Guidelines and Recommendations for Laboratory Analysis and Application of Pharmacogenetics to Clinical Practice

ABSTRACT (draft)

Objective: The objective of this LMPG on pharmacogenetics (PGx) is to provide a systematic rigorous assessment of the discipline of pharmacogenetics as it applies to clinical laboratory testing and its application to clinical practice. Issues to be addressed will be: methodological (pre-analytical and analytical) considerations, standardization and quality assurance of testing; selection of appropriate PGx testing profiles; recommended reporting of test results and interpretation; standards needed for demonstration of clinical utility and efficacy; and, recommendations for effective use of pharmacogenetic information in a clinical setting.

Background. Although still in its infancy, the availability and application of information derived from pharmacogenetic-related clinical laboratory tests has provided major in-roads and expectations to the concept of personalized therapeutics. PGx as a clinical adjunct to selection and dosing of drugs is relatively new and as such, medical practitioners, clinical laboratories, in-vitro diagnostic manufacturers and regulators of diagnostic tests have not established evidence-based guidelines needed to optimize practice in their respective areas of application. These present Guidelines provide a framework on which to build a rigorous and systematic approach to establishing optimum use of pharmacogenetic-information obtained from clinical laboratory testing. The Guidelines also establish criteria and critical pathways that must be met before the efficacy of this testing can be rigorously assessed.

Approach: An expert committee is drafting evidence-based recommendations (where available) pertaining to the areas of focus. An external panel of experts will review a draft of the Guidelines which will be modified in response to reviewer's suggestions. A revised draft will be posted on the internet and also presented for open comments at the IATDM/CT meeting in Louisville April 2005 (www.iatdmct.org and also see below) and at 2 other national open meetings (to be determined) before final presentations at the AACC 2006 Annual Meeting. Recommendations will again be modified after input from these activities and subsequently submitted for publication in CCJ (or /and other) by end of same.

Content: (Under development)

Summary: We recognize that this relatively new application derived from combining genetic–testing with traditional pharmacology is rapidly evolving and as such the guidelines are likely to also evolve rapidly. Nevertheless, these present guidelines will serve as a basis on which to establish a rigorous approach to defining the applications of this discipline to clinical practice and to define critical pathways and provide the laboratory support needed to bring this application to routine healthcare.

Projected timeline for development of the pharmacogenetics LMPG

April 2004	Organizing Cmte telecons to prepare structure, budget
June/July 2004	Seek financial support / NACB web posting to build LMPG
	(individual section outlines prepared, systematic reviews, etc.)
Aug / Sept 2004	Organizing Cmte meets physically to structure LMPG
Sept 2004	Selection of primary review group, approx 20-30 individuals
Jan 2005	First posting on NACB web page as announcement
Feb / Mar 2005	Prepared first draft for primary reviews and structure
April 2005	First consensus presentation at IATDM/CT, Louisville
June 2005	Submit draft for primary expert reviewers / comments compiled
August 2005	Near final document; start to present at several discipline-specific venues*
March 2006	Post again on NACB Web for additional comments
July 2006	Presentation of product at AACC Annual Meeting as Edutrack

* Please contact LMPG Chairperson if interested in having parts of this LMPG presented at your scientific or clinical venue.

NACB Laboratory Medicine Practice Guidelines on Applications of Pharmacogenetics Testing

First discussion to be presented at International Therapeutic Drug Monitoring and Clinical Toxicology (IATDM/CT) Congress in Louisville, Kentucky 2005 (April 27th and 28th)

Wednesday AM/PM and Thursday AM sessions

Objective is to establish practice guidelines for application of pharmacogenetics (PGx) in the practice of laboratory medicine.

These sessions we will be used to develop an understanding of the present evidence supporting the application of pharmacogenetics-testing to general clinical practice and specific areas of medical practice. In these discussion sessions will:

1) Define what parameters are necessary to provide optimum pharmacogenetics-testing in specific clinical settings

2) Define the potential links in the roles of pharmacogenetics and therapeutic drug monitoring in clinical settings

3) Discuss and formulate recommended guidelines for clinical laboratories introducing Pharmacogenetics-testing services

4) Provide in-vitro diagnostic companies parameters necessary for optimizing clinical assays needed in pharmacogenetics-testing

5) Provide third party payers and regulators of diagnostic laboratory testing recommended parameters for optimizing their reimbursement and regulatory functions

Committee for the 2006 LMPG on Pharmacogenetics

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