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The quality and scope of information provided by medical laboratories to patients before laboratory testing: Survey of the Working Group for Patient Preparation of the Croatian Society of Medical Biochemistry and Laboratory Medicine

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ABSTRACT

Introduction: The aim of this work was to evaluate to what extent the scope and content of information provided to patients is standardized across medical biochemistry laboratories in Croatia.
Materials and methods: Two on-line self-report surveys were sent out: Survey A regarding attitudes on importance of patient preparation and Survey B on the contents of patient preparation instructions.
Results: 13/118 laboratories (11%) do not provide written instructions to patients on how to prepare for laboratory testing, and 36 (40%) do not include information about water intake in their instructions. Only half of laboratories provide instructions for prostate-specific antigen (53.8%), female sex hormones (53.7%) and therapeutic drug monitoring (TDM) (52.5%). Inadequate information about fasting status (55.0%) and 24 hour urine collection (77.9%) were frequent errors with high severity and were associated with the greatest potential to cause patient harm.
Conclusions: Laboratory professionals in Croatia have a positive attitude towards the importance of patient preparation for laboratory testing. However, the information for laboratory testing is not standardized and frequently lacks guidance for tests related to TDM, coagulation and endocrinology. This study highlights the need for standardized, updated and evidence-based recommendations for patient preparation in order to minimize the risk for patients.

1. Introduction

Preanalytical variables such as physical activity, meals, water intake, drugs and dietary supplements can strongly influence the results of laboratory testing [1]. The concentrations of many analytes change after food consumption [2,3] and lipemia due to sampling too close to a meal can interfere with analyte determination [4,5]. Physical activity can cause increases in levels of enzymes and proteins associated with cardiac conditions and significantly change results of complete blood count, inflammation markers, hormones and metabolites [6]. Urine sample quality depends on whether or not the individual consumed water beforehand, whether and how the patient cleaned him or herself before sampling and what type of sampling container was used [7,8]. Laboratory professionals and patients alike must be aware of these issues and adopt practices that reduce the risk of erroneous laboratory results. Laboratory professionals are responsible for informing their patients adequately to ensure best practices are followed as much as possible.

Several previously published studies in Croatia suggest that a large proportion of patients are poorly informed about how to prepare for laboratory testing [9,10]. This is due at least in part to the lack of universally accepted standardized instructions for patient preparation. In

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2005, the Croatian Chamber of Medical Biochemists issued Standards for good laboratory practice [11]. This document provides instructions on preparation for urine collection and for measurement of general clinical chemistry analytes including lipids, glucose and oral glucose tolerance test (oGTT), iron and fecal occult blood test (FOBT). The instructions do not, however, cover how to prepare patients for certain specific tests related to toxicology, coagulation or endocrinology.

We hypothesized that existing information on how to prepare for laboratory testing provided by medical laboratories in Croatia is insufficient and non-standardized. To ascertain this, the Working Group for Patient Preparation (WG PP) of the Croatian Society of Medical Biochemistry and Laboratory Medicine (CSMBLM) conducted an on-line self-report survey of medical laboratories around the country in order to (i) examine the attitudes of medical biochemists in Croatia about the importance of patient preparation, (ii) examine the contents of instructions for patient preparation, and (iii) identify errors in patient preparation most likely to harm patients.

2. Material and methods

1. Questionnaires

This study involved two independent surveys distributed to CSMBLM members. The surveys were created using SurveyMonkey (Palo Alto, CA, USA) and distributed between December 1, 2013 and January 15, 2014.

Survey A was created to investigate attitudes among medical biochemists about the importance of patient preparation. The questionnaire was sent by e-mail to all CSMBLM members with a valid e-mail address in the CSMBLM database (N = 505). The survey asked about demographic data such as age, professional (specialists in laboratory medicine *vs.* non-specialists) and scientific qualifications (masters of science and higher *vs.* no scientific degree), laboratory type (hospital *vs.* non-hospital laboratories), and laboratory ISO 15189 accreditation status. The survey consisted of three statements about the importance of patient preparation for laboratory testing; participants were asked to evaluate their agreement with each statement using a Likert scale from 1 to 4, where 1 meant *I do not agree at all* and 4 meant *I completely agree*.

