea
<b>Rare</b>	chest pain slurred speech seizure	weakness	

# MATRIX

	<u>Dangerous</u>	<u>Mild</u>
<b>Common</b>		dry mouth
<b>Rare</b>	chest pain slurred speech seizure	headache nausea anxiety

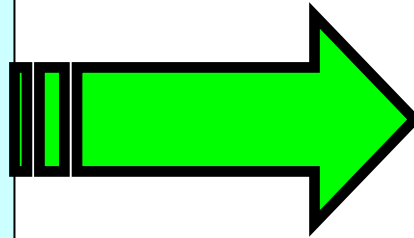
# Alternative Representations of Same Information

- Text**
- List**
- Linear Ordering**
- Matrix**
- Lots More (.....)**



# Alternative Representations of Same Information

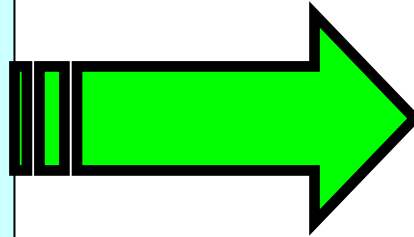
--Text  
--List  
--Linear Ordering  
--Matrix  
--Lots More (.....)



**Cognitive  
Consequences**

# Alternative Representations of Same Information

--Text  
--List  
--Linear Ordering  
--Matrix  
--Lots More (.....)



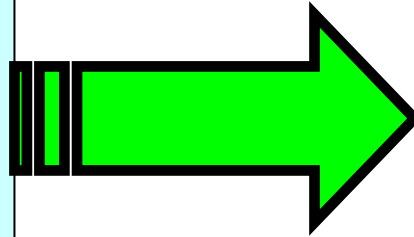
## Cognitive Consequences

### Effects on

--Perception  
--Attention  
--Comprehension  
--Memory  
--Problem Solving

# Alternative Representations of Same Information

--Text  
--List  
--Linear Ordering  
--Matrix  
--Lots More (.....)

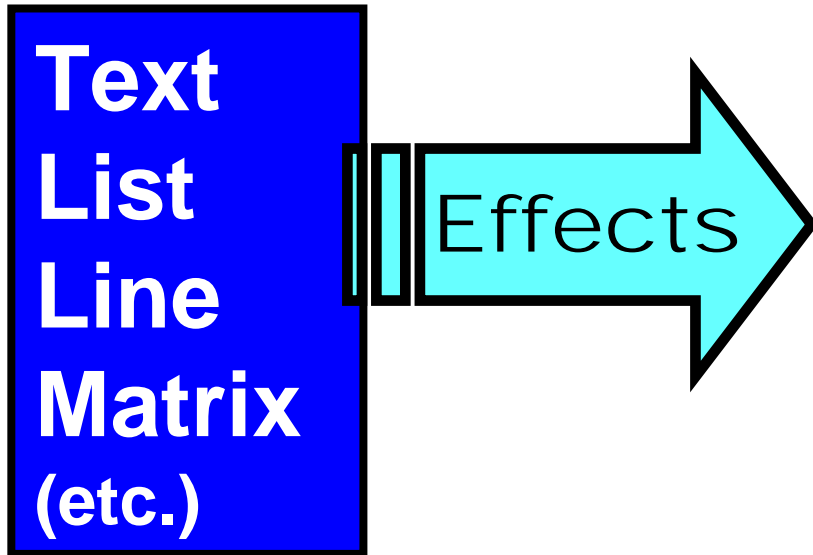


## Cognitive Consequences

### Effects on

--Perception  
--Attention  
--Comprehension  
--Memory  
--Problem Solving  
↓  
--Behavior & Health

# Alternative Representations

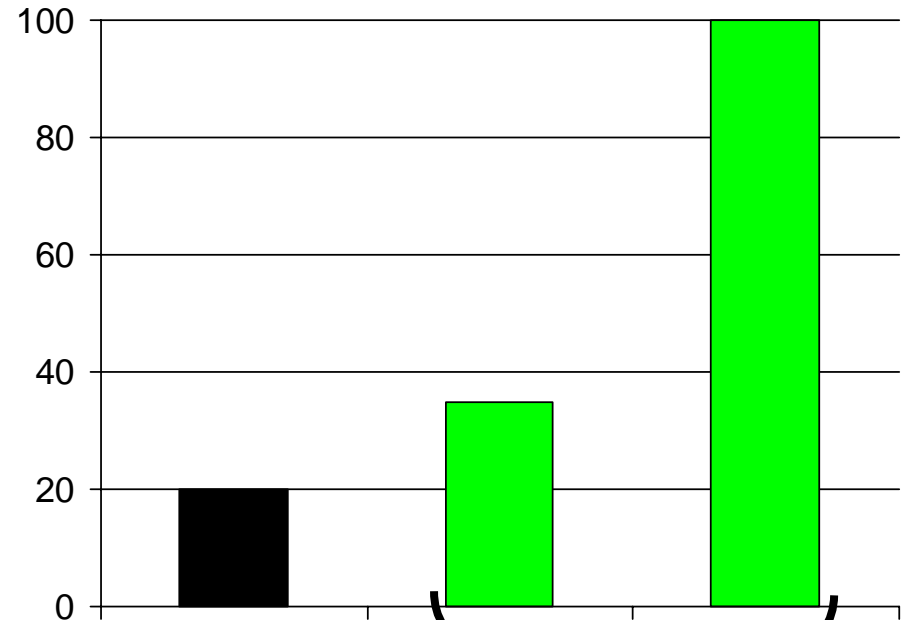


# Alternative Representations

Text  
List  
Line  
Matrix  
(etc.)

Effects

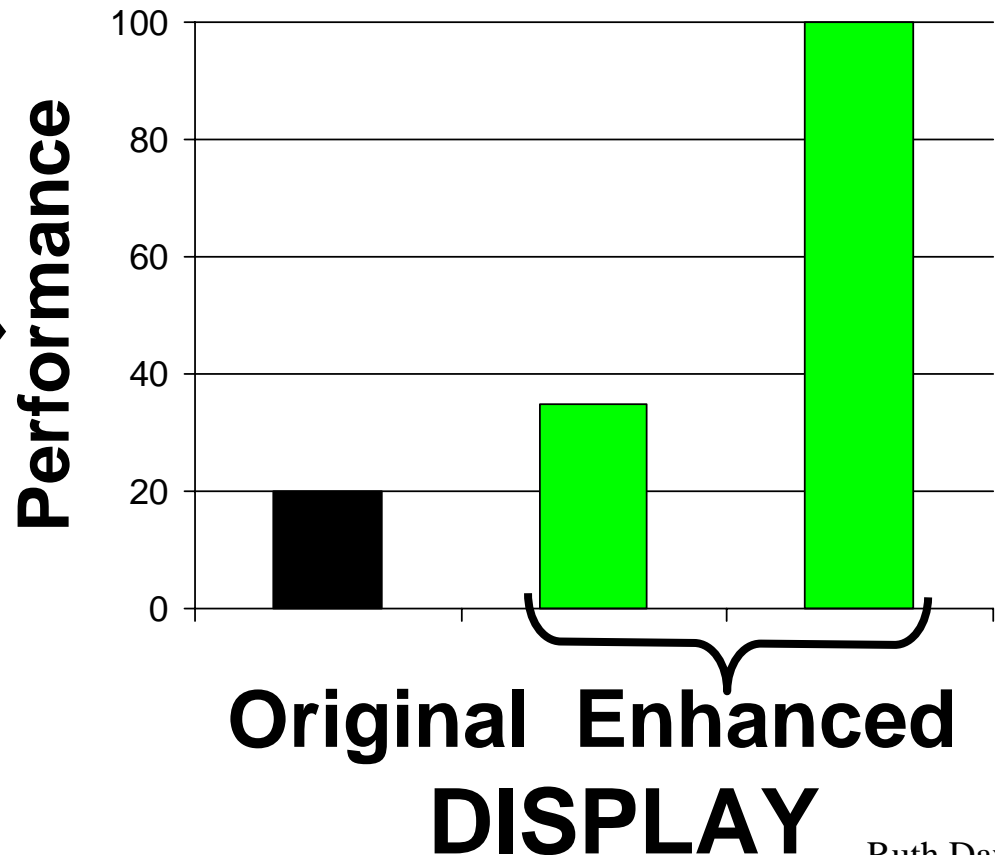
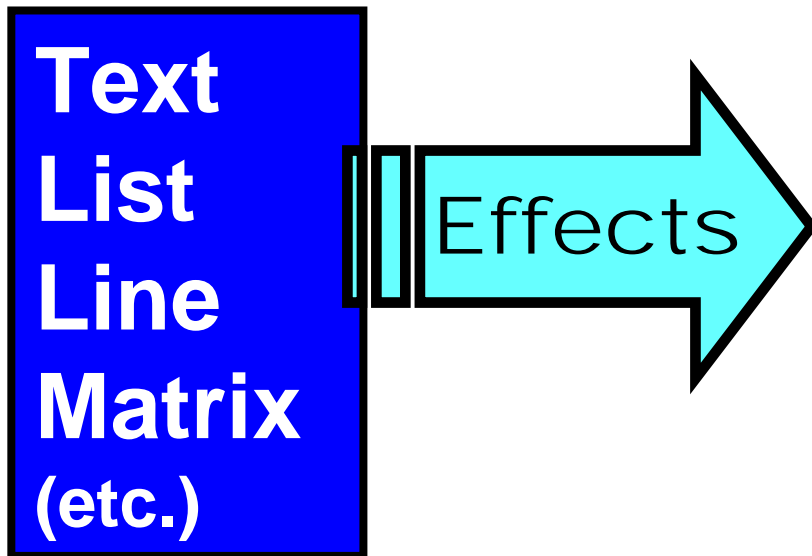
Performance



Original Enhanced  
**DISPLAY**

# Alternative Representations

Think anew!



