Healthcare Facilities Granting State Health Departments' Access to Electronic Health Record Data during a Healthcare-Associated infection Outbreak: A Retrospective Assessment

New Information Collection Request

OMB No. XXX

Supporting Statement – Section B

Submitted: February 19, 2015

Program Officials/Project Officers

Elizabeth Mothershed, Deputy Director for Policy (Acting)
Centers for Disease Control and Prevention
Division of Healthcare Quality and Promotion
1600 Clifton Rd, Mailstop A07, Atlanta, GA 30333
Phone: 404-639-4780
Email: emothershed@cdc.gov
Fax: 404-639-4043

Matthew Penn, Director, Public Health Law Program
Centers for Disease Control and Prevention
Office for State, Tribal, Local and Territorial Support
2500 Century Center Boulevard, Mailstop, E70, Atlanta, GA 30345
Phone: 404-498-0452
Email:mpenn@cdc.gov
Fax: 404-498-6882

Laura Conn, Lead, Health Information Technology Strategy Unit
Centers for Disease Control and Prevention
Office of Public Health Scientific Services
2500 Century Center Boulevard, Mailstop, E97, Atlanta, GA 30345
Phone: 404-498-0971
Email:lconn@cdc.gov
Fax: 404-498-6235

Table of Contents

Section B – Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

We will be requesting telephone interview participation (Appendix H, I & J) from 15 state health department (HD) epidemiologists and 150 healthcare facility employees in their official capacities in 15 states.

State Sample

The sample of healthcare facility employees will be drawn from 15 states: Florida, Indiana, Kansas, Maryland, Michigan, Minnesota, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oregon, Tennessee, Texas, and Virginia. These states, also used in Phase I data collection, were chosen based on four criteria: 1) fungal meningitis case count, 2) experience with other outbreaks, 3) legal leadership in EHR, and 4) EHR and health information exchange (HIE) leadership.

Healthcare Facility Sample

We will be requesting participation from the state HD epidemiologist, two hospitals, and two clinics from each of the 15 states listed above. To get this information we will contact the state health department epidemiologists who were included in Phase I, to ask for their assistance in identifying a point of contact in five hospitals and five clinics from a pre-populated list procured from CDC about location of case investigations and count, that they were most involved with during the HAI fungal meningitis outbreak, or other HAI outbreaks (Appendix G). We have asked the epidemiologist to provide double the information to decrease the burden of follow-up requests should a healthcare facility, hospital or clinic, decline to participate. We will include two hospitals and two clinics, to ensure we are gaining perceptions from multiple organizations and healthcare systems.

Roles in Healthcare Facilities'

Using the contact information provided by the state HD epidemiologists, we will email the healthcare facility point of contact and ask for the following information (Appendix H):

1. **Hospitals.** The ninety hospital staff includes the infection preventionist (n=30), informatics director (n=30), and other as referred (n=30) (e.g. privacy officer, risk management etc.). Infection preventionists are included because they are the most common point of contact in the exchange of patient related information between healthcare facilities' and public health (health departments). [1, 2, 3] Informatics directors are included because of the expertise in electronic health records (EHRs), and informational technology (IT). [3] Other as referred are included because it is important to include the key perspectives of those involved in granting HD EHR access; but because there is great variation amongst roles in healthcare facilities' it is challenging to identify and include all possible roles at the outset, which may include, but is not limited to roles such as privacy officer or risk management.
2. **Clinics.** The sixty clinic staff includes the clinic directors (n=30), and other as referred (n=30) (e.g. patient records manager etc.). Clinic directors are included because they were likely the first point of contact for HDs requesting EHR access, however, there is great variation amongst roles in clinics; therefore, again it is challenging to identify and include all possible roles at the outset

of data collection, so we have built in a role to provide the flexibility to help include all key perspectives, which may include, but is not limited to patient recorders managers.

2. Procedures for the Collection of Information

One week following OMB approval, the HD epidemiologist respondents from Phase I in the 15 states will be notified by email of Phase II of the project, and requested to identify a point of contact in 10 of the hospitals (n=5) or clinics (n=5) involved in a healthcare-associated infection (HAI) outbreak in their jurisdiction (Appendix G). Although we will be interviewing staff from only two hospitals and two clinics in each state, we are requesting that the epidemiologists provide points of contact in five hospitals and five clinics to decrease the burden of follow-up requests should a facility decline to participate.

During the next three to four weeks an email will be sent to the points of contact in healthcare facilities to ask for their help in identifying the names and contact information of the infection preventionist, health informatics director in their healthcare facility, and support in identifying another role that might be able to provide insight about HD EHR access in their healthcare facility (Appendix H & I). During the next eight weeks, we will send individual emails to those identified by the healthcare facility point of contact to ask for their participation (Appendix J). Those who do not respond to their email within five days will be sent a follow-up email. As participants reply to the emails, phone interviews will be scheduled. Three days before the interview a reminder email will be sent to all participants (Appendix K). Additionally, practice interviews with the external contractor, The Keystone Center, will be conducted to help ensure quality and consistency. Phone interviews will begin seven to eight weeks after OMB approval and will continue for the next eight weeks. After each interview is conducted, a thank-you email will be sent to the participant (Appendix L). Fifteen weeks after OMB approval, data analysis will begin and will continue for the next four weeks. Nineteen weeks after OMB approval, report writing and toolkit development will begin, and the final report will be completed twenty-two weeks after OMB approval.

