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13. ABSTRACT (Maximum 200 Words) This study is a community-based, essentially an observational study, in conjunction with local public health authorities across a multi-jurisdictional region. <u>Purpose:</u> The purpose is to develop feasible, useful syndromic surveillance capabilities that will improve CONUS force protection, and support local public health authorities. The approach is to design a system to monitor military bases and the communities surrounding military bases, and to facilitate military/civilian cooperation. <u>Scope:</u> The proposed work will characterize the feasibility of reporting in a variety of settings and implementation models; understand the relative utility of data gathered for both surveillance and detection; and develop feasible technical and policy approaches to implementing bi-directional data exchange between civilian and military health systems. <u>Major findings to date:</u> There is no current working syndromic surveillance system that has a functional data catch-up and roll-back process. A further finding is that Local Health Jurisdictions (LHJ's) have different practices for how they use existing systems. One LHJ uses the EARS system and primarily examines all interesting ER visits while other LHJ's (and the major syndromic surveillance systems) focus primarily on alerts. <u>Up-to-date report – results/significance:</u> The inconsistency of use of existing systems illustrates the need for flexibility in designing systems for multiple uses.				
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March 2005 Annual Report
Puget Sound Infectious Disease Tracking System
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Introduction:

This study will look at the organic, rapidly expanding, operational efforts to develop advanced tools for public health surveillance and disaster management and develop evidence-based knowledge to help shape these efforts. The approach is to rapidly leverage existing, deployed computerized public health data collection systems in the Puget Sound region, and build several new components to create a laboratory for the “field study” in this proposal. The project proposes to build a system of sentinel sites that will allow us to answer the following categories (themes) of questions: *feasibility* – characterize the feasibility of automated and manual reporting under a variety of settings and implementation models; *relative utility* – understand the relative utility of the data gathering through these techniques (evaluating each technique alone and the synergism from using both techniques in the same population for surveillance and detection; *technical and policy approaches* - develop technical and policy approaches to cooperation including the implication of bi-directional data exchange between civilian and military public health surveillance systems.

Statement of Work: Puget Sound Infections Disease Tracking System

Task 1	Status – Research Accomplishments
Task 1: Community Initiative – Use a community based approach to assist in gathering requirements for data collection and data sharing across jurisdictions. (Months 1-6)	Completed - Initial Step: Letters of support from: Seattle & King County Public Health, Kitsap County Health District, Washington State Department of Health, Tacoma-Pierce County Department of Health, State of Washington Department of Social and Health Services and Department of the Army – Madigan Army Medical Center.
a. Create an executive management team of key stakeholders including investigators, key participants and administrative resources.(Month 1)	Completed: See Appendix A for names, titles and organizational affiliations. In the initial stages of the project, the committee met on several occasions to develop plan for the project. The Committee is now scheduled to meet quarterly with formal agenda, minutes and regular updates and progress reports.
b. Identify potential participant sites to include the principal emergency departments in the participating counties. These sites will be representative of the “Sea-Tac” corridor and will include facilities contiguous to the Ft. Lewis, McChord A.F.B, Bremerton Naval Yard, Everett Home Port, and the NAS Whidbey Island. (Month 1)	Completed: Potential participant sites are identified as follows: Emergency Room data from LHJ’s including Tacoma-Pierce County Health Department, Kitsap County Health District, and Seattle King County Public Health. This characterizes data from 5 Puget Sound counties representing approximately 23 hospital facilities in Kitsap, Jefferson, Clallam, Pierce and King Counties. These participant sites are representative of Sea-Tac corridor and do include facilities contiguous to Ft. Lewis, McChord AFB, and Bremerton Naval Yard.

c. Implement a joint application development process using identified subject matter experts to identify and document data and system requirements for the web-based data collection. Identify all necessary mechanisms to ensure the security and privacy of proposed data collection is consistent with HIPAA requirements. (Months 1-3)	The joint application development process was implemented within the initial 3 months of the project. The joint development process was developed and implemented as directed by the general and special interest forums of the project Steering Committee. The Rapid Application Development (RAD) approach was selected as the approach to for software development. This is a common approach used in software system design. Each phase of the project contains specific tasks, deliverables, and sign offs for software development to ensure scope, budget and timelines are maintained. Ongoing review and refinement of this process will continue throughout the project. Each shareholder was invited to participate in the joint development process. In addition, a "super user" who is not part of the program development team is working with each stakeholder organization to perform assessments of workflow and technical capacity at participating sites. This allows for careful review and characterization of variations in operational patterns, personal technical capacity and other key implementation issues.
Initial analysis of HIPAA application is completed and initial recommendations have been developed. Security and data obfuscation are both specified in the design at levels in excess of the most stringent interpretation of HIPAA requirements for security and privacy. The application of HIPAA and companion state laws to PSIDTS data and participants is analyzed in Appendix B. To ensure successful implementation of security and privacy mechanisms, the following approach is planned: 1. The PSIDTS Steering Committee will continue to guide the development of policies, procedures and technical solutions applicable to the development of the system which are consistent with participants' internal HIPAA	Initial analysis of HIPAA application is completed and initial recommendations have been developed. Security and data obfuscation are both specified in the design at levels in excess of the most stringent interpretation of HIPAA requirements for security and privacy. The application of HIPAA and companion state laws to PSIDTS data and participants is analyzed in Appendix B. To ensure successful implementation of security and privacy mechanisms, the following approach is planned: 1. The PSIDTS Steering Committee will continue to guide the development of policies, procedures and technical solutions applicable to the development of the system which are consistent with participants' internal HIPAA

