**ICR: Understanding Patient's Knowledge and Use of Acetaminophen**

**Questions and Comments:**

**I. Description of the problem / Justification of data collection**:

**1.** Proposal: The aim of this study is to "identify issues that relate to the misuse and overdosing of over-the-counter (OTC) acetaminophen." (Abstract)
Response: Based on previous research and medical reports, are there any hypotheses regarding what these issues may be? Can the research aim of this study be defined any more specifically to guide questionnaire and focus group questions? (For example: "What do individuals know about the proper uses and risks of acetaminophen? Is this information sufficient/accurate? In what situations is acetaminophen most likely to be misused?")

Based on our review of the literature, we believe that data is insufficient to propose a more specific hypothesis. The development of a specific hypothesis may be premature and could possibly result in missing important, relevant information. This is why we have chosen a qualitative design to identify issues that may be lacking in the current scientific literature. The issues that relate to misuse and overdosing of OTC acetaminophen have not been fully explored. Issues that have been identified or proposed through previous studies are consumer's lack of knowledge, dosing errors related to low literacy, error's in reading or interpreting product labels, human error in dose calculation, underestimation of toxicity, intentional overdose, and overdoses due to concurrent use with prescription medications or other medications all of which are addressed in the focus group/interview questions we have formulated. Additionally, the nature of the open-ended questions and probes are designed to elicit rich stories and meaningful accounts from the participants with the intent of expanding our current understanding of this topic from the cultural perspective and health belief systems of consumers.

In regards to situations where acetaminophen is most likely to be misused, we have identified the following from the scientific literature: 1) parent's administration to young children; 2) adolescents intentional overdosing; 3) language incongruence, low-health literate or low-literate consumers; 4) low socioeconomic status consumers which results in reduced access to health information; 5) physical impairment (sight, hearing, and hand dexterity); and 6) frequent use of OTC and prescription medications. To address each of these situations, we propose the recruitment of segments of the population that find themselves in such circumstance. For example, we will recruit parents of young children to address situation 1, adolescents to address situation 2, Spanish–speaking consumers to address situation 3, uninsured consumers from publicly-funded health clinics to address situations 3 and 4, and older adult consumers to address situations 5 and 6.

**2.** Proposal: "AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and (B) health care for priority populations, which shall include (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs…" (Supporting Statement, Page 3, Part A (1)).
Response: Does the misuse of acetaminophen occur frequently among these groups? Will this study have substantial impact on these goals and populations?

This study will have impact on health care for priority populations. The priority populations which we will target are low-income groups, minority groups, women and young adolescent females, and the elderly. Approximately half of the overdose exposures occur in children <20 years of age (Watson, Litovitz et al. 2004). Overdosing is more likely to be intentional in adolescents, with the highest self-poisoning rates reported in the 15 to 19 year old female group (Bialas, Reid et al. 1996; Hawton, Bergen et al. 2007). Older adults use more medications than their younger counterparts. Yet, as prescribed medication use increases OTC drug use may decline, and older adults are more likely to use benzodiazepines (Hawton, Bergen et al. 2007) than acetaminophen for intentional overdose, but there is scant data on OTC medication use in this population.

Little is known about acetaminophen use in ethnic minority or disadvantaged populations in the U.S. The 3rd National Health and Nutrition Examination Survey found that OTC analgesic use was lower among African Americans and Mexican-Americans than their non-Hispanic white counterparts (Paulose-Ram, Hirsch et al. 2003). However, no studies have examined overdosing with acetaminophen in ethnic populations.

**3.** Proposal: "Toxicity from acetaminophen has been on the rise in the past 3 decades, and is now the most common cause of acute liver failure in the U.S., surpassing viral hepatitis" (Supporting Statement, Page 3, Part A (1)).
Response 1: How frequently in the general population does acute liver failure from acetaminophen toxicity occur? How frequently in the target populations (defined above) does acute liver failure from acetaminophen toxicity occur?

