Supporting Statement

Part A

Feasibility of Secure Messaging for Pediatric Patients with Chronic Disease: Pilot Implementation in Pediatric Respiratory Medicine

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Agency of Healthcare Research and Quality (AHRQ)

Task Order Officer:
Robert Mayes
Senior Advisor
Center for Primary Care, Prevention & Clinical Partnerships
Agency for Healthcare Research & Quality
540 Gaither Road, Room 6131
Rockville, MD 20850
Tel. 301-427-1492

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A. Justification

1. Circumstances of Information Collection

The mission of the Agency for Healthcare Research and Quality (AHRQ) set out in its authorizing legislation, The Healthcare Research and Quality Act of 1999 (see Attachment A), is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

1) research that develops and presents scientific evidence regarding all aspects of health care; and

2) the synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

3) initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and (B) health care for priority populations, which shall include (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

AHRQ proposes to evaluate how the implementation of a secure email messaging (e-messaging) system between clinicians and adolescent patients affects: (1) time spent by providers communicating with patients, (2) Emergency Department utilization for medication refills, and (3) qualitative satisfaction with care of the patients. The study will be conducted in the Yale University School of Medicine Pediatric Respiratory Medicine Clinic.

Several studies have evaluated the use of email between providers and patients and found that it is typically satisfactory to both, has not been abused by patients, and has not been used inappropriately for urgent items. Studies have not evaluated the use of emailing or secure messaging by children or adolescents with chronic diseases as well as their families. The setting of chronic disease provides a natural forum for discussion about the use of such technologies since these families may need more frequent contact with their care-providers, need more frequent medication refills, and may have close relationships with their providers that encourage a communication genre such as secure messaging.

In particular, because many adolescents are comfortable with text messaging and email, the investigators hypothesize that adolescent patients themselves may feel empowered to contact their providers using this medium. This potential shift to having adolescents communicate with the providers presents two main hypotheses of interest. (1) Adolescents may be more prone to send a message that may be of an urgent nature because of the sense that messaging is "instant" as well as a possible feeling of more privacy. This issue presents the concern that adolescents in particular could send a secure message about information that is potentially urgent in nature such as a severe asthma exacerbation or suicidal ideation. Such messages will need immediate attention. (2) Adolescents may be more apt to disclose questions about their care that they would not have otherwise brought up with the provider. By giving adolescents a medium where they feel comfortable communicating, clinicians may be able to better meet the medical and psychosocial needs of adolescents and their families.

2. Purpose and Use of Information:

The project will use data collected from: 1) e-messaging content to understand what children, adolescents and their parents will send in secure messages to their provider. 2) demographic surveys to determine race, income, etc. 3) qualitative interviews with patients/families and clinic staff to assess their attitudes and satisfaction with electronic messaging. Data collection activities will be monitored to determine if the study poses a burden on respondents and to identify enabling factors or barriers to project participation.

The intervention has the potential to benefit patients by improving their communication with their clinicians. The risk-benefit ratio is favorable as the risks are low. Having a better understanding of the impact of secure messaging on pediatric patients and their families and clinicians will improve patient-centered care for the patients in this study and allow extension of these technologies to others.

3. Use of Improved information Technology:

Use of the e-messaging system offers a powerful data collection tool for the project. Perhaps its most powerful benefit is in the area of customer interface. It has the potential to transform survey collection into an interactive experience. The e-messaging system can be used not only to collect information from respondents, but provide information back to respondents in a fast, efficient, and user-friendly manner. This should help solidify the reporting arrangement and reduce attrition, important considerations since respondents in most studies involving patients are voluntary. For the components of the project that are not using the e-messaging system (demographic survey and qualitative interviews), the minimum amount of information necessary to answer the research questions will be collected

4. Efforts to identify Duplication:

The data collection effort of the project is not duplicative. The information required for this study is not currently collected for other purposes, and is unique to Yale New Haven

Hospital. There is no similar information that is currently being collected that could be used for the purpose of the study. A thorough literature review was conducted and found that no previous studies have been performed to test the ability of these organizations and their practices to collect data similar to that which will be collected during the proposed project. To avoid duplication of data collection efforts internally and externally, the study's data collection instruments are designed to gather the information necessary for the study using the most efficient methods available.