# Alternative Representations

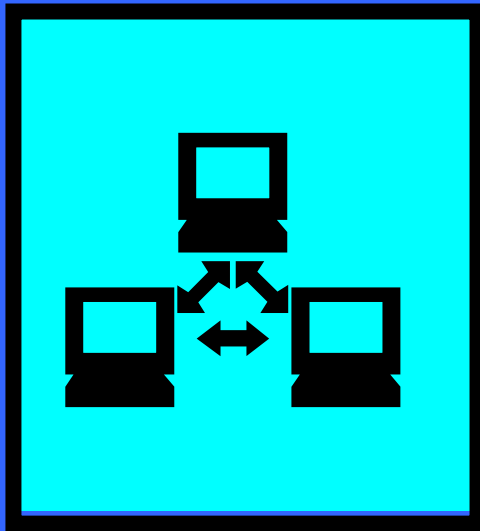
# Experiment

# Alternative Representations

Print Ad



Product Website



Possible side effects include:



# Experiments

time



Study  
Side Effects

Test

**Original Rep**

**Enhanced Rep.**



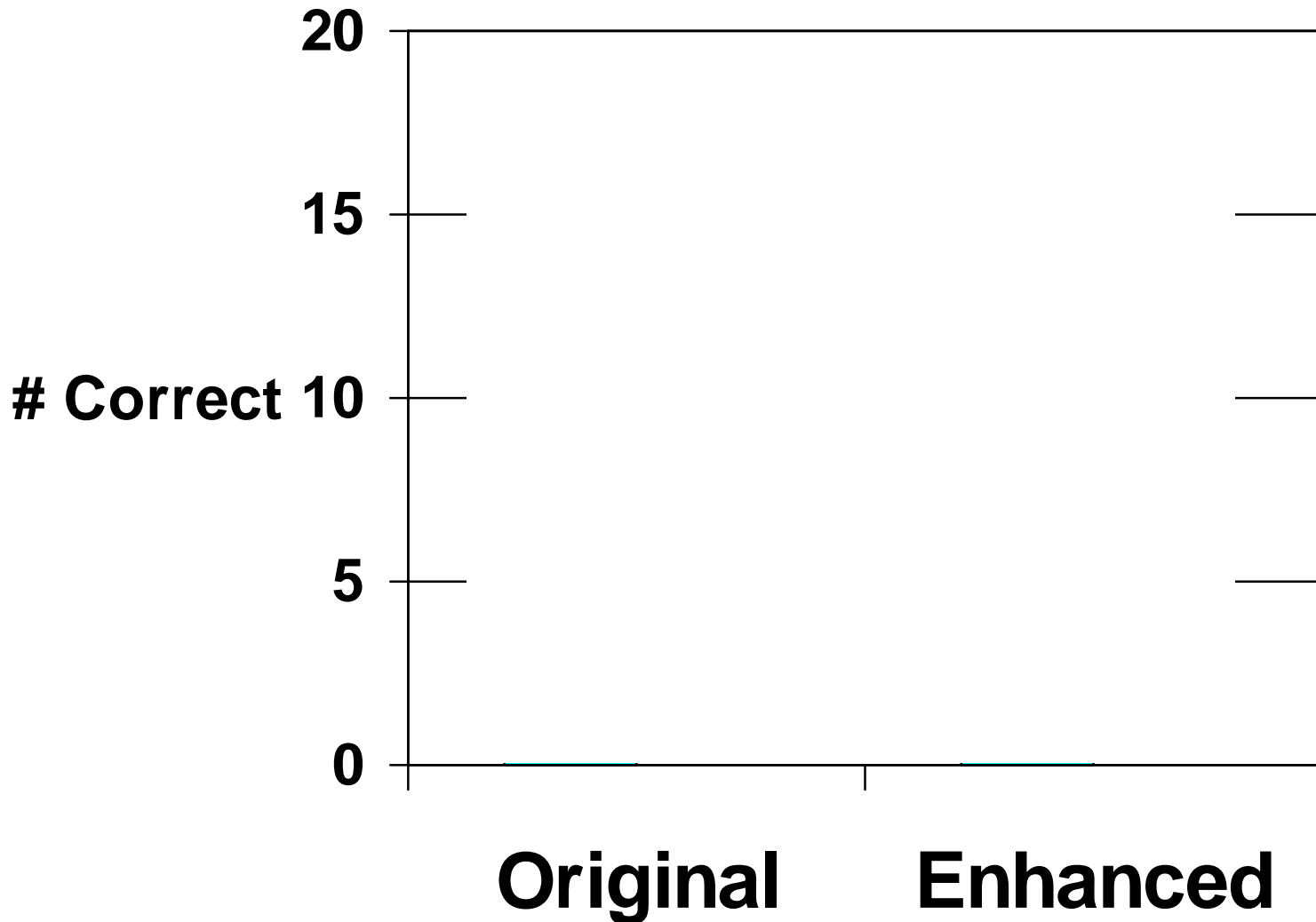
Multiple  
cognitive  
tasks

## One Task

*“What are the possible side effects?”*

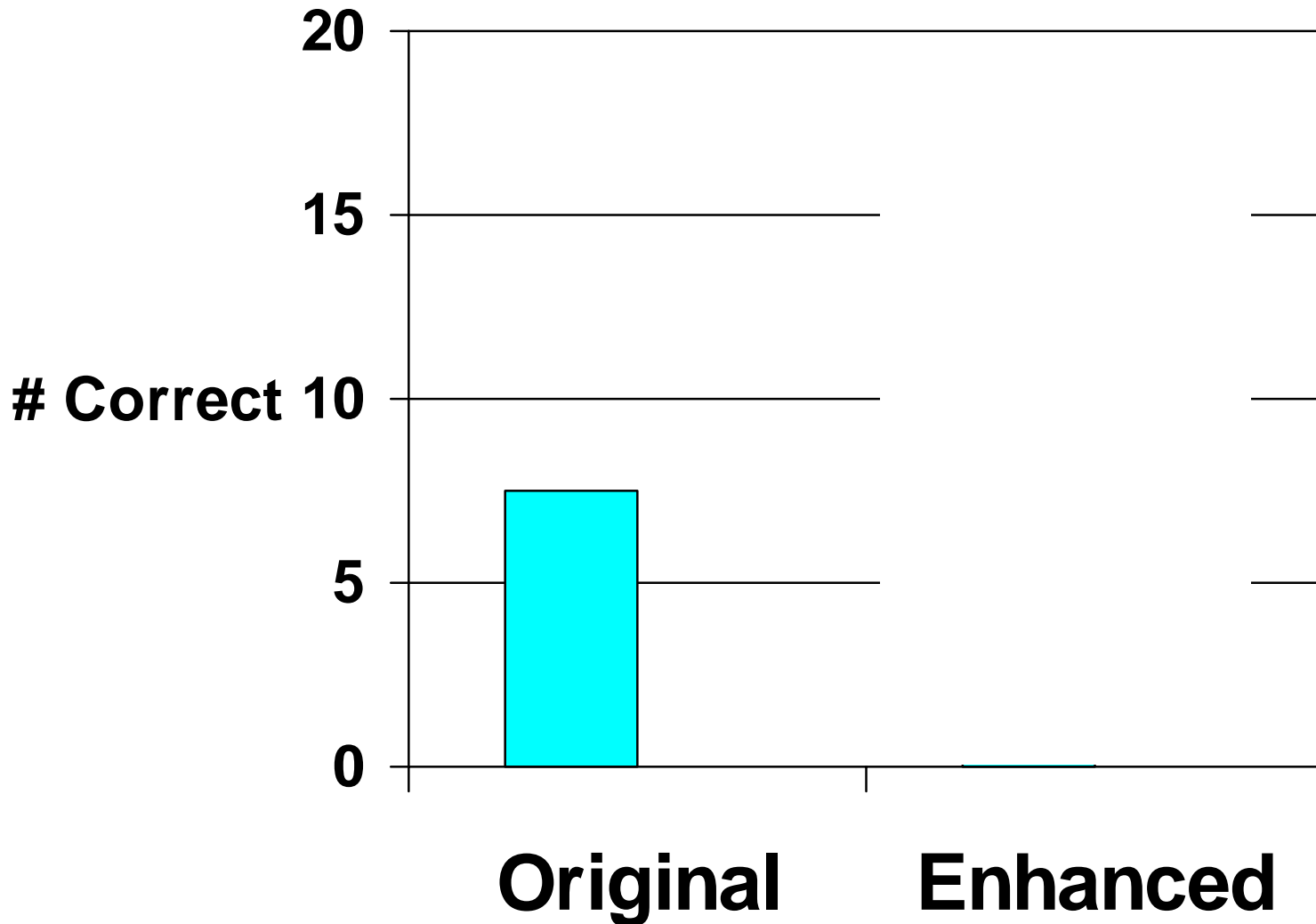
# One Task

*“What are the possible side effects?”*



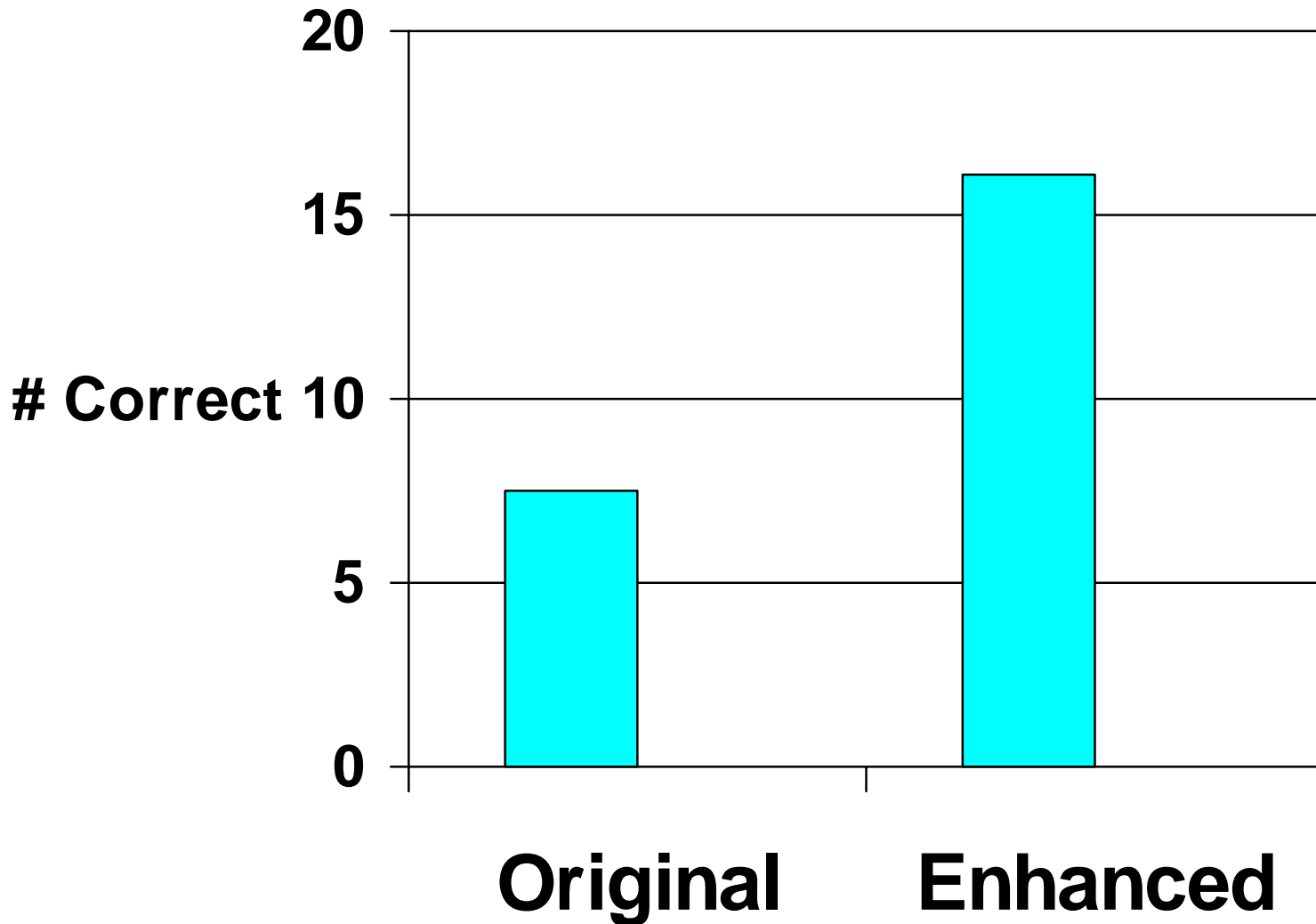
# One Task

*“What are the possible side effects?”*



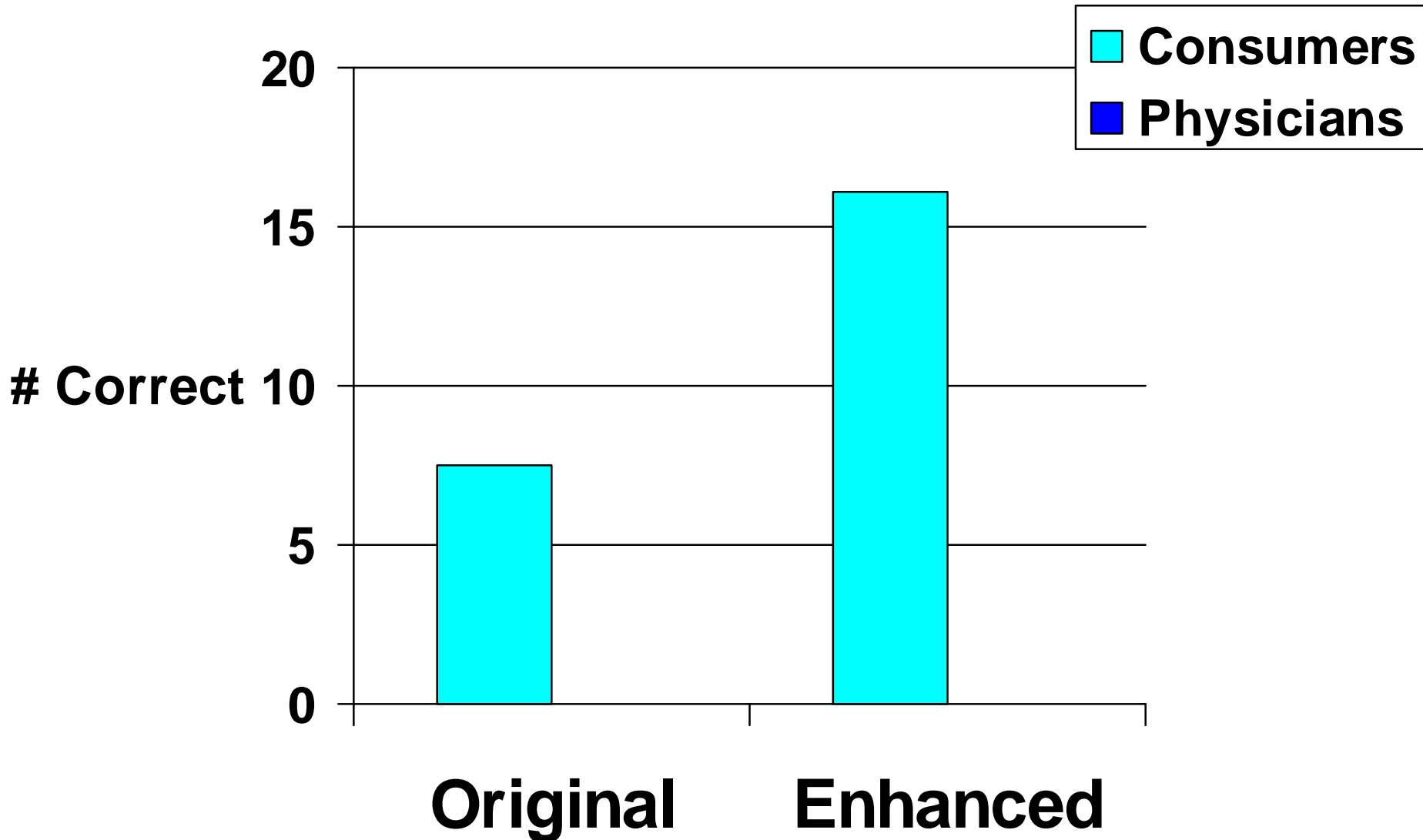
# One Task

*“What are the possible side effects?”*



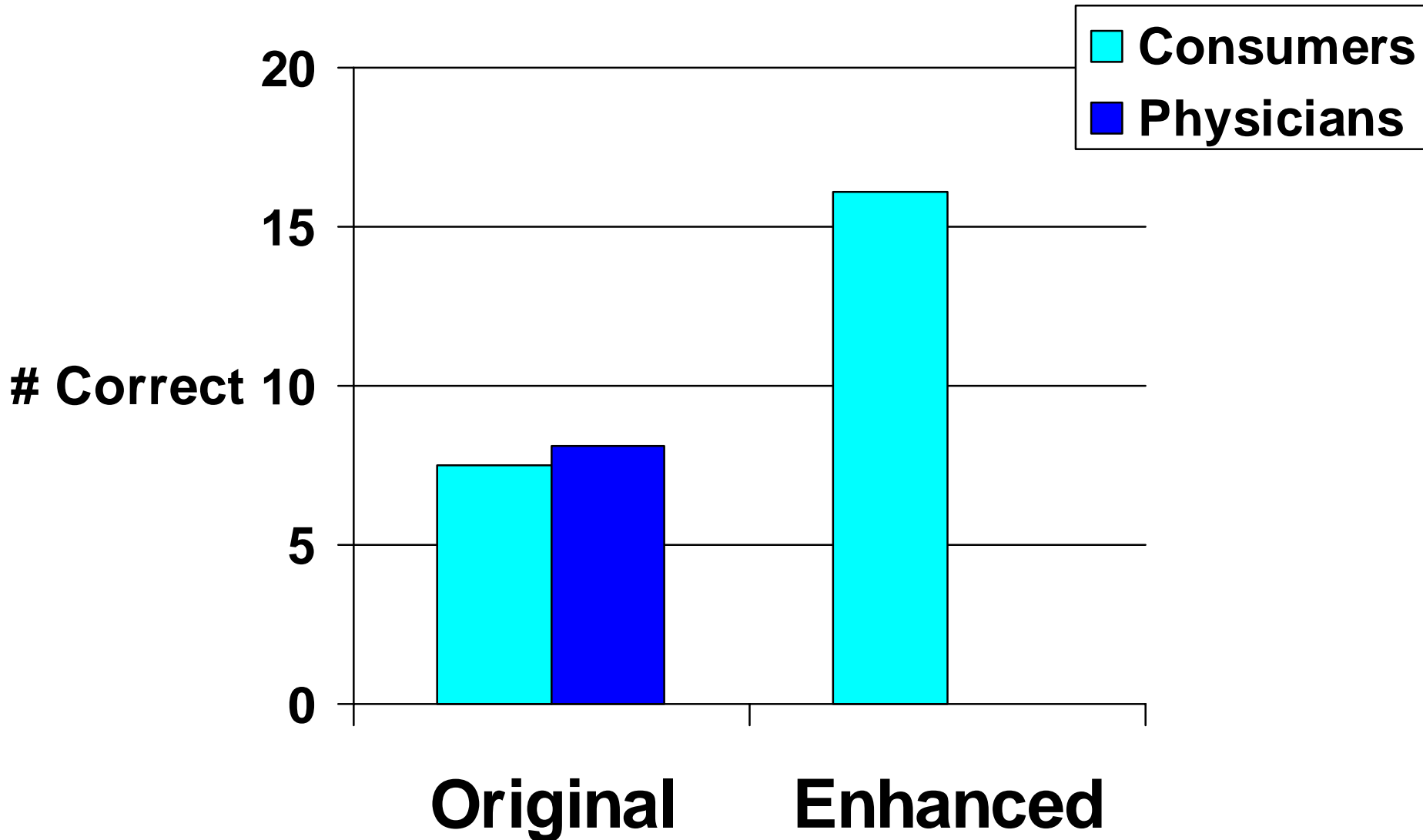
# One Task

*“What are the possible side effects?”*



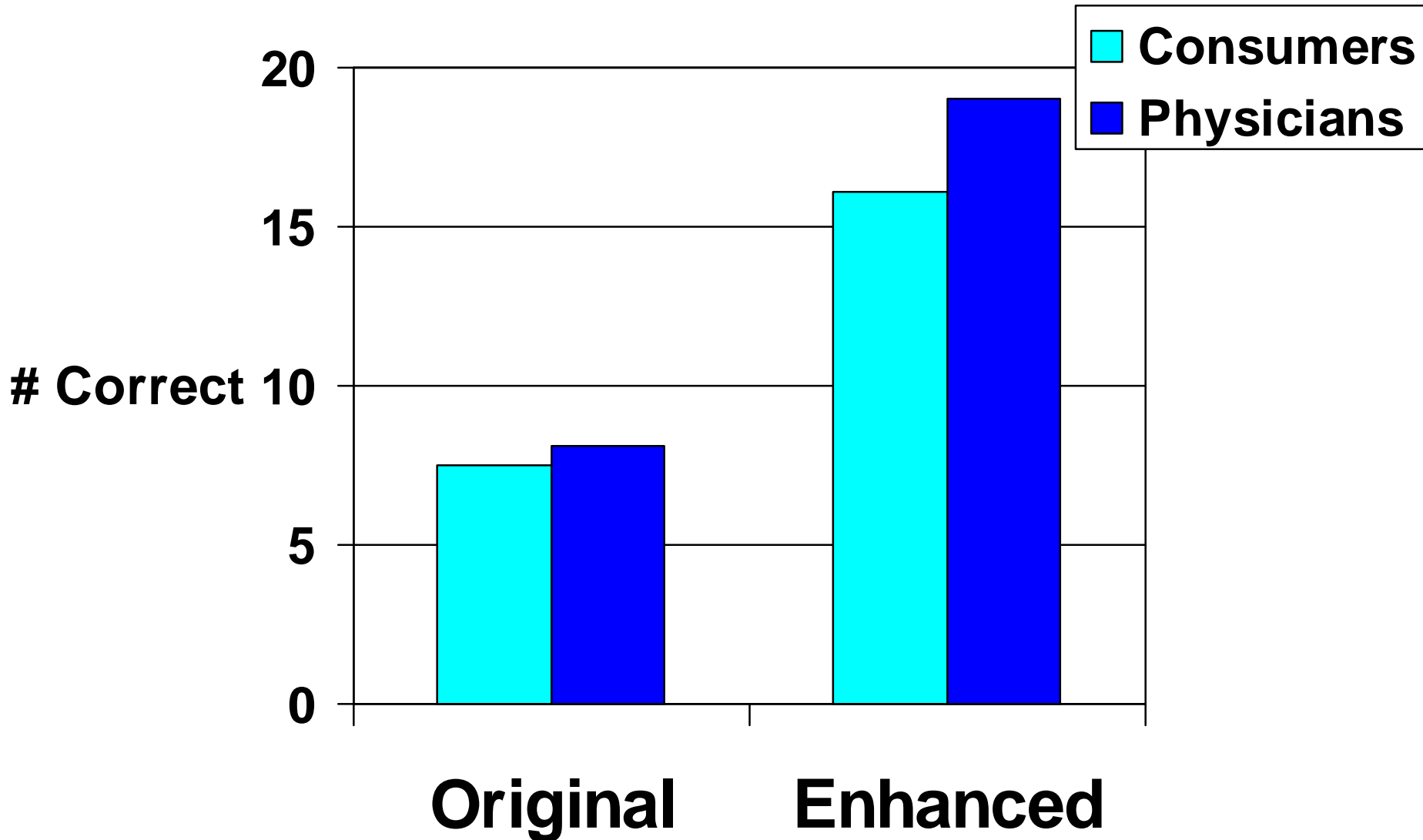
# One Task

*“What are the possible side effects?”*



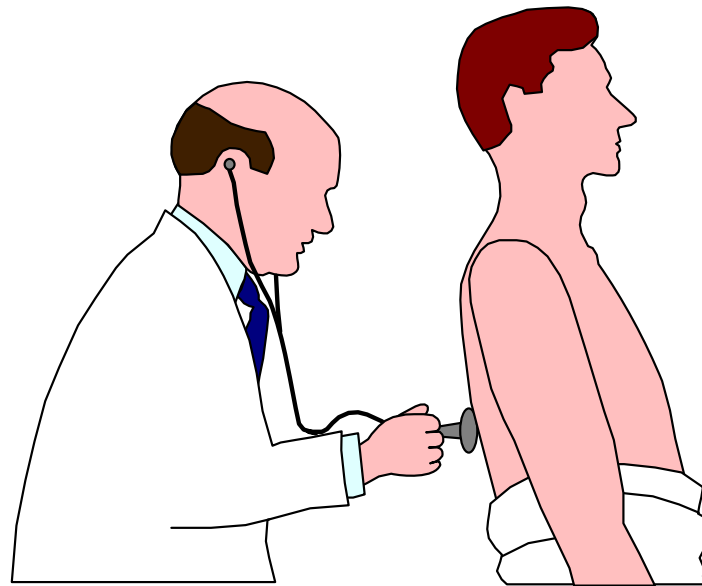
# One Task

*“What are the possible side effects?”*



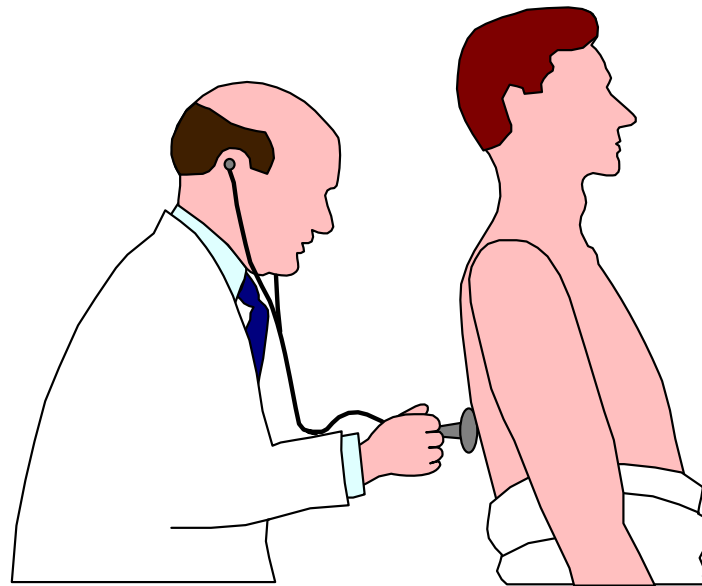


# Physicians & Patients



Much knowledge  
Much expertise

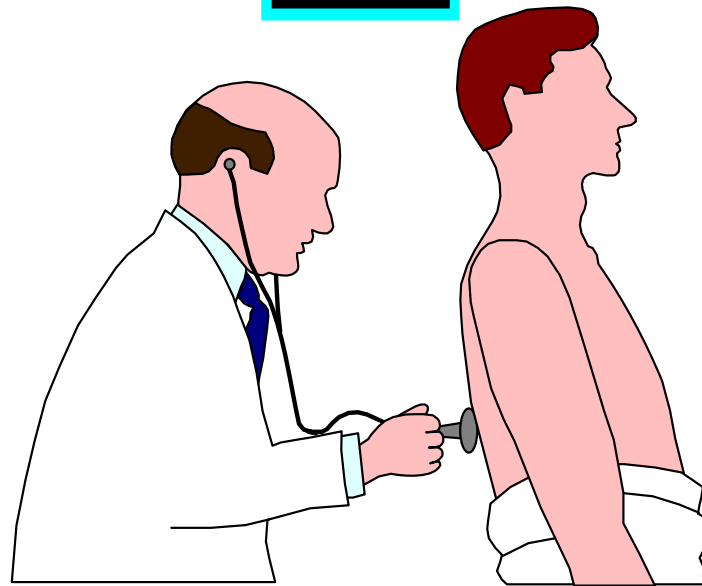
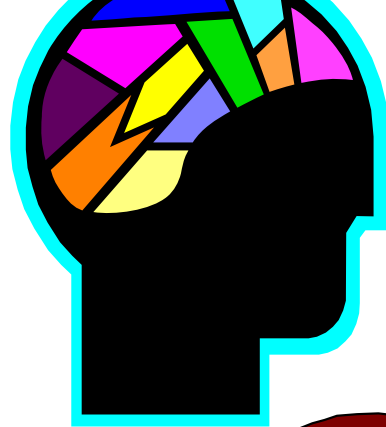
# Physicians & Patients



Much knowledge  
Much expertise

Little knowledge  