In 2003, more than 1200 cases of liver failure and 21 deaths were attributed to acetaminophen overdose, accounting for 23 percent of all drug-related deaths(Watson, Litovitz et al. 2004). There is insufficient data on the frequency of acute liver failure from acetaminophen toxicity in the target populations. Several international studies have examined the role of socidemographic risk factors reporting that socially disadvantaged and marginalized populations were at higher risk of hospitalization related to both intentional and unintentional acetaminophen overdose. (Smith 1995; Newsome, Bathgate et al. 2001; Schmidt and Dalhoff 2001; Myers, Li et al. 2007) We are unaware of similar work which has been done in the US and were unable to identify such studies in the literature.

Response 2: Is there a specific demographic (age, gender, race, socio-economic status) disproportionately affected by toxicity from acetaminophen (that could perhaps be more specifically targeted in the sample)? Is this group (or these groups) affected more often because misuse of acetaminophen occurs more frequently within it, or because of other reasons (e.g. limited access to medical care, weakened physical condition with age, etc.)?

Children account for about half of all reported acetaminophen overdose. The majority of this occurrence is due to unintentional dosing errors. Factors which have been identified or proposed as contributing to this unintentional overdose are low socioeconomic status resulting in poor access to health care, non-English speakers, and low literacy. It has also been reported that adolescents, and particularly female adolescents, are at

greatest risk for intentional overdose with acetaminophen. Adolescence is a time of life that presents the greatest risk of injury related to risk taking behaviors. This, in conjunction with readily accessible supply of acetaminophen, may contribute to increased rate of misuse. Older adults are believed to be at increased risk for unintentional overdose due to age related factors (sight, hearing, hand dexterity) and increased use of medications. Again, data is limited and these are the issues we seek to gain insight to.

Response 3: How fatal is acute liver failure from acetaminophen toxicity?

Chronic doses in excess of 5 Gm. per day and acute doses of as little as 7 Gm. have caused hepatic damage in adults. Larger doses may be fatal. Blood levels over 200 micrograms per mL. four hours after ingestion correlate with severe hepatotoxicity. (Bailey, 1980) Analysis of national mortality files shows 458 deaths occur each year from acetaminophen-associated overdoses; 100 of these are unintentional. The poison surveillance database showed near-doubling in the number of fatalities associated with acetaminophen from 98 in 1997 to 173 in 2001 (Nourjah, et al. 2006). The outcome of acetaminophen intoxication is good if N-acetylcysteine (NAC), is administered within 12 hours of ingestion. However, many patients develop symptoms after this window of opportunity and do not seek care at a time when the administration of an antidote can be effective.

Response 4: In addition to acute liver failure, are there any other conditions of note that result from toxicity from acetaminophen?

Acute renal failure can also occur but it is less frequent than acute liver failure. (Boutis and Shannon 2001)

Response 5: Is it known whether health complications resulting from acetaminophen toxicity are largely the result of intentional or unintentional overdose? If this answer is not known, it may be worthwhile to address specifically in this study (see items (II)(2)(Response 4) and (IV)(1)).

Acetaminophen overdose can be intentional or unintentional. Intentional overdoses are usually related to self-harm and suicide intent, although cases of intentional poisoning of others, particularly children, have been reported occasionally. Approximately half of the overdose exposures occur in children <20 years of age, and they occur equally with acetaminophen alone, or in combination with other drugs (Watson, Litovitz et al. 2004). In younger children, in whom most studies have been conducted, overdose is generally unintentional, a result of inappropriate dosing. A few studies have assessed parents' knowledge about acetaminophen and have reported that it is often used for minor ailments (e.g. irritable child) (Allotey, Reidpath et al. 2004), and that parents have difficulty understanding dosing, more so with weight than age directions (Bilenko, Tessler et al. 2006). Overdosing is more likely to be intentional in adolescents, with the highest self-poisoning rates reported in the 15 to 19 year old female group (Bialas, Reid et al. 1996; Hawton, Bergen et al. 2007). Lack of knowledge in regards to toxicity is also likely to play a role. In a study of 569 adolescents, 42% underestimated the dose to cause harm and 50% underestimated the dose to cause death (Harris and Myers 1997).

