

ESPS PEER-REVIEW REPORT

Name of journal: World Journal of Methodology

ESPS manuscript NO: 22164

Title: Standardization in laboratory medicine - Adoption of common reference intervals to the Croatian population

Reviewer's code: 03354106

Reviewer's country: Italy

Science editor: Fang-Fang Ji

Date sent for review: 2015-08-21 09:57

Date reviewed: 2015-09-09 18:18

CLASSIFICATION	LANGUAGE EVALUATION	SCIENTIFIC MISCONDUCT	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input checked="" type="checkbox"/> Grade A: Priority publishing	Google Search:	<input checked="" type="checkbox"/> Accept
<input type="checkbox"/> Grade B: Very good	<input type="checkbox"/> Grade B: Minor language polishing	<input type="checkbox"/> The same title	<input type="checkbox"/> High priority for publication
<input checked="" type="checkbox"/> Grade C: Good	<input type="checkbox"/> Grade C: A great deal of language polishing	<input type="checkbox"/> Duplicate publication	<input type="checkbox"/> Rejection
<input type="checkbox"/> Grade D: Fair	<input type="checkbox"/> Grade D: Rejected	<input type="checkbox"/> Plagiarism	<input type="checkbox"/> Minor revision
<input type="checkbox"/> Grade E: Poor		[Y] No	<input type="checkbox"/> Major revision
		BPG Search:	
		<input type="checkbox"/> The same title	
		<input type="checkbox"/> Duplicate publication	
		<input type="checkbox"/> Plagiarism	
		[Y] No	

COMMENTS TO AUTHORS

To authors, please, enclosed you find the suggestions regarding the revision of the manuscript. ESPS Manuscript NO: 22164 Title: Standardization in Laboratory Medicine - Adoption of Common Reference Intervals to the Croatian Population Manuscript Type: Review The revision was performed following the "GUIDELINES AND REQUIREMENTS FOR PEER-REVIEW REPORT: REVIEW ARTICLES" The review "Standardization in Laboratory Medicine - Adoption of Common Reference Intervals to the Croatian Population" contains useful information, suggestions and examples in the standardization and harmonization procedures in Laboratory Medicine. The overall structure of the manuscript is complete. The "discussion" section is not present but the discussion is inserted inside of each chapter containing the results of the study. The manuscript containing an additional section named "conclusion". Please revised if this format is suitable for review in this journal. The overview of standardization and harmonization issues are clearly presented and explained. The experience proposed by the authors improved the approach for standardization and harmonization of procedure for serum creatinine and aspartate/alanine aminotransferase concentrations and evaluation of

common reference intervals to Croatian adult/pediatric population and inference to IFCC/CLSI reference methods and reference intervals. The authors adequately referred their findings and purposes to international references and supported the historic evolution of standardization/harmonization topics. Taking in consideration that this article is a review on standardization and harmonization of laboratory medicine mainly in Croatia, the authors provide an adequate analysis and discussion of the literature concerning it. The article is an appropriate overview on standardization procedure used in Croatia, as the title suggested. The manuscript underlines the need of standardization and harmonization of procedures in order to define common reference intervals in according to IFCC and CLSI recommendations and gives two practical examples concerning serum creatinine and aspartate/alanine aminotransferase concentration evaluation in order to define common reference intervals for Croatian population and comparison of these results to reference standard intervals. The manuscript concise, clear, comprehensive, and convincing. The language reaches the standard of publishing. Suggestion for the improvement of the manuscript: Global evaluation of the manuscript does not show weakness or deficiencies, but some few improvements can be done: A - Title: The first part of the title fits to the content of the review, the second part of the title is less clear for me. Reading this second part I expected to find in the manuscript an overview concerning several procedures/tests in Laboratory Medicine for the definition of common reference intervals and if and how they fits to Croatian population (not present in the manuscript, in which tests were analyzed focused on a single methods and performed by a single laboratory (no evaluation of influence of interlaboratory bias on the definition of reference intervals); on the other hands, the authors want to related this second part of the title to the experimental section (creatinine and AST/ALT), in this case I expected that in the title was underlined that the evaluation was performed only on 3 analytes and by a reference centre. B - Main manuscript 1- Chapter "the role of long term evaluation of national EQA in harmonization of reference intervals in Croatia". The last sentence could be implemented by a description of the main EQA performed by medical biochemistry laboratories. 2-Chapter "Global standardization/harmonization in laboratory medicine". The last sentence is not too much clear. 3- Chapters "applicability of common reference intervals for serum creatinine concentrations to the Croatian population" and "transferability of aspartate and

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<input type="checkbox"/> [] Grade D: Fair	<input type="checkbox"/> [] Grade D: Rejected	<input checked="" type="checkbox"/> [Y] No	<input type="checkbox"/> [] Minor revision
<input type="checkbox"/> [] Grade E: Poor		BPG Search:	<input type="checkbox"/> [] Major revision
		<input type="checkbox"/> [] The same title	
		<input type="checkbox"/> [] Duplicate publication	
		<input type="checkbox"/> [] Plagiarism	
		<input checked="" type="checkbox"/> [Y] No	

COMMENTS TO AUTHORS

Harmonisation / standardisation of methods is a major problem for laboratories worldwide. It is difficult to resolve the issue because different manufacturers platforms tend to produce clusters of results, and there is little commercial advantage in ensuring cross-platform compatibility. This is not too bad for simple analytes such as ions (Na / K), difficult for enzymes due to variations in buffers / assay conditions and can be almost impossible for immunoassays due to variation in the epitopes identified, meaning that assays are not actually measuring the same substance, even if they call it the same name. Harmonisation efforts have taken place in many countries but have often stalled at the enzyme assay phase and have almost never managed to crack the immunoassay problem... This manuscript describes creatinine and ALT/AST harmonisation which is usually about the limit that is achievable. IT may be that to achieve true harmony within a country a single analytical platform should be decreed but this would give one manufacturer too much pricing power so is clearly not a sensible solution. AS a description of the method used to achieve some form of harmony however, this is useful because it shows what can be achieved with sufficient will and organisation