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jbpml@sbpc.org.br,adagmar.andriolo@gmail.com
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Guatimosim Vidigal, Pedro; Henriques Resende, Letícia Maria; Guimarães Cardoso, Joanna Paula; Custódio Souza Seabra, Liz; Rabelo Maia, Mariana; de Araújo Mendes, Tasso Amós; de Gouvêa Viana, Luciana

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Challenges of the Unified Health System: present status of public laboratory services in 31 cities of Minas Gerais, Brazil

Desafios do Sistema Único de Saúde: situação da assistência laboratorial pública em 31 municípios de Minas Gerais, Brasil

Pedro Guatimosim Vidigal[1]; Letícia Maria Henriques Resende[2]; Joanna Paula Guimarães Cardoso[3]; Liz Custódio Souza Seabra[3]; Mariana Rabelo Maia[3]; Tasso Amós de Araújo Mendes[3]; Luciana de Gouvêa Viana[4]

ABSTRACT

Introduction: Modifications in the Brazilian Unified Health System (SUS) have led to a significant improvement in the national health indexes. However, some challenges still need to be faced, especially concerning SUS patients' access to high-quality laboratory support services. **Objective:** To evaluate the present status of laboratory services in SUS in 31 cities of Minas Gerais, Brazil, between 2008 and 2011. **Material and method:** This analysis was performed through data from the Information Technology Department of SUS (DATASUS) and through interviews with local public health managers with structured questionnaires. **Results:** Among all the studied cities, 21 had their own laboratory, 90.2% of which were in precarious conditions, not meeting the requirements established by the legislation in force, and employing inappropriate procedures and techniques, in addition to using obsolete equipment. The range of available laboratory tests was limited, what demanded the services of supporting laboratories. None of the evaluated laboratories developed any systematic activity on quality management, including control of analytical quality, maintenance of laboratory equipment, calibration and performance evaluation of critical equipment, continuing education programs, and safety and biosecurity. **Conclusion:** The effective role of laboratory test results in medical decision is unquestionably impaired, risking the safety of SUS patients. The present work reveals the deficiencies of public laboratory services in Minas Gerais, and proposes a new management model, which is able to associate operational quality, technological development and optimization of human and material resources with higher productivity.

Key words: Unified Health System; laboratory tests; health services; health planning; health management; Brazil.

INTRODUCTION

The Brazilian Unified Health System (SUS), created by the Federal Constitution of 1988[4], and ruled in 1990[5], aimed at the provision of universal, equal and integral access to health, with the participation of local community and emphasis in prevention. Created in 1994[8], the Family Health Program (PSF) was an important governmental achievement in primary health care, which is considered the first level of health care, according to the model adopted by SUS. PSF was a strategy for re-organizing the primary health care program of SUS, and involved a number of individual and collective actions for prevention, diagnosis and treatment of diseases, rehabilitation of patients, and health promotion in the community. Also in 2004, the government organized the Public Health Laboratories National System (SISLAB), which consisted of national laboratory groups hierarchically organized by complexity levels in activities related to health surveillance – including epidemiological, environmental

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1. Doctorate in Tropical Medicine from Universidade Federal de Minas Gerais (UFMG); senior associate professor of Laboratory Medicine at UFMG.
2. Master's degree in Biological Sciences (Microbiology) from UFMG; senior assistant professor of Laboratory Medicine at UFMG.
3. Graduating student of Medicine at UFMG.
4. Doctorate in Cellular and Molecular Biology from Fundação Oswaldo Cruz (Fiocruz); associate professor of Laboratory Medicine at UFMG.

health and sanitary surveillance, as well as medical assistance[7]. All these modifications have led to a significant improvement in national health indexes, and this new system has become a model for other countries[16]. However, some challenges still need to be faced, especially concerning SUS patients access to laboratory support services that offer high-quality tests in medical care.

Laboratory tests are the main and most important resources to support clinical practice, not only in primary health care but also in secondary and tertiary care. Laboratory test results are critical and define 70% of medical decisions, including diagnosis, monitoring, treatment, hospitalization and discharge[30]. They provide precise data on patients' health, enabling the identification of risk factors, early diagnosis and the evaluation of the severity of diseases and their prognosis, as well as the selection and monitoring of treatments and the evaluation of side effects. Some laboratory tests are crucial for handling chronic conditions. The services offered by clinical laboratories are critical for public, individual and collective health, concerning the identification of nosocomial infections, antimicrobial resistance, infectious diseases outbreaks, and exposure to toxic drugs. In addition, laboratory tests may be useful as indicators of health care quality, especially in conditions as diabetes, hypertension, heart and renal failure, colon and prostate cancer[10].