5. Involvement of Small Entities:

Burden will be kept to a minimum for all entities.

6. Consequences if Information is Collected less Frequently:

Respondents will respond to data collection initially through two pre-arranged times. The first time respondents will be asked to complete a short demographic survey. The demographic survey is necessary to compare patterns of usage of secure messaging by type of disease, age, gender, and socioeconomic status. The second time, a purposeful sample of respondents will be asked to participate in face-to-face qualitative interviews to assess their attitudes towards electronic messaging. The respondents will also be providing data through the e-messages they send to their provider.

7. Special Circumstances:

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d) (2). No special circumstances apply.

8. Federal Register Notice and Outside Consultations

8.a. Federal Register Notice

As required by 5 CFR 1320.8(d), notice was published in the Federal Register on 2/15/2008, Vol. 73, page 8874, for 60 days (see Attachment B).

8.b. Outside Consultations

The project has consulted with the following members of the Yale University School of Medicine's Human Investigation Committee regarding this project on topics such as data security, frequency of data collection, and issues affecting respondent burden:

Raymond Seligson, MD, JD
Pediatric Physician
Yale-New Haven Hospital
Member, Yale University School of Medicine Human Investigation Committee (HIC-1)
(203)-488-8345

Steven Bartolotta
Manager, Information Systems Security
Yale-New Haven Hospital
(203)-688-2425

Paula Burns
Manager, MIS Corporate Systems, Yale New Haven Hospital
(203)-688-8844

9. Payments to Respondents

A small, age-appropriate "thank you" gift (~$10) for each child who participates in the qualitative interviews/focus groups will be provided. Parents/guardians will receive a pass for free parking.

10. Assurance of Confidentiality:

All individuals participating in this study will be informed that the information they provide be treated in a confidential manner and will not be released in a form that identifies individual respondents, unless required by law (see Attachment C). No information will be reported by the contractor in any way that permits linkage to individual respondents. Below is a description of each type of data collection used in the study and how confidentiality will be maintained.

Content Analysis
Because the content of the messages will be reviewed, there is potential risk to privacy for the patients. Several steps to minimize this risk will be taken. 1) A blanket informed consent when patients first register to use the product so that they know that the messages will be monitored for the purposes of this study will be provided. 2) The content of the messages will be maintained in a secure, HIPAA-compliant manner in a password-protected database that resides on the server behind the hospital's firewall. 3) Patients will be assigned a unique, anonymous study identification number. This number will be used for analysis. 4) Only Drs. Hsiao, Bazzy-Asaad, and Benin and the project manager will see the content of the messages. 5) All information will be kept confidential.

Qualitative Interviews
The potential risks of the qualitative interviews are negligible. There is some potential risk to a participant's privacy. This will be minimized by ensuring the opinions expressed by the parents and children will not be shared with their physicians (Dr Bazzy-Asaad and Tina Tolomeo, MSN, APRN, AE-C will only see the unique study identification number – not the name associated with the interview). There will be no ramifications for medical treatment, and complete confidentiality will be maintained. All information will be kept confidential. Each participant will have a unique study identification number assigned. That number will be used for all identification purposes. We will collect names only so that we can create linked identifiers to know who has used the messaging system and who has not. All data will be maintained on a HIPAA-

compliant password-protected computer server that is behind the Yale-New Haven Hospital firewall. All recordings will be destroyed as soon as the data analysis is completed; we expect this to be 12 months from the time of taping.

