

Supporting Statement for Collection of Information Follow-up Activities for Product-Related Injuries

A. Justification

1. Information to be collected and circumstances that make the collection of information necessary

Section 5(a) of the Consumer Product Safety Act (CPSA)(15 U.S.C. § 2054(a)) requires the Commission to collect information related to the cause and prevention of death, injury, and illness associated with consumer products. CPSC staff conducts continuing studies and investigations of deaths, injuries, diseases, other health impairments, and economic losses resulting from incidents involving consumer products. CPSC staff obtains information about product-related deaths, injuries, and illnesses from a variety of sources, including news outlets, death certificates, consumer complaints, and medical facilities.

CPSC staff also operates the National Electronic Injury Surveillance System (NEISS), which provides timely data on consumer product-related injuries treated in hospital emergency departments in the United States. CPSC staff also uses the NEISS system to collect information on childhood poisonings in accordance with the Poison Prevention Packaging Act of 1970.

From these sources, the CPSC staff selects cases of interest for further investigation by contacting persons who witnessed or were injured in incidents involving consumer products. These investigations are conducted on-site (face-to-face), by telephone, or by the Internet. On-site investigations are usually made in cases where the CPSC staff need photographs of the incident site, the product involved, or detailed information about the incident. This information can come from face-to-face interviews with persons who were injured or who witnessed the incident, as well as via contact with state and local officials, including police, coroners and fire investigators, and others with knowledge of the incident.

Through Interagency Agreements, the CPSC staff also use the NEISS system to collect information on injuries for the Centers for Disease Control and Prevention (NEISS All Injury Program (NEISS-AIP)). In addition to the standard data variables collected on all NEISS injuries, the NEISS-AIP collects additional variables on several studies for CDC (Firearm-Related Injuries, Adverse Drug Events, Assaults, Self-Inflicted Violence, and Work-Related Injuries) and one study on non-crash motor vehicle-related injuries for the National Highway and Transportation Safety Administration (NHTSA).

2. Use and sharing of collected information

CPSC staff uses the information from this collection to support development and improvement of voluntary standards; proceedings for the development of

mandatory standards and regulations; information and education campaigns; and administrative and judicial proceedings for enforcement of the statutes, standards, and regulations administered by the agency. The information informs the agency in its efforts to remove unsafe products from channels of distribution and consumers' homes, and it provides information to the public about the safety of consumer products.

No records released to the public contain personally identifiable information; geographic and personal identifiers have been masked.

3. Use of information technology (IT) in information collection

All NEISS data are reported electronically, and NEISS respondents directly submit data to CPSC through the Internet and on laptops provided by CPSC. Information for follow-up investigations from NEISS and other sources are collected through traditional face-to-face, telephone, or Internet-based interviews with consumers, witnesses, and other knowledgeable parties, such as fire, police, and healthcare professionals.

4. Efforts to identify duplication

There is no other national surveillance system of product-related injuries, childhood poisonings, and other injuries treated in emergency departments. The detailed information obtained from hospital emergency records about incidents associated with consumer products is not available from any other source.

5. Impact on small business

This collection of information is voluntary and does not have a disproportionate impact on small businesses.

6a. Consequences to Federal program or policy activities if collection is not Conducted or is conducted less frequently

If this information were not collected or were collected less frequently, the CPSC and other agencies that rely on this data would lack timely and detailed information to identify new hazards and support rulemaking proceedings, assist in efforts to develop or improve voluntary standards; perform actions to obtain correction of products that present a substantial product hazard, and conduct informational campaigns.

6b. Consequences to Federal program or policy activities if collection is not used for statistical estimates

The current NEISS probability sample was drawn and recruited in 1995-1996 and implemented in 1997. The current NEISS sample consists of 96 hospital emergency

departments grouped into four strata, based on size, as measured by the annual number of emergency department (ED) visits, and a fifth stratum for children's hospitals. When a hospital stops participating in the NEISS, staff recruits a hospital of similar size and geographic location as a replacement. If a participating hospital closes, it is not replaced, because its closure is presumed to represent other hospitals that have closed nationally. As of January 1, 2021, there are currently 81 hospitals participating in the NEISS.

In September 2019, CPSC contracted with Westat Inc. under CPSC contract 61320619F0134, to give an independent statistical assessment of the NEISS and the NEISS-AIP samples¹. The primary focus of this contract was to analyze the pros and cons of keeping, expanding, or resampling the current samples of NEISS and NEISS-AIP hospitals. The final Westat recommendation was for a redesign of the NEISS sample.