On the other hand, expenditure on laboratory tests in Brazil is significantly high. According to data from the Information Technology Department of SUS (DATASUS), when all outpatient procedures are computed, including scheduled or nonscheduled visits, and outpatient procedures for diagnostic purposes (laboratory and pathology, radiology, imaging and nuclear medicine services) with no requirement of hospital care[6], the total amount spent in 2011 was higher than US$7.5 billion[12]. The amount exclusively spent on laboratory tests, performed within outpatient procedures, was higher than US$1 billion, corresponding to 14.4% of the total amount spent on outpatient services[12]. Considering the amount spent on outpatient diagnostic procedures, laboratory tests represent 45.5% of the expenses, a higher value than the sum spent on procedures like pathology and cytopathology, radiology, imaging and nuclear medicine procedures. This profile is similar in nearly all Brazilian states[12].

Despite recognizing the problems involving patient care and high costs, little is known about SUS laboratory assistance. Planning and management of these services are complex duties, as they demand a combination of various technologies and an adjustment to local features and budget restrictions, particularly for public health. In Brazil, the Brazilian Health Surveillance Agency (ANVISA) establishes requirements for the operation of clinical laboratories and laboratory collection stations, either public or private, which work with laboratory, pathology and cytology tests, through the Resolution of the Collegiate Directorate (RDC) nº. 302/2005[3]. This resolution also rules the selection of establishments that will provide support in this field. Public laboratories shall as well follow the orientations provided by SISLAB for quality control and the implementation of the Laboratory Quality Management System, although this system prioritizes the diagnostic activities related to epidemiology surveillance, environmental health surveillance and sanitary surveillance[7]. However, a regular assessment of aspects that enable the performance evaluation of SUS clinical laboratories, as for quality and efficiency, is not known. The absence of such indicators hampers the proposal of actions that could improve patient assistance and optimize costs.

OBJECTIVES

The present work proposes the evaluation of SUS laboratory assistance, in outpatient clinics of cities in the state of Minas Gerais, using primary data gathered through interviews with local municipal health officers and laboratory staff, and secondary data from DATASUS database and the State Health Office of Minas Gerais.

MATERIAL AND METHOD

A transversal study was implemented, between January 2008 and January 2011, in a convenience sample of 31 cities of Minas Gerais. A team of properly trained investigators, composed of clinical pathologists and medical students, performed fieldwork. Individual interviews with the health manager or the person responsible for municipal laboratory assistance aimed at the characterization of the laboratory assistance available in the city. The questionnaire was specifically designed for this study, based on the legislation in force and according to the Laboratory Indicators Program of the Brazilian Society of Clinical Pathology/Laboratory Medicine (SBPC/ML), Control Lab[35] and the Accreditation Program for Clinical Laboratories (PALC) of SBPC/ML[36]. It consisted of two sets of questions: the first set referred to the general structure of the local health system; the second set aimed at the characterization of laboratory assistance, including the type of laboratory (whether public, private, outpatient clinic or hospital), infrastructure (collecting section, technical field, purge), human resources (number, schooling), volume and profile of local or outsourced tests, collection (local or outsourced), release of laboratory test results (whether printed, electronic, by telephone

or fax), quality management (quality control, certification, accreditation), use of performance indicators, and adequacy to the requirements of RDC 302/2005[3]. A secondary data search was performed using DATASUS database, aimed at the evaluation of the profile, volume and costs of laboratory tests. The interviewed people agreed to participate and signed the agreement after learning about the study and its goals.

RESULTS

Minas Gerais has 19,597,330 inhabitants, spread across 853 cities, with a gross domestic product (GDP) per capita of US$ 7,164.50[11], and a Human Development Index (HDI) of 0.773[17]. PSF is estimated to cover 60% of the total population in the state[12]. The studied sample represents 3.6% of the total cities in the state. According to the Brazilian Institute of Geography and Statistics (IBGE), in 2011, the 31 cities included in the present work had a total of 3,525,650 inhabitants, representing 18% of the total population in the state, with a GDP per capita of US$1,990.20 to US$13,841.42 and an HDI of 0.693 to 0.839[17, 32]. In the cities where PSF had been implemented, it covered 18% to 100% of the population[9]. Only one city was not served by PSF.

