ISPE Statement on the Registration and Public Disclosure of Pharmacoepidemiology Research Protocols

The ISPE Guidelines for Good Pharmacoepidemiologic Practices (GPP), which are "intended to apply broadly to all types of pharmacoepidemiologic research, including feasibility studies, validation studies, descriptive studies, as well as etiologic investigations…"(1, page 201) recommend that:

> "Each study should have a written protocol. A protocol should be drafted as one of the first steps in any research project, and the protocol should be amended and updated as needed throughout the course of the study." (1, page 201)

ISPE endorses the opportunity to register and publicly disclose hypothesis-driven pharmacoepidemiology research protocols in a suitable public site. Registration and disclosure should be permanent (without the option to retract the protocol). However, ISPE supports the option to register a protocol with a published timetable for its later disclosure, rather than immediately disclose the protocol at the time of registration. The procedures for protocol registration should also include a mechanism for amendment of previously posted protocols. Registered protocols should contain the elements recommended in the Guidelines for GPP.(1) In the registration statement, the investigators should declare the extent to which they were aware, through advance exploratory analyses, of the likely ultimate findings of the study at the time that the protocol is submitted.

In some instances, such as when conducting feasibility studies or performing "data mining" for the purposes of hypothesis generation, the protocol may describe the general process and methods to be used without pre-specifying specific exposures or outcomes of interest. In such settings, registration of protocols may not be feasible or warranted.

ISPE is aware of the activities within the US (FDA) and Europe (EMA) to implement registration of non-experimental pharmacoepidemiologic studies. ISPE strongly recommends worldwide harmonization of core requirements for study registration.

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1. ISPE. Guidelines for Good Pharmacoepidemiologic Practices (GPP). Pharmacoepidemiology and Drug Safety. 2008; 17: 200–208