Subjects chosen for qualitative interviews will be approached by study personnel with their families. The aims of the interview (whether in small focus groups or individually conducted) will be explained, as well as the risks and benefits, to each patient and family member. Parents will be asked for their permission, obtained through signed consent forms. Children older than 7 will be asked for their assent, and also asked to sign an assent form in basic language (attached). Permission will also be obtained for the participating providers through signed consent forms. Information Sheet for Survey Participation, Parental Permission/Consent Form, Patient (≥ 18yrs) Consent Form, Child Assent Form, Child (>12yrs)/Adolescent Assent Form, and Healthcare Provider Consent Form will be used for different phases of the study. All are appended to this application.

ED Utilization – Chart Reviews

Chart reviews will be done to assess the ED-utilization. Again, the main risk to participants is to the protection of their privacy. To protect against risks, all information abstracted from the charts will be maintained in a confidential manner. It will be necessary to collect personal health information (including medical record number) to maintain a linkage to the list of patients who have used the secure messaging system and so that comparisons can be made between the pre- and post-time periods. However, anonymous unique study identification numbers will be assigned and will be used for analysis. All information will be kept confidential. All data will be maintained on a HIPAA-compliant password-protected computer server that is behind the Yale-New Haven Hospital firewall. It would be prohibitively impractical to obtain consent for this portion of the study.

11. Questions of a Sensitive Nature:

No questions of a sensitive nature will be asked.

12. Estimates of Annualized Burden Hours and Costs:

Exhibit 1 shows the estimated annualized burden hours. Each of the 300 patient/family participants will complete a demographic survey and use the e-messaging system, sending an average of one e-message per month. Thirty of the patient/family participants will be randomly selected to participate in a qualitative interview. Each of the 138 provider participants will use the e-messaging system, responding to about twenty six e-messages per year, and keep a pre- and post-intervention log of patient/provider communications. Ten provider participants will be randomly selected to participate in a qualitative interview. The total burden for all participants is estimated to be 1,898 hours.

Exhibit 2 shows the estimated annualized cost burden for the participants' time to participate in this study. The total cost burden for all participants is estimated to be $66,114.

Exhibit 1. Estimated annualized burden hours

Interview Participants	Number of Respondents	Number of Responses per Respondent	Hours per Response	Total Burden Hours
Patient/Family Participants				
Demographic Survey	300	1	10/60	50
E-messaging	300	12	15/60	900
Qualitative Interview	30	1	30/60	15
Provider Participants				
E-messaging	138	26	15/60	900
Qualitative Interviews	10	1	30/60	5
Pre-intervention Provider Log	138	1	6/60	14
Post-intervention Provider Log	138	1	6/60	14
Total	**438**	**na**	**na**	**1,898**

Exhibit 2. Estimated annualized cost burden

Interview Participants	Number of Respondents	Total Burden Hours	Average Hourly Wage Rate*	Total Cost Burden
Patient/Family Participants				
Demographic Survey	300	50	$26.20	$1,310
E-messaging	300	900	$26.20	$23,580
Qualitative Survey	30	15	$26.20	$393
Provider Participants				
E-messaging	138	900	$43.78	$39,402
Qualitative Interviews	10	5	$43.78	$219
Pre-intervention Provider Log	138	13.8	$43.78	$605
Post-intervention Provider Log	138	13.8	$43.78	$605
Total	**438**	**1,898**	**na**	**$66,114**

*For Patient/Family Participants: Based upon the mean of the average wages for all occupations, National Compensation Survey, "U.S. Department of Labor, Bureau of Labor Statistics."

*For Provider Participants: Based upon the mean of the average wages for physicians ($65.54/hr) and nurses ($43.85/hr) in the New York, New Jersey, Connecticut and Pennsylvania region, National Compensation Survey, "U.S. Department of Labor, Bureau of Labor Statistics." For Pulmonary Fellows: Based upon internal Yale University School of Medicine data.

