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Evaluation of urinalysis pre-analytical phase in a private laboratory of Maringá city, Paraná, Brazil

Avaliação da fase pré-analítica do exame de urina de rotina em laboratório privado da cidade de Maringá, Paraná, Brasil

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ABSTRACT

Introduction: Routine urinalysis is among the most requested exams in the clinical laboratory, assisting in the diagnosis of various diseases and treatment follow-up. In this case, the pre-analytical phase is extremely important because the quality of the sample directly influences the analysis and interpretation of the result. **Objective:** The aim of this study was to identify the main errors in the pre-analytical phase of routine urine examination in a private laboratory and their frequency of occurrence. **Material and method:** Data were collected from 2014 to 2018. In all, 107,277 urine samples were registered and 98 (0.09%) were sent for recollection. **Results:** Recollect requests were higher among females (81.6%), and the most affected age groups were 51 to 60 years old and 21 to 30 years old. The most common justification for recollection was insufficient material (48.0%), followed by confirmation of results in 24.5% of cases. The predominance of urine recollection in women was due to their having urine tests more often since they are more prone to urinary tract infections, especially in the sexually active and postmenopausal life stages. **Conclusion:** In general, the urine recollection rate obtained in the research was lower than the goal set by the laboratory; however, the main reasons that led to recollection request could be avoided or minimized if patients had been well educated on the correct collection procedures, indicating the need for constant training and training programs of the work team.

Key words: urinalysis; pre-analytical phase; quality control; management indicators.

RESUMO

Introdução: *O exame de urina de rotina está entre os exames mais solicitados no laboratório clínico, pois auxilia no diagnóstico de várias doenças e no acompanhamento do tratamento dos pacientes. Nesse caso, a fase pré-analítica é fundamental, uma vez que a qualidade da amostra influencia diretamente a análise e a interpretação do resultado.* ***Objetivo:*** *O objetivo deste estudo foi identificar os principais erros na fase pré-analítica no exame de urina de rotina de um laboratório privado e sua frequência de ocorrência.* ***Material e método:*** *Dados entre 2014 e 2018 foram coletados. Ao todo, 107.277 amostras de urinas foram cadastradas; 98 (0,09%) foram encaminhadas para recoleta.* ***Resultados:*** *A solicitação de recoletas foi maior no sexo feminino (81,6%); as faixas etárias mais acometidas foram de 51 a 60 anos e de 21 a 30 anos. A justificativa mais comum para recoleta foi material insuficiente (48%), seguida por confirmação de resultado, em 24,5% dos casos. O predomínio de recoletas de urina no sexo feminino ocorreu devido à frequência da realização dos exames de urina em mulheres, pois elas estão mais propensas a infecções urinárias, principalmente na fase de vida sexualmente ativa e na pós-menopausa.* ***Conclusão:*** *De forma geral, o índice de recoletas de urinas obtido na pesquisa foi menor que a meta estipulada pelo laboratório, mas os principais motivos que levaram à solicitação de recoleta poderiam ser evitados ou minimizados se os pacientes tivessem sido bem instruídos quanto aos corretos procedimentos de coleta, o que indica a necessidade de programas de capacitação e treinamento constantes da equipe de trabalho.*

Unitermos: *urinálise; fase pré-analítica; controle de qualidade; indicadores de gestão.*

