From: Doris Lefkowitz

To: Karen Matsuoka

Re: Medical Office Survey of Patient Safety Culture "benchmarking ICR"

1. **Please address the "bench mark issue." How will this measure—whatever it is called—be described/characterized to the users of this data? Please revise the supporting statement to include this, as well as the user guide.**

As discussed in our first response regarding this issue, the AHRQ Medical Office Survey on Patient Safety Culture Comparative Database will serve as a central repository for survey data from U.S. medical offices that have administered the survey and voluntarily submitted their data to be included in the database.

This database and its submissions will be submitted for approval under the PRA. You and I have agreed to discuss the best mode for this submission sometime in April. This discussion is intended to give you our thoughts on the purpose and scope of this database, but is not intended to prejudice the outcome of OMB's review of the forthcoming database ICR.

AHRQ does not intend to post the data from this survey to the database until approval of the database ICR is obtained.

The database data will be used to produce an annual database report that will provide overall averages and percentile scores on the survey items and composites, as well as results broken down by medical office characteristics (office size, single or multi-specialty, implementation of EMR/EHR, etc) and by staff position (physicians, PA/NP, nursing, etc).

The annual Comparative Database will be used for the following purposes:

1) Comparison--to allow medical offices to compare their patient safety culture survey results to other medical offices in the U.S.

2) Internal Assessment and Learning--to enable medical offices to identify their strengths and areas with potential for improvement in patient safety culture

3) Trending--in Year 2 of the database and beyond, trending data will be presented to describe changes in patient safety culture over time for medical offices that submit data more than once

4) Research and Analysis--de-identified data from the database will be made available to researchers for projects examining relationships involving patient safety culture survey data in medical offices. Note: Researchers will be required to submit proposals for approval by AHRQ before de-identified survey data will be made available to them. Medical offices submitting to the database will sign a data use agreement indicating their consent to release their de-identified data for research purposes.

The database will be described as a central repository for survey data from U.S. medical offices that have administered the survey and voluntarily submitted their data to be included in the database. The annual database report will provide overall averages and percentile scores on the survey items and composites, as well as results broken down by medical office characteristics (office size, single or multi-specialty, implementation of EMR/EHR, etc) and by staff position (physicians, PA/NP, nursing, etc) to allow for more tailored comparisons. There will be a "data limitations" section that will convey the fact that the data are not from a statistically selected, nationally representative sample and that the limitations of the data should be kept in mind when using it to make comparisons.

Purposes 1-4 listed above have been incorporated into Section A.2 of the Supporting Statement (see attached).

The Medical Office User's Guide does not contain the word "benchmark" or refer to "benchmarking". It primarily provides guidance to a medical office about how to administer the survey. Only the last section, titled "Submit Your Data to the Medical Office Comparative Database", refers to the comparative data file. Rewording of the first paragraph of this section is shown in response to Question 2 below. We will also add a paragraph to this section that lists purposes 1-4 above.

The AHRQ web site itself refers to benchmarking twice in the section about the Comparative Database. These references will be removed and replaced with the phrase "comparative database."

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2. To the extent that AHRQ is using this purposive sample to arrive at the "benchmark" is a temporary fix, please spell this out more clearly, both in the supporting statement as well as in the user guide.

In Supporting Statement Part A we have clarified that the data collected through this survey will constitute a temporary solution to the need for comparative data that medical offices can use to assess their own responses. We have changed the wording in paragraphs 3-6 of Section A.1 to read as follows (changes are noted in **bold**):

> "AHRQ requests that the Office of Management and Budget approve, under the Paperwork Reduction Act of 1995, AHRQ's intention to (1) collect information needed to establish **preliminary comparative data** for the Medical Office Survey on Patient Safety and (2) collect descriptive information on barriers and facilitators to survey participation by medical offices, and on the utility/value of survey data in improving ambulatory patient safety.
>
> The ambulatory Medical Office Survey on Patient Safety (MO-SOPS), an adapted version of AHRQ's Hospital Survey on Patient Safety Culture (HSOPSC), was developed in 2005 to measure specific factors of patient safety culture in the ambulatory setting. A pilot study (OMB #0935-0131) assessed and refined the psychometric properties of specific survey items, and a final version of MO-SOPS is now ready for public dissemination (see Attachment B). However, in order for the survey to be useful to ambulatory medical offices in identifying areas of relative strength and weakness in patient safety culture, reliable **comparative data** to which a practice's responses can be compared need to be established.
>
> AHRQ has determined, through discussions with potential end-users of MO-SOPS including leaders of physician and other provider groups, that an ambulatory practice is unlikely to have confidence in an MO-SOPS **comparative data** unless it is based on responses derived from offices with similar characteristics. Office characteristics perceived to have a potential effect on MO-SOPS responses include such factors as provider mix (single specialty/multi-specialty), size of practice, and use of electronic information technology. A separate Practice Characteristics Survey to collect standardized information about these and other practice characteristics has been developed and was tested and refined as part of the pilot study (see Attachment C).
>
> AHRQ's overall goal is to generate and make available to each MO-SOPS end-user **comparative data** summary measures of patient safety culture based on survey responses from ambulatory practices with similar characteristics. Toward this end, AHRQ intends to administer MO-SOPS to a **purposive** sample of ambulatory medical offices across the country that has been selected on the basis of a set of practice characteristics. **This purposive sample will provide preliminary comparative data that can be accessed by medical offices until a permanent comparative**