Much less information is available for adults, but it is likely that in younger adult groups, overdose is also intentional. Adult patients are not likely to report and discuss OTC drug use with their physicians(Chen, Schneider et al. 2002), and over half (52%) of adults may not be aware that acetaminophen toxicity causes liver damage (Chen, Schneider et al. 2002). Older adults use more medications than their younger counterparts. Yet, as prescribed medication use

increases OTC drug use may decline, and older adults are more likely to use benzodiazepines (Hawton, Bergen et al. 2007) than acetaminophen for intentional overdose, but there is scant data on OTC medication use in this population.

## II. Sample

**1.** Proposal: "… the data collection will employ convenience samples of individuals from different segments of the population." (Supporting Statement, Page 3, Part A (1)).
Response: How and from where will these samples be obtained? How will those who have misused acetaminophen be recruited?

Two recruitment sites will be employed: 1) the largest private pay healthcare system in the Houston area and 2) a publicly-funded county healthcare system which serves the uninsured of Harris County. For the private pay system, eligible participants will be identified through a database and mailed a letter which explains the study and invites them to participate. For the publicly funded clinic, participants will be identified through physicians' schedules and approached in the clinic waiting area to ask for their participation. Different segments of the population that we hypothesize are at risk of problematic use of acetaminophen will be targeted for participation such as parents of young children, adolescents, Spanish-speakers, and the elderly.

| Patient Demographic Information for Recruitment Sites | | | | | | | |
|---|---|---|---|---|---|---|---|
| Harris County HD[1] | 115,757 | | | | | | |
| Casa | 15,291 | 42.1% | 57.9% | 10.3% | 20.0% | 68.9% | 0.5% |
| People's | 25,009 | 33.7% | 66.3% | 7.2% | 19.7% | 58.7% | 12.0% |
| Martin Luther King | 23,195 | 34.8% | 65.2% | 4.9% | 67.3% | 26.1% | 1.4% |
| Gulfgate | 18,219 | 38.8% | 61.2% | 4.5% | 12.7% | 82.0% | 0.7% |
| Northwest | 15,661 | 36.8% | 63.2% | 15.6% | 18.6% | 59.3% | 5.5% |
| Strawberry | 18,382 | 36.6% | 63.4% | 23.8% | 4.6% | 67.6% | 3.3% |
| Kelsey-Seybold[2] | 783,227 | 41.8% | 58.2% | * | * | * | * |

[1]Publicly-funded clinics [2] Private pay clinics *Gender and ethnic data not available through the KSC patient-data systems

It is not the intent of this study to identify persons whom have specifically misused acetaminophen. The goal is to gain insight into how the general population perceives and uses acetaminophen.

**2.** Proposal: This project will collect data from parents of young children, adults, adolescents (ages 13-20 years), primary care physicians, and pharmacists (Supporting Statement, Page 4, Part A (1)).
Response 1: Is it necessary to interview all of these groups? How were these groups selected?

Yes. See Section I. Question 1 response regarding situations where acetaminophen is most likely to be misused. These segments of the population are specifically targeted because it is

believed they are at increased risk for the misuse of acetaminophen and they represent priority populations.

Response 2: While interviewing primary care physicians may yield insight into the types of information that is either asked for or provided in an individual's regular exam, might it also be useful to interview those that actually deal with complications resulting from acetaminophen toxicity (presumably emergency medical technicians and other hospital doctors and nurses)?
Response 3: Particularly if toxicity for acetaminophen is a concern for adolescents, would it make sense to interview health educators and other school instructors who may or may not endeavor to teach this topic?

The goal of interviewing the primary care physicians and the pharmacists is to identify what occurs in routine care. Specifically, to learn, how often patients discuss acetaminophen use with their health care providers, how and what is communicated to patients in the clinical and out-patient pharmacy settings about the use of acetaminophen. This is with the goal of identifying avenues for intervention. While emergency room personnel are the first responders to the crisis of an overdose and could provide great insight into the outcome of overdose, the acute setting may be inappropriate for prevention or education.
Interviewing school counselors and school health educators has some potential to provide insight into adolescent behavior and education. However, adding this to the protocol at this late date will push the start date for data collection back further due to the need to reinitiate the IRB process and gain access and/or school district approval to identify and interview school counselors or school health educators. This work could be considered by AHRQ at a later date or in a separate project.

