SUPPORTING STATEMENT
U.S. Department of Commerce
National Institute of Standards and Technology
Workflow and Electronic Health Records
in Small Medical Practices Questionnaire
OMB CONTROL NO. 0693-XXXX

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary.

Healthcare is a continuing, evolving industry. Information technology is becoming essential in managing physicians' practice operations. Many hospital systems have adopted the use of the Electronic Health Record (EHR) but there is very slow adoption in the case of solo or small group offices. In the U.S., a 2007 National Ambulatory Medical Care Survey reports that in over 161,200 medical practices, there was an average of 311,200 physicians practicing in office-based environments. The report also identifies that 69.2% of practices consisted of solo practitioners; About 19.5% of the practices contain three or more physicians. Specialty practices accounted for about 8.4 % of the total. The study also estimated that about 19% of the physicians used electronic medical records, and 9.2% used computerized prescription order systems.[1]

The various studies conducted across an array of healthcare settings have claimed that introduction of EHR can lead to an improvement in quality and has improved operational efficiency and workflow.[2] In spite of these claims, the overall adoption rates of EHR's have been reported to be as low as 17%.[3] A report on "Adoption Gap" claims that less that 11.3 % of the small physician offices have fully implemented EHR (see footnote 4 below). Given that 88% of all medical offices are small practices, the report also identifies barriers to adoption. One of the main barriers, the report identifies is the nature and variety of workflow in the small physician offices leading to resistance in incorporating EHR systems with workflows with very little flexibility. The report also found that successful adoption requires close attention to office

[1]Hing, E, Burt, C.W., "Office based Medical Practices: Methods and Estimates from the National Ambulatory Medical Care survey: Advanced Data: From Vital and Health Statistics, Number 383, CDC, Department of Health and Human Services, March 12, 2007.

[2] Hillestad R., Bigelow J., Bower A., Girosi F., Meili R., Scoville R. and Taylor R.. "Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, And Costs; the adoption of interoperable EMR systems could produce efficiency and safety savings of $142-$371 billion," *Health Affairs*, 24(5), pp1103-1117., Sept. 2005.

[3] Burt, C. W., and Sisk, J.E... "Which Physicians And Practices Are Using Electronic Medical Records?" *Health Affairs*, 24 (5), pp1334-1343. Sept. 2005.

workflow, or how tasks are organized and resources used to achieve outcomes along with appropriate change management, planning and process re-engineering.[4] It urges for a more detailed case study of workflows.

There have been several studies in the area of electronic patient records that vary from those that attempt to estimate huge costs savings and those that disagree with their cost savings and problems with adoption.[5] Some studies point to poor current incentive structures and argue for a need for new incentives to physicians to overcome the lack of capital, multiple-vendors, inter-operability, misaligned incentive structures, and fears of privacy and perception of economic benefits for adoption of EHR.[6] While these studies point to the diversity of reasons that are barriers to adoption, we need to delve deeper into understanding the workflow, mode of operation in completing a task, effect of context (Family practice vs. Specialty offices) and the interactions with external entities that are part of the work flow.

Hence, the goal is to study the workflow and information flow characteristics of small physician offices and to understand the impediments to the adoption of health information systems. The purpose is to perform a case study based on a structured interview of personnel and observation of the offices to get a detailed understanding of the processes in contrast to the more common statistically-based studies of physician offices.

The proposed questionnaire (Workflow and Electronic Health Records in Small Medical Practices) has been developed to collect the information.

This work will be conducted under the supervision of Dr. Ram D. Sriram, Group Leader, Design and Process Group, Manufacturing Systems Integration Division, National Institute of Standards and Technology (NIST) who previously headed a program entitled "Manufacturing Metrology and Standards for the Health Care Enterprise" from 2005-2008. During this time, Dr. Sriram came into contact with various participants in the healthcare field, in particular several doctors who expressed their desire to participate in this collection. Both specialists and internists will be participating in this study.

Out of the numerous contacts approached, 14 offices volunteered for the study. These offices were not chosen based on any specific criteria except to attempt a breadth of specialties and internists. As these are in-situ studies NIST concentrated on enlisting willing participants for this study. A combination of questionnaire, interviews and in-situ observations and data collection will be used. The questionnaire will be distributed to the participating offices, to review and answer the questions, prior to the interview. This information will be used in the

---

[4] Lee J.N, Cain C., Young S., Chockley N. and Burstin H., "The Adoption Gap: Health Information Technology in Small Physician Practices," *Health Affairs*, 24 (5), pp. 1364-1366, Sept. 2005.

[5] Wang, , S.J., et.al, "Cost Benefit Analysis of Electronic Medical Records in Primary Care, The American Journal of Medicine, Vol 14, pp 397-403, April 2003.