Twenty-one cities had their own laboratory, while the other ten outsourced their laboratory services to local private laboratories, philanthropic entities or public laboratories in neighbor cities. One city had six processing units, while another had two. The other municipal laboratories had precarious facilities and/or did not meet the requirements of the legislation in force, both for collection of biological material and tests. One city was building a new laboratory and had its project approved by the Regional Sanitary Surveillance. All laboratories had at least one graduated professional in biochemical pharmacy as the responsible technician. **Table 1** shows the productivity and analytical profile of the studied laboratories.

In the studied cities, the time span between test request by the physician and collection of the biological material was seven to 30 days. The time span between collection and result delivery varied from seven to more than 30 days. The profile of tests of 20 (95.2%) laboratories was restricted to hematological tests, basic biochemistry, urinalysis, fecal parasitology tests and some other rapid tests. These laboratories needed outsourced services for tests like hormonal dosages, tumor markers and infectious diseases. The criterion for choosing the private laboratories, including the outsourcing for cities that did not have their own laboratories, was merely price. Quality and commitment with the legislation in force, certifications or accreditations were not taken into account for selecting the laboratories.

TABLE 1 – Profile and productivity of the 21 studied laboratories

Characteristics	Laboratory *n* (%)
Preferential use of a close system of venipuncture (vacuum system)	5 (23.8)
Exclusive use of an open system of venipuncture (needle and syringe)	16 (76.2)
Reuse of collection vials	16 (76.2)
Exclusive use of manual or semi-automated analytical techniques	20 (90.5)
Use of automated analytical techniques	1 (4.8)
Use of laboratory computer systems	1 (4.8)
Number of tests lower than 1,000/month	0 (0)
Number of tests between 1,000 and 10,000/month	20 (95.2)
Number of tests between 10,000 and 100,000/month	0 (0)
Number of tests higher than 100,000	1 (4.8)
Productivity lower than 600 tests/employee/month	21 (100)
Productivity between 600 and 1,000 tests/employee/month	0 (0.0)

None of the studied laboratories developed any systematic activity on quality management. None was certified or accredited by any national or international organization. None of the programs or plans investigated in the present study, as listed below, was observed for any laboratory studied:

- continuing education program;
- maintenance of laboratory equipment plan;
- calibration and performance evaluation of critical equipment plan;
- safety and biosecurity program;
- waste management plan;
- medical control and occupational health management program;
- nternal quality control management program;
- laboratory proficiency testing plan;
- laboratory performance evaluation.

In 2011, SUS spent US$7.63 billion on outpatient procedures, and Minas Gerais had the second highest expenditure (9.9%) – US$0.75 billion –, which was only lower than that of the state of São Paulo (**Figure 1**).

The sum spent in Minas Gerais on outpatient procedures for diagnostic purposes, including laboratory tests, proportionally increased with the increase of expenses on outpatient procedures between 2008 and 2011 (**Figure 2**). The average amount spent