Response 4: People who have overdosed on acetaminophen could be included specifically as another group of interviewees; it would be valuable to understand their reasons for misusing acetaminophen, and to determine whether this misuse was intentional or unintentional.

The goal of this project is to gain an understanding of what the general public understands and uses acetaminophen.. Inquiries and in-depth interviews with persons who have overdoses on acetaminophen goes beyond the scope of the resources available for this project. The limited resources and the time constraints of this project do not allow for such an investigation. In another phase of this study, a chart review of emergency room visits will examine whether admissions where due to intentional or unintentional misuse.

## III. Research Methodology

**1.** Proposal: "Participants will respond verbally to guiding questions" (Supporting Statement, Page 4, Part A (3)).
Response: Is there a strong reason to elicit verbal responses? If not, it may be more cost-effective, and may take significantly less time on the part of the experimenter, if the adolescent interview was made available as a questionnaire online. If it is deemed important for the interviewer to be able to ask questions relating specifically to the interviewee's responses, it may make sense to hold these conversations in an online environment as well. While the utmost care

may be taken to assure anonymity of phoned participants, a participant may still feel a greater sense of anonymity online, and may therefore be more open to sharing potentially demeaning things in which themselves or friends had been involved (such as intentionally overdosing on acetaminophen). In addition, computer conversations may allow for more privacy, if there is a concern that one's conversation may be overheard by others in the house. (However, if this switch from verbal to written responses elicits greater costs in obtaining the needed technology, this method may not be feasible.)

The cost to design and implement an online data collection which ensures full anonymity and protection of participants and assure an adequate sampling frame goes well beyond the resources available for this project and is not feasible at this time.

**2.** Proposal: Payments/Gifts to Respondents (Supporting Statement, Page 5, Part A (9))
Response: The proposed payments to respondents are very generous; these payments are not intended to function as a substitute for forgone wages. Consider a reduction in payment or small gifts to thank participants for their time (e.g. for adolescents, a movie ticket, which when purchased in bulk may be around $5 each). (Note: Documentation from previous research would be required to justify large incentives to achieve desired response rates, and for a pilot qualitative study, high response rates may not be as crucial.)

We propose reducing the payment to adolescents to $10. We believe the $20 payment to the focus group participants should remain the same. The majority of the participants will be low-income populations. In order to participate, they will incur transportation costs and, possibly child care costs. We have found through our experience that transportation and child care are significant barriers to low-income and minority populations. This is substantiated in the literature (Gonzalez, Gardner, et al 2008). We feel payments in the amount suggested are necessary to offset these costs and reduce the barriers to participation for these populations. Please note that the change in participant reimbursement from $20 to $10 is not shown in the attached consent form. This will require institutional IRB approval. This process will take approximately 2 weeks to complete.

**3.** Proposal: "Adolescents with depressive symptoms will be excluded from the study and will be referred for evaluation and counseling to the health care entity through which they were identified and recruited. Parents, and where available, the primary care provider will be notified of the referral." (Supporting Statement, Page 6, Part A (11))
Response: Why not contact the parents first, and allow them to make the referral to a medical facility?
The protocol will be amended to provide referral information to the parents.

**4.** Proposal: Adolescents are aged 13-20 years (Supporting Statement, Page 4, Part A (1))
Response: Why are those aged 18-20 years considered adolescents? If there is a specific reason for including these ages in the adolescent population, consider adding in a different consent form for those old enough to give consent themselves.