EPDS staff used a resampling method that maximizes the probability of retaining as many of the current NEISS hospitals as possible, while maintaining the statistical integrity of the NEISS. Among eligible hospital emergency departments, some have migrated from one stratum to another; come into existence since the last resampling of the NEISS; or ceased to exist. The method used in resampling the NEISS is an extension of the Keyfitz procedures for stratified simple random samples.² The advantage of retaining as many of the current NEISS hospitals as possible is that the contracting, data collection, and quality-control mechanisms already exist in the hospitals in the current sample, and it is a cost-effective procedure. Another advantage is that there is far less disruption in trend analysis. The new NEISS sample will contain a mixture of current NEISS hospitals along with new hospitals recruited to join the NEISS as follows:

New NEISS Sample

Stratum	NEISS Redesign	2021 NEISS: Reporting (Retained)	2021 NEISS: Reporting (Dropped)	2021 NEISS: Replacements (Retained)	2021 NEISS: Replacements (Dropped)	New
Small	43	30	0	8	3	5
Medium	26	14	1	1	0	11
Large	12	11	8	0	1	1
Very Large	11	9	0	2	0	0
Children's	8	7	1	0	0	1
Total	100	71	10	11	4	18

From the table above, it is noted that of the 81 hospitals reporting in the NEISS as of January 1, 2021, 71 hospitals will remain in the new NEISS sample and 10 will be dropped. There are currently 15 hospitals no longer participating in the NEISS where replacement hospitals are being recruited. Of these 15, 11 replacement hospitals will remain in the new NEISS sample and 4 will be dropped. Recruitment efforts of replacement hospitals will focus on the 11 hospitals that will remain in the new NEISS sample along with the 18 new hospitals.

One of the advantages of a long-running NEISS sample is the ability to track trends across time. Updating the NEISS sample will interfere with that analysis. One of the best ways to adjust any time series that crosses over two NEISS samples is to have

¹ David Marker, Jim Green, Frost Hubbord, Richard Valliant, “Statistical Assessment of the NEISS and NEISS-AIP Samples: Final Technical Report,” Westat Inc., September 24, 2020.

² J. Michael Brick, David R. Morganstein, Charles, L. Wolter, “Additional Uses for Keyfitz Selection,” Westat Inc., 1987. (http://www.asasrms.org/Proceedings/papers/1987_140.pdf).

an overlap or bridge period, during which data are collected from the old and the new samples. EPDS staff plan to conduct a 12-month overlap as part of the implementation of the new NEISS sample. Having a full 12-month overlap period accounts better for seasonality of some consumer product-related injuries. By comparing estimates calculated from both samples, it is possible to adjust (backcast) old estimates to be consistent with the new sample.

The overlap period will consist of all of calendar year 2023, but it is very dependent on the successful recruitment of the 11 replacement and 18 new hospitals. If NEISS hospital recruitment is successful, the overlap period will run all of calendar year 2023. The national estimates for 2023 will be calculated using the new NEISS sample with historical estimates from 2022, and prior years “backcast” to adjust for the sample update. If NEISS hospital recruitment is delayed, and the 12-month overlap period spans July, 2023 through June 2024, then 2023 national estimates will be calculated using the old NEISS sample, and 2024 national estimates would use the new NEISS sample.

7. Special circumstances requiring respondents to report information more often than quarterly or to prepare responses in fewer than 30 days

Timely reporting of consumer product-related injuries and childhood poisonings treated in emergency departments is necessary to identify, investigate, and respond to new or changing hazards. In CY2020, 50% of the NEISS records were received within 5 days of treatment and 90% within 35 days.

8. Agency’s Federal Register Notice and related information

A notice in the *Federal Register* was published October 26, 2021 (86 FR 59154).

9. Decision to provide payment or gift

NEISS respondents enter into contracts with CPSC and are compensated for their efforts. See Section 12(a) for details of the estimated burden and costs. A number of persons are contacted through a face-to-face, telephone, or Internet interview to provide additional information about selected injuries or incidents associated with consumer products of special interest to CPSC. See Section 12(b) for details of the estimated burden and costs. In general, respondents are not compensated for participating in an interview.

