

Overview of Consumer Studies

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Objectives

- **Overview of Consumer Study Designs**
- **Overview of Proposed Study Designs for Pandemic Influenza MedKits**

Consumer Studies

I. Label Comprehension Studies

II. Self-Selection Studies

III. Actual Use Studies



Consumer Studies

Type of Consumer Study	Consumer Studies Proposed *
I. Label Comprehension Study	Label Comprehension Study- Relenza Label Comprehension Study-Tamiflu Simulation Study-Tamiflu
II. Self-Selection Study	Incorporated into the Label Comprehension Studies
III. Actual Use Study	Compliance Studies (2)-Relenza Compliance Study-Tamiflu Human Factor Study-Relenza Mixing Study-Tamiflu
*Based on information received by the FDA as of October 6, 2008	

Label Comprehension Study (LCS)



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I. Label Comprehension Studies

- Determine if written materials communicate the important information about a drug without aid from a HCP
- Test key communication elements on the label
- Not a clinical trial (No drug administered)
- Should be first phase of a development program
- May require multiple revisions and re-testing
- Test comprehension not behavior

I. LCS: Target Population

- **Representative sample of U.S. population**
 - **Potential product users and nonusers**
- **Low literacy cohort**
 - **Validated literacy testing instrument (e.g., Rapid Estimate of Adult Literacy in Medicine (REALM) and Teen-REALM)**
- **Minimal exclusion criteria**
- **Enrich with subgroups of interest**

I. LCS: Questionnaire

- **Primary data collection**
- **Scripted interviews**
- **Types of questions:**
 - **Open-ended**
 - **Closed-ended**
 - **Scenario**

I. LCS: Questionnaire

- **Open-ended:**
 - answer unrestricted
 - all verbatim responses are recorded and coded
- **Closed-ended:**
 - Choose answer from a restricted answer set (i.e., multiple choice, yes-no)
 - Follow-up by open-ended probing questions to validate correct responses and obtain information on incorrect responses

Questionnaire

- **Scenario:**
 - Hypothetical medical situation
 - Tests ability of the respondent to apply information from the label
 - Closed and open-ended questions

I. LCS: Questionnaire

Example scenario question:

- Janet is a 38-year-old with diabetes who has a headache (scenario)
 - Is it ok or not ok for her to take medication X? (closed-ended question)
 - Why do you say that? (open-ended probing question)

I. LCS: Information Obtained

- **Determines if consumers understand key communication elements in the written materials**
- **May or may not predict behavior in an actual use study or in “real-world” conditions**

Label Comprehension Studies Proposed for Both MedKits

**Key communication elements being tested
in the proposed LCS:**

- When to use the Medkit**
- When not use the Medkit**
- Who should not take the drug**
- Prevention vs. Treatment**
- Dosing for Prevention vs. Treatment**
- When to seek medical attention**

II. Self-Selection (SS) Studies

II. Self-Selection Studies

- **Assess consumer ability to correctly choose a product based on the information on the label**
- **Not a clinical trial (No drug administered)**
- **Separate study or combined with a label comprehension study or actual use study**

II. SS Study: Target Population

- **Representative sample of U.S. population**
 - **Potential product users and nonusers**
- **Low literacy cohort**
- **Minimal exclusion criteria**
- **Enrich with subgroups of interest**

II. SS Study: Testing Procedure

- Participant reads the label
- Self-selection question is asked
 - “Is this product appropriate (right) for you to use?”
 - “Why did you say that?”
- Demographic information and medical history are collected
- Correct self-selection is based largely on the self-reported information

Self-Selection Testing Proposed for Both MedKits

- Medkits currently proposed as an Rx product
- Contraindicated use is not initially determined by the individual
- Once in the home self-selection decisions will need to be made without the assistance from a HCP

Self-Selection Testing Proposed for Both MedKits

- **When to take the product:**
 - **Pandemic vs. Seasonal Flu**
 - **Prevention vs. Treatment**
 - **New medical contraindications**
- **What dose to take:**
 - **Prevention vs. Treatment**
 - **Based on age/weight of child**

Self-Selection Testing Proposed for Both MedKits

- Test self-selection decisions
- Separate SS studies are not proposed
- SS questions are incorporated into the LCS

III. Actual Use Study (AUS)



III. Actual Use Studies

- **Purpose:** To simulate use of product in a “real-world” setting without input from HCP
- **Objectives:**
 - **Primary:**
 - Adherence to labeled directions and warnings
 - **Secondary :**
 - Provide data on safe use of the product in an unsupervised setting
- **Can be considered a clinical study because drug is generally given**

III. AUS Endpoints

- Depending on the behavior of interest, there may be a variety of different endpoints, e.g. :
 - Failure to follow dosing instructions
 - Failure to seek medical attention when appropriate based upon the label

III. AUS: Target population

- Ideally all individuals who may have an interest in the product
- Limited exclusion criteria

III. AUS: Design Issues

- **Difficult to achieve a true “real-world” setting**
- **Minimal healthcare provider and/or study personnel involvement**
- **Fine line between collecting enough data for a meaningful assessment and collecting too much data and influencing behavior**
- **Data collection methods:**
 - **Diaries**
 - **Phone interviews**
 - **Follow-up visits**

III. AUS: Design Issues

- **Duration of study varies depending on the labeled duration of use**
- **Cannot always predict correct behavior when the product is marketed**

AUS Proposed for Both MedKits

- **Compliance studies**
 - **Participants are prescribed a MedKit**
 - **Primary objectives:**
 - **Appropriate non-use of the drug for seasonal flu**
 - **Ability to retain/locate Medkits in their homes**

AUS Proposed for Relenza MedKit

- **Human Factor Study**
 - Using only the written instructions
 - Demonstrate the ability to correctly perform all the steps required for safe and effective use of the Diskhaler device

AUS Proposed for Tamiflu MedKit

- **Mixing Study**
 - Using only the written instructions
 - Demonstrate the ability to prepare the correct dose of Tamiflu for children < 10 years of age using the contents of a 75 mg capsule

Summary

- **Creating a well understood label and written materials may require multiple revisions and re-testing**
- **Successful label comprehension studies may not predict correct behavior in an actual use study**
- **An actual use study cannot always predict correct behavior when the product is marketed**

Conclusions

- The proposed consumer studies will test:
 - Comprehension of specific communication elements in the written materials
 - Ability to mix a proper dose of Tamiflu for a child <10 years of age
 - Ability to properly use the Relenza Diskhaler device
 - Ability to locate the Medkit in the home
 - Ability not to use the Medkit in the absence of pandemic flu

Conclusions

- The proposed consumer studies do not test:
 - More complex decision making that requires the ability to understand multiple label elements at one time
 - Whether the written materials-instructions accurately select the intended population for use during a flu pandemic
 - Actual “use” of the Medkits
 - Behavior during a simulated flu pandemic

Conclusions

- **What we need from the AC members is to help us determine if:**
 - **The proposed consumer testing is adequate**
 - **Additional consumer testing is needed**