The individual interviews with adolescents will drive the development of a survey which is planned to be administered to high school students enrolled in the area public school district to

students in grades 9th through 12th. Therefore, an age range of 13 to 20 years was used as the adolescent population as this reflects the ages of 9th through 12th graders. The Texas Education Agency policy is to provide free public education to those persons up until the age of 21 years. It is anticipated that persons 19 and 20 years old may be enrolled in public school and participate in the survey. This age delineation is supported in the Handbook of Cognitive Behavior Group Therapy for Children and Adolescents which points out that there is no definitive point in the American culture for reaching adulthood. Most 19 and 20 year olds do not consider themselves full fledged adults and many remain dependent on their families for educational and financial support.

The 18 to 20 year old participants will not be required to complete the parental assent form in addition to the consent form. Permission from the legal guardian and assent will be required for all participants under the age of 18. The consent and assent form has been attached in Attachment K for full review.

## IV. Materials

**1.** Proposal: Adolescent interview: (Attachment E)
Response 1: Consider adding a question about the type of information adolescents may have been given specifically by their doctor or health educator regarding the use of acetaminophen and/or other OTC drugs (teachers, pharmacists, parents, nurse, case workers, and friends are all explicitly mentioned in this script).

Doctor, health educator, and counselor have been added to the adolescent script.

Response 2: Asking more specific questions about the participant's knowledge of acetaminophen (assuming that a lack of knowledge about the drug accounts for at least some instances of overdosing) may help elicit clearer responses applicable to the aim of this study. Examples: "Why do you/have you used acetaminophen?" "For what other purposes can this medicine be taken for?" "How much and how often do you (or would someone else) take this medicine?" "Is this medicine dangerous?" "How much of this medicine would you need to take to experience dangerous effects?" "What types of effects (wanted or unwanted) could you experience from taking this drug?" "What types of effects (wanted or unwanted) could you experience from taking an increased amount of this drug?" (Questions such as these may also indicate whether there is a general lack of knowledge about acetaminophen overdose and toxicity, or whether overdosing is used to achieve a certain end or experience.)

The goal of a focus group is to facilitate interaction between the participants to the point that they begin to provide insight into their shared cultural and real life experiences on the topic of interest. Asking very specific and direct questioning can reduce the natural flow of conversation of a focus group. Below is a comparison between the questions posed above and the focus group questions we have formulated. We feel all of these topics are addressed in the current questions and that rewording to direct questioning is counter to the purpose of focus group methodology. However, to ensure that the specific information of interest is obtained. We will incorporate a method of questioning known as funneling where questions and probes will continue until the specific question is addressed. This allows the participants the opportunity to share their life experiences

in their own language but continues the inquiry until the focus is narrowed to the specifics.

| Proposed question | Formulated question |
|---|---|
| Why do you/have you used acetaminophen? | Tell us the story of how you or a family member has used it. [Probe: Where do you get this medicine? What was it for?] |
| For what other purposes can this medicine be taken for? | Describe what it is it used for. |
| How much and how often do you (or would someone else) take this medicine? | Share with us how you know how much to take and how often.<br>Think about the times you use this medication. Tell me about that. [Probes: How much do you take? How often? Do you take it with other medicines?]<br>I'm wondering if you keep this at your home? [Probes: How do you store it? Do you carry it with you? Do you share it with other people?] |
| What types of effects (wanted or unwanted) could you experience from taking this drug? | Can you describe any side effects from this medicine? [Probe: Can it harm your kidneys or your liver?]<br>What I would like to hear about is does this medicine work when you use it? Explain to me how you know if it works. [Probes: How long do you think it takes to work?] |
| What types of effects (wanted or unwanted) could you experience from taking an increased amount of this drug? | I would like for you to talk to each other about how strong you think this medicine is. [Probe: Do you think this medicine is safe to use?]<br>If you took too much, could it make you sick or hurt you? How important is that concern?<br>How much of this medicine would someone have to take to cause harm? Why do you think that amount would cause harm? [Probe: is that more than the recommended dose] |

**2.** Proposal: Parental consent form

Response: Consider adding a note about what parents should say to their child about this study when asking them to participate (assuming some parents will ask their children first whether or not they want to be included in the study before giving their consent). By being specific about what this study is about, parents may inform their children about the proper use and risks of acetaminophen, making study participants more informed than the average adolescent. (Also, would parents who have more thoroughly informed their children already be the ones more likely to consent to the study? Perhaps a note stating that many people seem to be misinformed or may

lack important information about acetaminophen will make parents who have not addressed such issues with their children more likely to participate.)