database can be established from the responses of a wide variety of medical offices throughout the country. An alternative method of initially populating the comparative database would be to make the surveys available to the public immediately and wait until a sufficient number of practices with the targeted characteristics have submitted responses. However, this approach is unacceptable to AHRQ since (1) no comparative data would be available to provide feed back to the first wave of responders, and (2) the amount of time that may be required before sufficient numbers of practices with the desired range of practice characteristics voluntarily provide survey responses is unpredictable and likely to be excessive. In addition, AHRQ intends to collect from these practices evaluative information about administrative barriers and facilitators to survey participation as well as a description of how the office used (or plans to use) the survey results to enhance patient safety culture (see Attachment D)."

The User's Guide primarily provides guidance to a medical office about how to administer the survey. Only the last section, titled "Submit Your Data to the Medical Office Comparative Database", refers to the comparative data file. The first paragraph of this section will be reworded as follows (changes are noted in **bold**):

> "The Agency for Healthcare Research and Quality (AHRQ) has posted **preliminary** comparative data **from a purposive sample of medical offices from 14 Practice Based Research Networks who completed** the *Medical Office Survey on Patient Safety Culture* on its Web site (http://www.ahrq.gov/qual/hospculture **). While this preliminary database is a temporary solution that allows us to provide comparative information to you, the medical office respondents are not necessarily representative of all medical offices in the United States.** In the future, AHRQ will **establish a permanent comparative database by asking** all medical offices that have administered the survey to voluntarily submit their data files to the *Medical Office Survey on Patient Safety Culture Comparative Database*. This database will be modeled on the *Hospital Survey on Patient Safety Culture Comparative Database*, which contains comparative data for users of AHRQ's *Hospital Survey on Patient Safety Culture*. You will be able to compare your medical office results with the overall medical office comparative data."

Again, the data from this survey will not be posted to the database until OMB approval for the database and its submission process has been received.

2. It is not clear why the post-survey evaluation is not simply administered via paper. It does not make sense to provide a $100 incentive to encourage online responses. OMB does not approve incentives for survey like this that are essentially customer satisfaction surveys.

In meetings with the PIs from the PBRNs in the Consortium, it was agreed that completing the follow up evaluation online would be most efficient. Either the practice manager or the lead clinician will be the main point-of-contact at each clinic and will be the only staff member completing the follow up evaluation. PBRNs have had good return when using online surveys.

As noted in Supporting Statement Part A, Section A.3 (Use of Improved Information Technology and Burden Reduction), the post-survey evaluation includes several items that require (or allow) a free-text response. AHRQ estimates that hand written responses to such items could increase by more than five minutes the time required to complete each evaluation (compared to typed responses). To avoid this additional burden, evaluations will be conducted via the internet for all offices having access to high speed internet connections. In a previous study conducted in similar practice sites, 100% of offices reported access to such connections. AHRQ considers the benefit of reducing the burden to responders to outweigh the risk of a reduced response rate for this part of the project. In addition, an internet-based approach will benefit AHRQ in assuring more consistent legibility of free-text responses than would be expected with hand-written responses.

Regarding the proposed incentives, we will not provide any incentives for evaluation survey participation.

3. **It is not clear that the sample size is adequate for estimate 5 different percentiles with confidence intervals of +/- 5 percentage points. Please provide the supporting formulas and calculations.**

The sample percentile has an asymptotic normal distribution with an asymptotic variance given by this formula:

$$AV(\xi_p) = \frac{p(1-p)}{f^2(\xi_p)n}$$

where n is the sample size, p is the proportion corresponding to the percentile (e.g., $P(X \leq \xi_p) = p$), and f represents the density of the underlying random variable X.

To calculate confidence intervals for percentiles, we first calculated the standard error for percentiles of the standard normal distribution using the formula shown above, with $n = 40$. Table 1 gives the proportion (0.10, 0.25, etc), the corresponding percentile from the standard normal distribution (1.282, 0.674, etc), the standard normal density function evaluated at the percentile value (0.1755, 0.3178, etc), and the corresponding standard error (0.270, 0.215, etc), which was calculated as the square root of the formula shown above. The half-widths of the confidence intervals for the standard normal percentiles is also shown in Table 1 (0.530, 0.422, etc), which was calculated was 1.96 times the standard error.