security compliance programs. 2. Conduct further analysis, as deemed necessary by the Steering Committee, of potential implications and uses of public health reporting exceptions and obligations for support of disclosure of protected health information through the PSIDTS system, and specify materials limitations on or potential opportunities for data gathering, distribution and analysis under public health law. 3. Clarify public health authority of PSIDTS data receivers, and if necessary or desirable develop strategies for delegating public health authority to appropriate non-agency participants. 4. Develop an integrated interpretation of HIPAA and Washington law provision which support participation in PSIDTS, including any policies and procedures necessary or prudent to assure compliance with HIPAA and Washington State law, which is accepted as valid by PSIDTS participants. 5. Review potential for re-identification of data in PSIDTS repository, and if necessary perform statistical studies to demonstrate impossibility of re-identification, and/or implement policies and procedures preventing re-identification.	d. Draft detailed requirement documentation including logical data models, use cases, activity diagrams and functional specifications, and review with all participants, stakeholders and potential users. This would include the reconciliation of requirements with pertinent data, privacy and other standards, including National Health Information Infrastructure (NHII) and National Electronic Disease Surveillance System (NEDSS). Create prototype models to test the functional acceptances and The system is being built in two distinct phases. Phase 1 (through July 2005 timeline) is focusing on building the core elements of the system. Documentation for initial design specifications for Phase I has been completed. The SCRUM overall project development model has been implemented to ensure the completion of the Phase I prototype. The SCRUM method is an enhancement of iterative and incremental approach to delivery of object-oriented software.
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review the prototype models or the proposed system with all participants, then re-craft requirements based on prototype review. (Months 3-5)	Prototype models were developed as a joint collaboration between Paladin Data Corporation, Subcontractor and Dr Ian Painter, Project Biostatistician. To achieve greater efficiencies, Dr Painter acted as a surrogate end user, providing requirements. These requirements are distilled from: 1. Interactions with the LHJ's, 2. Interactions with University of Washington 3. Systematic review of current syndromic surveillance systems (including CDC's BioSense project, Electronic Surveillance System for the Early Notification of Community-Based Epidemics (ESSENCE), Realtime Outbreak and Disease Surveillance (RODS), Over-the-Counter drugs and other items (OTC), and Early Aberration Reporting System (EARS). 4. Systematic review of the syndromic surveillance literature. These draft requirements were reviewed with Paladin Data Corporation, and adjusted and clarified based on Paladin Data's experience with developing similar systems. The SCRUM development model requires that requirements are updated as the model is developed in more detail. Paladin Data Corporation staff and Dr Ian Painter are meeting weekly to update requirements and elucidate requirements in more detail. A major finding is that no current syndromic surveillance system has a functional data catch-up and roll-back process. A further finding is that LHJ's have different practices in how they use existing systems. One LHJ uses the EARS system and primarily examines all interesting ER visits on a case by case basis, other LHJ's (and the major syndromic surveillance
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	systems) focus primarily on alerts. Some of this difference is in how the systems are being used and differences in resource levels. However, it illustrates the need for flexibility in designing a system for multiple uses. Several aspects of the requirements for the PSIDTS system borrow from the positive aspects of existing systems, trying to correct for aspects that are not as helpful.
Task 2 – Case Reporting Task 2 – Case Reporting – Rapidly develop a web-based case reporting system for syndromic clinical data, and implement that system in a variety of healthcare organizations throughout a four County area in Western Washington region. (Months 5-24)	Status- Research Accomplishments Public Health leaders, both local and national, were found to be highly skeptical of a web-based system approach. AIBS Peer Review to USAMRMC identified this component of the study as a weakness. Public health leadership recommended a more reliable and affordable approach to developing an accurate information system for syndromic surveillance. Public health officials requested the project focus on developing techniques with reasonable expectations for the long-term value. Status: Based on immediate feedback on this approach, the web-based case reporting system is not being pursued. This decision does not require a change in the Statement of Work. See Appendix C dated 12/23/04 documenting that the Statement of Work remains an accurate description of the proposal. The four Sub-tasks under Task 2 remain relevant except that they will be applied to other collection methods consistent with ESSENCE.

