SUPPORTING STATEMENT

Part A

Understanding Patients' Knowledge and Use of Acetaminophen

Version
March 8th, 2009

Agency of Healthcare Research and Quality (AHRQ)

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A. Justification

1. Circumstances that make the collection of information necessary

The mission of the Agency for Healthcare Research and Quality (AHRQ) set out in its authorizing legislation, The Healthcare Research and Quality Act of 1999 (see Attachment A), is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

1. research that develops and presents scientific evidence regarding all aspects of health care; and

2. the synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

3. initiatives to advance private and public efforts to improve health care quality.

Also, 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, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

This proposed data collection is a qualitative study to preliminarily identify issues that relate to the misuse and overdosing of over-the-counter (OTC) acetaminophen. Acetaminophen is the most widely used analgesic and antipyretic drug in the U.S. When appropriately used, it is a very safe agent. However, a single large overdose, or several supratherapeutic dosages in a short period of time, has been associated with acute liver failure, which can occur with dosages over 250 mg/kg over a 24-hour period, or > 12 g in an adult. 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. Because this study is exploratory, the data collection will employ convenience samples of individuals from different segments of the population. Parents of young children, adolescents, adults and health providers will be included. Populations that have not been previously evaluated in the U.S. including ethnic minorities and older adults will be recruited. The results of this qualitative phase will provide an understanding of the issues of relevance and will be used to develop a comprehensive survey.

In turn, the results of this survey, which will be addressed in a second OMB clearance package once the questionnaire is available, will provide data to develop consumer education programs targeting specific groups, such as adolescents and parents and aimed at aspects

identified as misconceptions and barriers to adequate use of OTC acetaminophen. Because physicians and pharmacists will also be interviewed, the gathered information will also assist in the development of materials and interventions that can be implemented at points of care such as pharmacies and primary care outpatient clinics. Finally, participants will be asked about their views on packaging, labeling and delivery of acetaminophen. This information will be useful for policy makers to consider and to evaluate regulations and legislation with respect to the distribution, dispensing and sales of OTC acetaminophen.

This project consists of the following data collections:

1) Screening forms to be completed by all participants (see Attachment B);

2) Focus groups – 4 groups with parents of young children (age ≤ 8 years), and 4 focus groups with adults (see Attachments C, D and D1);

3) Semi-structured interviews with adolescents (ages 13 to 20 years), physicians and pharmacists (see Attachments E and E1, and Attachments F and F1);

4) Self-administered questionnaire with participants of the focus groups and adolescent interviewees (see Attachment G).

This project supports AHRQ's Centers for Education and Research on Therapeutics initiative to promote the safe and effective use of therapeutics. It also supports AHRQ's mandate for the inclusion of priority populations.

2. Purpose and Use of Information

The information that is collected in the focus groups will be used to develop questions for a survey. The focus group data will identify the issues, barriers, and psychosocial factors surrounding how, when, and why people use over-the-counter acetaminophen. This information will be used to create a survey that will in turn be used to collect information from a larger sample of people.

Each participant will participate in one focus group session. Once the focus group data is collected, it will be transcribed. A process of qualitative analysis will be used to identify common themes that were discussed by the participants. From these themes, questions that are relevant to people who use OTC acetaminophen will be developed. These questions will be compiled into a survey that will be used to collect information from a larger group of participants with the aim of collecting information that will be generalizable to the population and will seek to inform public policy makers.

3. Use of Improved Information Technology

This data collection will utilize digital recording technology to collect, store, and manage the focus group data. Participants will respond verbally to guiding questions.

4. Efforts to Identify Duplication

An extensive review of the scientific literature was conducted. Most studies examining acetaminophen overdose in the U.S. have addressed the clinical consequences of liver

toxicity. Because drug data sources do not capture individual OTC acetaminophen use, the few studies reporting on determinants of misuse have generally been in small convenience samples in emergency rooms (ER) or clinics. These studies do not provide the data necessary to understand how or why overdose has occurred which is essential to promoting safe use of OTC acetaminophen.

