Alternative Presentations of Clinical Pharmacology in Approved Drug Labeling: Effect on Comprehension, Memory, and Action

Test Instrument

[Notes to reviewers in italics, within square brackets.]
[Instrument based on methods developed and tested in the Medical Cognition Lab at Duke.]

Brief Overview

This study is offered by the FDA Center for Drug Evaluation and Research's Office of Clinical Pharmacology in collaboration with the Medical Cognition Laboratory at Duke University. You will see some information about a prescription drug, then answer some questions about it. The drug is hypothetical, developed for this study, but the information is the same type provided in all FDA-approved labeling ("prescribing information"). The purpose of the study is to determine effective ways to display drug information in approved labeling.

Drug-X: General Information

You will see information about "Drug-X." Your job is to read the information as you would in everyday practice. To get a quick overview of Drug-X, we'll start with the Table of Contents and Highlights sections of the labeling. You will have ___ minutes to look at this information. If you finish before time is up, click "NEXT."

Drug-X: More Detailed Information

Now you will see some more detailed information about Drug-X. Again, read this as you would in everyday practice. We will ask you some questions about it later. You will have ___ minutes to look at this information. If you finish before time is up, click "NEXT."

Questions

Now you will see some questions about Drug-X, your experience in reading the information and your evaluation of it. Click the NEXT button to start the questions and when you finish each page.

Reading about Drug-X

You had some time to read the Table of Contents and Highlights sections of the labeling.
Was it about: ___enough time   ___too little   ___too much

Later you had some time to read the more detailed information.
Was it about   ___enough time   ___too little   ___too much

The more detailed information came from one section of the labeling. What section was it? If you are not sure, it is OK to guess. If you don't know, enter a question mark (?).
Name of section: _____

Enter a number for each question below:
  --About what % of the detailed section did you read completely?____
  --About what % did you just skim?___
  --About what % did you not read at all?___

Your Evaluation
Please answer all remaining questions for the detailed information you saw, the section on pharmacokinetics (PK).

Overall, how easy/hard was it to understand the information about PK?
  ___ver easy ___easy ___moderate ___hard ___very hard

Overall, how easy/hard would it be to remember this information?
  ___ver easy ___easy ___moderate ___hard ___very hard

How confident are you -- that you know enough to consider Drug-X as a possible treatment for patients, based on what you read (before you consult other parts of the labeling)?
  __very confident __confident __somewhat confident __unconfident __very unconfident

Drug-X: PK Content
Now we will ask you questions about PK information you just read. Try to answer each question as quickly and accurately as you can. Base your answers on the information provided in this study. If you are not sure about an answer, it is all right to guess. If you have no idea, enter a question mark (?); don't worry about this – if you don't know, that just tells us that the information could be more clear. So just do the best that you can.

We do not expect you to answer all of the questions correctly. We just want to know how effective the labeling is and what "take-home" messages it emphasizes. So do not worry if you are uncertain or don't know – just give your best guess.

Labeling Sections
The PK information is divided into major sections.
--About how many sections are there? You do NOT have to say what they are, just
  estimate about how many there are. If you are not sure, make your best guess – a
  ballpark number. Enter a number:____

--What are the names of the major sections? If you are not sure, it is OK to guess. If you have
   no idea, enter "?" Put a comma after each section name. _____

--Now you will see topic names, one at a time. For each, decide whether it was – or was not –
  a section in the PK information. If you think it was a major section in the labeling, click YES;
  if you think it was not, click NO. If you are not sure, make a guess anyway.
        ___elimination   ___drug interactions
        ___distribution   ___pharmacodynamics
        ___absorption   ___contraindications

General PK Information
Drugoxide exposure
Given a single dose of Drug-X, what is the approximate drugoxide exposure:
--for C_{max} (mcg/mL)
　___1-2 ___2-3 ___3-4 ___5-6 ___6-7

--for AUC (mcg*h/mL)
　___0-25 ___26-50 ___51-75 ___76-100

Given steady state sampling, what is the approximate Drugoxide exposure:
--for C_{max} (mcg/mL)
　___1-2 ___2-3 ___3-4 ___5-6 ___6-7

--for AUC (mcg*h/mL)
　___0-25 ___26-50 ___51-75 ___76-100

Dose Proportionality
Steady-state drugoxide AUC increases proportionally with doses of about what amount over the recommended dosage?
　___>25 mg ___>50 mg ___>75 mg ___>100 mg