Little expertise

# Same



Much knowledge  
Much expertise

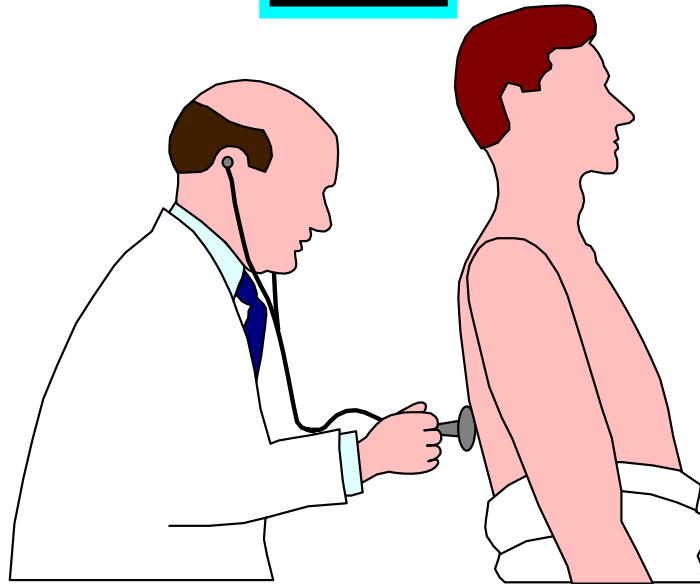
Little knowledge  
Little expertise

# Cognitive Processes

Attention

Comprehension

Memory



Much knowledge  
Much expertise

Little knowledge  
Little expertise

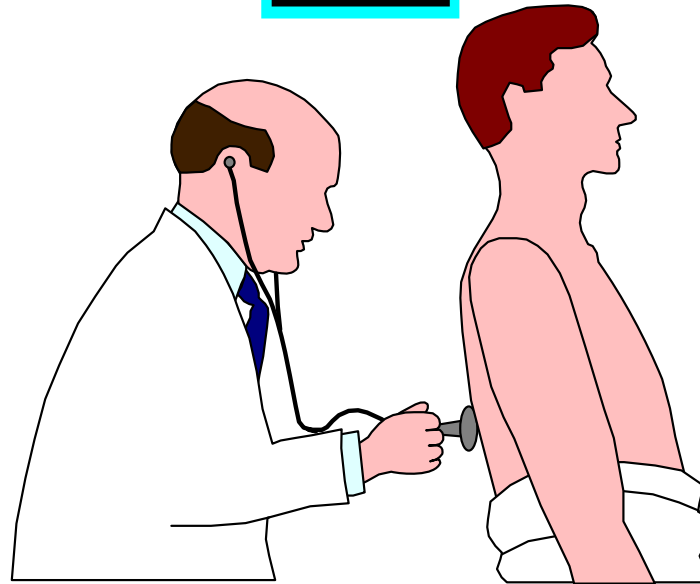
# Cognitive Processes

Attention  
Comprehension  
Memory



# Cognitive Factors

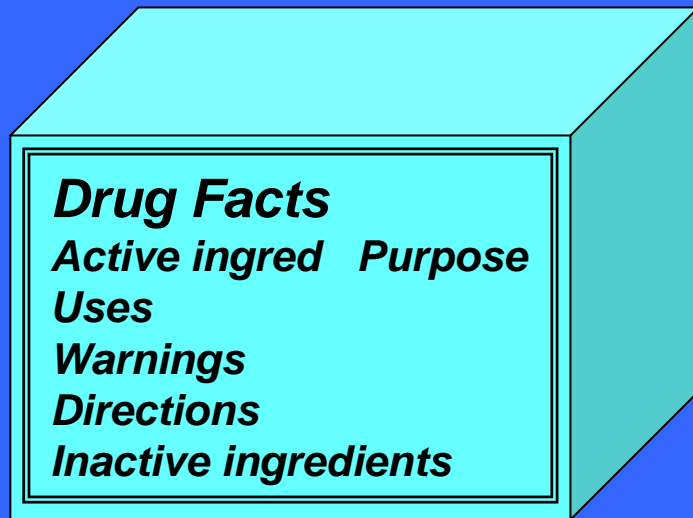
Chunking  
Location  
Readability



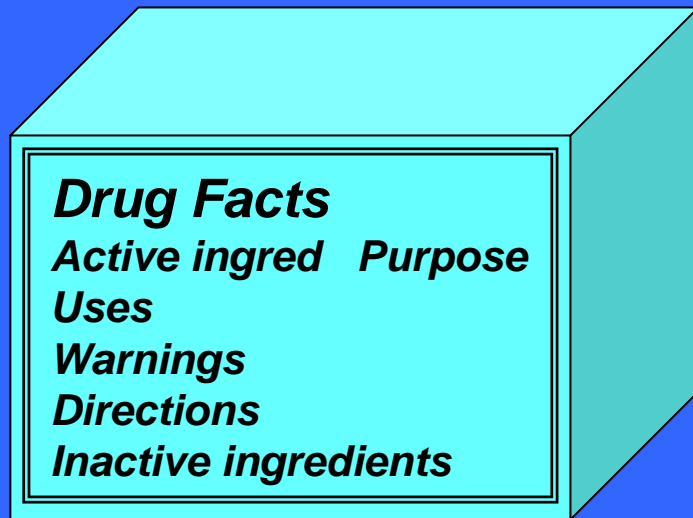
Much knowledge  
Much expertise

Little knowledge  
Little expertise

**OTC**



**OTC**



**Drug Facts**

**Package  
Insert**

**Package**

# Ibuprofen (2002)



## ***Drug Facts***

---

### ***Active Ingredient (in each tablet)***

Ibuprofen 200 mg

### ***Purpose***

Pain reliever/fever reducer

---

### ***Uses***

- temporarily relieves minor aches and pains due to:
  - minor pain of arthritis ■ headache ■ backache ■ menstrual cramps
  - the common cold ■ muscular aches ■ toothache
  - temporarily reduces fever
- 

### ***Warnings***

**Allergy alert:** Ibuprofen may cause a severe allergic reaction which may include:

- hives ■ facial swelling ■ asthma (wheezing) ■ shock

