



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

February 2, 2007

Ross Lazarus, MD, MBBS, MPH
Department of Ambulatory Care
and Prevention
Harvard Medical School
Boston, MA

Dear Dr. Lazarus,

This letter confirms the strong interest and enthusiastic support of the Center for Disease Control's Immunization Safety Office (ISO) for your proposed project, ESP-VAERS "Electronic Support for Public Health - Vaccine Adverse Event Reporting System". Your intention to create software to prospectively identify potential vaccine adverse effects in electronic medical records, and to facilitate clinicians' evaluation and electronic reporting to VAERS, will constitute an important, exciting, and long-awaited advance in the field of vaccine safety. The capability you hope to create will serve both individual clinicians as well as national efforts.

I see several important strengths to your work. First, I am pleased to see that you plan to study the effects of an advance in technology by using a randomized clinical trial. This study design will provide the strongest evidence to clinicians and policy makers alike as to the benefit of this system. Second, by and large this system will be transparent to clinicians – that is, it will not impede the clinician's day-to-day clinical practice. However, in the event that there is a suspect vaccine adverse event, clinicians can submit reports with very little effort (in fact, this system will likely save time compared with the more cumbersome system currently in place). Third, the ability of this system to gather (in the background, using available electronic data), more complete information about the vaccinated individuals, and the ability of the system to provide data on the entire population of persons who were immunized, will be important enhancements to current reporting systems. Fourth and finally, the fact that your software will be open source and is designed work in a wide range of software environments will create the right conditions for its widespread adoption. All of these are important additions to your earlier work on elicited surveillance "reference here".

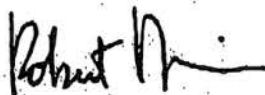
It is important for me to note that conducting this work in clinical practices that currently participate in the CDC's Vaccine Safety Datalink (VSD), (which the Immunization Safety Office leads), means there will be substantial opportunities for the VSD to collaborate in ensuring the success of this new research. Your plan to use VSD information as the gold standard for assessing the performance characteristics of your software is one excellent example of this collaboration, and I expect there will be others.

In addition to encouraging further alignment of the VSD to facilitate your work, I will be having VAERS staff work with you to address the wide range of technical issues that are

sure to arise, to develop standards governing which events should be reported, and to support the randomized clinical trial that you will conduct to evaluate the impact of this system.

Finally, I will mention that it makes great sense to me to build this work on the existing programs and activities of Harvard's CDC-supported Center of Excellence in Public Health Informatics. Combining the accumulated resources and expertise of the Center of Excellence and VSD will allow you to make great strides quickly.

Sincerely yours,



Robert L. Davis, MD, MPH
Director, Immunization Safety Office
Centers for Disease Prevention and Control



a program of the Agency for Healthcare Research and Quality

February 2, 2007

Ross Lazarus, MBBS, MPH, MMED
Department of Ambulatory Care & Prevention
Harvard Medical School / Harvard Pilgrim Healthcare
133 Brookline Ave., 6th Floor
Boston, MA 02115

Dear Ross:

This letter is to document the enthusiastic support of the Steering Committee of the Centers for Education & Research on Therapeutics (CERTs) for your proposed study entitled "Electronic Support for Public Health: Vaccine Adverse Event Reporting System (ESP:VAERS)."

Your proposed study addresses a crucial area in therapeutics: the need to improve adverse event detection and reporting for vaccines. The ESP:VAERS has the potential to substantially increase the number, completeness, and timeliness of case reports submitted to the CDC compared to the existing spontaneous reporting system. Your initiative to provide electronic monitoring of adverse events for vaccines is an important one.

As you know, CERTs is a program administered by the Agency for Healthcare Research and Quality (AHRQ), in consultation with the Food and Drug Administration. It was authorized by Congress as part of the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115). The vision of the CERTs program is to serve as a trusted national resource for people seeking to improve health through the best use of medical therapies. The mission of the CERTs is to conduct research and provide education that will advance the optimal use of drugs, medical devices, and biological products.

Your aim – to determine if electronic monitoring will improve the detection and reporting of adverse events for vaccines – will clearly advance the CERTs mission. Therefore, the Steering Committee wholeheartedly supports your application.

Sincerely,

Hugh H. Tilson, MD, DrPH
Chairman, CERTs Steering Committee



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

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COMMISSIONER

Ross Lazarus, MD, MBBS, MPH
Department of Ambulatory Care and Prevention
Harvard Medical School

Dear Dr. Lazarus,

This letter is to express my strong support of your AHRQ Enabling Quality Measurement through Health IT proposal entitled ESP:VAERS. Your intention to create software to prospectively identify potential vaccine adverse effects in electronic medical records, and to facilitate clinicians' evaluation and electronic reporting to VAERS, will constitute an important advance in vaccine safety. The capability you will create will serve individual clinicians as well as state and national programs.