a) Develop and review technical specifications to support detailed requirements identified by participants, stakeholders and users. Develop plan for unit and acceptability testing. Develop use cases from functional specifications to guide development and testing (Months 5-7)	As a result of the joint application system development process, the technical specifications are summarized below: The system currently under development will provide a central processing repository for Emergency Room (ER) syndromic reporting and the collection and analysis data sources such as over the counter drug sales, absenteeism, 911 (EMS) system logs, etc. The software will provide a common platform and set of tools for organizations that do not share a common approach or methodology in the gathering, analysis, and response to syndromic surveillance information. The system is being developed to offer a variety of analytical tools and visualization techniques allows for complex statistical, spatial, and temporal analysis and display of the information with the system. The is being developed to support a number of analytical tools as well as provide the framework for the user to develop their own tools and extensions, and to share those extensions with others in the project community. And most importantly, this system is being designed to offer a region-wide view of the information in the system, integrating and displaying data without regard to artificial boundaries such as political or organizational lines. Central to the system design is the relational database system, based on ANSI Structured Query Language technology configured to operate both as transactional processing system and a data warehouse. This initial Phase (Phase I) is focusing on building the core elements of the system to ensure a "proof of concept" application.
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	By focusing these early activities on system architecture, user interface, data warehouse database, import, process and export functions, this allowed for the initial consolidation of data from 3 LHJ's. As this process continues it will characterize data from the participating counties and hospitals.
b) Perform assessments of workflow and technical capacity at participating sites to select an option, and then document implementation plan, both to assure implementation of success as well as to characterize variations in operational patterns, personal technical capacity and other key implementation issues. (Months 7-9)	Assessment of workflow and technical capacity at the participating sites has been completed. Based on assessment and input from sites, the system is being designed to support a number of tools as well as allow the user to develop their own tools and extensions. The system is being designed with functions as listed below: 1. Securely encrypt, transmit, stage, process, store and present data using data warehousing industry's best practices 2. Plug-in capability for interchangeable tools or methods to group (unstructured text chief complaint data into syndromic classes 3. Plug-in capability for interchangeable tools or methods to analyze the data and detect anomalies and patterns 4. Present data analysis result summaries using table, graph and geo-spatial map visualizations and drill down capability. 5. Automatically trigger anomaly alerts based on detection findings and queue notification messages for distribution.

c) Implement the case reporting application, and perform unit and acceptance testing on both the web application and the central server. (Months 8-11)	Implementation of the application is in process. Current login and basic data display elements have been completed. Implementation of the first analytical components are underway. A demonstration version of the application has been developed, and will be used to demonstrate functionality and features to LHJ's, Foundation for Health Care Quality and the University of Washington
d) Implement the system at participating sites, and provide ongoing follow-up assessment, support and documentation of implementation issues through the use of third party web-deployed issues tracking tools, and through contract reporting (Months 11-24)	Implementation of system prototype testing is scheduled for June/July 2005.
Task 3 – Automated Data Collection/Integration	Status- Research Accomplishments
Task 3 – Automated Data Collection/Integration – Data will be collected from the sentinel healthcare organizations in all participating counties, with the direct reporting of data to the local health jurisdictions. Integrate the data from the web-based case reporting system, the automated data collection system, and the military's public health surveillance system, the support appropriate access by both military and civilian health authorities. (Months 1-24)	In process: The system design specifications and scope documents identify the approach and methodology to be used for Automated Data Collection and Integration. The system is designed to incorporate a "smart" rules based data collection engine which is capable of collecting data in a variety of formats from a wide range of organizations. Automated implementation of system prototype testing of data collection is scheduled for real time testing at 1 site by June/July 2005. After the testing is complete, the system will be implemented at the participating counties and health care organizations.

a) In concert with the Community Initiative, develop technical agreements with the IT groups of sentinel sites healthcare organizations with all counties, to cover data elements, coding, security, and service-level agreements. Develop similar agreements with Madigan for centralized exchange of ESSENCE II or similar regional military data. (Months 1-12)	Draft template is in the review and comment period. Estimated timeline for this task is March/April 2005.
b) Extend our present serve architecture to accommodate required scaling, add additional site-specific normalizations, and extend query structure to include multi-jurisdictional data access. (Months 1-6)	The system design specification is scalable both in capacity and capability. Based on industry standard data management products, the system uses self-defining data structures throughout its design, allowing for future expansion and addition of data sources without requiring a programmatic change. Access to the information in the system is controlled by a robust security protocol which provides granular access management and system journaling.
c) Implement automated data collection, easing the present 3-tier, HIPAA compliant data model at the sentinel sites. We anticipate being able to implement at multiple site in each participating county over this period. (Months 3-21)	Automated implementation of system prototype data collection is scheduled for one site by June/July 2005. After the prototype testing is complete, the system will be implemented at the participating counties and health care organizations.
d) Develop and implement support for bi-directional exchange of data with military systems, working at either the regional level with Information Technology staff at Madigan Army Medical Center, or at the national level with the ESSENCE staff. (Months 6-12)	Julie Pavlin, M.D., M.P.H., Walter Reed Army Institute of Research initially served on the Steering Committee. After the ESSENCE project was transferred to Health Affairs, Col Kenneth L Cox, Director, Force Health Readiness, Health Affairs replaced Dr. Pavlin. Dr. Peter Dunbar, PI and Linda Lekness, Executive Director participated in a conference call with Col. Cox on 2/3/05. Col. Cox expressed interest and support for the project. As "lessons learned" become available from other similar projects, he will provide that information to the project.