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RESUMEN

Introdución: *El análisis de orina de rutina es una de las pruebas más solicitadas en el laboratorio clínico, pues ayuda en el diagnóstico de diversas enfermedades y en el seguimiento del tratamiento de los pacientes. En este caso, la fase preanalítica es fundamental, puesto que la calidad de la muestra influye directamente en el análisis y en la interpretación del resultado.* ***Objetivo:*** *El objetivo de este estudio fue identificar los principales errores en la fase preanalítica en la prueba de orina rutinaria de un laboratorio privado y su frecuencia de ocurrencia.* ***Material y método:*** *Se recopilaron datos entre 2014 y 2018. En total, se registraron 107.277 muestras de orina; 98 (0,09%) fueron enviadas para nueva extracción.* ***Resultados:*** *La solicitud de nueva extracción fue mayor entre las mujeres (81,6%); los grupos de edad más afectados fueron de 51 a 60 años y de 21 a 30 años. La justificación más común para la toma repetida fue cantidad insuficiente (48%), seguida de confirmación de resultado, en el 24,5% de los casos. El predominio de las muestras de orina en las mujeres ocurrió debido a la frecuencia de los análisis de orina en las mujeres, porque ellas son más propensas a las infecciones urinarias, especialmente en las etapas de la vida sexualmente activa y posmenopáusica.* ***Conclusión:*** *En general, la tasa de toma repetida de orina obtenida en la investigación fue menor que el objetivo estipulado por el laboratorio, pero las principales razones que llevaron a la solicitud de nueva extracción podrían evitarse o minimizarse si los pacientes hubieran sido bien instruidos sobre los procedimientos correctos de recolección, lo que indica la necesidad de programas de capacitación y entrenamiento constante para el equipo de trabajo.*

Palabras clave: *urinálisis; fase preanalítica; control de calidad; indicadores de gestión.*

INTRODUCTION

In the last decades, the quality of laboratory medicine has undergone many changes, especially with the use of information technology. There was the implementation of the automation process and the development of more effective tests, what made results faster, more efficient and safer, and effectively helped diagnostic and therapeutic decisions[1-4].

Thus, the quality assurance phase was initiated in clinical laboratories through internal quality control (IQC) and external quality assessment programs [external quality control (EQC)][4-7].

Despite the development of quality management processes, errors still occur in clinical laboratories, whose rates vary from 0.1% to 10%. Studies indicate that the pre-analytical phase is that which concentrates the highest frequency of errors associated with laboratory tests, with an estimate between 46% and 84% of the overall error rate in the laboratory, incurring high rates of recollection, which are directly associated with the result release time. The main reason for this high incidence of errors is the difficulty of controlling the pre-analytical variables, as the errors are concentrated in the guidance for patient preparation and collection time, practices that are not always under the control of the clinical laboratory supervisors and that involve activities of several professionals[6,8-11]. According to Codagnone *et al*. (2014)[12], it is also necessary to consider staff turnover, negligence, lack of understanding of good laboratory practices and ineffective training of professionals.

Routine urine testing is among the most requested tests in the clinical laboratory; it assists in the diagnosis and detection of numerous diseases, besides contributing to the investigation of asymptomatic patients and the monitoring of treatment evolution. Sample quality of in the routine urine test is very important, as it directly influences the analytical phase and the final result interpretation. The pre-analytical phase in the routine test is the most prone to errors, because it practically depends on manual processes and occurs principally outside the clinical laboratory[13-15]. These errors involve: 1. conflict in filling in data, such as missing or incorrect medical request, misunderstanding or misinterpretation of the medical request, incorrect patient registration and/or test and incorrect sample identification; 2. collection problems: insufficient and/or inadequate guidance to the patient, lack of understanding and/or inattention by the patient, use of the wrong vial, sample with insufficient volume, exchange of material, contamination; 3. improper transport or storage conditions: non-observance of temperature, problems with centrifugation and aliquoting and sample loss[1-3, 5, 8, 12, 16].

The detection of these errors will generate rejection and subsequent recollection of the biological sample, which provokes inconvenience to the laboratory and the patient, besides additional costs due to the duplicated use of materials, employees and time; loss of credibility, trust and patient safety occurs. To minimize these problems, a fundamental strategy is to learn the frequency and the causes of recollections and associated errors in a certain service so that effective control and quality measures can be implemented[1, 5, 16].

OBJECTIVES

The objective of this study was to identify the main errors in the preanalytical phase of the routine urinalysis at a private laboratory in the city of Maringá, Paraná, Brazil, besides its frequency of occurrence, verifying the number of rejected and recollected samples.