10. Assurance of confidentiality

If a person who is asked to provide information about a product-related injury or incident claims that any information submitted to the CPSC is trade secret or confidential business information, that information is subject to the agency's procedures for withholding confidential information from public disclosure codified

at 16 CFR part 1015, subpart B. If such information is requested under provisions of the Freedom of Information Act, the person who provided the information is notified and given the opportunity to respond and seek judicial relief before the CPSC's release of the information. In addition, any accident or investigation report made under the CPSC by an officer or employee of the CPSC shall be made available to the public in a manner that will not identify any injured person or any person treating him or her, without the consent of the person so identified.

11. Questions of a sensitive nature

The CPSC's staff takes care to design interview guides so that persons who witness or are injured in incidents associated with consumer products are not requested to provide any information of a sensitive nature.

12 (a). Estimate of hour burden to NEISS respondents

The NEISS system collects information on consumer product-related incidents and other injuries from a statistical sample of hospitals in the United States. The number of hospitals participating in CY2021-CY2024 will fluctuate from the current 81 reporting to as high as 110 as the current NEISS sample is retained, the new NEISS sample is recruited, and an overlap period of 12 months is conducted prior to the current NEISS sample being retired.

Respondents to NEISS include hospitals that directly report information to NEISS, and hospitals that allow access to a CPSC contractor who collects the data. Collecting emergency department records for review, correcting error messages, and other tasks takes between 2.5 and 6 hours weekly. Each record takes about 30 seconds to review. Coding and reporting records that involve consumer products or other injuries takes about 2 minutes per record. Coding and reporting on additional special study information (Adverse Drug Effects) takes about 2 minutes and 90 seconds per record for other special studies. Respondents also spend about 8-36 hours per year in related activities (training, evaluations, and communicating with other hospital staff).

During CY2023, assuming there is a total of 110 hospitals participating in the NEISS, there will be an estimated 160 NEISS respondents (total hospitals and CPSC contractors). These NEISS respondents will review an estimated 6 million emergency department records and report 1.2 million total cases (470,000 consumer product-related injuries for CPSC, and 730,000 other injuries for the NEISS-AIP). The table below lists the estimated number of reported cases, and the estimated number of reported cases with additional special study information.

Total NEISS Cases Reported	1.2 million
Consumer Product-Related Injuries	470,000
CDC NEISS-AIP	730,000

Special Studies Reported (subset of above)	
Child Poisoning (CPSC)	5,000
Adverse Drug Events (CDC)	94,000
Assaults (CDC)	84,000
Firearm-Related Injuries (CDC)	12,000
Self-Inflicted Violence (CDC)	22,000
Work-Related Injuries (CDC)	54,000
Motor Vehicle Non-Crash Injuries (NHTSA)	17,000

The total burden hours for all NEISS respondents are estimated to be 130,000 for CY 2023. The average burden hours per respondent is 800 hours. However, the total burden hours on each respondent varies, due to differences in the sizes of the hospitals (*e.g.*, small rural hospitals versus large metropolitan hospitals). The smallest hospital will report an estimated 250 cases with a burden of about 150 hours, while the largest hospital will report an estimated 60,000 cases with a burden of about 4,500 hours.

The total costs to NEISS respondents for CY 2023 are estimated at approximately \$6.5 million. NEISS respondents enter into contracts with CPSC and are compensated for these costs. The average cost per respondent is estimated to be about \$41,000. The average cost per burden hour is estimated to be \$50 per hour (including wages and overhead). However, the actual cost to each respondent varies, due to the type of respondent (hospital versus CPSC contractor), size of hospital, and regional differences in wages and overhead. Therefore, the actual annual cost for any given respondent may vary between \$3,000 at a small rural hospital, and \$450,000 at the largest metropolitan hospital.

12 (b). Estimate of hour burden to other respondents

CPSC staff conducts field interviews of about 375 persons each year using the supplementary Criteria and Rationales manual. On average, an on-site interview takes about 4.5 hours. Staff also conducts about 2,000 in-depth investigations (IDIs) by telephone through the use of a Computer Assisted Telephone Interview (CATI) or self-administered Computer Assisted Internet Interviews (CAII) questionnaires. Each CATI or CAII IDI requires about 20 minutes.

CPSC staff estimates 2,355 annual burden hours on these respondents: 1,688 hours for face-to-face interviews; 667 hours for in-depth telephone or internet interviews.

CPSC's staff estimates the value of the time required for reporting is \$38.60 an hour (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," March 2021: <https://www.bls.gov/new.release/ecec.toc.htm>). At this valuation, the estimated annual cost to the public is about \$90,903.