13. Estimates of Annual Respondent Capital and Maintenance Costs

Capital and maintenance costs include the purchase of equipment, computers or computer software or services, or storage facilities for records, as a result of complying with this

data collection. There are no direct costs to respondents other than their time to participate in the study.

14. Estimates of Annualized Costs to the Government

The total cost to the Federal Government for this project is $399,970 over a two year period. The average annual cost is $199,985. The following is a breakdown of the average annual costs:

Direct Costs	
Personnel	$159,488.5
Consultancies	$5,475
Data support	$5,336.5
Indirect Costs	
Indirect costs	$29,685
Total	**$199,985**

15. Changes in Hour Burden:

This is a new information collection.

16. Time Schedule, Publication and Analysis Plan:

Tabulations and Statistical Analysis:

Analysis Plan

As a qualitative study on a convenience sample, all of the analysis planned are essentially exploratory and hypothesis generating in nature.

Content Analysis of e-messages: A full audit trail of number, type of messages, and message participants is saved on the Kryptiq SQL database. Queries can be easily run off this database to generate reports of statistical usage of the clinical messaging system. A report will be written to pull this audit information together with the actual message content information that is saved directly in the EMR (Centricity) Oracle database. Using this tool, the actual message contents and audit trails for all communication between patients and providers during the period of March – June 2008 will be reviewed. Using the tools of content analysis, the themes of the messages will be grouped and analyzed [1]. The categories outlined by other authors [2,3] will be expanded with particular attention to understanding the types of actions that are required by different types of messages, issues that are specific to adolescent patients and patients with chronic illness,

the proportion that required urgent attention, and the proportion wherein patients offered new information that they had not told the physician in the clinic.

Qualitative analysis of the different patterns of usage of secure messaging by patients compared by type of disease (e.g., cystic fibrosis versus asthma), age, gender, and socioeconomic status will be done.

Analysis of Qualitative Interviews: Transcribed data will be analyzed using the common coding techniques for qualitative data and the constant comparative method of qualitative data analysis [4-6]. Using these validated qualitative techniques, the attitudes expressed by the children and their families will be described and categorized [4-8]. The data will be analyzed in a series of iterative steps; during the coding process, revision and refinement of the code structure will be iterated multiple times as new insights and new relationships are identified. Enrollment of participants in the interviews will continue until a point of thematic saturation is reached, when there is no new data being elicited from additional interviews [6]. Typically, thematic saturation will occur with around 20-30 interviews. Additional purposeful sampling will be used to ensure adequate representation of the views from both patients and parents as well as from the different minority groups represented by the patient population.

Assessment of provider-time spent: This portion will be analyzed by comparing the time providers spend on emails, phone calls, and related follow-up with patients and their families pre-intervention versus time providers spend on secure-messaging, phone calls, and related follow-up with patients and their families post-intervention. Non-parametric tests (such as the Wilcoxon rank sum) to compare mean and median times will be used.

Assessment of ED-utilization for medication refills: To analyze this, a review of ED-utilization for patients in the clinic pre and post-intervention will be done. The full-list of all patients who are registered patients of the clinic will be obtained from Dr. Bazzy-Asaad's records as well as from the administrative database. Patients will be defined as patients of our clinic if they have had 2 or more visits in the past 2 years.

Assessment of patient and provider satisfaction: Qualitative interviews with patients and separately with clinicians will be conducted to elicit feedback about the process and degree of satisfaction. Interviews with the patients and their families will be part of the qualitative assessment described above. A parallel methodology to conduct qualitative interviews with all of the providers who care for patients in the clinic will be used.

Time Schedule and Publication Plan:

A project time schedule and Publication plan is outlined below.