	Dr. Peter Dunbar met with Lieutenant Colonel Andrew Wiesen, MD, PhD, Clinical Assistant Professor, Madigan Army Medical Center, Department of Preventive Medicine in November 2004. LTC Wiesen stated that since Madigan was already reporting data to ESSENCE it would be relatively simple to send data to PSIDTS once the project had reached the appropriate milestones. Dr. Dunbar and LTC Wiesen agreed to meet after there is additional progress with the technical development of the system and the agreement with TPCHD is complete. At the time of this report, Project Leaders have are negotiating an agreement with TPCHP and in addition have met with the leadership of MultiCare system that owns 90% of the hospital beds in the county and a significant number of ambulatory care clinics. Dr. Peter Dunbar met with Brigadier General Michael A. Dunn, Madigan Army Medical Center in December 2004. Gen. Dunn expressed support for the project. Gen. Dunn submitted a written letter of support to the Foundation for Health Care Quality for the project.
e) Continue to improve and maintain centralized integration server, and continue to improve and maintain secure data transmission using both accepted and evolving standards for security and message protocols. (Months 12-24.)	As noted in the task description, the work activities for the next 12-24 months will continue to build on the accomplishments of the initial 12 months of the project. Phase II (July 2005 and beyond) will expand functionality through inclusion of additional hospital data streams, novel data sources, additional toolsets, geo-spatial features, and refinement to notification and alerts for expanded audience such as hospitals, physicians, etc. Further refinement of Phase II elements will be documented as part of the Phase II plan and scope.

Task 4 – Utility Assessment/Detection and Visualization	Status- Research Accomplishments
Task 4 – Assess the individual and combined utility of web-based case reporting and automated data collection on the same populations through application of existing algorithms and visualizations. (Month 1-24)	AIBS Peer Review to USAMRMC identified the component of assessing web based reporting as a weakness in the project. Based on immediate feedback on this approach, the web-based case reporting system is not being pursued. See Appendix C dated 12/23/04 documenting that the Statement of Work remains an accurate description of the proposal. The Sub-tasks under Task 4 remain relevant as reported below.
a) Gather algorithms inclusion criteria: use in a bioterrorism or epidemic detection system.	A systematic review of all statistical methods and algorithms used in syndromic surveillance has been conducted. This review is in manuscript preparation and will be submitted for publication to a major journal in the field.
b) Test/evaluate the performance of the above approaches against set historical outbreaks and novel outbreaks.	This is an ongoing process throughout the project. A literature review of testing performance and existing evaluations is being conducted. Dr Ian Painter, Biostatistician, is currently working with a University of Washington graduate student on an internship at Seattle King County Public Health (SKCPH) to conduct a systematic evaluation of the major algorithms against simulated outbreaks using SKCPH data as background. Evaluation will include an examination of the relationship between outbreak characteristics and detection algorithm performance. Code to conduct the simulations has been written and is currently undergoing testing. The simulations are anticipated to start within the 2-4 week timeframe, and will be conducted on multiple computers at SKCPH. An initial finding is that for one major algorithm the implementation that the CDC has done of the algorithm differs from the published information on the

algorithm. SKCPH is in communication with the CDC to try and resolve whether the published information or the implemented algorithm is the correct algorithm.

Dr Thomas Lumley, Associate Professor, Biostatistics, University of Washington School of Public Health and Community Medicine and a graduate student (Krisztian Sebestyen) at the University of Washington are simultaneously developing a comprehensive extendable architecture for a syndromic surveillance algorithm test bed. The analytical side is being developed in R and the simulation of data being conducted in a database environment. A theoretical examination of Cusum methods is also being conducted by Krisztian Sebestyen and Dr Thomas Lumley. Dr Painter, Biostatistician is advising and supporting this work along with Dr Bill Lober, Assistant Professor, Division of Biomedical and Health Informatics at the University of Washington.

Dr Painter, Biostatistician is currently conducting an evaluation of the usefulness of the syndromic surveillance data being collected at Kitsap County for detection of influenza like illness. Preliminary work on the feasibility of doing this has been completed.

Task 5 – Ethnographic Analysis	Status- Research Accomplishments
Task 5 – Ethnographic Analysis – Appraise the value of syndromic clinical data to decision makers in public health and disaster management by conducting structured, retrospective assessments of the personnel involved with three recent events: the ongoing smallpox vaccination program, the SARS outbreak, and the 2003 Seattle TOPOFF exercise. (Months 1-24)	The analysis is proposed to be conducted much like the Foundation for Health Care Quality Clinical Outcomes Assessment Program (COAP). The Foundation for Health Care Quality will serve as a trusted and neutral party to hold data collected as part of syndromic surveillance. The analysis will be conducted in a manner to provide a rigorous, evidence-based mechanism to promote internal quality improvement activities while meeting a variety of external quality improvement and accountability requirements.
Dissemination of Results – All investigators will seek to present intermediate and final results through conference presentation and peer review publication. This is anticipated to begin in month 6, based on extension of prior work, and extend past the end of the contact. (Months 6-36)	Dr. Bryant Karras, Assistant Professor School of Public Health University of Washington, has recently submitted a manuscript to MMWR Special Supplement on the 2004 National Syndromic Surveillance Conference. If accepted the publication will be in the September 2005 MMWR. The title and authors are: Bryant T. Karras MD, D Bliss, M Barclay, B Lober, S. Lindquist. A technical solution to protecting privacy in Syndromic Surveillance Information Collection (SSIC – MD5) Dr. Ian Painter, Biostatistician, has in preparation a manuscript summarizing the statistical approaches to syndromic surveillance. When this manuscript is complete, it will be submitted for publication. Two manuscripts are in preparation for submission to the AMIA (American Medical Informatics Association) annual meeting for Fall 2005. The deadline for submission is March 15, 2005.

