referred for surgical intervention, what is the comparative effectiveness (benefits/harms) of various types of surgical interventions (including laser and resection)?

PICOTS (Population, Intervention, Comparator, Outcomes, Timing, Setting)

KQ 1

Population

Newborns, infants, and children up to 18 years of age with known or suspected infantile hemangiomas.

Intervention(s)

Diagnostic imaging:
- Magnetic resonance imaging
- Computed tomography
- Magnetic resonance angiography
- Echocardiography
- Ultrasonography
- Endoscopy

Comparator

- Other workup evaluation approaches for treatment planning
- Other imaging modalities

Outcomes

- Ability to identify presence, number, and extent of hemangiomas and associated structural anomalies (sensitivity and specificity)
- Harms including, but not limited to, effects of sedation or imaging dye

Timing

- Immediate and short-term (≤3 months)
- Long-term (>3 months)

Setting

Inpatient and outpatient settings (*e.g.,* pediatric radiology clinic, otolaryngology clinics, dermatology clinics, pediatric surgical unit)

KQs 2, 3, and 4

Population

Newborns, infants, and children up to 18 years of age with infantile hemangiomas.

Intervention(s)

KQ2 Pharmacologic interventions
- Systemic (*e.g.,* propranolol) or topical (*e.g.,* timolol) beta-blockers
- Corticosteroids (topical, intralesional, or systemic)

KQ3 Pharmacologic interventions
- Immunosuppressants (*e.g.,* sirolimus)
- Immunomodulators (*e.g.,* imiquimod, interferon)
- Antineoplastics (*e.g.,* intralesional bleomycin, intravenous vincristine)
- Angiotensin-converting enzyme inhibitors
- Antiangiogenic agents

KQ4 Surgical interventions

Laser treatment
- Pulsed dye
- Fractionated laser
- Argon
- Carbon dioxide
- Neodymium (Nd): Yttrium Aluminium Garnet YAG
- Erbium

Surgical treatment
- Cryotherapy
- Resection
- Embolization
- Radiofrequency ablation therapy

Comparator

KQ2, 3
- No treatment
- Other pharmacologic interventions
- Observation
- Complementary and alternative medicine (CAM) (*e.g.,* massage, compression therapy, essential oils)

KQ4
- No treatment
- Other laser or surgical interventions
- Observation
- CAM (*e.g.,* massage, compression therapy, essential oils)

Outcomes

Intermediate outcomes (KQ2, 3, 4)
- Size/volume of hemangioma
- Impact on vision
- Aesthetic appearance as assessed by clinician or parent
- Degree of ulceration
- Harms
- Quality of life

Final outcomes (KQ2, 3, 4)
- Marked improvement of hemangiomas
- Prevention of disfigurement
- Resolution of airway obstruction
- Preservation of vision
- Preservation of organ function (*e.g.,* thyroid function, cardiac function)
- Resolution of ulceration
- Psychological impact on the patient
- Harms including: pain, bleeding, sequelae of scarring, skin atrophy, venous prominence, disfigurement, distortion of anatomic landmarks, ulceration, infection, hypopigmentation

Timing

KQ2, 3
- Immediate and short-term (≤2 years of age)
- Long-term (>2 years of age)

KQ4
- Immediate and short-term (≤3 months)
- Long-term (>3 months)

Setting

Inpatient and outpatient settings (*e.g.,* pediatric radiology clinic, otolaryngology clinics, dermatology clinics, pediatric surgical unit)

Dated: December 30, 2014.

Richard Kronick,

AHRQ Director.

[FR Doc. 2015–00766 Filed 1–22–15; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–15–15LB]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404–639–7570 or send comments to Leroy A. Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology

and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project

Enhancing Dialogue and Execution of Dust Reduction Behaviors through Workgroup Communication—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NIOSH, under Public Law 91–596, Sections 20 and 22 (Section 20–22, Occupational Safety and Health Act of 1977) has the responsibility to conduct research relating to innovative methods, techniques, and approaches dealing with occupational safety and health problems.

This project focuses on mineworkers' overexposure to respirable coal dust and how using the Continuous Personal Dust Monitor (CPDM), as an educational tool, can help provide information to mineworkers and their respective workgroups, about ways to reduce respirable coal dust exposure in their work environment. NIOSH proposes a 3 year approval for a project that seeks to understand what group communication practices are important for mine worker H&S and how those practices can be developed, implemented, and maintained over time. The following questions guide this study:

What impact does a communication/technology intervention model that was designed and implemented have on: (1) Workers' health/safety behaviors, including those that lower exposure to dust; and (2) workers' perceptions of their organizations' health and safety values?

To answer the above questions, NIOSH researchers developed an intervention that focuses on workers' communication about and subsequent actions taken to reduce respirable dust exposure over time, using information provided by their Continuous Personal Dust Monitor (CPDM). The intervention will inform how workgroups communicate with each other about health and how this communication impacts individual behavior such as corrective dust actions taken by workers.

Coal Workers' Pneumoconiosis (CWP) or ''Black Lung Disease'' is caused by miners' exposure to respirable coal mine dust and is the leading cause of death due to occupational illness among US coal miners—making this an issue worth placing emphasis in mine health research. X-rays provided from the US National Coal Workers' X-ray Surveillance Program show that new cases of CWP are occurring among miners who have worked exclusively under previous respirable coal mine dust exposure limits. Previously, federal law stated that respirable coal dust levels must not exceed 2 mg/m^3 for any work shift [Code of Federal Regulations]. However, under the new respirable dust rule that passed May 1, 2014 (CFR part 70), the dust level may not exceed 1.5 mg/m^3. The new rule also requires mine operators to use CPDMs by February 1, 2016, for designated occupations (DO). Although CPDMs provide miners with near real-time feedback about their level of respirable coal dust exposure, they do not ensure that miners will use the information to reduce their level of exposure. Previous research indicates that the use of information technology can enhance lateral and horizontal communication within organizations, showing support for using the CPDM in the current study (Hinds & Kiesler, 1995).

