

PICOTS (POPULATION, INTERVENTION, COMPARATOR, OUTCOME, TIMING, SETTING)—Continued

Category	Definition
	<ul style="list-style-type: none"> ▪ Small for gestational age (e.g., birth weight <10% for similar age neonates),* low birth weight (e.g., <2.5 kg [5 lb, 8 oz]).* ▪ Abnormal Apgar score (threshold, e.g. <7).* ▪ Breastfeeding*—must be adjusted to account for patient preferences. ▪ Need for social services. • Care utilization: <ul style="list-style-type: none"> ▪ Attendance at planned antenatal visits (adherence/compliance). ▪ Completion of ACOG recommended services.* ▪ Number of unplanned visits.* ▪ Number of referrals to other providers. ▪ Unplanned hospital admissions. ▪ Emergency room/triage visits. ▪ Neonatal intensive care unit [NICU] admissions*/length of stay. ▪ Number of unplanned contacts (e.g., portal/phone messages). • Provider outcomes: <ul style="list-style-type: none"> ▪ Provider satisfaction with antenatal care. • Harms: <ul style="list-style-type: none"> ▪ Overdiagnosis (“unnecessary” negative workups or misdiagnoses). ▪ Delayed diagnoses (e.g., gestational diabetes).* ▪ Harms to marginalized groups/equity outcomes. <p>KQ3:</p> <ul style="list-style-type: none"> • Perspectives and preferences related to interventions covered by KQ 1 and KQ 2. • Barriers and facilitators related to interventions covered by KQ 1 and KQ 2.
Study Design	<p>KQ1 & KQ2:</p> <ul style="list-style-type: none"> • Comparative studies (comparisons of different interventions), including parallel design, pre-post studies, and other comparisons. <ul style="list-style-type: none"> ▪ Randomized or observational (nonrandomized). ▪ Prospective or retrospective. • Surveys that compare interventions (specifically for patient preferences and satisfaction). • Registry (e.g., PRAMS [Pregnancy Risk Assessment Monitoring System], National family study) and other retrospective data sources may be eligible, but only if the comparison is between different numbers of planned or scheduled visits (KQ1) or if there is a specific evaluation of telemedicine (KQ2). • Single group studies (no direct comparison of interventions). <ul style="list-style-type: none"> ▪ Preference and satisfaction outcomes only. • N ≥10 per intervention group. • (Existing systematic reviews and guidelines will be used as sources of otherwise missed eligible studies). <p>KQ3:</p> <ul style="list-style-type: none"> • Qualitative studies. • Interviews. • Focus groups. • Ethnographic studies. • Surveys with open-ended questions amenable to qualitative analysis.
Timing	<p>KQ1 & KQ2:</p> <ul style="list-style-type: none"> • Interventions: During antenatal period (excluding labor and delivery). • Followup/Outcomes: Any (antenatal, peripartum, postpartum, or later). <p>KQ3:</p> <ul style="list-style-type: none"> • Any (as long as interventions of interest occurred during antenatal period).
Setting	<p>All KQs:</p> <ul style="list-style-type: none"> • High income countries based on World Bank classifications. • Outpatient care.

Dated: August 18, 2021.
Marquita Cullom,
Associate Director.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Agency for Healthcare Research and Quality
Agency Information Collection Activities: Proposed Collection; Comment Request
AGENCY: Agency for Healthcare Research and Quality, HHS.
ACTION: Notice.
SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request

that the Office of Management and Budget (OMB) approve the renewal of the information collection project “Medical Office Survey on Patient Safety Culture Database.” This proposed information collection was previously published in the **Federal Register** on May 3rd, 2021 and allowed 60 days for public comment. AHRQ did not receive any substantive comments from members of the public. The purpose of this notice is to allow an additional 30 days for public comment.
DATES: Comments on this notice must be received by September 23, 2021.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at doris.lefkowitz@AHRQ.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Medical Office Survey on Patient Safety Culture Database

In 1999, the Institute of Medicine called for health care organizations to develop a “culture of safety” such that their workforce and processes focus on improving the reliability and safety of care for patients (IOM, 1999; *To Err is Human: Building a Safer Health System*). To respond to the need for tools to assess patient safety culture in health care, AHRQ developed and pilot tested the Medical Office Survey on Patient Safety Culture with OMB approval (OMB No. 0935-0131; Approved July 5, 2007).

The survey is designed to enable medical offices to assess provider and staff perspectives about patient safety issues, medical error, and error reporting. The survey includes 38 items that measure 10 composites of patient safety culture. In addition to the composite items, 14 items measure staff perceptions how often medical offices have problems exchanging information with other settings as well as other patient safety and quality issues. AHRQ made the survey publicly available along with a Survey User’s Guide and other toolkit materials in December 2008 on the AHRQ website.