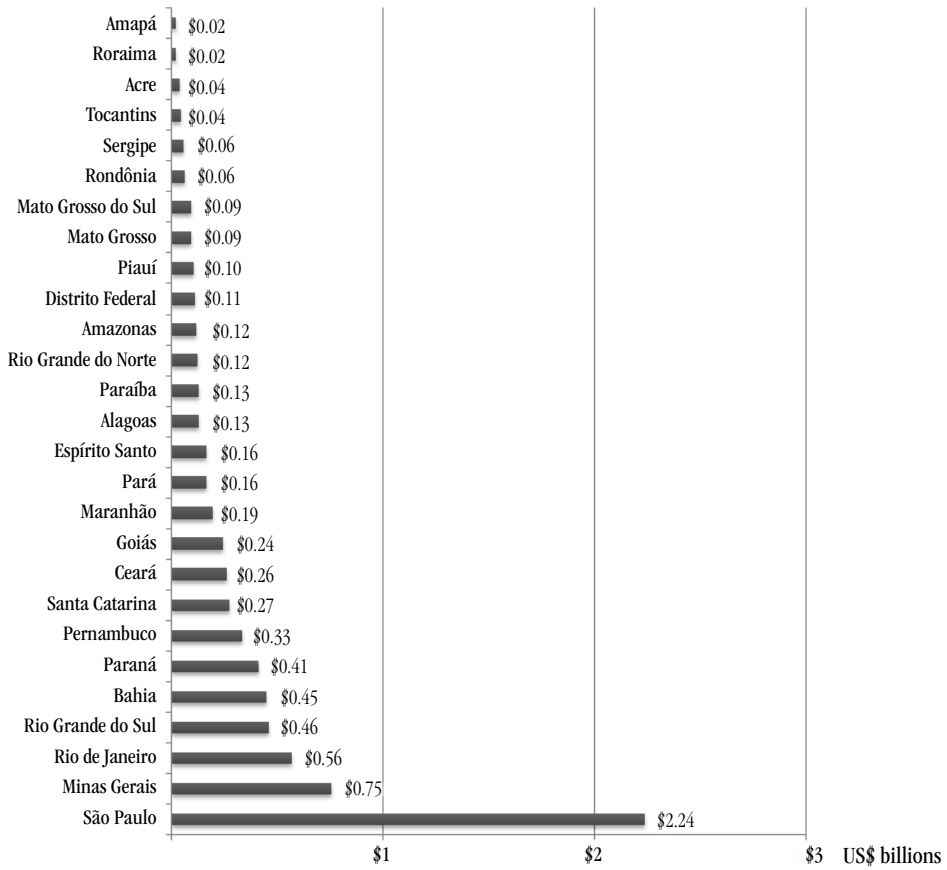

FIGURE 1 – *SUS expenses on outpatient procedures in Brazil per state, 2011 (US$ billion)*

Source: DATASUS, 2012[12].

SUS: Unified Health System.

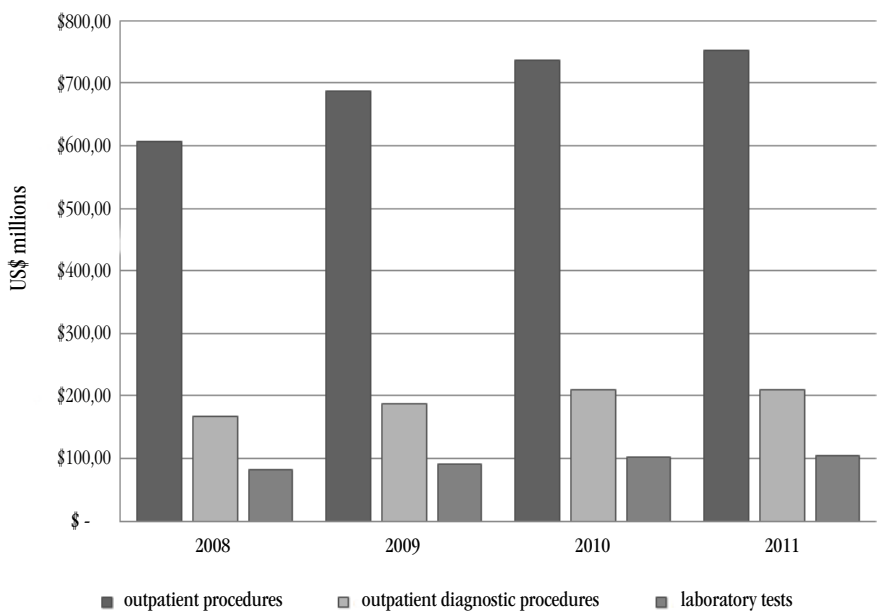

FIGURE 2 – *The evolution of SUS expenses on outpatient procedures in Minas Gerais, 2008-2011 (US$ million)*

Source: DATASUS, 2012[12].

SUS: Unified Health System.

on outpatient diagnostic procedures and laboratory tests was, respectively, 27.9% (US$194.03 million) and 13.6% (US$94.90 million) of the total amount spent on outpatient procedures in the same period.

In 2011, Minas Gerais spent US$210.43 million on 74.57 million outpatient procedures for diagnostic purposes, of which 49.9% (US$104.42 million) were spent on laboratory services (**Figure 3**). For pathology and cytopathology services, including material collection (biopsy), US$8.01 million (3.8%) were spent. The sum spent on radiology and imaging services (ultrasound, tomography, and magnetic resonance), was US$57.69 million (27.4%).