	Representatives from this project (PSIDTS) will be actively involved in planning for and participating in the upcoming 2005 National Surveillance conference scheduled to be held in Seattle, Washington in November 2005. Several aspects of the ongoing work effort are likely to be suitable material for presentations at this conference including but not limited to the following: 1. System and database design 2. Overview of statistical methodology 3. Assessment of method performance by simulation 4. Design and implementation aspects related to this test bed project 5. Detection of influenza like illness using chief complaint text 6. Results of major simulation study being conducted by SKCPH. It is anticipated that the work activities related to Phase II of this project will lead to additional opportunities for dissemination of the results of this project.
Project Reporting – All investigators will assist the Principal Investigator in providing reporting as required to satisfy contact terms (Months 1-24)	2005 Syndromic Surveillance Conference is schedule to be held in Seattle, Washington. Investigators participating in the Puget Sound Disease Tracking System Project will present findings to-date at the conference.

Key Research Accomplishments:

- Research and Development: created a research and development team with members of the Foundation for Health Care Quality, Paladin Data Corporation and the University of Washington.
- Relationship Building: building relationships with Local Health Jurisdictions and selected hospital groups to facilitate data provisioning.
- Center for Public Health Informatics at the University of Washington: participation in planning for a new Center for Public Health Informatics at the University of Washington.
- System design and implementation: basic architectural design of the data system and initial implementation of the design. This includes review of end user needs and requirements.

Reportable Outcomes:

- Dr. Bryant Karras has recently submitted a manuscript to MMWR Special Supplement on the 2004 National Syndromic Surveillance Conference. If accepted the publication will be in the September 2005 MMWR. The title and authors are: Bryant T Karras MD¹, D Bliss², M Barclay², B Lober³, S Lindquist⁴ A technical solution to protecting privacy in Syndromic Surveillance Information Collection (SSIC-MD5).
- Dr. Ian Painter, Biostatistician, has in preparation a manuscript summarizing the statistical approaches to syndromic surveillance.
- Funding - Paladin Data Systems received notice of award on 12/17/04 for \$1.8 million contract from the US Army Space and Missile Defense Command for Phase II. This funding will be used to conduct additional research and expand the PSIDTS.

Conclusions – Preliminary:

- There have been both political and technical challenges in this project but we have identified key stakeholders and strong potential allies. The University of Washington has proven to be a key partner and will bring increasing value to the project as it develops. The University of Washington School of Public Health is starting a Center for Public Health Informatics that shall ensure the Puget Sound Infectious Disease Tracking System project has a much longer life than at first envisioned. We believe that the Puget Sound Infectious Disease Tracking System will be able to evaluate the feasibility of not only a local but a statewide syndromic surveillance system.

Appendix A

Puget Sound Infectious Disease Tracking System

Executive Management Team of Key Stakeholders including Investigators, Key Participants and Administrative Resources:

Dr. Peter Dunbar, Principal Investigator, Puget Sound Infectious Disease Tracking System

Dr. Mark W. Oberle Professor and Associate Dean, School of Public Health, University of Washington

Gary Macy Executive Vice President/CTO, Paladin Data Systems

Andy Fallat CEO, Foundation for Health Care Quality

Dr. Ian Painter, Biostatistician, Puget Sound Infectious Disease Tracking System

Jerry Tonkavich Consultant, OTB Solutions Group Seattle, Washington

Nigel Turner, MPH, RS Epidemiologist, Pierce County

Michael C. Davisson, State of Washington Department of Health

Linda Lekness, MBA, MSN, RN, Executive Director, Puget Sound Infectious Disease Tracking System

Jude Van Buren, Dr. PH, MPH, RN, RS Assistant Secretary, Epidemiology, Health Statistics and Public Health Labs, State of Washington Department of Health

Dr. Chris Leininger, Chief Information Officer, Swedish Hospital Seattle, Washington

Dr. Jeff Duchin Chief Epidemiologist, Seattle/King County Health Department

Dr. Scott Lindquist, MD, MPH Chief Epidemiologist, Seattle/King County Health Department

Appendix B

HIPAA Compliance Model for PSIDTS

I. Objectives

- A. ***Principal Objective:*** Identification of all necessary mechanisms to ensure the security and privacy of proposed data collection is consistent with HIPAA requirements.
- B. ***Secondary Objective:*** Reconciliation and incorporation of requirements of applicable state laws and public health legal requirements with mechanisms implemented for HIPAA compliance purposes.

II. General Discussion.

Participants in PSIDTS will include a mix of entities required to comply with HIPAA, including hospitals, clinics, healthcare payors and other Covered Entities, and entities which are not required to comply with HIPAA. The latter will principally include services organizations such as Inland Northwest Health Systems.

