



Centers for Disease Control
and Prevention (CDC)
Atlanta, GA 30341-3724

Subject: Real Time Immunization Monitoring System (RTIMS)

The pandemic (H1N1) 2009 virus is presenting unique challenges for health care providers and public health officials throughout the country. It is anticipated that the safety profile of influenza A (H1N1) 2009 monovalent vaccine will be similar to seasonal influenza vaccines. Serious adverse events after vaccination are rare; however, as with all vaccines, it is anticipated that coincidental adverse events will occur. The Centers for Disease Control and Prevention (CDC) wants to detect any unanticipated problems as quickly as possible. As part of our efforts to monitor influenza vaccines, CDC is supporting Johns Hopkins University (JHU) to help actively monitor the safety of 2009 H1N1 influenza vaccine as well as seasonal influenza vaccine in the 2009/10 influenza season. This study is intended to supplement other vaccine safety monitoring systems administered by CDC, the Food and Drug Administration (FDA), and other agencies.

This study will use an automated web-based system to follow up vaccinees, provide information for them to give informed consent to participate in the study online and collect, analyze and present participant-reported data and symptoms following 2009 H1N1 influenza vaccine and seasonal influenza vaccine. We are asking that you help us with this effort by providing contact information (e.g., name, phone number, email address) for vaccinees expressing interest in participating in the study. The study will be described in specific informational flyers made available at influenza vaccination clinics and patients will be encouraged to read them and indicate whether they agree to be contacted while they are waiting for vaccination. Those agreeing to be contacted will be emailed or text messaged by an automated system within 5 days of receiving 2009 H1N1 influenza vaccine or seasonal influenza vaccine. This email or text will give the individual directions on how to enroll in the study. Study enrollees will be followed periodically up to 42 days post vaccination. The study investigators will share the findings from this study with CDC and interested health departments throughout the influenza season.

We are hoping to enroll large numbers of vaccine recipients in states throughout the country in this project. Your efforts to help capture safety data by sharing contact information of vaccinees expressing a willingness to participate with the Johns Hopkins team will be most appreciated and an important contribution to public health efforts. We sincerely appreciate any support that you can offer in this endeavor.

Please contact Laura Leidel, MPH, at the CDC Immunization Safety Office, Phone (404) 639-1446 or the Principal Investigator, Neal Halsey, MD, at JHU Phone, (410) 955-6964 if you need any further information.

Thank you,

A handwritten signature in black ink, appearing to read "Frank DeStefano". The signature is fluid and cursive, with the first name "Frank" being the most prominent.

Frank DeStefano, MD, MPH
Director
Immunization Safety Office
Division of Healthcare Quality Promotion
National Center for Preparedness, Detection
and Control of Infectious Diseases
Centers for Disease Control and Prevention