Considering the studied cities, in 2011, the sum spent on all kinds of outpatient procedures was US$199.78 million, corresponding to 26.6% of the total amount spent in Minas Gerais (**Table 2**). Between 2008 and 2011, this percentage was stable, varying from 26.6% to 29.3%.

The expenses on outpatient diagnostic procedures in the studied cities were 28.2% of the total amount spent in Minas Gerais, corresponding to US$59.54 million. Of this sum, 49.3% (US$29.38 million) were spent on laboratory tests (**Figure 4**). The total amount spent on pathology and cytopathology procedures was US$167 million (2.8%), while on radiology and image procedures (ultrasound, tomography, magnetic resonance) was US$12.03 million (20.2%).

TABLE 2 – Annual amount spent on SUS patients procedures in the studied cities in comparison with the state of Minas Gerais, 2008-2011 (US$ million)

Number of procedures (millions)			Costs	
Year	Cities *n* (%)	Minas Gerais *n*	Cities US$ million (%)	Minas Gerais US$ million
2008	67.7 (20.8)	326	176.6 (29.1)	607.06
2009	80.5 (22.6)	357.2	201.46 (29.3)	688.38
2010	71.9 (20.3)	355.2	203.76 (27.7)	735.91
2011	76.9 (20)	384.2	199.78 (26.6)	752.35
Mean	74.3 (20.9)	355.7	195.4 (28.1)	695.93

Source: DATASUS, 2012[12].
SUS: Unified Health System.

DISCUSSION

The present work revealed the deficiencies of SUS laboratory services in 31 cities of the state of Minas Gerais, both in technical aspects and in the operational flow of patients and exams. None of the visited laboratories met all the requirements of RDC 302:2005[3]. When we consider the checklist of the SBPC/ML PALC[36], the level of inadequacy is even higher. All technical deficiencies, especially the use of obsolete procedures and equipment, no upkeep, the absence of quality control procedures and skilled personnel, certainly affect the quality of the results. Other common features of the studied laboratories were the misalignment between supply and demand, the delay in booking biologic material collections for tests, and the

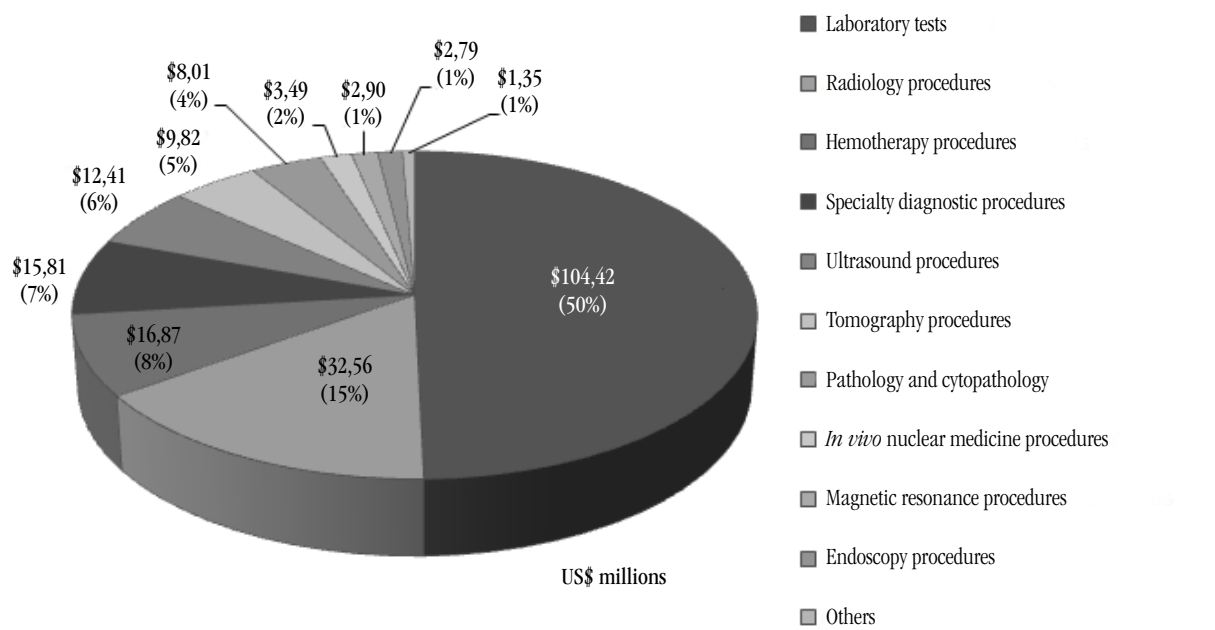

FIGURE 3 – *Distribution of SUS expenses according to the type of outpatient diagnostic procedure in Minas Gerais, 2011 (US$ million)*
Source: DATASUS, 2012[12].
SUS: Unified Health System.