The consent form fully informs the parent and the child. The Institutional Review Board policy is one of full disclosure of the study objectives to study participants. This is of particular importance to the board when study participants are minors.
Information about risk of overuse of acetaminophen among adolescents is provided in the letter to the parents of adolescents in Attachment E1 submitted with the clearance package.

**3**. Proposal: Patient Demographic Information (not marked with an attachment number)
Response 1: Is this the questionnaire mentioned in the Supporting Statement, Page 4, Part A (2)?
Yes. This is the self-administered questionnaire for the focus group participants. We have created a separate document (Attachment L) for adolescents which will be administered along with the individual interview.

Response 2**: See pages 5-6 for suggested questions to include on questionnaire.
Response 3: For whom was this questionnaire intended? (Who is the "Patient" referred to in the title?)
All focus group participants

Response 4: Will adolescents take this questionnaire? Or will the parents of adolescents fill it out? If parents of adolescents are responsible for filling it out (as some information such as annual household income or insurance plans may not be known to the adolescent), do the parents fill the questionnaire out in reference to themselves, or on behalf of their child? Clear directions should be included.
A separate form for adolescents has been created and is located as Attachment L. Zip code and parent/guardian occupation has been added as an indicator of socioeconomic status as adolescents will most likely not be able to provide household income.

Response 5: Consider adding to this questionnaire space for participants to write any other comments that they did not wish to share verbally with the focus group or experimenter.
Space has been added to the form

Response 6: Consider changing the wording of the title to "Participant" rather than "Patient."
The word "patient" has been replaced with "participant"

Response 7: Why is insurance information important?
Insurance information is collected as a marker of access to health care and health services

**4.** Proposal: How to Read an OTC Drug Label
Response: What is this for? Will this information be given to participants after completing this study? May want to include in addition the FDA Q&A about acetaminophen for consumers: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm168830.htm.

This is patient education material to be provided to participants after they have completed the study. The FDA material will be used instead as it is much more comprehensive, but was not available at the time this was originally prepared. It now replaces "How to Read an OTC Drug Label" as Attachment D1.

**5.** Proposal: Screening Form
Response: When asking parents whether they have given their child "an over-the-counter medicine containing acetaminophen," consider adding the names of such common drugs (e.g. "such as Tylenol, Children's Tylenol, or [other common acetaminophen-containing drugs]") to avoid screening out the parents who may not know what acetaminophen is and/or which drugs contain acetaminophen.

We will incorporate names such as Tylenol, Children's Tylenol and other common acetaminophen drugs when screening patients.

**6.** Proposal: Assurance of Confidentiality (Supporting Statement, Page 5, Part A (10))
Response: Is there an actual assurance of confidentiality written on any of the materials that will be provided by participants? Consider adding such a statement, writing "We will keep your information private to the extent permitted by law" rather than using the word "confidential," unless it would truly be possible to keep such information confidential in response to a FOYA (Freedom of Information Act) request.

The following statement has been added to the Self-Administered Questionnaire and the Adolescent Demographic forms:
"Your responses will be kept confidential to the extent permitted by law, including AHRQ's confidentiality statute, 42 USC 299c-3(c). That law requires that information collected for research conducted or supported by AHRQ that identifies individuals or establishments be used only for the purpose for which it was supplied unless you consent to the use of the information for another purpose."

**7.** Proposal: No consent form included
Response: Include customized consent forms for each of the different groups being interviewed (with assurances of confidentiality/privacy as deemed fit).

Consent forms are in Attachment K.

**8.** Minor language changes:
**(a)** Proposal: Probe in adolescent interview: "Do you give it [acetaminophen] to them with other drugs?" (Attachment E)
Response: Assuming that this question was intended for parents administering medicines to their child, it should be rewritten for the adolescent interview script to state: "Do you take it with other drugs (including alcohol)?"

