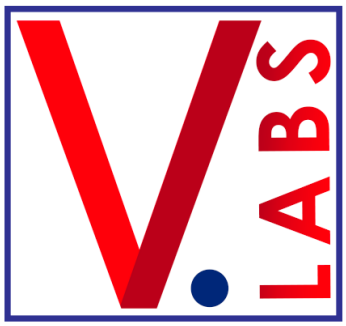

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White Paper

Advancing the State-of-the-Art in Medical Infectious Disease Surveillance

Background

A number of studies have pointed out the potential usefulness of establishing a medical surveillance system, in an attempt to intervene positively in outbreaks of disease, thereby reducing morbidity and mortality. Collecting syndromic data to predict events as they occur in the health care setting will hopefully provide early warning of potential bioterrorist attacks. This concept is well described in the article by Kaufman, Figure 1, below.

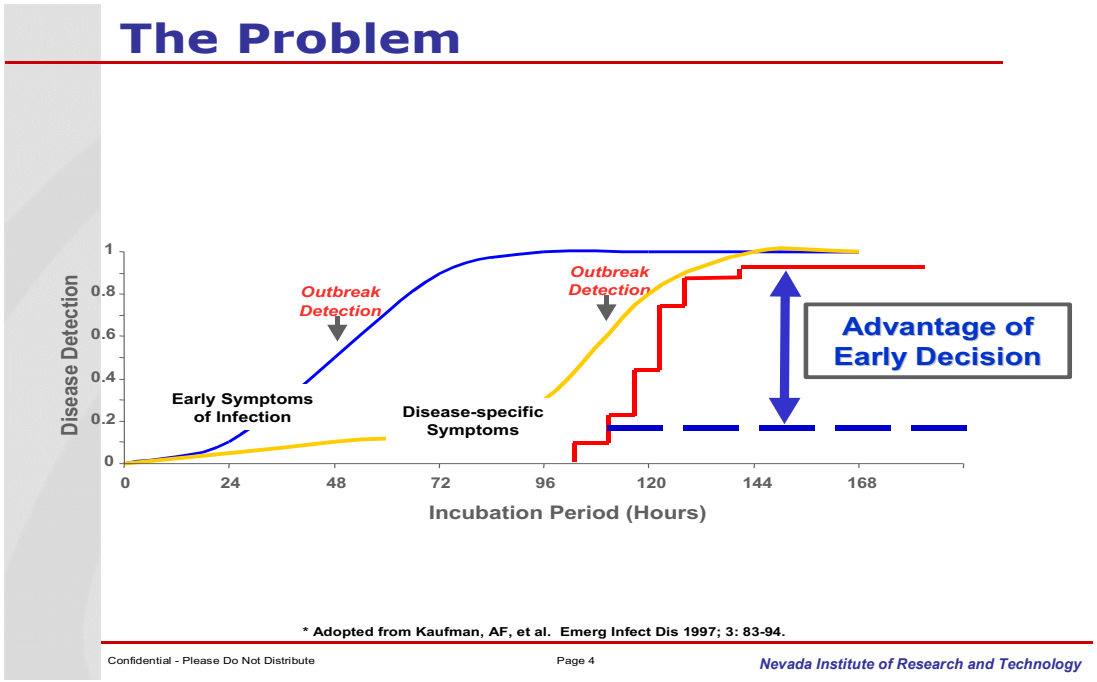

Figure 1

The Air Force attempted to establish a sophisticated tracking system to not only identify disease outbreaks in the served medical population, but also included the capability to manage Emergency Response and cope with the consequences of a potential outbreak of illness. The effort included programs with the names Desert Care, Desert Care II, Yorktown, GEMS and finally culminating in a program called LEADERS. This paper defines a strategy to advance the state of the art of the Air Force existing prototype ***Lightweight Epidemiology Advanced Detection & Emergency Response System*** (LEADERS) towards a new capability called the Vigilent Labs – Bio-defense Digital Nervous System ("BDNS"). BDNS advancements will demonstrate the ability to effectively transfer clinical and medical administrative data from existing databases into a real time BDNS analytical repository for rapid disease trend determination and disease anomaly detection. A key portion of this effort will include a survey of some of the more promising analytical capabilities employed by the Centers for Disease Control (CDC), those being developed under Defense Advance Research Projects Agency (DARPA), those developed under other HHS/BARDA sponsorship, and existing commercial analytical software to provide an evaluation of these capabilities. The proposed BDNS system will enable any military branch the capability to utilize multiple analytical tools to assess their medical, health and/or clinical data and provide a "plug and play" architecture allowing new algorithms and tools to be added to a Biowarfare Extensible Analytic Toolkit. Our proposed BDNS

will allow for the ability to rapidly identify anomalies or trends, work up the significance of the identified event or outbreak and present this early warning information to senior managers in an actionable manner. BDNS provides the information necessary to make effective decisions early and returns useful clinical information to the healthcare providers and concerned organizations.