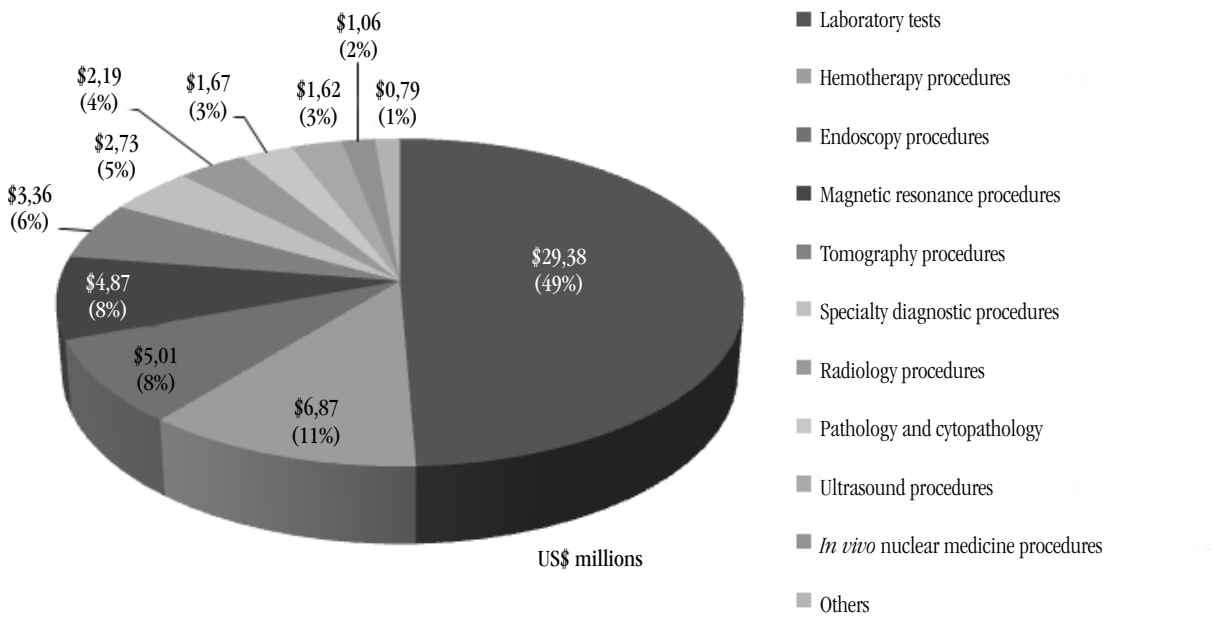

FIGURE 4 – *Distribution of SUS expenditures according to the type of outpatient diagnostic procedure in the studied cities, 2011 (US$ million)*
Source: DATASUS, 2012[12].
SUS: Unified Health System.

excessively long lag between collection and result delivery. Thus, the effective role of laboratory test results in medical decision is unquestionably impaired, risking the safety of SUS patients.

Despite the small number of cities studied herein – 31 (3.6%) out of 853 cities that constitute the state of Minas Gerais – the investigated sample is responsible for almost a third of the total expenditure with outpatient laboratory tests in the state. We do not know any other study with the same objectives as the present one, neither in Minas Gerais nor in Brazil. When we consider the features of the studied cities, it seems plausible to suppose that the situation brought to light in the present study is not different from those in other regions of the state.