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.

---

**Do not use** if you have ever had an allergic reaction to any other pain reliever/fever reducer.

---

### **Ask a doctor before use if you have**

- problems or serious side effects from taking pain relievers or fever reducers
  - stomach problems that last or come back, such as heartburn, upset stomach, or pain
  - ulcers
  - bleeding problems
  - high blood pressure, heart or kidney disease, are taking a diuretic, or are over 65 years of age
- 

### **Ask a doctor or pharmacist before use if you are**

- under a doctor's care for any serious condition
  - taking any other product that contains ibuprofen, or any other pain reliever/fever reducer
  - taking a prescription drug for anticoagulation (blood thinning)
  - taking any other drug
- 

**When using this product** take with food or milk if stomach upset occurs

---

**Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- stomach pain or upset gets worse or lasts
- redness or swelling is present in the painful area
- any new symptoms appear

**If pregnant or breast feeding**, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.** In case of overdoses, get medical help or contact a Poison Control Center right away.

***Directions***

- **do not take more than directed**
- adults and children 12 years and over
  - 1 tablet every 4 to 6 hours while symptoms persist
  - if pain or fever does not respond to 1 tablet, 3 tablets may be used
  - do not exceed 6 tablets in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

***Other information***

- **each tablet contains:** ibuprofen
- store at 20 -25° C (68-77° F)
- avoid high humidity and excessive heat above 40°C (104° F)
- do not use if seal on bottle has been opened

***Inactive ingredients*** acetylated monoglyceride, beeswax and/or carnauba wax, croscarmellose sodium, iron oxides, lecithin, methylparaben, microcrystalline cellulose, pharmaceutical glaze, povidone, propylparaben, silicon dioxide, simethicone, sodium benzoate, sodium lauryl sulfate, starch, stearic acid, sucrose, titanium dioxide

# Drug Facts

time



Read label

Test

Uses

Warnings

Other

# Drug Facts

time



Read label

Test

Uses

Warnings

Other

**Good**

**Poor**

# Original

## *Warnings*

**Allergy alert:** Ibuprofen may cause a severe allergic reaction which may include:

■ hives ■ facial swelling ■ asthma (wheezing) ■ shock

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.