3. Methods to Maximize Response Rates and Deal with No response

Advanced notifications (Appendices H & I) and email reminders (Appendix K) will be utilized to maximize response rates. Additionally, HD epidemiologists will be asked to provide points of contact in five hospitals and five clinics to decrease the burden of follow-up requests should a facility decline to participate.

4. Test of Procedures or Methods to be Undertaken

Testing of the design, methodology, and sample was conducted in two key ways: stakeholder participation and Phase I data collection. First, a group of expert external stakeholders reviewed the design, methodology, and sample for this assessment during an hour-long conference call. These experts included state epidemiologists, state HAI coordinators, informatics specialists, HD legal counsel, and representatives from Consumers Union, Society of Healthcare Epidemiology of America (SHEA), and the Association for Professionals in Infection Control and Epidemiology (APIC). Second, very similar versions

of these interview guides were used in Phase I data collection. Feedback from each of these methods was used to refine questions and probes and estimate burden hours. In Phase I data collection interviews took on average 27 minutes, including time for review of instructions. For the purposes of estimating burden hours, the 30-minute upper limit of this range is used.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The following individuals were consulted to provide advice about the design of these collection activities:

Christine Prue, PhD
Associate Director for Behavioral Science in NCEZID
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS C-12
Atlanta, GA 30333
(O) 404-639-2273

The team of individuals working on this information, including instrument development, supporting data collection and analysis will consist of members from NCEZID, OSTLTS, CSELS, ASTHO, and The Keystone Center.

Name	Organization	CIO	Title	Email	Phone Number
Cairns, Catherine	ASTHO	Infectious Diseases	Director, Infectious Disease	ccairns@astho.org	571-527-3150
Conn, Laura	CDC	CSELS	Health Scientist	lconn@cdc.gov	404-498-0971
Dolen, Virgina	ASTHO	Immunization and Infectious Disease	Senior Analyst, Immunizations and Infectious Diseases	vdolen@astho.org	571-527-3161
Meinhold, Lorez	The Keystone Center	Contractor	Senior Researcher	lmeinhold@keystone.org	
Menon, Akshara	CDC	OSTLTS	Fellow and Senior Legal Analyst	amenon@cdc.gov	404-498-0419
Mothershed, Elizabeth	CDC	NCEZID	Associate Director for Policy (Acting)	emothershed@cdc.gov	404-639-4780
Penn, Matthew	CDC	OSTLTS	Director of Public Health Law Program	mpenn@cdc.gov	404-498-0452

Prue, Christine	CDC	NCEZID	Health Communication Officer	cprue@cdc.gov	404-639-2273
Raber, Anjanette	CDC	NCEZID	Evaluation Fellow	araber@cdc.gov	404-639-4662
Ramanathan, Tara	CDC	OSTLTS	Public Health Analyst	tramanathan@cdc.gov	404-498-0455
Ruebush, Elizabeth	ASTHO	Immunization and Infectious Disease	Analyst, Infectious Disease and Immunization Policy	eruebush@astho.org	571-527-3139
Saindon, John	CDC	CSELS	Health Scientist Informatics	jsaindon@cdc.gov	404-498-2242
Samuel, Anita	ASTHO	e-Health	Director, Informatics	asamuel@astho.org	571-527-3174
Schmit, Cason	CDC	OSTLTS	Fellow and Legal Analyst	cschmit@cdc.gov	404-498-2387
Soper, Paula	ASTHO	e-Health	Senior Director, eHealth	psoper@astho.org	571-318-5412
Sperber, Brad	The Keystone Center	Research	Senior Mediator and Facilitator	bsperber@keystone.org	202-452-1593
Trainum, Brooke	The Keystone Center	Research	Associate Researcher	btrainum@keystone.org	970-513-5847

The open-ended questions from the phone interview will be analyzed using thematic analysis.

References

1. Association of State and Territorial Health Officials. Public Health's Direct Access to Hospital Electronic Medical Records: Benefits and Barriers. Published December, 2013.
2. Dixon BE, Jones JF, Grannis SJ. Infection preventionists' awareness of and engagement in health information exchange to improve public health surveillance. *Am J Infect Control.* 2013;41(9):787-7
3. Centers for Disease Control and Prevention. State Health Department Access to Electronic Health Record Data during an Outbreak: A Retrospective Assessment Preliminary Summary Report (unpublished data, 2014)

LIST OF ATTACHMENTS – Section B

Appendix A: Section 301 of the Public Health Service Act (42 U.S.C. 241); Authorizing Legislation

Appendix B: 60 Day Federal Register Notice

Appendix C: Phase I Summary Report

Appendix D: Telephone Interview Guide for Infection Preventionist and Clinics Directors, or other as Defined

Appendix E Telephone Interview Guide Informatics Directors

Appendix F: CDC IRB Letter of Determination

Appendix G: Emails to Health Department Point of Contact for Healthcare Facilities'

Appendix H: Email to Healthcare Facility Point of Contact

Appendix I: Email to Clinic Directors

Appendix J: Individual Email to Infection Preventionist, Health Informatics Director, other as referred Clinic Director or Other as referred by Clinic Director, other as referred

Appendix K-Email reminder to All Participants

Appendix L-Thank you Email to All Participants

Appendix M-60 Day FRN Comment