MATERIAL AND METHODS

Descriptive exploratory study developed at a private clinical laboratory of the city of Maringá, whose analyzed samples were collected between January 2014 and December 2018.

Data were collected from the database quality control reports of the laboratory selected for the research. All collections for routine urinalysis (type 1 urine or partial urine) were considered. Exclusion criteria were applied for urine not intended for this purpose.

The instrument for data collection was the model form of quality control of the researched laboratory, which includes patient data (age and sex) and information on the criteria for urine rejection with consequent recollection, as result confirmation (involving contaminated samples); wrong identification (including unidentified samples); insufficient material (samples with a volume smaller than 10 ml); menstruating patient; and damaged samples (involving problems in packaging and handling). The index of samples rejection and recollection for routine urine test during the study period was also assessed.

The obtained data were entered into a Microsoft Excel 2010 spreadsheet and analyzed statistically with the aid of the Statistica Single User Software, version 13.2. In the data descriptive analysis, the results were presented in simple graphs and tables; to assess possible associations between variables, the double entry table was used, in addition to the chi-square test. The level of significance adopted in the tests was 5%, that is, comparisons whose $p < 0.05$ were considered significant.

The research Project to conduct this work was approved by the Research Ethics Committee of UniCesumar (Copec), under number 3.706.016.

RESULTS

Between 2014 and 2018, 107,277 patients were registered for partial urinalysis. Of this total, 98 sample recollections were requested based on the criteria adopted by the laboratory, constituting a collection rate of 0.09% for the studied period. **Table 1** shows the stratification of the recollection index by year; the lowest rate was in 2014 (0.06%), and the highest rate, in 2016 (0.11%).

The profile of patients with recollected urine samples was men and women aged between 1 and 93 years, with a mean age of 41.3 ± 23.7; the most prevalent age groups were 51 to 60 years old and 21 to 30 years old. Of the total number of requests for urine recollection, 81.6% ($n = 80$) corresponded to female individuals, whereas 18.4% ($n = 18$), to samples from male individuals (**Table 2**). These data are justified due to the fact that women aged between 21 and 30 years and above 50 years have more partial urine tests (70%) than men.

Insufficient sample volume was the most prevalent reason for requesting recollections [48% ($n = 47$)], followed by result confirmation [24.5% ($n = 24$)] and wrong identification [14.3% ($n = 14$)].

TABLE 1 – Distribution of recollection requests for urine samples between 2014 and 2018

Year	Total urine samples collected	Total urine samples recollected
2014	15,605	10 (0.06%)
2015	19,715	20 (0.1%)
2016	18,287	21 (0.11%)
2017	24,143	19 (0.08%)
2018	29,527	28 (0.09%)
Total	107,277	98 (0.09%)

TABLE 2 – Distribution of urine sample recollections, according to age group, sex, and reason, between 2014 and 2018

Variables	*n*	%
Age group		
Below 10 years	8	8.2
11 to 20 years	10	10.2
21 to 30 years	23	23.5
31 to 40 years	10	10.2
41 to 50 years	1	1
51 to 60 years	24	24.5
61 years or over	22	22.4
Sex		
Male	80	81.6
Female	18	18.4
Recollection reason		
Result confirmation	24	24.5
Wrong identification	14	14.3
Insufficient sample volume	47	48
Menstruating patient	12	12.2
Damaged sample	1	1

Although the prevalence of urine sample recollection was higher in women, the **Figure** shows that there was no association between sex and the reason for recollection ($p = 0.2146$) – data not shown. Without considering the reason "menstruating patient" that occurs only in women, the main cause for recollections was insufficient material, followed by result confirmation, in both sexes. Incorrect identification predominated in males; however, it is a factor that does not depend on patients' conditions.