The very high level of public health experience and academic expertise along with the technical and informatics skills of your group has formed a solid foundation for the success of our collaborations over the past 6 years. Your group has been critical not only in the success of our syndromic surveillance projects, but also in integrating the alerts from this system with our Health Alert Network (HAN). This effort helped define the standards for electronic HAN to HAN communications across states.

As described in your proposal, the ESP software produced by your group, as part of our CDC Center of Excellence in Public Health Informatics project, is currently deployed at HealthOne, securely reporting statutory notifiable disease cases as HL7 messages, to our ELR system, for immediate transfer to appropriate officials, providing a new and efficient source of accurate and complete case reports. Your team quickly delivered valid HL7 messages and batch wrappers, to our ELR SOAP server, according to our specifications, and worked with our vendor on extensions we needed for ESP to report treatment to the ELR, in a very proficient, deft and professional manner.

Your proposal has our support, because our experience has shown your team has the range of skills needed and is capable of successfully integrating and completing the public health, validation, technical, and informatics tasks described in your proposal. In addition, our long collaborative experience suggests that your proposed collaboration with the CDC, FDA and their vendors, will proceed smoothly and professionally.

Additional functions will make the whole ESP software base even more sustainable and flexible, helping us and others to improve public health surveillance from electronic ambulatory care records in Massachusetts and elsewhere. The ESP system appears to be technically sound, stable and mature and source code is readily available. Since your systems are, and will be, adaptable, freely distributable, available for commercial vendors, and designed work in a wide range of software environments, there are no obvious barriers to their widespread adoption and prolonged sustainability.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Ja B. Daniel", written in a cursive style.

James Daniel, MPH
Chief Information Officer
Massachusetts Department of Public Health



**Harvard
Vanguard**
Medical Associates

A major teaching affiliate of Harvard Medical School

January 31, 2007

Ross Lazarus, MBBS, MPH, MMED
Department of Ambulatory Care & Prevention
Harvard medical School / Harvard Pilgrim Healthcare
133 Brookline Ave, 6th Floor
Boston, MA 02115

Dear Dr. Lazarus:

On behalf of the HealthOne Care System, I should like to confirm our enthusiastic support for your proposal to develop ESP-VAERS, a near real-time vaccine adverse event detection, clinician query, and automated reporting system that will be implemented in our practices. As you know, HealthOne is the largest independent physician network in Massachusetts with approximately 600 physicians serving 600,000 patients from across the greater Boston area. We now completing system-wide deployment of EpicCare, a sophisticated electronic medical record system that is used to document every patient encounter. HealthOne has always been a leader in harnessing clinical information systems to improve the care of both individuals and our patient population at large. We see your proposed ground breaking work in automated vaccine adverse event detection and reporting as continued progress for patient safety and physician practice.

We have a had very productive relationship with your research team on other projects and know that this proposal will be successful. To date, we have worked together to use automated data streams from our electronic medical record system for syndromic disease surveillance and for communicable disease detection and public health reporting. We also are currently using a simplified clinician-elicited vaccine adverse event surveillance system created by your group for our pediatric patients. This shared experience augurs well for further fruitful collaboration on the design, data interfacing, and elicitation of clinician participation in this new venture.

In particular, HealthOne anticipates being able to provide the following (pending Institutional Review Board approval of your planned activities):

- Continued timely access to the full range of codified EpicCare data that is currently being sent to the ESP server located within the HVMA firewall at the Kenmore Computing Center.
- Information Systems expertise to support creation of an interactive interface between ESP and EpicCare in order to enable ESP to communicate suspected adverse events to the responsible clinician via EpicCare's secure internal clinician mail system
- Permission to pilot ESP-VAERS on a small subset of clinicians and vaccines in order to validate your algorithms and informatics structures

- Permission for scaled deployment of ESP-VAERS across HealthOne once you have demonstrated smooth functioning of the system and minimal interference with clinician workflow.
- We will work with you to inform HealthOne clinicians about ESP-VAERS and to win their agreement to participate in reviewing personalized alerts about possible adverse effects suffered by their patients
- Permission to retain one year's worth of patient data on the ESP server at any one time and permanent records of all cases reported to the Vaccine Adverse Event Reporting System (VAERS)

We are confident that you and your team will continue to use our data in a responsible manner that respects all applicable patient privacy laws. We look forward to a mutually beneficial collaboration on this exciting new project.

Yours Sincerely,

A handwritten signature in cursive script that reads "R Marshall MD".

Richard Marshall, MD
Chief Medical Officer
Harvard Vanguard Medical Associates