

Appendix J
Actions Taken in Response to Comments

a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research, quality improvement and information dissemination functions, including whether the information will have practical utility.

1) Both Rx-acetaminophen and OTC acetaminophen containing products should be included in the information collection activity to understand consumer behavior associated with concomitant use.

Questions pertaining to prescription medication use and how this is used in combination with OTC acetaminophen products have been added to the focus group questions for parents of young children and adults.

2) Focus groups research such as that proposed by AHRQ qualitative survey has been useful for the design of education programs but should not be used in policy decisions or recommendations regarding packaging or labeling.

It is recognized that the results of this qualitative data collection are not appropriate for generalization to the population at-large. The intent is to provide sufficient insight into consumers attitudes and beliefs to drive the development of a survey. This qualitative information is not intended to inform policy.

c) Ways to enhance the quality, utility, and clarity of the information to be collected

1) The product(s) and packaging being demonstrated in the AHRQ study should be representative of those on the OTC market.

A wide variety of both name brands and store brand products will be used as prompts for the discussion on packaging.

2) During the interviews with pharmacists and physicians, retail-practice, community setting pharmacists should also be included in the study population so as to have a representative sample of sources of medication information utilized by consumers.

An inclusion criteria for pharmacists and physicians is that at least 50% of their professional practice is devoted to community practice. This is located in Appendix B – Screening Form.

Parent's Focus Group Questions

1. In Theme I: Knowledge where it calls for the facilitator to hold up a bottle of acetaminophen, we recommend that the focus group participants see a bottle of Children's Tylenol brand of acetaminophen. Children's Tylenol is the leading market share brand of children's acetaminophen-containing products based on IRI data (as of March 22, 2009) with 37.1% market share

Children's Tylenol packaging will be used as a prompt for the beginning question of the focus group with parents of young children as this is possibly the most widely recognized acetaminophen product. However, for the discussion of packaging a wide variety of product packages both name brand and store brand will be used to attempt to exhaust all possible package related topics.

2. To maximize learnings from the proposed research, the parent's focus group should be limited to acetaminophen users.

The inclusion criteria originally stated parents who have given their children any over-the-counter medication. This was based on the idea that given the wide variety and availability of products containing acetaminophen parents may not always recognize that

they are in fact medicating their children with acetaminophen. After consideration of the comment, the criteria will be amended to include only parents who have medicated their children with an acetaminophen product. To address the issue of number and variety of products, a picture of the most widely used products will be used to prompt parents during the screening.

3. Many store brand acetaminophen-containing products use the term “non-aspirin” in the product name (e.g., Children’s Non-Aspirin), which does little to inform the consumers that the products contain acetaminophen. We recommend adding questions to determine if consumers understand that the term “non-aspirin” pain reliever means the product contains acetaminophen and the impact of this term on consumer behavior.

A question specific to “non-aspirin” and its meaning and impact on behavior has been added to the focus group questions. A package containing the term non-aspirin will also be used as a prompt.

4. Following the question on how much would you have to give your child to cause harm, it would be useful to ask why the parent believes the stated dose may cause their child harm. ...we encourage the Agency to review the questionnaire in its entirety to ensure this concept is fully covered.

The focus group script has been fully reviewed to ensure that the concept of how parents discern a therapeutic dose from a harmful dose. Probes have been added to existing questions as well as an additional question.

5. We recommend including questions to determine if parents are aware of reports of attempted suicide by adolescents with acetaminophen and whether this knowledge impacts consumer behavior.

As suggested, Theme V: Related Experiences has been modified to engage focus group participants on their awareness of intentional overdose with acetaminophen and how that awareness has impacted their own behavior.

6. In Theme VI: Labeling and Packaging, one of the probe questions for the bottle label asks about the number of pills in each bottle. The majority of acetaminophen products for children is in liquid form (e.g. suspension) rather than in pill form...Children’s acetaminophen liquids/suspensions are often supplied with a device for dosing (e.g., a dosing cup or syringe). The ease of use of the supplied dosing device may impact a parent’s ability to properly dose their child...

Theme VI: Labeling and Packaging has modified to state number of doses as opposed to pills to best fit the products used for children. A question regarding the dosing devices has also been added.

Adult Focus Group Questions

7) In Theme I...we recommend that the focus group participants see a bottle of Tylenol brand acetaminophen.

Tylenol packaging will be used as a prompt for the beginning question of the focus group with adults this is possibly the most widely recognized acetaminophen product. However, for the discussion of packaging a wide variety of product packages both name brand and store brand will be used to attempt to exhaust all possible package related topics.

8) To maximize learnings from the proposed research, the adult focus group should be limited to acetaminophen users.

The inclusion criteria originally stated adults who used any over-the-counter medication. This was based on the idea that given the wide variety and availability of products

containing acetaminophen people may not always recognize that they are in fact medicating with acetaminophen. After consideration of the comment, the criteria will be amended to include only people who have medicated with an acetaminophen product. To address the issue of number and variety of products, a picture of the most widely used products will be used to prompt people during the screening.

9) *Many store brand acetaminophen-containing products use the term “non-aspirin” in the product name, which does little to inform the consumers that the products contain acetaminophen. We recommend adding questions to determine if consumers understand that the term “non-aspirin” pain reliever means the product contains acetaminophen and the impact of this term on consumer behavior.*

A question specific to “non-aspirin” and its meaning and impact on behavior has been added to the focus group questions. A package containing the term non-aspirin will also be used as a prompt.

10) *There appears to be an opportunity in Theme II: Beliefs about Benefits and Risks where probing questions may provide further information on consumer understanding of the therapeutic window for acetaminophen.*

In the interest of learning more about how consumers discern a therapeutic dose from a harmful dose and how that relates to packaging information a question and probes have been added to Theme II.

11) *We recommend including questions to determine if consumers are aware of reports of attempted suicide by adolescents with acetaminophen and whether this knowledge impacts consumer behavior.*

A question about awareness of intentional overdose with acetaminophen has been added to Theme V of the adult focus group questions. A follow-up question regarding any impact or change in behavior related to this awareness was also added to fully develop this concept.

Physicians/Pharmacist Interview Script

12) *We recommend adding a series of questions asking if the physicians or pharmacists has heard from a patient or customer that they or someone they know, intentionally overdosed on acetaminophen; the outcome, if known; and if the person who overdosed was an adult, adolescent or child.*

The Physician/Pharmacist interview has been amended to include a question on knowledge of either a consumer or someone they know intentionally overdosed on acetaminophen, the circumstances, the outcome if known and if the person who overdosed was an adult, adolescent or child.

13) *...we recommend that a question related to the quantity of pills in a bottle be included in Question 5 when packaging and labeling are discussed. Alternatively, this could be included as a question in relation to legislation/policy under Question 6 with reference to the UK experience.*

A reference to pack limitation legislation in the UK was added to the legislation/policy section of the physician/pharmacists interview questions with a subsequent question regarding supposed effectiveness of such policies in the US.

14) *Following recent restrictions on sales of over-the-counter products containing pseudoephedrine and restrictions on sales of other consumer products to children and adolescents (e.g., cigarettes), we recommend that question 6 be supplemented with a*

probing question on whether limiting purchase of acetaminophen containing products to adults would help reduce intentional overdose in adolescents.

A question was added to the physician/pharmacist interview to determine opinions on the effect of restricting over-the-counter sales of acetaminophen on intentional acetaminophen overdose among adolescents.