E-Messaging Timeline

1. Planning and evaluation: On-going process. Started 9/27/07.
2. IRB approval: Nearly complete. Expect to submit by 11/15/07.

    a. Target 1: First draft sent to project team 10/24/07.
    b. Target 2: Discussion regarding consents/assents/tools 10/25/07.
    c. Target 3: Comments back to PI. Expected date 10/31/07
    d. Target 4: Revisions. Expected date 11/7/07.
    e. Target 5: Submission.
2. OMB approval: In progress. Expect to submit by 11/30/07.
    a. Target 1: First draft to project team. Expected date 11/1/07.
    b. Target 2: Comments. Expected date 11/8/07.
    c. Target 3: Revisions. Expected date 11/15/07.
    d. Target 4: Submission.
3. Training: Planned for 12/15/07.
    a. Target 1: Set training dates. Expected date 11/30/07.
    b. Target 2: Provide trainings. Expected start date 12/15/07. Expected completion date 3/15/07.
4. Creation of web demo: Expected completion date 3/1/08.
5. Handbook development: On-going process. Started 9/27/07.
6. Go-Live: Expected start date 8/1/08.
7. Initial review of system:
    a. Target 1: Meet with staff for initial review. Expected date 9/1/08.
    b. Target 2: Adjust system as necessary. Expected completion date 10/1/08.
8. Pre-intervention data collection:
    a. Target 1: Create data collection tools. Complete 10/25/07.
    b. Target 2: Time-motion study of nurses. Expected start date 3/3/08. Expected completion date 3/7/08.
    c. Target 3: Time-motion study of physicians. Expected start date 3/10/08. Expected completion date 3/14/08.
    d. Target 4: ED medical record review. Expected start date 3/17/08. Expected completion date 6/17/08.
9. Post-intervention data collection:
    a. Target 1: Time-motion study of nurses. Expected start date 3/2/09. Expected completion date 3/6/09.
    b. Target 2: Time-motion study of physicians. Expected start date 3/9/09. Expected completion date 3/13/09.
    c. Target 3: Query administrative database to determine patients seen in the ED post-intervention (8/1/08-1/1/09)
    d. Target 4: Perform ED medical record review. Expected start date 3/16/09. Expected completion date 6/16/09.
10. Qualitative interviews:
    a. Target 1: Determine sample: Expected completion date 9/15/08.
    b. Target 2: Schedule interviews: Expected completion date 9/30/08
    c. Target 3: Begin interviews: 10/7/08.
    d. Target 4: Complete interviews: 3/1/09.
11. Preliminary qualitative analysis:
    a. Target 1: Begin content analysis (to be conducted by at least two members of the project team). Expected completion date 5/31/09.

b. Target 2: Two members compare results and revise as necessary. Expected completion date 6/30/09
c. Target 3: Share results with remainder of the project team. Expected completion date 7/7/09.

12. Quantitative analysis: Expected completion date: 8/1/09
13. Final qualitative analysis: Expected completion date: 8/1/09
14. Manuscript preparation: Expected completion date: 9/29/09
15. Dissemination: Expected completion date: 9/29/09.

17. Expiration Date Display Exemption

AHRQ does not seek this exemption.

References

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4. Glaser BG, Strauss AL. The discovery of grounded theory: strategies for qualitative research. New York: Aldine de Gruyter, 1967.
5. Miles MB, Huberman AM. Qualitative data analysis: an expanded sourcebook. second ed. Thousand Oaks, CA: SAGE Publications, 1994.
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7. Miller WL, Crabtree BF. Clinical research: A multimethod typology and qualitative roadmap. In: Miller WL, Crabtree BF, eds. Doing qualitative research. second ed. Thousand Oaks, CA: SAGE publications, 1999.
8. Miller WL, Crabtree BF. Depth interviewing. In: Miller WL, Crabtree BF, eds. Doing qualitative research. Thousand Oaks, CA: SAGE publications, 1999.

List of Attachments

Attachment A	AHRQ Authorizing Legislation
Attachment B	60-Day Federal Register Notice
Attachment C	Forms
Attachment D	Demographic Survey
Attachment E	Draft Qualitative Interview Questions