# Original

## *Warnings*

**Allergy alert:** Ibuprofen may cause a severe allergic reaction which may include:

■ hives ■ facial swelling ■ asthma (wheezing) ■ shock

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.

# Alternative Representations

## Original

### *Warnings*

**Allergy alert:** Ibuprofen may cause a severe allergic reaction which may include:

■ hives ■ facial swelling ■ asthma (wheezing) ■ shock

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.

# Alternative Representations

Original

## *Warnings*

**Allergy alert:** Ibuprofen may cause a severe allergic reaction which may include:

■ hives ■ facial swelling ■ asthma (wheezing) ■ shock

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.

NewLine  
&  
Coded

## *Warnings*

**Allergy alert:** Ibuprofen may cause a severe allergic reaction which may include:

■ hives ■ facial swelling ■ asthma (wheezing) ■ shock

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers.

**Stomach bleeding:** Ibuprofen may cause stomach bleeding.



# Alternative Representations

Original

## *Warnings*

**Allergy alert:** Ibuprofen may cause a severe allergic reaction which may include:

■ hives ■ facial swelling ■ asthma (wheezing) ■ shock

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NewLine  
&  
Coded

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Chunked  
&  
Coded

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Chunked  
&  
Coded

## WARNINGS

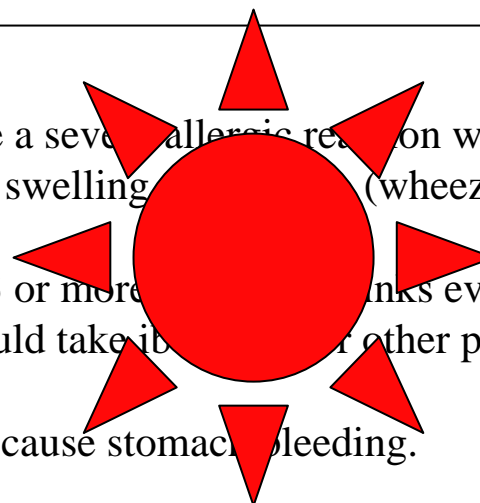
**Allergy alert:** Ibuprofen may cause a severe allergic reaction which may include:

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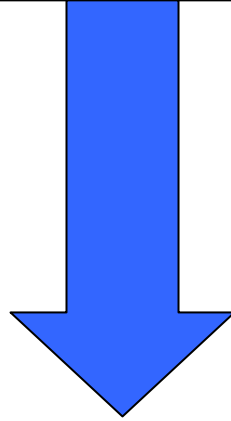
**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor

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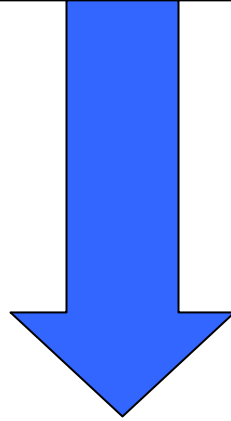


**Ibuprofen (2002)**



**Stomach bleeding**

**Acetaminophen + (2006)**



**Liver damage**

# Acetaminophen PM (2006)

#1

## Drug Facts

Active ingredients (in each 15 ml tablespoon)	Purpose
--------------------------------------------------	---------

Acetaminophen 500 mg . . .	Pain reliever/fever reducer
Dextromethorphan HBr 15 mg . . . .	Cough suppressant
Doxylamine succinate 6.25 mg . . . . .	Antihistamine

**Uses** temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- minor aches and pains
- runny nose and sneezing
- headache
- fever

## Warnings

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage. ▼

# Acetaminophen PM (2006)

#1

## **Drug Facts**

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# Acetaminophen PM (2006)

#1

#2

**Drug Facts**

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Acetaminophen 500 mg . . .	Pain reliever/fever reducer
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- runny nose and sneezing
- headache
- fever

**Warnings**

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.



**Drug Facts**

Active ingredients (in each 30mL = 2 Tablespoonfuls)	Purpose
Acetaminophen 1000 mg.....	Pain reliever
Diphenhydramine HCl 50mg...	Nighttime sleep aid

**Uses**

- temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

**Warnings**

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. →

# Acetaminophen PM (2006)

#1

#2



**Drug Facts**

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**Uses**

- temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

**Warnings**

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers.

**Drug Facts (continued)**

Acetaminophen may cause liver damage.

**Do not use**

- with any other product containing diphenhydramine, even one used on skin
- with any other product containing acetaminophen
- in children under 12 years of age

**Ask a doctor before use if you have**

- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- glaucoma

**Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers**



# Generality of Results

# Generality of Results

**People**

**Information  
Source**

**Cognitive  
Task**

Patients

NonPatients

Physicians

Other HCPs

Demographics

--age

--education

--literacy

--etc.

# Generality of Results

## People

Patients

NonPatients

Physicians

Other HCPs

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## Information Source

OTC label

OTC package

Package insert

Professional Label

CMI

Medication Guides

Print Ads

TV Ads

## Cognitive Task

# Generality of Results

## People

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--etc.

## Information Source

OTC label

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Package insert

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TV Ads

## Cognitive Task

Attention

Search

Recall

Recognition

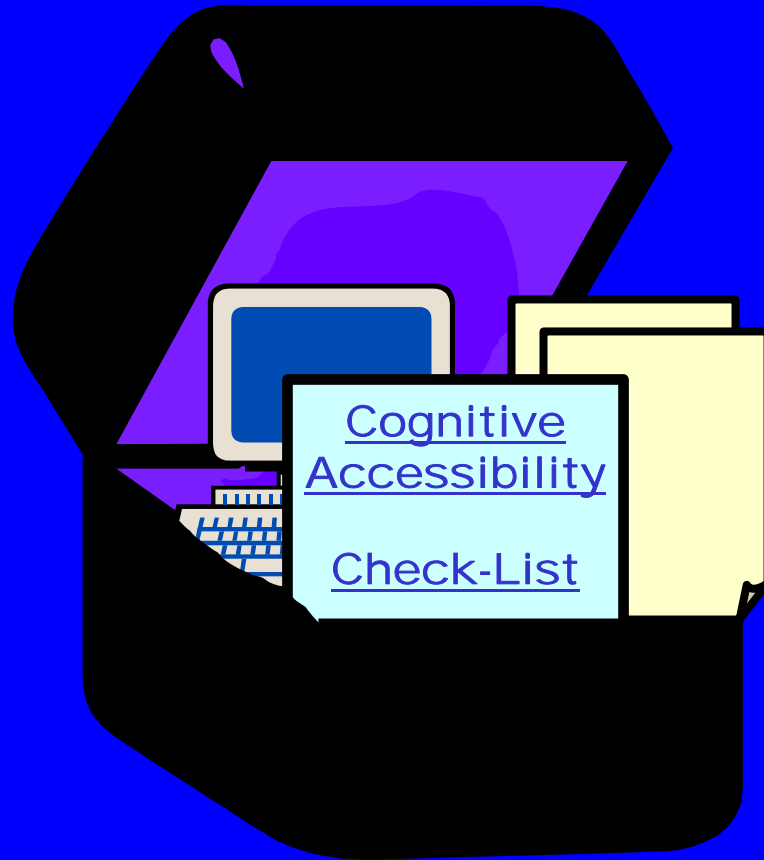
Definition

Comprehension

Problem Solving

Decision Making

# Drug Information Toolkit



# Cognitive Accessibility Check-List

Uses   Warnings   ....

**Chunking**

**Coding**

**Readability**

**Location**

**Format**

**[etc]**

# Cognitive Accessibility Check-List

Uses   Warnings   ....

Chunking	<input type="checkbox"/>	<input type="checkbox"/>
Coding	<input type="checkbox"/>	<input type="checkbox"/>
Readability	<input type="checkbox"/>	<input type="checkbox"/>
Location	<input type="checkbox"/>	<input type="checkbox"/>
Format	<input type="checkbox"/>	<input type="checkbox"/>

[etc]