The profile of tests offered by most of the studied laboratories did not include some tests considered essential in the guidelines on health care programs proposed by the State Health Office of Minas Gerais, such as *Prenatal care, birth and puerperium*[23]; *Adult health care: hypertension and diabetes*[24], *tuberculosis*[25] and *hanseniasis*[26] and *Mental health care*[27]. Outsourcing laboratory exams is a common practice in clinical laboratories, but, in general, it is focused on the conduction of more complex or low demand tests. In the investigated laboratories, a great number of exams, including those which are routinely demanded for diabetes control, hypertension and prenatal care, were outsourced to supporting laboratories, philanthropic laboratories or laboratories in neighbor cities. This situation leads to the frequent necessity of moving patients or sending biological samples to another laboratory, increasing the time between collection and result delivery. Moreover, the lack of adequate and standardized procedures for collection, transportation and maintenance of samples was common. Blood collection with syringe and needle is an old procedure and has become a rule in some health areas. Although not being an internationally recommended procedure anymore, up to now it is very common in clinical laboratories and hospitals[11]. However, this technique can bring negative impacts when applied on a large scale, if we consider the amount of samples and the risk of needle-stick injury[37]. Transport and storage of samples under inappropriate conditions, as noted herein, undermine their stability and affect the quality of test results.

The situation found in the evaluated laboratories is comparable to that observed in the United States of America (USA) in the 1940s. In 1946, the College of American Pathology (CAP) considered the delivery of trustable laboratory test results of prior necessity, since they were extremely important to patients' safety[20]. In 1947, the first study evaluating the performance of clinical laboratories was published, and showed high levels of analytical error (162,116 errors per million tests), with a great number of gross errors in apparently simple tests, like glucose, total protein, albumin, sodium, potassium and hemoglobin[2]. This study led to the creation of quality programs for clinical laboratories and, in the following decades, many measures were taken aiming at the reduction of the prevalence and magnitude of analytical errors, such as automation, improvement of laboratory technology and information technology applied to laboratory processes. Among

the measures adopted in the process of quality improvement, the adoption of well-defined rules for internal quality control, the introduction of effective systems of external quality control and better qualification of personnel are worth mentioning[13, 31]. In Brazil, quality control programs in clinical laboratories were introduced by the end of the 1970s[39] and became mandatory after the publication of RDC 302:2005[3].

The use of computer systems in clinical laboratories started by the end of the 1950s and aimed at saving time in analytical procedures, favoring standardized results, less exposed to variables influenced by human interference. After that, informatics became current in operational and supportive procedures in the laboratory, from client reception to result delivery, being associated with efficiency, effectiveness, quickness and quality[28]. It is worth mentioning the role of automation technologies in clinical laboratory procedures, as it contributes to enhance productivity and reduce operational costs[19]. Therefore, the low productivity observed in the present study can be partially explained by the absence of automation and the predominant use of manual and semi-automated techniques in most of the evaluated laboratories. The lack of qualification and continued education programs is certainly another fact that contributes to low productivity.

In the present study, we identified a decentralized model of laboratory assistance, which is based on the existence of one public laboratory per city. This model is considered inadequate, especially for small and average cities, since it has innumerable disadvantages, such as: high operational costs, due to the small number of tests (small scale); impossibility of technological improvement (automated processing systems); low productivity and inefficient operation. Such laboratories become, therefore, little useful for the population and economically costly, as evidenced, at least in part, by the high expenditure of Minas Gerais on laboratory tests. The profile of expenditures exclusively for laboratory services in Minas Gerais is similar to that observed in Brazil. Between 2008 and 2011, this value reached 13.6% of the total amount spent on SUS outpatient procedures in the state, a percentage highly superior to that observed in the USA (2.3%), in 2007[10], and in Italy (7%), in 2002[28].

In the design of laboratory service, processing centers should be gathered, in order to reach better level and quality. At the same time, biological sample collection should be decentralized, as much as possible, and should be available in all health care centers. The connection between collecting stations and processing centers should count on effective logistic systems. Hence, laboratories with small-scale capacity should be fused or strategically allied, in order to increase the number of processed exams, introduce automated processing and adopt quality control procedures[31]. Moreover, this model would enable automation of analytical and pre-analytical laboratory procedures.