Vigilent Labs "BDNS" is intended to address key shortcomings within military services current ability to effectively and rapidly analyze myriad clinical data from various sources and sites in an early warning system that identifies potential disease trends and patterns. The benefit of BDNS is the early detection of potential biological agent and/or biothreats, terrorist events or natural outbreaks allowing senior commanders to make timely decisions, allocate critical resources and accelerate responses. Specifically, BDNS will provide the necessary aggregation of existing surveillance tools data and comprehensive analysis of that data. Using algorithm based Artificial Intelligence (AI) techniques, BDNS will demonstrate the ability to provide real time data analysis of multiple clinical and medical administrative inputs and yield a picture of disease trends and anomalies. This capability provides a force multiplier for deploying units and homeland facilities, by increasing a commander's knowledge as to the state of health of his active duty population and degree of protection from biological threat agents. BDNS will maximize the use of Commercial-Off-The-Shelf (COTS) technology and existing DoD medical information systems. A properly constructed BDNS Deployment will include the following factors:

a. a survey of promising analytical tools currently being used by other agencies like DARPA, the Air Force, Army, Navy/USMC and CDC and other commercial products that profess to provide near real-time disease data tracking and analysis;

b. implementation of a proof-of-concept system to transfer clinical and medical administrative data, along with relevant text and images, over existing network connections. The system will operate over existing, and typical low, and narrowband communications. The project will investigate and prototype an analytical database and reporting system that allows the military sponsor to use multiple analytical tools to determine anomalous disease events and disease trends. It will also provide the necessary alerting and notification mechanisms to professional experts in disease management and intervention to assist in timely decision-making;

c. BDNS will provide a useful display system for each of the specialists involved utilizing the appropriate medical and administrative data, including: an epidemiologist's workstation; a public health officer's view; a commander's view; and necessary views for the primary care physician and infectious disease expert;

d. BDNS will contain appropriate methodologies for network security and procedures to ensure HIPAA compliance to protect individual patient privacy without sacrificing public health usefulness.

Definition of BDNS System

An example of a BDNS system is described in Figure 2 below. The components of the system are further described in each of the following sections.

