

ECDC IN COLLABORATION WITH THE VAESCO CONSORTIUM TO DEVELOP A COMPLEMENTARY TOOL FOR VACCINE SAFETY MONITORING IN EUROPE

Eurosurveillance editorial team (eurossurveillance@ecdc.europa.eu)¹

1. European Centre for Disease Prevention and Control, Stockholm, Sweden

This article was published on 1 October 2009.

Citation style for this article: Eurosurveillance editorial team. ECDC in collaboration with the VAESCO consortium to develop a complementary tool for vaccine safety monitoring in Europe. *Euro Surveill.* 2009;14(39):pii=19345. Available online: <http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=19345>

A consortium of researchers aiming for development of vaccine safety monitoring through linkage of large computerised clinical databases and immunisation registries (VAESCO-project) has recently signed a contract with the European Centre for Disease Prevention and Control (ECDC). This new tool will complement the routine monitoring of adverse events through National Regulatory Agencies reporting to the large European Medicines Agency (EMA) EudraVigilance database.

The consortium with participants from eight European Union Member States will utilise common software (the Jerboa Vaccine module) to look for possible events in each participating database. Aggregated data on specific events will be shared across country borders. The consortium had its start-up meeting a few weeks ago in Basel, where the coordinating institution is located.

The vaccine safety data linkage system will be used immediately to develop age- and sex-specific background incidence data on rare and more common conditions in larger European populations that possibly could be related to administration of vaccines. Brighton case definitions for events will be used when available [2].

Such data will be valuable when mass vaccination campaigns will start against the pandemic influenza A (H1N1) 2009 virus, if there is a need to perform analyses of observed versus expected events. The information will be available in the end of October for use by National Regulatory Agencies or EMA and will later be published in a peer-reviewed scientific journal.

Infectious diseases such as measles and polio are now close to being eliminated through large immunisation programmes. Vaccines are provided to individuals of all ages. The mere fact that large numbers of doses of vaccines are administered to healthy individuals creates conditions for events which are temporally associated with vaccination. These events can either be real or coincidental. To maintain public confidence in the immunisation programs, vaccine safety must be a focus for all stakeholders including manufacturers, vaccine providers and governments.

References

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2. Brighton Collaboration. Definitions and guidelines. Available from: http://www.brightoncollaboration.org/internet/en/index/definition___guidelines.html