Adolescent interview has been and amended.

**(b)** Proposal: Adolescent interview: "Can anyone think of other places they heard about this medicine?" (Attachment E)
Response: Assuming that this probe was intended for a focus group discussion, rather than a one-on-one interview, it should be rewritten for the adolescent interview script to state, "What other places have you heard about this medicine?"

Adolescent interview has been corrected.

**Note: The FDA has just written a new rule regarding the labeling of over-the-counter pain relievers, including acetaminophen:
http://edocket.access.gpo.gov/2009/pdf/E9-9684.pdf

New requirements for acetaminophen-containing drugs:
- Active drug ingredients must be prominently displayed
- Consumers must be informed specifically about the risk of liver damage when using acetaminophen

In its press release, the FDA writes:
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149573.htm
"[1] Safety data reported in medical literature indicate that people sometimes take more acetaminophen than the labeling recommends. [2] Others unknowingly take multiple products containing acetaminophen at the same time. [3] Exceeding the recommended dosage of acetaminophen may increase the risks for severe liver damage. [4] Alcohol use can also increase the risk of liver damage with acetaminophen."

From these statements, it may be highly beneficial to address the following in this current study:

1. Why do people take more acetaminophen than recommended? Is it intentional or unintentional (or due to lack of knowledge)?
2. Why/under what conditions are people most likely to take multiple products containing acetaminophen at the same time?
3. Do people know what the recommended dose of acetaminophen is? Do people know the dose at which acetaminophen can be harmful? Do people know how much acetaminophen their medicines actually contain (and/or how to find this information)?
4. Are acetaminophen and alcohol often used together (intentionally or unintentionally)? Why/under what conditions is this most likely to occur?

The current study addresses 1, 2, and 3. A question regarding use of alcohol in conjunction with acetaminophen is added to Theme III of the adult focus group questions and the adolescent interview.

Proposed questions to add to questionnaire:
A. To address the potential impact of the FDA labeling rule:

1. If Tylenol [or other acetaminophen containing drug] was clearly labeled as an acetaminophen-containing drug, would this change your response to the medicine? Describe what your response would be.

    a. Would you use the medicine any differently? If so, how? (Would you take a different/lesser dose?)
    b. Would you turn to other drugs for pain relief instead? (If so, which ones?)
2. If Tylenol [or other acetaminophen containing drug] was clearly labeled as causing a risk of liver damage, would this change your response to the medicine? Describe what your response would be. Would you use the medicine any differently? If so, how?
    a. Would you use the medicine any differently? If so, how? (Would you take a different dose?)
    b. Would you turn to other drugs for pain relief instead? (If so, which ones?)
3. Name all of the medicines that you can think have that contain acetaminophen. [Tylenol, some cold medicines, prescription painkillers such as Vicodin, etc.] Perhaps present participants with list of medicines – Ask them to check off the ones that they (or their children) have used as well as which ones they believe contain acetaminophen.

Questions 1 and 2 have been added to Theme VI. Question 3 will be collected at screening with a pictures/list.

B. The FDA has also recommended that the maximum over-the-counter dose of the popular pain reliever acetaminophen be lowered. To address the potential impact/unintended consequences of this:

1. How often do you take Tylenol [or other acetaminophen containing drug]? How much do you take? [These questions would hopefully give a sense of the size dose people are actually used to taking.]
2. What would you do if the strength of Tylenol [or other acetaminophen containing drug] was noticeably weakened? Would you take a greater dose? Would you turn to other drugs for pain relief? (If so, which ones?)
3. Do you experience chronic pain? If so, do you use acetaminophen containing drugs to combat this? [If those with chronic pain are of special concern, it may be worthwhile to compare their use of acetaminophen containing drugs with those of the no-chronic-pain population. It may be that restrictions on dosage would have the greatest impact on people who do experience chronic pain, potentially causing them to suffer more, or to take multiple (lowered) doses of acetaminophen.]

Question 1 has been addressed under Theme I, II and III of focus group questions. Questions 2 and 3 are added to Theme VI of focus group questions.

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