Some types of participants will be "Hybrid Entities," which perform both "covered functions" (*i.e.*, act as healthcare providers and/or payors) and non-covered functions. Hybrid entity participants will principally include state and local public health agencies and the Department of Defense.

HIPAA creates potential obstacles to data sharing for PSIDTS because of the privacy-oriented limitations it imposes on the use and disclosure of Protected Health Information ("PHI") by Covered Entities, and the security requirements it imposes on Covered Entities for the protection of PHI. PSIDTS systems and operating policies will therefore have to be structured to comply with both HIPAA's restrictions on PHI use and disclosure, and its security requirements.

A. Application of HIPAA to PSIDTS Data.

As a matter of prudence it should be assumed that all data transmitted or stored for PSIDTS purposes which identifies or could be used to identify an individual is PHI subject to HIPAA protections. Data which does not include or has had all identifiers listed in the HIPAA Privacy Rule, 45 CFR § 164.514(b), is not considered PHI and is not subject to HIPAA.

However, even data which has been scrubbed of the listed identifiers is not considered de-identified if the disclosing party actually knows the information "could be used alone or in combination with other information to identify an individual." This exception could come into

play with otherwise de-identified data which concerns a rare condition and/or an incident likely to be covered in the media, or where a large database and sophisticated data-mining and – indexing tools might allow re-identification. Where such a possibility is present, the rule allows for a demonstration that the data cannot be re-identified through expert statistical analysis.

B. Application of HIPAA to PSIDTS Participants.

Covered Entities are prohibited from using or disclosing PHI except in compliance with the HIPAA Privacy Rule, and are required to protect PHI as provided in the HIPAA Security Rule. Hybrid Entities are required to treat their health care components (which perform covered functions) as if they were Covered Entities separate from their other components.

The PHI use and disclosure limitations of the HIPAA Privacy Rule and the PHI protection requirements of the HIPAA Security Rule therefore control the transmission of PHI among Covered Entities and from Covered Entities to non-Covered Entities, as well as the transmission and use of PHI within Hybrid Entities.

C. Application of Washington Law to PSIDTS Participants.

HIPAA does not supersede state laws which are "more stringent" in their protection of PHI. Applicable Washington state laws include the Uniform Health Care Information Act, RCW 70.02 ("HCIA"), as well as a common law obligation of physician confidentiality. These are generally consistent with HIPAA, though the HCIA is more stringent in some respects and common law requirements have not been clarified very much by the courts.

III. Privacy Discussion

A. De-Identified Data.

Neither HIPAA nor Washington state law applies to de-identified information (as that term is defined in the HIPAA Privacy Rule). Covered Entities, and the health care components of Hybrid Entities, participating in PSIDTS will therefore generally not be restricted in their disclosures of de-identified data for Syndromic Surveillance purposes.

However, as noted above it is possible that there may be circumstances where de-identified data can be re-identified, potentially present when large quantities of data are subject to sophisticated analysis. It is therefore recommended that the PSIDTS repository be reviewed and analyzed to confirm data is not subject to re-identification.

1. Recommendation: Review potential for re-identification of data in PSIDTS repository, and if necessary perform statistical studies to demonstrate impossibility of re-identification, and/or implement policies and procedures preventing re-identification.

B. Public Health Disclosures through PSIDTS.

PSIDTS disclosures require more analysis with respect to disclosures of PHI. The HIPAA Privacy Rule prohibits Covered Entities from disclosing PHI without specific, written authorization except for purposes specifically authorized by the rule. Washington's HCIA follows the same approach.

Both the HIPAA Privacy Rule, 45 CFR § 164.512(b)(i) *permits* (but does not require) Covered Entities to disclose PHI for "public health activities and purposes," but only to:

A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions[.]

(Emphasis added.) The regulations also more generally allow disclosures where "necessary to prevent or lessen a serious threat the health or safety of a person or the public[.]" 45 CFR § 164.512(j)(1).

Washington law takes a somewhat different approach, which appears to *require* disclosures of protected information to "federal, state, or local public health authorities," but only "to the extent the health care provider is required by law to report health care information[.]" *See* RCW 70.02.050(2)(a). Washington law also requires "all state or local agencies obtaining patient health care information" under this exception "to adopt rules establishing their record acquisition, retention, and security policies" consistent with the HCIA. *See* RCW 70.02.050(3).

Washington law appears to be "more stringent" than HIPAA, and therefore probably applies though there is no binding authority on this point. In the absence of binding legal authority most Covered Entities are in any case likely to assume the more stringent provisions apply, and require that Washington law conditions be met.

Washington law does have some requirements for public health reporting of health care information, but these are not squarely on point for PSIDTS. While there are a number of proposals for state public health laws which would enhance reporting requirements, but these have not been adopted in Washington. The Washington law provision most on point for PSIDTS appears to be a Department of Health regulation requiring all health care providers to

cooperate with public health authorities during investigation of . . . circumstances of a case or suspected case of a notifiable condition or other communicable disease [and] an outbreak or suspected outbreak of illness.

