Ethical Requirements for the Conduct of Drug Utilization Studies in Latin America: A Cross-Sectional Survey

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This is an ongoing study. If your country is not yet covered and you would like to participate in the survey, please contact T. Arredondo Bisono (teigna.arredondo@yolarx.com)

BACKGROUND

- Drug utilization studies (DUS) are increasingly requested by health authorities and payers to evaluate the benefit-risk of drugs in the real-world clinical practice setting.
- Assessment of prescribing practices, including off-label use, often requires clinical chart review for detailed information on patient characteristics, sometimes supplemented by follow-up questionnaires with prescribers or patients.
- In the absence of guidance, ethical requirements for these studies appear heterogeneous across countries and settings.

OBJECTIVES

To define the ethical and/or legal framework applicable for the conduct of DUS in hospital and ambulatory care settings in Latin American countries.

METHODS

Study countries: Argentina, Brazil, Chile, Colombia, Costa Rica, Guatemala, Mexico and Peru.

1. Review of existing legislative sources and literature

- Local/Global regulations applicable for the conduct of DUS

2. Cross-sectional survey to ethics committees and/or key informants

- Supplemental information addressing gaps in the literature

RESULTS

Legislative sources & Literature review

- Great disparity across local legislations on DUS in Latin America.
- Heterogeneous ethical requirements at the level of institutions and variation in the data protection legislation.
- Major differences arise for DUS involving ad hoc data collection (i.e., chart review or questionnaire to prescribers or patients).

Argentina
- Well-defined legislation for DUS
- Institutional review boards (IRBs) evaluate every protocol in order to involve researchers in securing safeguards of personal data confidentiality

Brazil, Chile, Costa Rica
- Resolutions and regulations applicable to research involving human subjects

Colombia
- Clear information on regulatory requirements for DUS

Guatemala
- No specific legislation or guidelines regarding DUS or observational studies

Mexico
- Legislation applicable to all types of studies in which observational studies are defined as research without risk or with a minimum risk

Peru
- Guideline approved in 2010 by the health authority to help researchers in the presentation, approval, execution, follow-up and completion of observational studies

Survey

- Participation: Out of the 93 ethics committees and/or key informants contacted, 13 answered the survey (14% participation).

Figure 1. Geographical distribution of survey participants (n=13)

- Most ethics committees refer to the Declaration of Helsinki and/or to national guidelines regarding the ethical requirements applicable for DUS (n=9; 69.2%).
- These reference documents are often used in combination.

Figure 2. Reference documents used by ethics committees regarding the ethical requirements applicable for DUS

- In most countries, DUS have to be notified to competent health authorities and/or regional ethics committees. However, depending on various elements such as the country, setting or data collection method, applicable ethical requirements for DUS might differ, as shown below.

1. DUS with medical chart review – Hospital setting
- Approval from a hospital ethics committee or IRB appears to be required in every country.
- Need for patient informed consent and/or contractual agreements depends on the country considered and the data collection method.

For example, in Brazil, hospital physicians can request an exemption of informed consent forms in a retrospective review of medical records.

2. DUS with medical chart review – Community care setting
- Similar requirements as for DUS conducted in the hospital setting.
- Approval from a data protection agency is not required for any investigated country.
- Need for a local or regional ethics committee approval.

For example, in Guatemala, type of setting, either public or private, determines whether a national or institutional ethics committee approval is needed.

3. DUS with patient survey
- Usually, approval from a local or regional ethics committee is required.
- Patient informed consent appears to be necessary in every country.
- Additional requirements related to personal data protection only apply to Argentina and Costa Rica.

4. DUS in the pediatric population
- Depending on the country considered, the patient or legal guardian informed consent is not always required for DUS involving only a medical chart review.
- In most countries, similar ethical requirements apply to this population as those for the adult population.

CONCLUSION

The lack of consensus in the legislative and ethical framework for DUS across different Latin American countries leads to operational challenges for the implementation of cross-national drug utilization studies.

This study was approved by Canadian SHIELD Ethics Review Board

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