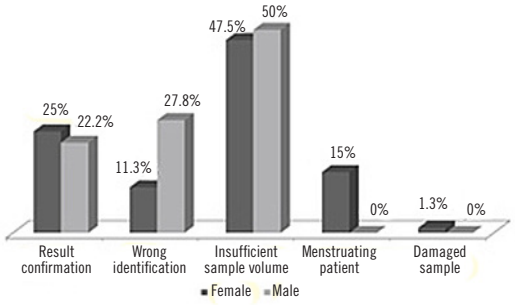

FIGURE – *Prevalence distribution of the recollection reason according to sex*

Table 3 shows the statistically significant association between reason for recollection in females and age group ($p = 0.0192$). Urine samples from women between 21 and 30 years old and above 50 years old were the most requested for a new collection. For males, the age groups of 11 to 20 years and 41 to 50 years were not represented in Table 3 due to the absence of recollections for these individuals. In this case, there was only a tendency for a higher rate of recollections in patients aged 61 years or older.

DISCUSSION

The concern with the quality of results gained prominence during the industrial evolution in the last century; from that moment on, inspection of the production process and the evaluation of the final product arose. The quality assurance phase started with the main objective of prevention. The customer has also become more demanding due to easy access to information and the creation of consumer protection bodies. The same philosophy of quality used for industries was applied to the health area and, since then, evolution has been continuous[5].

Laboratory medicine was a pioneer in the health area by promoting and introducing quality concepts in all stages of conduction of a test: pre-analytical, analytical and post-analytical. To that effect, clinical laboratories started using quality indicators, defined as numerical measures of errors or failures of a given process in relation to its total number. An indicator in the pre-analytical phase commonly used in the clinical laboratory is the recollection rate, although there is still no consensus on its limits of acceptability[4, 5].

The recollection goal set by the quality management of the researched laboratory is, at most, 0.25% for any type of sample; this index is based on exam costs. The average frequency of urine sample recollection obtained in the research was 0.09%, with little variability over the studied period.

A similar work was carried out in the same laboratory analyzing the average blood sample recollection rate (0.18%) from June 2013 to May 2015[4]. Comparing the frequency of

TABLE 3 – Distribution of reason for recollection of urine samples according to sex and age group

Age group	Recollection reason										*p*
	Result confirmation		Wrong identification		Insufficient sample volume		Menstruating patient		Damaged sample		
	n	%	*n*	%	*n*	%	*n*	%	*n*	%	
Female ($n = 80$)											
Below 10 years	1	1.3	0	0	5	6.3	0	0	0	0	
11 to 20 years	1	1.3	0	0	3	3.8	6	7.5	0	0	
21 to 30 years	8	10	4	5	9	11.3	1	1.3	0	0	
31 to 40 years	3	3.8	1	1.3	1	1.3	1	1.3	0	0	0.0192*
41 to 50 years	0	0	0	0	0	0	1	1.3	0	0	
51 to 60 years	4	5	3	3.8	11	13.8	3	3.8	0	0	
61 years or over	3	3.8	1	1.3	9	11.3	0	0	1	1.3	
Male ($n = 18$)											
Below 10 years	0	0	1	5.6	1	5.6	0	0	0	0	
21 to 30 years	0	0	1	5.6	0	0	0	0	0	0	
31 to 40 years	1	5.6	1	5.6	2	11.1	0	0	0	0	0.6692
51 to 60 years	0	0	1	5.6	2	11.1	0	0	0	0	
61 years or over	3	16.7	1	5.6	4	22.2	0	0	0	0	

**Significant chi-square test considering a 5% significance level.*

blood and urine recollections in the coincident period in both researches in 2014, we have 0.18% and 0.06%, respectively. The data indicate a very effective control in the pre-analytical phase of urine collections in the researched laboratory in relation to the stipulated goal.

Vale and Miranda (2015)[14] evaluated 1,038 urine samples and observed a frequency of 7.5% of pre-analytical errors that affected the urinalysis and generated the need for a new collection. Although some authors[13, 17] have also evaluated several quality indicators of the pre-analytical phase in the partial urine test, the recollection rate was not one of them. Therefore, the number of studies published in the literature on this topic is still scarce for comparison; for studies already available, data collection methodologies vary among researchers, what makes analysis difficult.