+  
**Combinations**

# **FORMAT SELECTION**



# FORMAT SELECTION

**CONTENT**

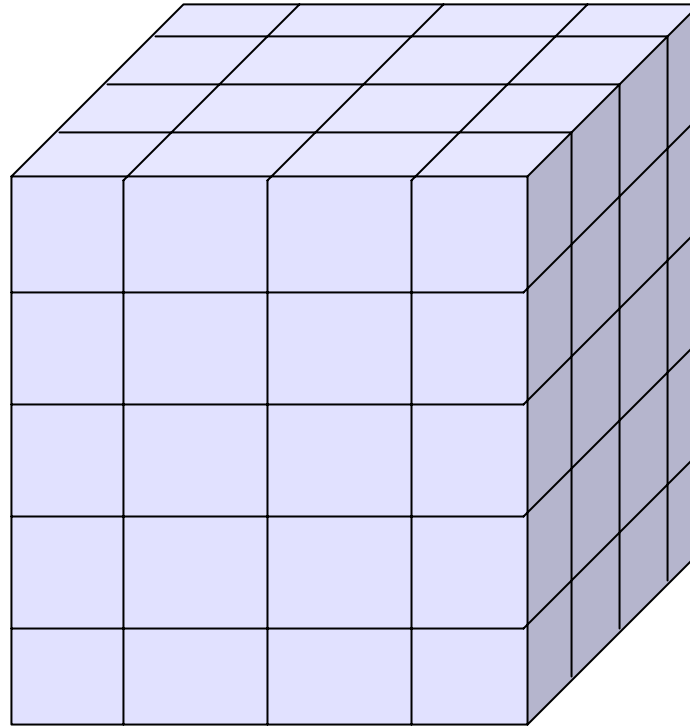
Purposes

Uses

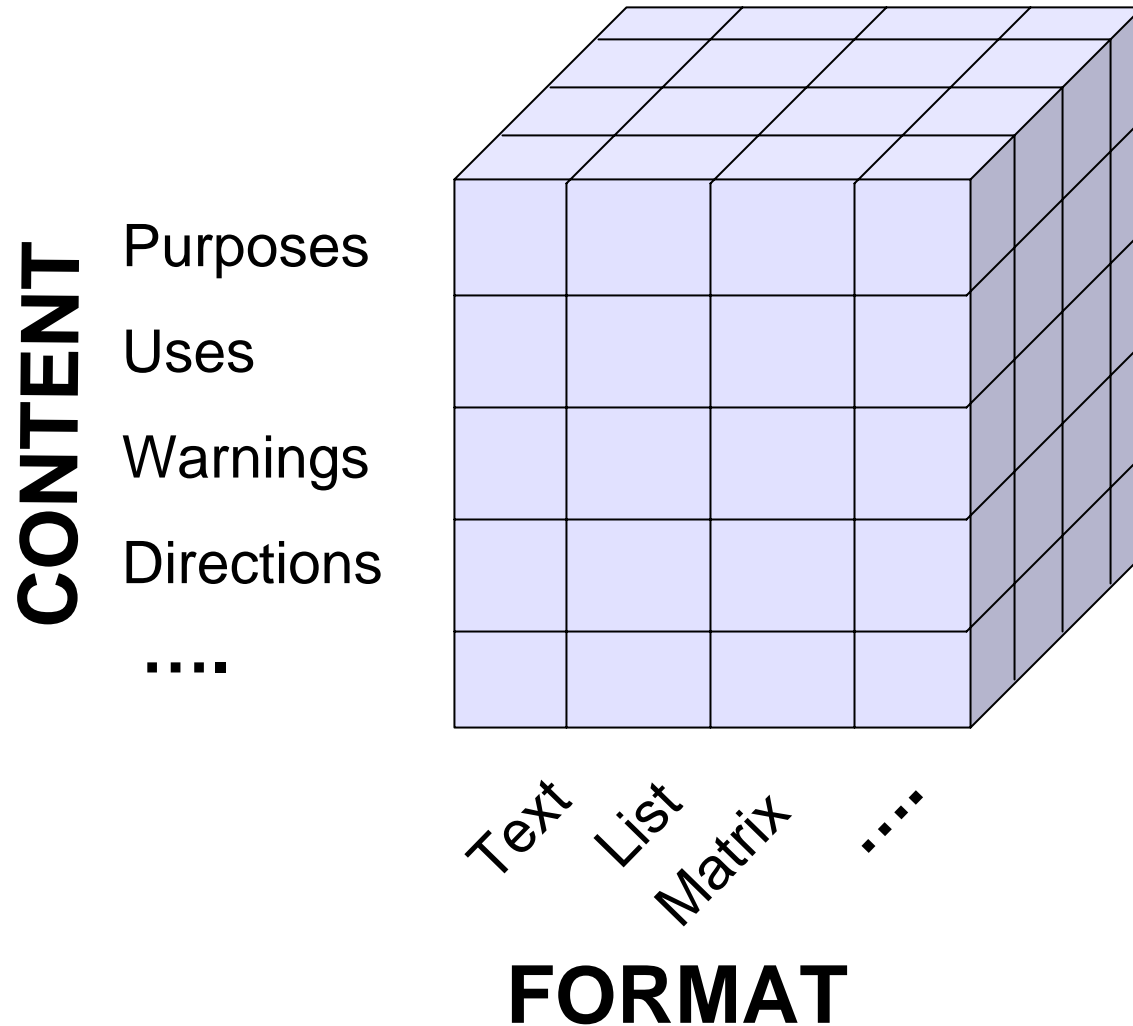
Warnings

Directions

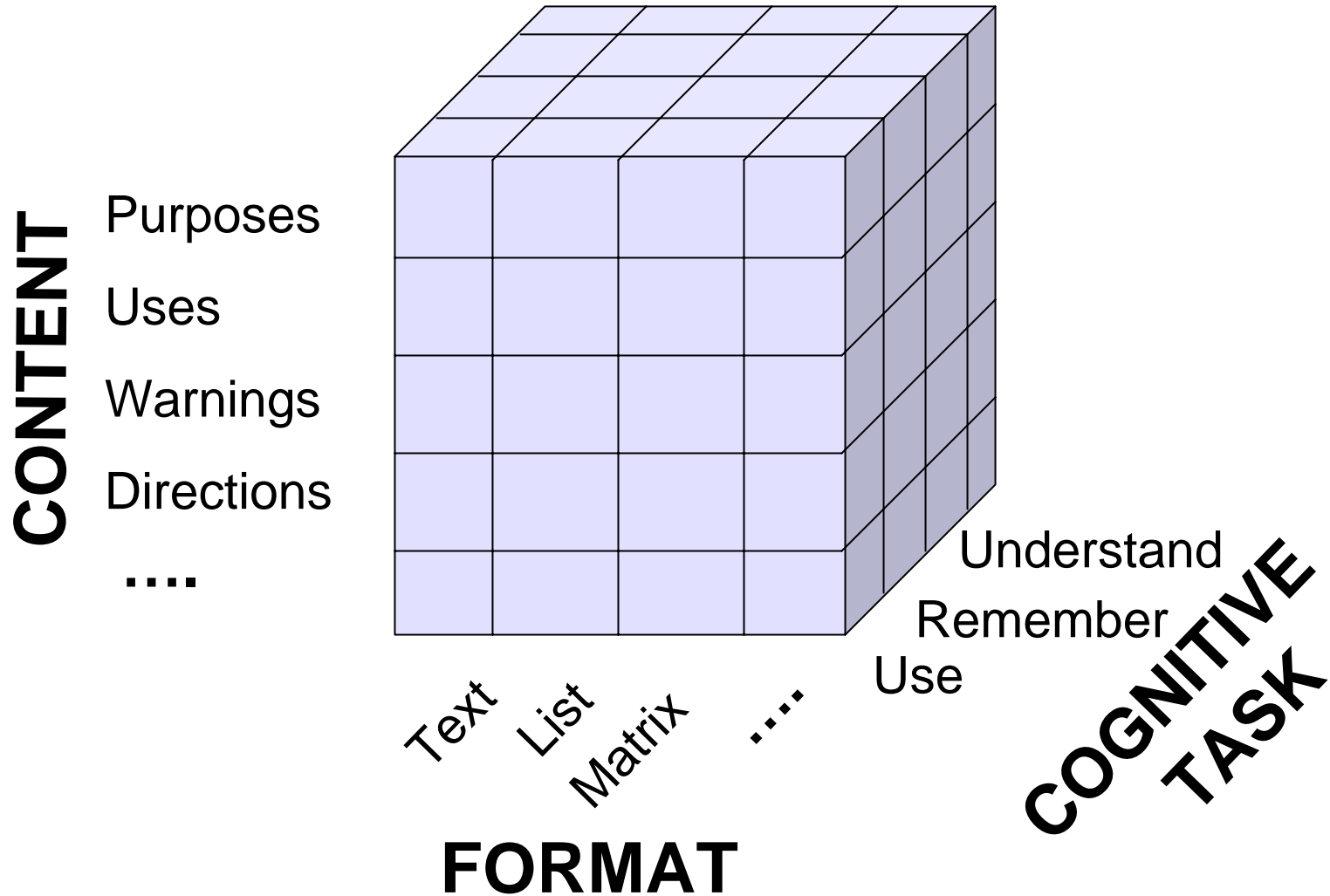
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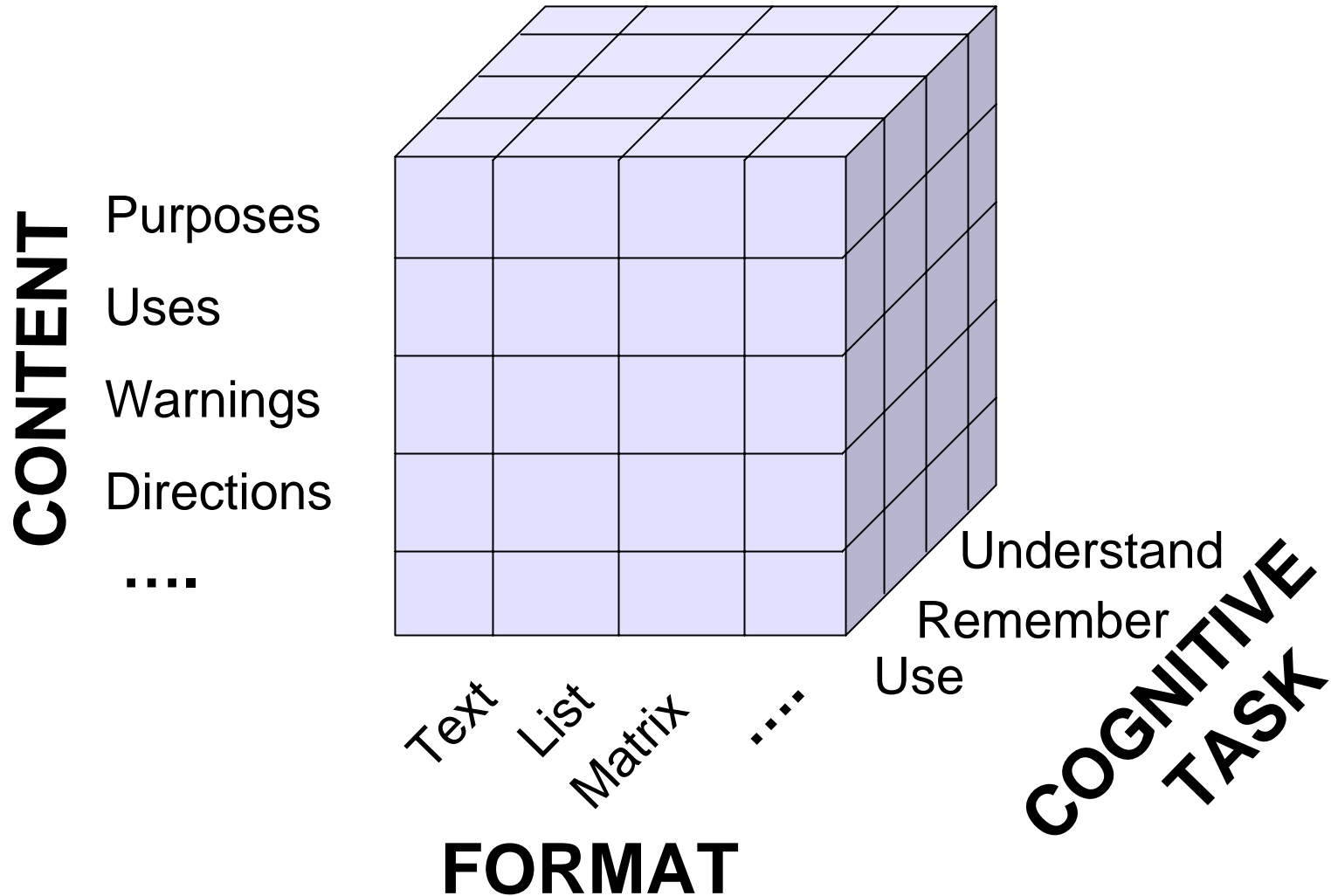
# FORMAT SELECTION