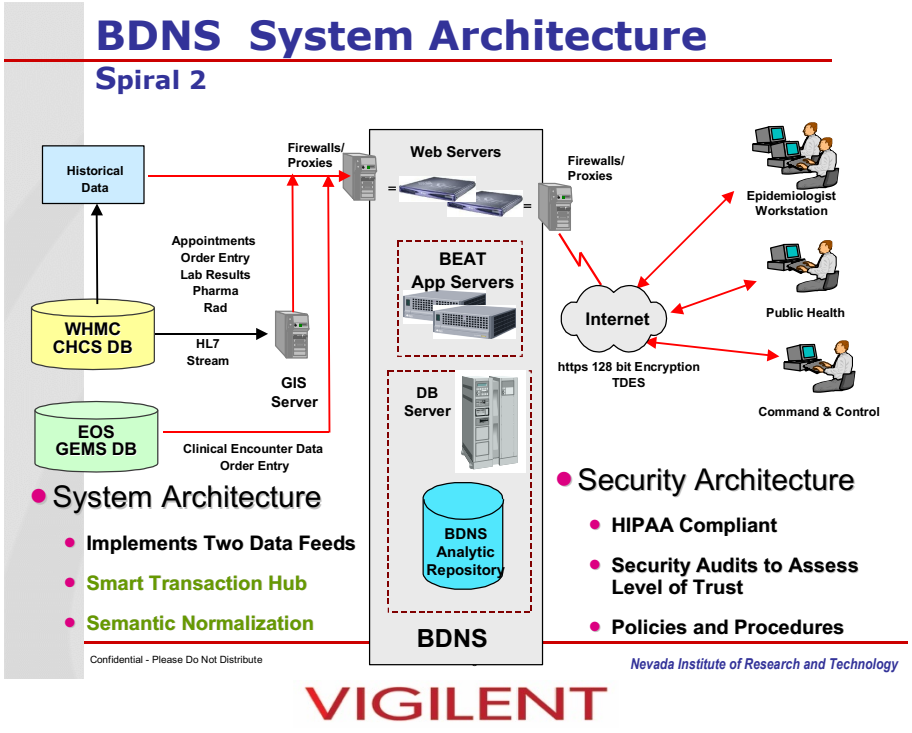

Figure 2. System Architecture

Survey Analytic Tools and Algorithms for BDNS System

Assessment of current analytical tools used currently by U.S. Air Force epidemiologists, CDC, the LEADERS-MAGIC program, and DARPA would be a reasonable starting point for a clinical early warning system. The goal of the BDNS system will be to establish a methodology to utilize any of these analytical tools to evaluate existing and developing Air Force clinical data on the fly. Establishment of tools to perform required format conversion, collation, text handling, code translation, de-identification and re-identification, summarization, filtering

and routing of records containing primary clinical data from multiple clinical settings intended for multiple user groups would be necessary aspects of such a program.

BDNS Analytic Repository Model

Essential to the success of such a program is the development of an initial data model for an Analytic Repository (AR). Included in such a model will be business rules for transforming source data, frequency of extracting and refreshing the AR data from source systems (E.G., once per hour or per day, as soon as available, etc) and data archive requirements. Samples of database types from which relevant clinical data is drawn should consist of CHCS I, GEMS including its true electronic medical record details. In the future it should include data within the developing CHCS II system and the theater medical information program.
BDNS will leverage Vigilent Labs existing v.DNS database structure and architecture that satisfies the proposed functionality. v.DNS utilizes our extensive Application Program Interface (API) to integrate myriad data sources into a comprehensive data repository.

Extraction, Transformation and Loading Capability for the BDNS Analytic Repository

Implementing a standards-based Smart Transaction Hub (STH) is also crucial to such a project. Development of an STH to application/system adapter using APIs for each of the source systems adapter architecture for "plug and play" extensions is necessary. These adapters will manage inbound and outbound authorized messages containing de-identified health information and various multi-source data between the STH and the data source. Protected health information (PHI) will be removed at the data source. Privacy, authentication and non-repudiation services as an integral component of the STH are necessary. Providing semantic normalization by transforming local codes, text or valid values to Unified Medical Language System unique concepts is a crucial step to analyze data. Both the vocabulary term and the original local value should be retained in the AR. Tools will be needed to perform required format conversion, collation, text handling, code translation, de-identification and re-identification, summarization, filtering and routing of records containing primary clinical data from multiple clinical settings intended for multiple user groups. The BEAT should also include identifying existing and proposed ways to combine records of different clinical types (e.g. laboratory results and outpatient diagnoses) into a single stream for purposes of outbreak detection.

BDNS Bio-Warfare Extensible Analytic Toolkit (BEAT)

Development of an easy-to-use common interface for authorized novice and expert users to gain access to the various tools in the BEAT should be the primary goal of any effort to develop a medical surveillance digital nervous system. Developing a set of routine reports and presenting them in tables, graphs or other useful user oriented graphical displays for the local hospital and public health community, major command headquarters (MAJCOM) and the Medical Operations Center at the Office of the Surgeon General could be the primary users of the development of a surveillance tool.

BDNS will leverage Vigilent Labs v.COP application to provide an interoperable data visualization environment Command Center capability (aka Common Operating Picture). This implementation includes adapting our v.COP integration with our v.DNS and near real-time Weathercast functions to not only provide a comprehensive, integrated data environment but also provide analytical tools including visualization of the impact of biologic warfare within localized and regional environments and with weather conditions that can affect environments.

Summary

In conclusion, a BDNS system will provide state of the art analysis capability along with the appropriate tools for experts in the health care chain from the initial provider through the epidemiologist, the public health officer, and the commander, decision maker, in a useful, secure framework to provide early warning of infectious disease trending as well as anomaly detection. It can establish a new Model for Medical Surveillance in the field of Public Health Surveillance.

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