This research detected a predominance of urine recollection in women aged between 21 and 30 years and above 50 years precisely due to the number of tests performed in female patients. Among males, there was a lower rate of requests for new urine collections, with a predominance of individuals aged 61 years or older.

Anatomically, the urinary system is identical in both sexes, but they differ in the size of the urethra: the male is about five times longer than the female. The female urethra, being shorter and closer to the vagina and anus, facilitates contamination of the urinary tract via the ascending route. This difference gives men additional protection against urinary infections, which are more common in women with active sex life and post-menopause. Due to changes in immune and neuroendocrine functions, elderly people of both sexes are also more susceptible to urinary tract infections (UTIs). In addition, men over 50 years of age are more vulnerable to prostatism, which is the compression and obstruction of the urethra by the prostate caused by benign prostatic hyperplasia or prostate cancer, what contributes to the incidence of UTIs[18].

The main reason for the urine recollections observed in this work was insufficient material, that is, a volume smaller than the 10 ml required in the automation technique adopted by the laboratory. This fact is justified by the structural and/or functional changes in the urinary tract caused by the infectious process that can interfere in the normal urinary flow, causing pain and difficulty in urinating[19]. If patients were properly informed about the need for an adequate sample volume, with this volume monitored when samples were received by the technical sector (the urine collection vials are graduated), the request for the patient to return to the laboratory for further urine collection could be decreased or avoided.

Another important factor recorded in the laboratory database as result confirmation that led to the request for new urine collections was sample contamination. This can occur at the time of collection due to incorrect or not performed hygiene, but also due to inadequate urine storage.

According to Piçarra (2015)[19], urine must be processed immediately after collection; if it is impossible to do so, it is recommended to refrigerate the sample at 4°C for four hours at the most, since at room temperature, bacterial multiplication will occur.

Despite the fact that the study urine recollection rate is below the criteria stipulated by the laboratory, the main justifications for this express the need for better clarification in patient guidance, since most recollections occurred in individuals over 50 years of age. Probably, many of them go to the laboratory alone to be tested and have difficulties in understanding the explanations about procedures for collection and, when necessary, packaging and transportation of the urine sample. In fact, there is a close link between quality guidance and success in the sample collection, indicating the need for qualification and training of professionals involved in pre-analytical processes[16].

Cezar (2016)[17] also clarifies that, although partial urine test is simple, fast and inexpensive, the effectiveness of diagnosis depends on the standardization of all stages of the test, which include collection, packaging, transport and analysis. The correct guidance to patients is fundamental and depends on the good training of the technical team. Instructions can be written and/or verbal and must include hygiene, type of collection (first urine in the morning, midstream specimen, etc.), minimum volume and form of storage and transportation, if not collected in the laboratory. And the laboratory quality assurance sector must determine the acceptance and rejection criteria of the sample in a documentary manner, as well as keep the records updated and available.

Other authors believe that in order to guarantee a result reliable and consistent with the patient's clinical condition, it is essential that he is well instructed by the laboratory as to the correct procedures for urine collection. Therefore, the professionals involved in the process must be educated on the importance of a present and effective quality management system[13, 15].

CONCLUSION

Although there are difficulties in finding studies that address laboratory quality in urinalysis, this theme is very relevant, as clinical decisions are affected by the results of routine urine tests. The pre-analytical phase is the most critical, mainly due to the involvement of processes occurring outside the clinical laboratory and involving manual tasks.

The urine recollection rate obtained in this research was lower than the target stipulated by the laboratory, but the main reasons that led to recollection request could be avoided or minimized if the patients had been well instructed in the correct collection procedures.

It is worth highlighting that although the complete elimination of pre-analytical errors in the urine test is very difficult, it is necessary to point out measures that reduce these errors through the implementation of training programs and constant training of the work team.

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