5. Involvement of Small Entities

This data collection does not involve or impact small businesses or other small entities

6. Consequences if Information Collected Less Frequently

This is a one-time data collection.

7. Special Circumstances

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

8. Federal Register Notice and Outside Consultations

8.a. Federal Register Notice to be added after FR notice

As required by 5 CFR 1320.8(d), notice was published in the Federal Register on February 26, 2009 on page 8798 for 60 days (see attachment H). The full comments received are located for review in attachment I. Actions taken in response to the comments are located for review in attachment J.

8.b. Outside Consultations

Scientists at the University of Texas M.D. Anderson Cancer Center, Baylor College of Medicine, University of Pennsylvania, Kelsey Seybold Research Foundation, and Harris County Hospital District were consulted to develop and design this study.

9. Payments/Gifts to Respondents

Adult focus group participants will receive a $30 gift card and adolescent interviewees will each receive a $20 gift card. Physician and pharmacist interviewees will reach receive a $40 gift card.

10. Assurance of Confidentiality

Individuals and organizations will be assured of the confidentiality of their replies under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). They will be told the purposes for which the information is collected and that, in accordance with this statute, any identifiable information about them will not be used or disclosed for any other purpose.

Individuals and organizations contacted will be further assured of the confidentiality of their replies under 42 U.S.C. 1306, and 20 CFR 401 and 4225 U.S.C.552a (Privacy Act of 1974). In instances where respondent identity is needed, the information collection will fully comply with all respects of the Privacy Act.

Information that can directly identify the respondent, such as name and age will be collected. Participant confidentiality will be protected by de-identifying audio data upon transcription. All data will be stored on encrypted and password protected files. Data will only be presented in aggregate and de-identified format. Only the principal investigator and research staff necessary to conduct research will have access to the data. All questionnaires will be coded and key will be stored separately in a locked and password protected file. All research data is maintained in locked cabinets within a locked data storage area. All electronic files are password and encryption protected. All activities stated in this project will be performed in concordance with the Health Insurance Portability and Accountability Act (HIPPA) Privacy Rule, 45 CFR Parts 160 and 164. The protocol has undergone full review and was approved by the University of Texas M. D. Anderson Cancer Center Internal Review Board protocol 2008-0055. All investigators have completed protection of human subjects and good clinical practices training and are certified to conduct human subject research. The University of Texas M. D. Anderson Cancer Center has filed a Federal wide Assurance with the Office of Human Research Protections (OHRP). The Federal wide Assurance document number is FWA 363. Informed consent process will be conducted with all participants. Parent assent will be sought for all adolescents who participate in the semi-structured interviews.

11. Questions of a Sensitive Nature

Adolescent interviews have the potential to reveal anti-social or demeaning behaviors related to the misuse of acetaminophen. There are reports in the scientific literature that OTC acetaminophen over dose may be intentional in this segment of the population. It is important that an understanding of adolescent use of OTC acetaminophen is gained in order to reduce the opportunity for intentional and unintentional misuse. Adolescents will be screened for depressive symptomalogy using the Center for Epidemiological Studies Depression Scale for Children (CES-DC) prior to participation. Adolescents with depressive symptoms will be excluded from the study and will be referred for evaluation and counseling to the healthcare entity through which they were identified and recruited. Parents, and where available, the primary care provider will be notified of the referral. The benefit of understanding this behavior to promote safe use of OTC acetaminophen outweighs the risk of embarrassment to potential adolescent participants. Informed consent process will be conducted with all participants. Parent assent will be sought for all adolescents who participate in the semi-structured interviews.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1 shows the estimated annualized burden hours for the respondent's time to participate in this project. The screening form will be completed by all participants and is expected to take approximately 3 minutes to complete. Focus groups will include 2 populations: parents of children ≤ 8 years of age and adults, and will last about 1 ½ hours. Semi-structured interviews will be conducted with 20 adolescents, 20 primary care physicians, and 20 pharmacists and will last 20 to 30 minutes. The self-administered questionnaire will be completed by the focus group participants and the adolescent participants of the semi-structured interviews, and will take about 6 minutes to complete. The total burden for all participants is estimated to be 134 hours.