Table 1: Calculation of confidence intervals for percentiles

Proportion	Percentile	Density function	Standard error	Confidence interval	× 0.10
0.90	1.282	0.1755	0.270	0.530	0.053
0.75	0.674	0.3178	0.215	0.422	0.042
0.50	0.000	0.3989	0.198	0.388	0.039
0.25	-0.674	0.3178	0.215	0.422	0.042
0.10	-1.282	0.1755	0.270	0.530	0.053

To transform these confidence intervals for percentile rankings for the Medical Office Survey on Patient Safety, we used information on standard deviations on percentiles from the Hospital Survey on Patient Safety Culture 2008 Comparative Database Report[1]. Table 6-3 in that document shows standard deviations for the items used in the hospital survey. These standard deviations range from roughly 6% to 14%, so we took the midpoint, 10%, as an approximate standard deviation for the distribution of proportions of positive responses among medical offices.

Since the standard deviation of the standard normal distribution is 1.0, we multiplied it by 0.10 was to transform the confidence intervals from the standard normal distribution to confidence intervals for the distribution of proportions reported by medical offices. This step is shown in the last column of Table 1. Note that all values round to 0.05 or less.

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[1] See Sorra J, Famolaro T, Dyer N, et al. Hospital Survey on Patient Safety Culture 2009 comparative database report. (Prepared by Westat, Rockville, MD, under Contract No. HHSA 290200710024C). Rockville, MD: Agency for Healthcare Research and Quality; March 2009. AHRQ Publication No. 09-0030.

The justification for multiplying by the standard deviation (i.e., 0.10) is as follows. First, the percentile from the standard normal distribution is defined by this equation:

$$P(Z \le \varsigma_p) = p$$

which implies

$$P\left(\frac{X-\mu}{\sigma} \le \varsigma_p\right) = p$$

where μ and σ are the mean and standard deviation of *X*. Thus, ξ_p^*, the *p*-th percentile of the distribution of *X*, is given by

$$\xi_p^* = \mu + \varsigma_p \sigma .$$

Now, if the confidence interval for $\hat{\xi}_p$ has the form

$$P(a - b \le \hat{\xi}_p \le a + b) = 0.95$$

then the confidence interval for $\hat{\xi}_p^*$ has the form

$$P\left(a - b \le \frac{\hat{\xi}_p^* - \mu}{\sigma} \le a + b\right) = P(\mu + a\sigma - b\sigma \le \hat{\xi}_p^* \le \mu = a\sigma + b\sigma) = 0.95$$

which shows that $\hat{\xi}_p^*$ has a confidence interval with half-width of $b\sigma$, i.e., that of the standard normal percentile multiplied by the standard deviation of the transformed distribution.

One remaining point requires discussion: the reviewer's question raises the issue of estimating "5 *different* percentiles with confidence intervals of ± 5 percentage points." Please note that we are not claiming to provide simultaneous confidence intervals for the 10th, 25th, 50th, 75th, and 90th percentiles, but rather that 95% confidence intervals for a single estimated percentile will be within ± 5 percentage points, assuming that the percentile is the 10th, 25th, 50th, 75th, or 90th. This statement actually holds for any percentile between the 10th and 90th; however, the confidence intervals become larger as percentiles move outside this range (e.g., toward either the 1st or 99th percentile).

4. **Comments/questions on the evaluation survey:**

   a. **questions 6 & 8 seem to rely on respondent recall. Will a copy of the survey questions be provided?**

   Yes, a copy of the survey will be provided. The MO-SOPS will be provided by paper, a pdf file attached to the email, or a link on SurveyMonkey so that each person will refer to it while completing the follow up evaluation.

   b. **Questions 15 and 16 seem to presuppose a "yes" answer. Might be a good idea to provide a prompt for those who say "no" (i.e. if you don't plan to use the survey results, why not?)**

   An additional line for collecting information regarding a "no" response will be added, as follows:

   Q. 15. If "no" please provide an explanation of why you would not use the results within your office.

   Q. 16. If "no" please help us to understand why the survey is not of benefit to the office.

   c. **The survey seems anonymous, but questions 19 and 20 seem to require a way to track respondents. Please clarify.**

   The evaluation survey is not actually anonymous, but it is confidential. ORPRN will communicate with the point-of-contact (either the office manager or the lead clinician) at each medical office to request that they complete the evaluation survey online. We plan to use SurveyMonkey.com, which is a secure site that provides confidentiality, and although a name or ID number can be requested for tracking purposes, the data can be separated so there is no way to link the name to the response. In SurveyMonkey, it is possible to track who responds and create a custom email to send as a follow-up reminder to those who have not responded. ORPRN also plans to use Fax or phone calls as reminders, if needed.

   Questions 19 and 20 are intended to determine whether the office point-of-contact believes the survey to be of value and useful to the office. There is no intention to recontact the respondent about his/her responses. The questions will be rephrased as follows:

   19. Do you think your office would want to participate in further group discussion about the survey results?

   20. Do you think your office would be interested in completing the SOPS in the future?