The AHRQ Medical Office SOPS Database consists of data from the AHRQ Medical Office Survey on Patient Safety Culture and may include reportable, non-required supplemental items. Medical offices in the U.S. can voluntarily submit data from the survey to AHRQ, through its contractor, Westat. The Medical Office SOPS Database (OMB No. 0935-0196, last approved on September 10, 2018) was developed by AHRQ in 2011 in response to requests from medical offices interested in tracking their own survey results. Those organizations submitting data receive a feedback report, as well as a report of the aggregated, de-identified findings of the other medical offices submitting data. These reports are used to assist medical office staff in their efforts to

improve patient safety culture in their organizations.

Rationale for the information collection. The Medical Office SOPS and the Medical Office SOPS Database support AHRQ’s goals of promoting improvements in the quality and safety of health care in medical office settings. The survey, toolkit materials, and database results are all made publicly available on AHRQ’s website. Technical assistance is provided by AHRQ through its contractor at no charge to medical offices, to facilitate the use of these materials for medical office patient safety and quality improvement.

Request for information collection approval. AHRQ requests that OMB reapprove, under the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ’s collection of information for the AHRQ Medical Office SOPS Database; OMB No. 0935-0196, last approved on September 10, 2018.

This database:

- (1) Presents results from medical offices that voluntarily submit their data,
- (2) Provides data to medical offices to facilitate internal assessment and learning in the patient safety improvement process, and
- (3) Provides supplemental information to help medical offices identify their strengths and areas with potential for improvement in patient safety culture.

This study is being conducted by AHRQ through its contractor, Westat, pursuant to AHRQ’s statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to: The quality, effectiveness, efficiency, appropriateness and value of healthcare services; quality measurement and improvement; and database development. 42 U.S.C. 299a(a)(1), (2), and (8).

Method of Collection

To achieve the goal of this project the following activities and data collections will be implemented:

(1) Eligibility and Registration Form—The medical office point-of-contact (POC) completes a number of data submission steps and forms, beginning with the completion of an online Eligibility and Registration Form. The purpose of this form is to collect basic demographic information about the medical office and initiate the registration process.

(2) Data Use Agreement—The purpose of the data use agreement, completed by the medical office POC, is to state how data submitted by medical offices will

be used and provides privacy assurances.

(3) Medical Office Site Information Form—The purpose of the site information form also completed by the medical office POC, is to collect background characteristics of the medical office. This information will be used to analyze data collected with Medical Office SOPS survey.

(4) Data Files Submission—POCs upload their data file(s), using the medical office data file specifications, to ensure that users submit standardized and consistent data in the way variables are named, coded, and formatted. The number of submissions to the database is likely to vary each year because medical offices do not administer the survey and submit data every year. Data submission is typically handled by one POC who is either an office manager or a survey vendor who contracts with a medical office to collect their data. POCs submit data on behalf of 20 medical offices, on average, because many medical offices are part of a health system that includes many medical office sites, or the POC is a vendor that is submitting data for multiple medical offices.

Survey data from the AHRQ Medical Office Survey on Patient Safety Culture are used to produce three types of products:

- (1) A Medical Office SOPS Database Report that is made publicly available on the AHRQ website; and
- (2) Individual Medical Office Survey Feedback Reports that are customized for each medical office that submits data to the database; and
- (3) Research data sets of individual-level and medical office-level de-identified data to enable researchers to conduct analyses. All data released in a data set are de-identified at the individual-level and the medical office-level.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents’ time to participate in the database. An estimated 85 POCs, each representing an average of 20 individual medical offices each, will complete the database submission steps and forms. Each POC will submit the following:

- Eligibility and registration form (completion is estimated to take about 3 minutes).
- Data Use Agreement (completion is estimated to take about 3 minutes).
- Medical Office Information Form (completion is estimated to take about 5 minutes).
- Survey data submission will take an average of one hour.

The total burden is estimated to be 235.5 hours.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data.

The cost burden is estimated to be \$12,312 annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
Eligibility/Registration Form	85	1	3/60	4.25
Data Use Agreement	85	1	3/60	4.25
Medical Office Information Form	85	20	5/60	142
Data Files Submission	85	1	1	85
Total	NA	NA	NA	235.5

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Registration Form	85	4.25	\$52.28	\$222
Data Use Agreement	85	4.25	52.28	222
Medical Office Information Form	85	142	52.28	7,424
Data Files Submission	85	85	52.28	4,444
Total	NA	235.5	NA	12,312

* Mean hourly wage rate of \$52.28 for Medical and Health Services Managers (SOC code 11-9111) was obtained from the May 2019 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 621100—Offices of Physicians located at https://www.bls.gov/oes/current/naics4_621100.htm.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: August 18, 2021.

Marquita Cullom,
Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0856]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. Members will participate via teleconference. At least one portion of the meeting will be closed to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on September 30, 2021, from 8:30 a.m. to 3:40 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an

online teleconferencing platform. The online web conference meeting will be available at the following link on the day of the meeting: <https://youtu.be/VeknygU5MKM>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2021-N-0856. The docket will close on September 29, 2021. Submit either electronic or written comments on this public meeting by September 29, 2021. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 29, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 29, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before September 23, 2021, will be provided to the committee. Comments received after September 23, 2021, and by September 29, 2021, will be taken into consideration by FDA. In the event that the meeting is canceled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.