# FORMAT SELECTION



# FORMAT SELECTION

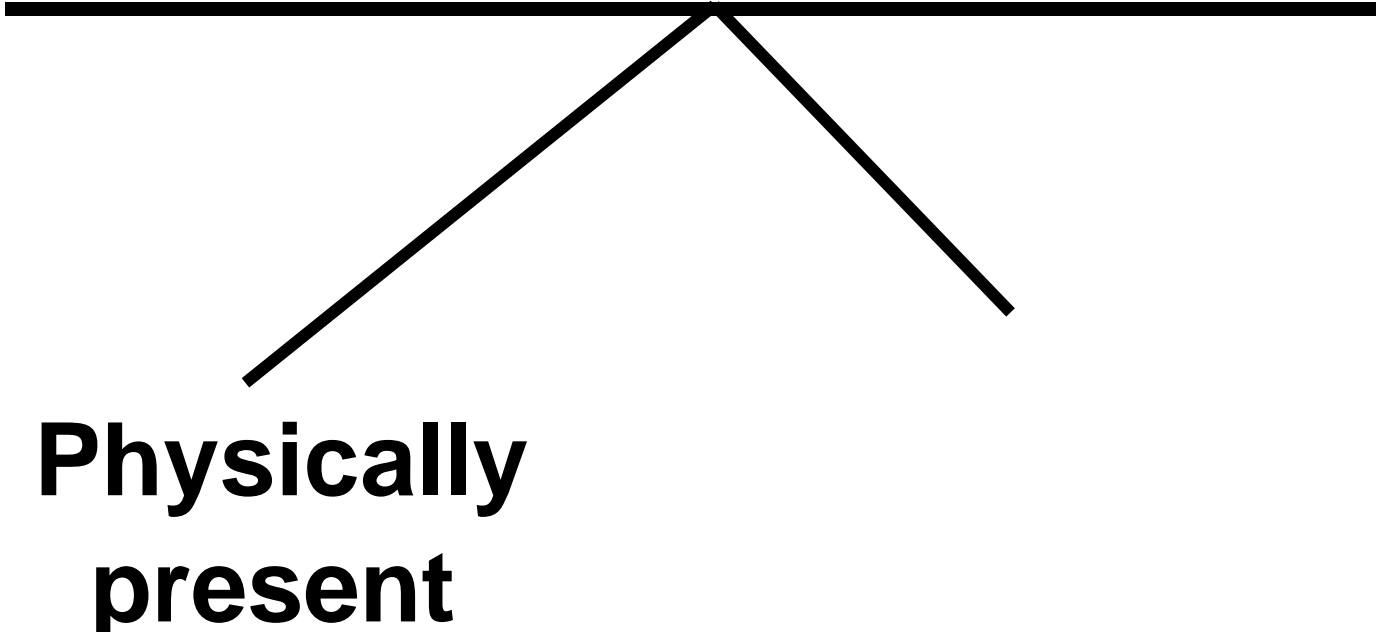


Source:

Adapted from Day, R.S. (1988) Alternative representations. In G.H. Bower (Ed.), *The Psychology of Learning and Motivation*, 22, 261-306. New York: Academic Press.

# **DRUG INFORMATION**

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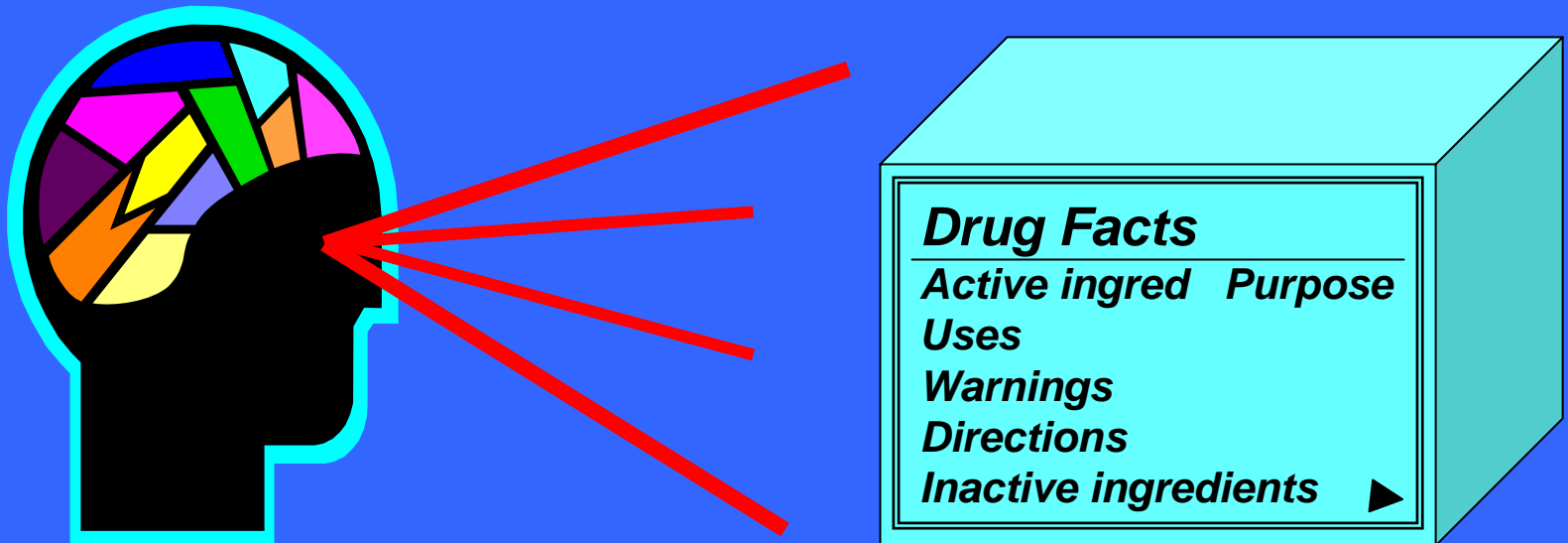
**Physically  
present**

# DRUG INFORMATION

**Physically  
present**

**Functionally  
absent**

# Cognitive Accessibility of OTC Drug Information



[ruthday@duke.edu](mailto:ruthday@duke.edu)

<http://www.duke.edu/~ruthday/medcog.html>

**Day, R.S. (2006) Comprehension of prescription drug information: Overview of a research program.** *Proceedings of the American Association for Artificial Intelligence, Argumentation for Consumer Healthcare.* <http://www.aaai.org>

**Day, R. S. (1988) Alternative representations.** In G.H. Bower (Ed.), *The Psychology of Learning and Motivation.* New York: Academic Press, 22, 261-305.

**Day, R.S. (2000) Brandname.Com' – Cognitive accessibility of drug information on drug product websites.** Drug Information Association.