National and international public and private experiences have demonstrated, throughout the years, the advantages of this model[1, 14, 15, 29, 33, 34]. Satisfactory results in quality, costs and management have been described after the integration of clinical pathology laboratories in the Legacy Health System, in Portland, USA[1, 34]. A disarticulated group of various laboratories, distributed among various hospitals and without intercommunication, was incorporated as a support to the health care system. Major challenges included transportation of collected material, information system, standardization procedures and centralization of test processing. The adoption of a centralized management in countries like Canada, Italy, Austria and the USA resulted in a reduction of 10% to 40% in the sum spent on clinical pathology procedures, without quality loss[14, 15, 29, 33]. In Curitiba, state of Paraná, Brazil, various clinical laboratories were replaced by a unique processing center, what led to an increase in test volume, automation of procedures, online operations and implementation of internal and external quality control systems. Another important achievement was the decentralization of collecting stations for all health units in the municipal system. The result of the diagnosis supporting system in Curitiba was a delivery of SUS laboratory tests with good quality and time, with costs 60% lower than those of traditional models[22]. Private laboratories in Brazil and in other countries have been following this trend for some years, focused on cost reduction. Big corporations have acquired small and average laboratories, and units with big centers have been established for test procedures, while decentralized collecting stations have been created[18]. A study by the State Health Office of Minas Gerais, in 2006, showed that with the existing laboratory assistance model, the mean unitary cost of a laboratory test is US$2.06[21]. In 2007, the public laboratory of Curitiba performed 2,128,397 tests with a mean unitary cost of US$1.26[22]. This means that, with the same money spent by SUS, an increase in the processing capacity could enable the performance of more tests, with better quality and faster result delivery.

Laboratory assistance is, probably, one of the areas that is most benefitted from economies of scale. The centralization of laboratories and material collection in health units organizes a structure able to combine operational quality, technological development, human and material resource optimization and higher productivity for the health care system. Moreover, this model offers precise and homogeneous data about health and assistance quality, important parameters for managing health system[38]. The greatest difficulty that hampers centralization of laboratories is related to regional strategies, professional and political relationships and logistics[34, 40].

CONCLUSION

Despite the important role of laboratory tests in medical attention, public laboratory services in the evaluated cities are based on a management model that does not meet the necessities of health care or the requirements of the legislation in force. This situation is probably the same in most of the small and average cities of the state. The present study shows the utmost necessity of reorganizing public laboratory assistance, aiming at the migration to a management model able to attend the population with quality and ethics, in a sustainable way, looking for excellence through operational methodologies, management and updated techniques. It is worth mentioning that PSF has been working in the organization of demands and health promotion, but users' access to a suitable laboratory service remains a challenge. Therefore, these actions risk not being translated into benefits to the population or an improvement in health indexes for the communities covered by the program. Laboratory assistance must be included in public health policies that are aligned with medical, social and economical necessities.

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RESUMO

Introdução: *Desde a sua criação, modificações no Sistema Único de Saúde (SUS) levaram a uma melhoria significativa nos índices nacionais de saúde. No entanto, alguns desafios ainda precisam ser enfrentados, especialmente o acesso de pacientes do SUS aos serviços de apoio de laboratório de qualidade.* ***Objetivo:*** *Avaliar a situação atual da assistência laboratorial no SUS em 31 municípios de Minas Gerais, Brasil, entre 2008 e 2011.* ***Material e método:*** *Foi realizado levantamento de dados do Departamento de Informática do SUS (DATASUS) e de entrevistas com gestores utilizando questionário estruturado.* ***Resultados:*** *Dos municípios estudados, 21 possuíam laboratório próprio, sendo que 90,2% deles apresentavam instalações físicas precárias, fora das especificações previstas na legislação vigente, e empregavam procedimentos e técnicas inadequadas, com utilização de equipamentos obsoletos. O perfil de exames era restrito, necessitando da utilização de laboratórios de apoio. Nenhum dos laboratórios avaliados apresentava programas de educação permanente, de controle da qualidade dos exames laboratoriais, de manutenção dos equipamentos analíticos, de aferição de instrumentos críticos e de segurança e biossegurança.* ***Conclusão:*** *O papel efetivo dos resultados dos testes de laboratório na decisão médica mostrou-se, sem dúvida, prejudicado, acarretando risco à segurança dos pacientes usuários do SUS. O presente trabalho revelou a precariedade da assistência laboratorial pública em MG e propõe a mudança para um modelo de gestão capaz de aliar qualidade operacional, desenvolvimento tecnológico, otimização de recursos humanos e materiais e maior produtividade.*

Unitermos: *Sistema Único de Saúde; exames laboratoriais; serviços de saúde; planejamento em saúde; gestão em saúde.*

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MAILING ADDRESS

Pedro Guatimosim Vidigal
Av. Prof. Alfredo Balena, 190/419; Santa Efigênia; CEP: 30310-080; Belo Horizonte-MG, Brazil; e-mail: pedrovidigal@ufmg.br.