WAC 246-100-021.

The HIPAA and Washington state provisions can be interpreted together to require (and therefore legally permit) health care providers and the health care provider components of Hybrid Entities to disclose PHI to public health agencies through PSIDTS where there is a specific actual or suspected case, cases or outbreak under investigation. This interpretation may put limitations on the subsequent use of PHI obtained through for surveillance or investigation purposes for research not related to the surveillance or investigation.

1. *Recommendation:* Conduct further analysis of potential implications and uses of public health reporting exceptions and obligations for support of disclosure of PHI through PSIDTS, and specify any material limitations on or potential opportunities for data gathering, distribution and analysis.
2. *Recommendation:* Clarify public health authority of PSIDTS data receivers, and if necessary or desirable develop strategies for delegating public health authority to appropriate non-agency participants.
3. *Recommendation:* Develop an integrated interpretation of HIPAA and Washington law provisions which support participation in PSIDTS, including any policies and procedures necessary or prudent to assure compliance with HIPAA and Washington law, which is accepted as valid by PSIDTS participants.

IV. Security Discussion.

HIPAA and Washington law do not appear to differ materially with respect to security issues. Washington law does require health care providers to "effect reasonable safeguards for the security of all health care information [they] maintain." RCW 70.02.150. This highly general requirement is easily reconciled with the more detailed provisions of the HIPAA Security Rule.

Like the HIPAA Privacy Rule, the HIPAA Security Rule applies only to Covered Entities and the health care components of Hybrid Entities. Since PSIDTS is not a Covered Entity – and in fact the PSIDTS proposal does not currently contemplate the establishment of any entity separate from the participants – security compliance must therefore be accomplished on an entity-by-entity basis by each participant.

However, the implementation of security solutions within organizational "silos" creates the potential for interoperational failures. For example, data sent by one participant may be rejected by another participant for failure to meet the latter participant's authentication requirements. Or, negligent perimeter control by one participant might permit a hostile outsider to "spoof" a participant's identity and communicate false data or otherwise interfere with PSIDTS operations and data quality.

PSIDTS therefore requires operational consistency, including but not limited to consistent solutions for identification and authentication of individuals and entities using the system, access controls, and other policies, procedures and technical solutions which are also reasonable and appropriate for the participants' use under the HIPAA Security Rule.

PSIDTS currently lacks a governing body which can solve these problems, and the solutions ought to be developed will need to meet the needs of and be accepted by the participants in any case. Specific security solutions and requirements for PSIDTS should therefore be developed

through a process which identifies and develops consensus solutions to security issues affecting PSIDTS participation.

1. *Recommendation:* Steering Committee to oversee the ongoing develop of policies, procedures and technical solutions applicable to PSIDTS systems which are consistent with participants' internal HIPAA security compliance programs.

Appendix C

-----Original Message-----

From: Andrew Fallat [mailto:afallat@qualityhealth.org]
Sent: Tuesday, December 23, 2003 2:34 PM
To: 'Ward, Sherry L Dr USAMRMC'
Cc: 'Peter Dunbar (E-mail)'; 'Todd Langton (E-mail)'
Subject: PRO33147 - Puget Sound Infectious Disease Tacking System (PSIDTS)

The purpose of this email is to follow-up on our telephone conversation on Monday, December 22, 2003. We appreciate your observations and believe we have addressed each topic. I am concerned that the memo is longer than anticipated but I concluded that it was better to provide a more thorough record for your review.

Does PSIDTS still have value to DoD?

PSIDTS has immediate and time sensitive value to Department of Defense (DoD) personnel. We are concerned that benefit may be compromised if the Proposal is delayed and opportunity to work with DoD ESSENCE leadership at Madigan Army Medical Center is lost during DoD's JSIPP implementation. We believe that the (unfunded) work we have accomplished since receiving Patricia Evans, Contracting/Grants Officer's 9/10/03 Recommendation for Funding letter has significantly improved the Proposal's value to the military.

The Military Relevance Statement provided with the Proposal remains sound, without any reservation whatsoever. PSIDTS will develop and evaluate different techniques to acquire data on civilian health populations. In collaboration with cross-jurisdictional public health leaders, this data provides the first Immediate Benefit: a regional sentinel system. The Long Term benefits remain the same, with the exception of researching additional means of integrating with ESSENCE rather than a web-based system. This improvement addresses a weakness identified and articulated by DoD Programmatic Reviewers in their critique (see next section).

The 9/10/03 Funding letter recommended that a partnership with researchers at the Department of Defense Global Emerging Infections System <http://www.geis.ha.osd.mil/>. We have accomplished this partnership and have secured GEIS participation on PSIDTS Steering Committee, through LTC Julie Pavlin, Head, Electronic Surveillance System for the Early Notification of Community-Based Epidemics (ESSENCE) <http://www.geis.ha.osd.mil/GEIS/SurveillanceActivities/ESSENCE/ESSENCE.asp>.