[6] Miller, R, Sim, I, Physicians use of Electronic Records: barriers and Solutions, Health Affairs, 23(2), pp 116-126, 2004.

structured follow-up interview reducing the time for detailed investigation of specific points. Finally, the information will be processed to tabulate tasks to normalize the task nomenclature to be able to characterize the offices uniformly. Further, data on the tasks will be used to identify those tasks that are time-consuming and the reasons.

2. **Explain how, by whom, how frequently, and for what purpose the information will be used. If the information collected will be disseminated to the public or used to support information that will be disseminated to the public, then explain how the collection complies with all applicable Information Quality Guidelines.**

The information will be used primarily to report the finding of the study. The study will be published in an appropriate journal for wide dissemination. Once the appropriate clearances are obtained, the collection of information is expected to be completed in six months but one year has been requested to allow for any unforeseen delays. After gathering the information, the report will be proposed for publication in various journals for wide dissemination.
Some examples of those publications would be, International Journal of Medical Informatics, Elsevier and the Journal of the American Medical Informatics Association.

The study complies with information quality rules as follows:

Utility: the information gathered will be unique in its depth of analysis of work and information flow and get at explicating the reasons in terms of work practice that impede the adoption of health information services.

Integrity: the information collected will be kept secure. The results of the analysis presented in the report will not identify the offices studied in any place.

Objectivity: the study follows what is known as an interpretive case study method in social sciences. Here multiple modes of collection of data are used to explicate phenomena that are not directly observable through statistical studies. The work will follow the case study methodology to maintain utmost objectivity.

All records of the study will be preserved electronically and/or as paper documents to address issues of reproducibility and review of results.

There will be no reporting of financial or statistical information.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology.

This collection does not require use of automated, electronic, or mechanical techniques.
The questionnaire will be distributed by paper to the participating offices. Interviews and

observations will be noted on paper, and in some situations, interviews may be recorded (on paper) for archival purposes. No electronic recording devices will be used.

4. Describe efforts to identify duplication.

There is no duplication of effort identified.

5. If the collection of information involves small businesses or other small entities, describe the methods used to minimize burden.

The information requested is the minimal required by all respondents. Since the questionnaire is distributed before the interview and will be used in the structured follow-up interview reducing the time for detailed investigation of specific points. The characterization of the workflow and task data will be presented to each of the physician offices for verification. These tasks are well structured to minimize effort and through direct interaction. Hence, the process used to collect the information will minimize the burden effort for all respondents.

6. Describe the consequences to the Federal program or policy activities if the collection is not conducted or is conducted less frequently.

If this information is not collected, NIST would be unable to assist the federal government and other state health agencies to set policies for effective implementation of health information systems. The collection will allow us to understand the problems associated with the lack of computerization in physician offices.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with OMB guidelines.

There are no special circumstances that require the collection to be conducted in a manner inconsistentant with OMB Guidelines.

8. Provide a copy of the PRA Federal Register notice that solicited public comments on the information collection prior to this submission. Summarize the public comments received in response to that notice and describe the actions taken by the agency in response to those comments. Describe the efforts to consult with persons outside the agency to obtain their

views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

The Federal Register Notice soliciting public comments was published on February 27, 2008 (Volume 73, Number 39, pg. 10423). No comments were received.

9. Explain any decisions to provide payments or gifts to respondents, other than remuneration of contractors or grantees.

There will be no payments or gifts to the respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for assurance in statute, regulation, or agency policy.

No information on the identities of the participants will be made public. NIST will get the necessary written permission from the participating physicians.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

Not Applicable

12. Provide an estimate in hours of the burden of the collection of information.

It is estimated that the questionnaire will take 1 hour to complete; 4 hours for in-situ observations, and 30 minutes at the end of the observation period for any follow-up questions. This totals 5 hours and 30 minutes per respondent X 14 = **77 hours**

13. Provide an estimate of the total annual cost burden to the respondents or record-keepers resulting from the collection (excluding the value of the burden hours in #12 above).

None.

14. Provide estimates of annualized cost to the Federal government.

The estimated cost would be approximately $5,000. This cost would cover the travel expenses, and time of the staff members conducting the interviews and analysis of the results, as well as the cost to duplicate the questionnaire.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB 83-I.

This is a new collection.

16. For collections whose results will be published, outline the plans for tabulation and publication.

From the information collected the following data will be tabulated.

a) The number and names of the tasks in the offices and whether these tasks are supported by computers or not.
b) The number of persons doing a particular task.
c) The workflow process (diagrams) of the selected example offices.
d) The information flow diagrams.
e) Identification of the most time consuming tasks.

The results of the findings will be proposed for publication in various Medical Informatics Journals. Some examples of those publications can be found at the following link: http://www.informatics-review.com/journals/index.html

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons why display would be inappropriate.

Not applicable

18. Explain each exception to the certification statement identified in Item 19 of the OMB 83-I.

Not applicable

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection does not employ statistical methods.