Response to: "US Food and Drug Administration Docket No FDA-2008-N-0234 Developing Guidance on Conducting Scientifically Sound Pharmacoepidemiologic Safety Studies Using Large Electronic Healthcare Data Sets; Public Workshop; Request for Comments

Submitted by the
International Society for Pharmacoepidemiology (ISPE)
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Introduction

The International Society for Pharmacoepidemiology (ISPE) is an international professional organization dedicated to advancing the health of the public by providing a forum for the open exchange of scientific information and for the development of policy, education, and advocacy for the field of pharmacoepidemiology, including pharmacovigilance, drug utilization research, and therapeutic risk management. ISPE's more than 1200 members come from over 45 countries and work in academic institutions, the pharmaceutical industry, government agencies, and non-profit and for-profit private organizations. ISPE's members have been involved in epidemiologic research using large electronic healthcare datasets since the inception of such databases. Our scientific meetings have served as the principal public forum for presentation and discussion of methodologic issues relating to the use of these databases for drug safety research. Moreover, ISPE has served as a forum for public evaluation of studies that have yielded discrepant findings from the same or similar data sources. Because of our membership's methodologic expertise, our experience with all major electronic healthcare data sets in the US and abroad, and our multi-sector representation, ISPE is well-positioned and willing to help the US Food and Drug Administration (FDA) develop guidance that will contribute to FDA's public health mission and also enhance the field of pharmacoepidemiology.

Background

On May 7, 2008, FDA held a public workshop to solicit comments and suggestions on its intent to prepare guidance on best practices for Conducting Scientifically Sound Pharmacoepidemiologic Safety Studies Using Large Electronic Healthcare Data Sets. This document constitutes ISPE's response to FDA's request.

Comments and Proposals

ISPE is committed to the advancement and application of core principles of epidemiologic research to the field of pharmacoepidemiology. Prompted by a request from FDA, in 1996 ISPE issued its Guidelines for Good Pharmacoepidemiology Practices. The Guidelines have been revised twice since that time (August 2004, April 2007). These guidelines and their revisions reflect ISPE's ongoing focus on this critical area.

ISPE would welcome the opportunity to offer FDA the benefit of its membership's broad knowledge and experience to assist the agency in its development of best practices for Conducting Scientifically Sound Pharmacoepidemiologic Safety Studies Using Large Electronic Healthcare Data Sets. ISPE would be willing to prepare a written document that would provide recommendations on topics including the following:

1. Developing an annotated listing of key descriptors, characteristics and core variables that need to be taken into account before conducting pharmacoepidemiologic studies in Large Electronic Healthcare Data Sets (Claims and Electronic Medical Records)

2. Compiling and reviewing existing best practice guidances worldwide of direct relevance to the conduct of observational database practice with respect to potential applications for the safety of medical interventions.

3. Exploring potential mechanisms that will improve the transparency and availability of methods for conducting pharmacoepidemiologic safety studies. To enhance the understanding of future research and facilitate evaluation of results across studies of similar topics derived from the same or other databases, we will consider, among other approaches, developing mechanisms to enhance the sharing of exposure and outcome coding sets and algorithms, coding libraries and descriptions of full study methods.

The ISPE document would also identify and compile existing information, develop new specific information to fill gaps in existing published information, explore implications of various potential solutions to methodological issues or changes in pharmacoepidemiology practice, and articulate proposals to address the need for further technical or methodological development.

The resulting document will be developed and endorsed by the ISPE membership, and could be available within about 6-8 months of FDA expressing interest in such a document.

We hope that ISPE's expertise in the methods of database research, combined with the multi-sector representation of our membership, can provide expertise, information, and perspective that will be useful to the FDA. In addition to the proposed document, ISPE would also be receptive to providing its feedback on other specific areas that may be of interest to FDA.