Through collaboration with Madigan Army Medical Center and ESSENCE we learned that Fort Lewis (the home base for Madigan Army Medical Center) was selected as a JSIPP site. PSIDTS is committed to partnership and value to DoD: therefore it appeared to increase PSIDTS's value to DoD to work within the priorities and interests of DoD as established for Fort Lewis.
<http://www.geis.ha.osd.mil/GEIS/SurveillanceActivities/ESSENCE/JSIPPexsum.asp>.

Our partnership with GEIS, ESSENCE and Madigan has increased value to DoD. On the other hand, if we fail to move ahead and secure the immediate benefits of a regional sentinel system in the strategically valuable Pacific Northwest (using the collaborative interests of DoD's other major initiative ESSENCE) we may lose a time sensitive opportunity.

Does the absence of a letter confirming access to data on military subjects merit a delay?

The absence of a letter confirming access to data on military subjects is not unusual at this stage in the Proposal. In fact, it was anticipated that Tasks 1 and 3 would articulate the privacy/security issues prior to securing access. It may be ironic that a Proposal designed to research practices/policies to improve partnership between civilian/DoD may be delayed because it could not secure, in advance, an objective that was scheduled for its end.

Unlike research utilizing the clinical details of specific DoD personnel (and therefore clearly described in a proposal and dependent on access to clinical data on military subjects), PSIDTS relies on access to civilian data which creates a regional, sentinel system available to DoD. This civilian information is valued by DoD, will be integrated into ESSENCE and used by DoD to expand its knowledge of Community-based Infections affecting DoD personnel. It is the intent and on-going practice of DoD/ESSENCE to share data with civilian authorities; however, before a specific confirmation of access can be solicited, Proposal's Task 1 needs to begin.

Access to data on military subjects is being addressed in accordance with the original Statement of Work. DoD leadership accepts responsibility for releasing access to data and will do so only when the utility to DoD is addressed and security in place to assure mandated confidentiality. Indeed, this work was anticipated in Proposal's Tasks 1c, 1d, 3a, 3c, 3d and 3e (all related to developing standards and policies related to data access).

It was also recognized that PSIDTS may be in partnership with either Madigan or GEIS, or both. (Tasks 3a, 3d) We secured a Letter of Collaboration with Madigan indicating that more specific requests would go to their IRB if and when that request was essential. We consulted with LTC Julie Pavlin who described the ESSENCE approach to access to data on military subjects (see attached Word document entitled "Memo for Sharing), in which citations are provided indicating that it is both authorized and previous practice for DoD to share surveillance data with civilian authorities.



Memo for sharing
TMA data.doc

We conclude that a major accomplishment of this Proposal will be to assist civilian communities and DoD learn methods and policies essential to timely and appropriate sharing of surveillance information. We believe that DoD's ESSENCE project is leading the way and we intend to work with ESSENCE through Task 1 to bring in other military approvals as necessary.

We conclude it is futile (and perhaps a detriment to developing future infectious surveillance partnerships with DoD) to attempt to secure detailed letters of assurance without first accomplishing the work described and funded in Task 1.

Should the Statement of Work be amended and resubmitted?

The Statement of Work remains an accurate description of our Proposal. We will broaden input methods into the Surveillance system, in recognition of comments made by Programmatic Reviewers and other DoD leaders in ESSENCE.

The Statement of Work describes five major Tasks, with 16 sub-tasks. Task 2 identifies developing a web-based case reporting system. The four Task 2 sub-tasks are generic to case reporting and not dependent on web-based reporting. Collaboration with DoD personnel within ESSENCE indicates that other input systems are preferred. These comments are consistent with weaknesses identified in the Programmatic Reviewer's comments (p.7): "The proposal may overestimate the workability of the Web-based tool for providers to use". And again: "One concern relates to...the time required to input data into the automated data collection system". The four sub-tasks under Task 2 remain relevant except that they will be applied to other collection methods consistent with ESSENCE. Stated differently, all 16 of the sub-tasks are relevant and will be performed.

We also believe that bi-directional exchange of information will occur with DoD, in accordance with the stated goal of ESSENCE and the established practice of DoD related to Infectious Surveillance. We see no change to Statement of Work in that arena.

I have neither expertise nor experience on which to base a conclusion regarding the necessity of an amendment. It seems to be administratively complex, however, to resubmit a new Statement of Work

because of a heading change when all the sub-tasks remain the same. We believe the input process was improved by replacing a technique that was described as a "weakness" by Programmatic Reviewers with another process preferred by DoD partners we were encouraged by DoD to invite to the Proposal.

Is "cost-reimbursed" grant acceptable to the Foundation?

Yes, a cost-reimbursement grant award is acceptable to the Foundation. The Foundation does not have working capital sufficient to make other than nominal advances to staff and vendors. Likewise, the Foundation cannot risk incurring expenses without assurance that they will be reimbursed. As long as "cost-reimbursed" permits both a reasonable amount of working capital and staffing adequate to handle Foundation requests (with quick turn around) for assurance about specific potential expenses, then "cost-reimbursed" is acceptable.

Thank you for the opportunity to respond to your observations. We appreciate your consideration of funding decisions essential to our beginning work on PSIDTS. We anticipate your call to Todd Langton on December 30.

Andrew Fallat
President/CEO
Foundation for Health Care Quality
Seattle, WA