The intervention is designed to involve workers in the interpretation of CPDM feedback and discuss, with their coworkers/workgroups, potential changes to work practices that can decrease exposure to respirable coal mine dust. Data is collected during three time points throughout a six-week intervention to assess the ongoing communication using CPDM feedback and effects of the workgroup communication on behavior. Data collection and analysis will occur via a pre/post survey with workers and focus groups with workers and mine site leaders. Safety circles are used to communicate and encourage specific behavior changes. A typical circle includes a facilitator or leader (who directs the meetings), 7–10 members, and one-hour weekly meetings that take place during the workday. During the meetings, members review data relevant to the problem and brainstorm possible solutions. Industries have successfully used ''safety circles'' to generate lists of safety concerns that circle members would like to analyze and solve. Edwards [1983] documented that one surface coal mine was able to decrease the number of accidents on circle members' shifts by 27%. If underground coal miners are able to actively participate in the discussion of respirable coal mine dust exposure levels and what can be done to limit future exposure, they may be more inclined to behave in ways that limit their exposure.

With the stricter regulations that just passed the opportunity to proactively improve communication around the CPDM and identify appropriate corrective actions, as required by the Mine Health and Safety Administration, is favorable. NIOSH proposes this intervention design at three coal mine sites. Coal mine sites will be recruited who have inquired interest in learning how to improve utility of the CPDM on their site and/or interest in improving their employees' communication efforts. Only a small sample of workers will participate at each mine site because of the time required for completion and to ensure the longitudinal data can be adequately collected over the six weeks. In other words, we would rather collect data multiple times with the same worker and have fewer participants than collect data from more workers but not have the ability to appropriately follow-up during the subsequent two visits.

Data collection will take place with no more than 150 mine workers and nine mine site leaders over three years. The respondents targeted for this study include any active mine worker and any active site leader at a coal mine site. It is estimated that a sample of up to 150 mine workers will participate, which includes participating in three focus groups (in the form of workgroup meetings) that will take approximately 60 minutes. The focus groups will debrief general CPDM data so participants can dialogue about ways to lower their exposure levels. In addition, workers will be asked to complete a pre and post-test survey (~15 minutes). It also is estimated that a sample of up to nine mine site leaders will participate in the form of interviews/focus groups about HSMS practices at the same mining operations which have agreed to participate. The interviews/focus groups also will occur three times during each of the NIOSH field visits and will take no more than 30 minutes each.

All participants will be between the ages of 18 and 75, currently employed, and living in the United States. Participation will require no more than 3.5 hours of workers' time over the six-week intervention and no more than 1.5 hours of site leaders' time over the six-week intervention period.

There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Mine Site Leaders/Managers.	Mine Recruitment Script	3	1	5/60	1
	Initial/Mid/Post HSMS interview or focus group	3	3	30/60	5
Mine Worker	Individual Miner Recruitment Script	50	1	5/60	4
	Pre/Post Org Perceptions Survey	50	2	15/60	25
	Pre/Mid/Post Behavior Focus Groups	50	3	1	150
Total					185

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–01094 Filed 1–22–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–15–15ZK]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404–639–7570 or send comments to Leroy A. Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project

Research on the Efficacy and Feasibility of Essentials for Parenting Toddlers and Preschoolers—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

It is estimated that 1 in 58 U.S. children had been maltreated in a 1-year period (*i.e.,* victims of physical, sexual, and emotional abuse or neglect). Parent training is arguably the single most effective prevention initiative recognized to date. The Centers for Disease Control and Prevention has developed ''Essentials for Parenting Toddlers and Preschoolers'' (EFP). This web-based resource uses a psychoeducational approach incorporating modeling (through its videos) and practice (through its activities). Thus, EFP is likely to improve parenting (*e.g.,* discipline practices), reduce child behavior problems, and may ultimately reduce child maltreatment. Moreover, it is free for parents and can be accessed through any device that can use the Internet, including computers, tablets, and smart phones. If it proves to be effective, it may ultimately be less expensive to develop, evaluate, and disseminate EFP.

CDC is proposing an information collection to OMB for a period of one year. The purpose of this data collection request is to determine whether a web-based platform for delivery of positive parenting information yields changes in parent and child behaviors that are consistent with those observed in the clinic setting. If EFP is successful at increasing positive parenting and safe, stable, nurturing relationships and environments for children, then CDC has a resource that can be easily and freely disseminated to communities that can potentially impact rates of child maltreatment.

We will conduct a two-arm study of 200 parents of 2- to 4-year-old children. In one arm, parents will be guided in how and when they use specific intervention modules. In the other arm, parents will have access to the same EFP content but will use as much or as little of the intervention as they wish and on whatever time line they wish. Parents in both arms will complete assessments of child externalizing behavior, parenting behaviors (*e.g.,* use of praise and time outs), parenting thoughts (*e.g.,* perceived parenting competence and burden), and parent psychological adjustment (*e.g.,* depression and anxiety), as well as knowledge and perceived usefulness of EFP intervention content. The impact of this data collection on participants' privacy is low.

The survey data will be housed in a database on encrypted, password protected electronic storage files. All information shared will be in an aggregate form for the scientific