Exhibit 2 shows the estimated annualized cost burden for the respondent's time to participate in the project. The total cost is estimated to be $2,001.

Exhibit 1. Estimated annualized burden hours

Data Collection Mode	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Screening form	**124**	**1**	**3/60**	**6**
Self-administered questionnaire	**84**	**1**	**6/60**	**8**
Focus group with Parents of children ≤ 8 years of age	**32**	**1**	**1.5**	**48**
Focus group with Adults	**32**	**1**	**1.5**	**48**
Semi-structured interviews with Adolescents(13 to 20 years of age)	**20**	**1**	**30/60**	**10**
Semi-structured Interview with Primary care physicians	**20**	**1**	**20/60**	**7**
Semi-structured interviews with Pharmacists	**20**	**1**	**20/60**	**7**
Total	**332**			**134**

Exhibit 2. Estimated annualized cost burden

Data Collection Mode	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Screening form	**124**	**6**	**$10.30**	**$62**
Self-Administered questionnaire	**84**	**8**	**$10.30**	**$82**
Focus groups with Parents of children ≤ 8 years of age	**32**	**48**	**$10.30**	**$494**
Focus groups with Adults	**32**	**48**	**$10.30**	**$494**
Semi-structured interviews with Adolescents (13 to 20 years of age)	**20**	**10**	**$10.30**	**$103**
Semi-structured interviews with Primary care physicians	**20**	**7**	**$61.10**	**$428**
Semi-structured interviews with Pharmacists	**20**	**7**	**$48.22**	**$338**
Total	**332**	**134**		**$2,001**

* Patient average hourly wage based on the average per capita income of $21,435 (computed into an hourly wage rate of $10.30) in Harris County, Texas. Provider hourly wage based on an average of the following estimates from National Compensation Survey: Occupational wages in the United States 2006, "U.S. Department of Labor, Bureau of Labor Statistics: primary care physician = $61.10/hour; pharmacist = $48.22/hour.

13. Estimates of Annualized Respondent Capital and Maintenance Costs

There are no direct costs to respondents other than their time to participate in the study.

14. Estimates of Annualized Cost to the Government

Exhibit 3 shows the estimated cost to the Federal government for this six month project. The total cost is $164,440. This amount includes all direct and indirect costs of the design, data collection, analysis, and reporting phase of the study.

Exhibit 3. Estimated Cost

Cost Component	Total Cost
Project Development	13,250
Data Collection Activities	61,699
Data Processing and Analysis	14,080
Publication of Results	750
Project Management	17,000
Overhead	57,661
Total	$164,440

15. Changes in Hour Burden

This is a new collection of information.

16. Time Schedule, Publication and Analysis Plans

	2009								
	Q1			Q2			Q4		
	Jan	Feb	Mar	Apr	May	June	Aug	Sept	Oct
AHRQ submits OMB "Clearance Package" to OMB									
60 day Federal Register Notice									
30 day 2nd Federal Register Notice									
--Focus groups and interviews									
--Analysis and generation of preliminary reports: Aims 1 & 2									

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

Attachments:

Attachment A – AHRQ's Authorizing Legislation

Attachment B -- Screening form

Attachment C -- Focus group guide for parents of children

Attachment D -- Focus group guide for adults

Attachment D1 -- How to read an OTC drug label

Attachment E -- Semi-structured interview with adolescents

Attachment E1 – Adolescent recruitment letter

Attachment F -- Semi-structured Interview with primary care physicians

Attachment F1 – Pharmacist and Physician recruitment letter

Attachment G -- Self-administered questionnaire

Attachment H – Federal Register Notice

Attachment I – Comments

Attachment J – Actions Taken in Response to Comments