Survey B was created to investigate selected aspects of the instructions provided by medical biochemistry laboratories to their patients. The questionnaire was sent to all laboratory managers with valid e-mail addresses in the CSMBLM database (N = 202). The survey included set of multiple-choice questions for various preanalytical variables, including physical activity, water consumption, fasting, alcohol, caffeine and dietary supplement intake. Additionally, the survey also included questions that asked about instructions for specific laboratory tests, including glucose, lipids, iron and analytes in urine.

2. Statistical analysis

Categorical data were presented as counts and percentages when N was at least 100 and as ratios when N < 100. Agreement with statements on Survey A was expressed as a mean score with an associated 95% confidence interval (95% CI). Normal distribution of scores was tested using the Kolmogorov–Smirnov test. Differences in mean score according to scientific and professional qualifications, laboratory type or laboratory accreditation status were assessed for statistical significance using the non-parametric test for unpaired samples (Mann–Whitney test). The threshold for significance was set at 0.05. Statistical analyses were performed using Medcalc 12.7.2.0 (Frank Schoonjans, Mariakerke, Belgium).

On the basis of responses to Survey B, errors in patient preparation were identified and their frequency and severity were determined. Errors were classified into one of four groups based on their frequency: rare (O1), when frequency <25%; moderate (O2), when frequency was 25–50%; frequent (O3), when frequency was 51–75%; and very frequent (O4), when frequency >75%. Errors were also classified into one of three groups based on their severity, as defined by consensus opinion among members of the Working Group for Patient Preparation. Errors of low severity (S1) affect few laboratory tests, are unlikely to cause diagnostic errors and/or are likely to cause only patient discomfort. Errors of high severity (S3) affect numerous laboratory tests and/or are likely to cause misdiagnosis or delayed diagnosis. Errors of moderate severity (S2) fell between these two categories.

A risk-occurrence table was constructed to identify errors with the highest combination of frequency and severity [12]. Patient preparation errors in the green area of the table were judged to be relatively infrequent and of low severity and so were considered not to require further action. Errors in the yellow area of the table were considered to be frequent and of low severity, severe and of low frequency or of both intermediate severity and frequency. These errors were judged to require some action but not urgently. Errors in the red area of the table were considered to be frequent and of high severity and therefore to require immediate action. These errors were judged to pose the greatest risk of harm to the patient.

Table 1
Responses to an on-line survey of medical biochemists in Croatia about attitudes toward the importance of patient preparation for laboratory testing.

	Statement 1: Inadequate patient preparation can significantly influence the results of laboratory tests.		Statement 2: If the patient is not adequately prepared for laboratory testing, the sampling should be repeated.		Statement 3: All laboratories in Croatia should have standardized instructions for patient preparation.	
	Score (95% CI)	P[a]	Score (95% CI)	P[a]	Score (95% CI)	P[a]
Entire sample (N = 145)	3.93 (3.89–3.98)	/	3.78 (3.71–3.85)	/	3.92 (3.88–3.97)	/
Professional qualification						
Laboratory medicine specialists (N = 69)	3.90 (3.82–3.98)	0.256	3.81 (3.72–3.91)	0.558	3.93 (3.86–3.99)	0.888
Non-specialists (N = 76)	3.96 (3.92–4.00)		3.75 (3.64–3.86)		3.92 (3.86–3.98)	
Scientific qualification						
MSc, PhD or Professor (N = 34)	3.94 (3.86–4.00)	0.924	3.94 (3.86–4.00)	**0.016**	3.97 (3.91–4.00)	0.263
None of the above (N = 111)	3.93 (3.87–3.98)		3.73 (3.64–3.82)		3.91 (3.86–3.96)	
Type of laboratory						
Hospital (N = 96)	3.96 (3.90–4.00)	**0.037**	3.84 (3.77–3.92)	**0.022**	3.92 (3.86–3.97)	0.694
Other (N = 47)	3.87 (3.77–3.97)		3.64 (3.47–3.80)		3.94 (3.86–4.00)	
Accreditation status (ISO 15189)						
Accredited (N = 16)	4.00 (4.00–4.00)	0.295	3.94 (3.80–4.00)	0.157	3.94 (3.80–4.00)	0.900
Non-accredited (N = 126)	3.92 (3.87–3.97)		3.78 (3.70–3.85)		3.93 (3.88–3.97)	

Scores are presented as a mean value with the associated 95% confidence interval.
Statistically significant differences are marked in bold.
[a] Mann–Whitney test.