Absorption
What is the general duration of Drug-X half-life? ___short ___medium ___long

What is the time to peak plasma concentrations after fasting at least 8 hours? _____
What is the general range for this value: ___narrow ___moderate ___wide
Which range for this value is correct? ___2-6 hours ___2-10 hours ___2-23 hours

How many metabolites does Drug-X have?
　　___1 ___2 ___3 ___4

What is the active metabolite? ___M-1 ___M-2 ___M-3

Effect of Food
What were the effects of a low-fat meal? Choose one in each row:
　___It increased drugoxide AUC ___It decreased drugoxide AUC

　___It increased metabolite M-3 ___It decreased metabolite M-3

What were the effects of a high-fat meal? Choose one in each row:
　___It increased Drugoxide AUC ___It decreased Drugoxide AUC

　___It increased metabolite M-3 ___It decreased metabolite M-3

Distribution
About what % of drugoxide and its metabolite exhibit plasma protein binding?

___60-69%   ___70-79%   ___80-89%   ___90-99%

Elimination
About how long does it take to eliminate drugoxide?
  ___10 hours   ___20 hours   ___30 hours   ___40 hours
Is the range in this value
  ___narrow   ___moderate   ___wide

About how long does it take to eliminate the metabolite?
  ___10 hours   ___20 hours   ___30 hours   ___40 hours
Is the range in this value
  ___narrow   ___moderate   ___wide

What are the primary metabolic pathways for each?
  Oxidation: _____
  Conjugation:_____

What is the primary route of elimination?   ___liver   ___kidneys

Excretion in feces
About what percent is excreted in feces?
  ___0-25%   ___26-50%   ___51-75%   ___76%-100%
About what percent is drugoxide?
  ___0-25%   ___26-50%   ___51-75%   ___76%-100%
About want percent is metabolite?
  ___0-25%   ___26-50%   ___51-75%   ___76%-100%

Excretion in urine
About what percent is excreted in urine?
  ___0-25%   ___26-50%   ___51-75%   ___76%-100%
About what percent is glucuronides?
  ___0-25%   ___26-50%   ___51-75%   ___76%-100%

Terms
Some abbreviations were used in the labeling. Please define each term below. If you are not sure about an exact definition, give a general idea of what it is about. If you don't know, enter "?"

C_{max}:_____

AUC:_____

CV:_____

T_{max}: _____

Patient Scenarios
Assume that the following patients all have the indication approved for Drug-X. For each, consider whether Dtug-X would be appropriate.

Patient A is already taking [Drug Y].
Would you be concerned about prescribing Drug-X for this patient? __Yes ___No
If OK, what dose is appropriate: ___recommended dose ___higher dose ___lower dose

Patient B likes [food].
Would you be concerned about prescribing Drug-X for this patient? ___Yes ___No
If OK, what dose is appropriate: ___recommended dose ___higher dose ___lower dose
.

Evaluate Alternative Displays

Now you will see different ways to show PK information. They have the same information that
you saw in this study. For each display, take a look at how the information is shown. Then
answer the questions below.

Display-1
How easy/hard is it to understand the information in this display?
  ___very easy   ___easy   ___moderate   ___hard   ___very hard

How well do you like this display?
  ___like very much ___like   ___neutral   ___dislike   ___dislike very much

Display-2
How easy/hard is it to understand the information in this display?
  ___very easy   ___easy   ___moderate   ___hard   ___very hard

How well do you like this display?
  ___like very much ___like   ___neutral   ___dislike   ___dislike very much

Compare Displays
Here are both displays, side by side. They contain the same information but differ in their overall
format. Please take a look, then answer the questions below.

How well do you like the display on the left?
  ___like very much ___like   ___neutral   ___dislike   ___dislike very much

How well do you like the display on the right?
  ___like very much ___like   ___neutral   ___dislike   ___dislike very much

Which do you prefer? ___left   ___right   __no preference

Comments
If you have any comments about the displays or study, please write them here: _____

Submit
Please click NEXT to submit your responses.

Explanation
Thank you for participating in this study. Here is a brief overview.

This study examines different ways to show information about prescription drugs. Do some formats help health professionals understand, remember, and use the information in a more efficient and accurate manner?

Today, you read just one of the formats we are studying. On an random basis, participants see this format or a different version. We will compare the results for these formats, to help make prescription drug labeling easier to understand, remember, and use.