13. Estimate of other total annual cost burden to respondents or record keepers

The only costs to respondents from this collection of information are those described in item 12, above.

14. Estimate of annualized costs to the Federal government

The cost to the government of the collection of the NEISS information is estimated to be about \$8.7 million a year. This estimate includes \$6.5 million in compensation to NEISS respondents described in section 12(a) above. This estimate also includes \$2.237 million for about 185 professional staff months each year. The estimate of professional staff months includes the time required to: oversee NEISS operations (*e.g.*, administration, training, quality control); prepare questionnaires, interviewer guidelines, and other instruments and instructions used to collect the information; conduct face-to-face and telephone interviews; and evaluate responses obtained from interviews and completed forms. Each month of professional staff time costs the agency about \$12,093. This is based on a GS-12 mid-level salaried employee. The average yearly wage rate for a mid-level salaried GS-12 employee in the Washington, DC metropolitan area (effective as of January 2021) is \$98,827 (<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2021/DCB.pdf>, GS-12, step 5). This represents 68.1 percent of total compensation³. Adding an additional 31.9 percent for benefits brings average yearly compensation for a mid-level salaried GS-12 employee to \$145,120.

15. Program changes or adjustments

This request for the approval of an estimated 132,355 (130,000 NEISS and 2,355 other) burden hours per year is an increase of 34,884 hours, due to an increase in the number of emergency department charts being reviewed and coded since this collection of information was last approved by OMB in March 2021.

This information collection request excludes the burden associated with other publicly available Consumer Product Safety Information Databases, such as Internet complaints, Hotline, and MECAP reports, which is accounted for under OMB control number 3041-0146. This information-collection request also excludes the burden associated with follow-up investigations conducted by other federal agencies.

16. Plans for tabulation and publication

The agency provides yearly reports of NEISS data to the public on its website. NEISS data are also available for public use through the CPSC website. The CPSC publishes results from some of its investigations of product-related injuries and incidents in *Federal Register* notices during rulemaking proceedings, and in safety alerts, news

³ U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” March 2021, Table 1) percentage of wages and salaries for all civilian management, professional, and related employees: <https://www.bls.gov/web/ecec/ececqrtn.pdf>

releases, and other informational materials that are disseminated to the general public, voluntary standards groups, firms, and trade associations. The agency has no specific plan to publish all of the data obtained from this collection of information.

17. Rationale for not displaying the expiration date for OMB approval

Not applicable.

18. Exception to the certification statement

Not applicable.

B. Collection of Information Employing Statistical Methods

1. The potential respondent universe includes patients treated in statistically selected hospitals participating in NEISS to report emergency department-treated, product-related injuries and other injuries. The affiliated NEISS hospitals will report about 1.2 million emergency department visits annually using existing information extracted from hospital records. Of those reported visits, about 470,000 will be consumer product-related cases. Since hospital record data are limited, further information is frequently necessary, and about 2,375 of these cases are selected for further investigation.

The potential respondent universe also includes individuals involved with incidents recorded in newspaper articles, consumer complaints, death certificates, coroner's reports and any other injury sources that may be reported to the CPSC. These other data sources contribute more than 116,000 cases annually, of which about 2,000 are selected for further investigation.

2. Cases associated with categories of interest are selected daily from the hundreds of incident reports received each day by the CPSC. CPSC investigators call to interview or to arrange to visit the victim or others to determine specific details about the accident sequence. Information collected from the victim, family member, witness, or others is reported on an investigation form designed for this purpose.

When less than 100 percent of the surveillance cases are selected for investigation, the universe of cases is stratified by relevant factors, such as type of injury or consumer product involved and a simple random sample of cases is selected.

The estimation procedure for probability surveys involves multiplying the original surveillance case weight by the case weight appropriate for the follow-back investigation. Normally, the latter is the reciprocal of the probability of selection, adjusted, where needed, for non-response and an annual ratio adjustment to take into account hospitals that open and close and/or change in size.

3. About 57 percent of the victims involved in the selected incidents are successfully contacted. Of those contacted, about 82 percent agree to provide information voluntarily on the circumstances of the incident. For probability surveys, responses are weighted to account for non-responses. The results from probability surveys can be generalized to the universe studied.

4. No tests of procedures or methods will be undertaken.

5. Contact for collection and analysis of NEISS data:

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