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Laboratory medicine in the 2000s: programmed death or rebirth?[1)]

Laboratoriumsmedizin am Beginn des 21. Jahrhunderts: Programmierter Tod oder Wiedergeburt?

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Abstract

Changes have occurred in the organization, complexity and role of medical laboratories in healthcare, requiring a great increase in global productivity and diagnostic efficiency by enrolled professionals to withstand new challenges. Such a radical evolution, which should be very attractive for new generations of professionals, is counterbalanced by an increasing shortage of laboratory vocations worldwide, particularly in community hospitals and large reference laboratories, which may lead to a serious crisis in the field of laboratory medicine in the very near future. Some reasons can be highlighted, including the decreased interaction between clinicians and laboratory professionals, centralized testing, and the development of innovative, minimally invasive techniques that can easily be handled without direct control or supervision by laboratory staff. The prospect of a professional decline in laboratory medicine can be offset by increased awareness of the radical changes occurring within clinical laboratories and re-professionalization of laboratory scientists. This will require new resources to attract young professionals, and should include reaffirmation of the role of laboratory consultants and active participation in the development, implementation and monitoring of innovative diagnostic systems. The "patient" appears to be in a serious condition; it is in our hands to let him be reborn.

Keywords: innovative technologies; laboratory medicine; professional vocation; professionalization.

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Zusammenfassung

Erhebliche Veränderungen in der Organisation und Komplexität medizinischer Laboratorien sowie ihrer Rolle innerhalb des Gesundheitssystems verlangen von den beteiligten Fachleuten eine bedeutende Steigerung produktiver und diagnostischer Effizienz, um den neuen Herausforderungen gewachsen zu sein. Dieser radikalen Entwicklung, die für neue Generationen junger Laboratoriumsmediziner sehr attraktiv sein könnte, steht jedoch auf der anderen Seite eine zunehmende weltweite Verknappung labormedizinischer Stellen gegenüber. Dies trifft insbesondere auf kommunale Krankenhäuser und große Referenzlaboratorien zu und könnte in naher Zukunft zu einer ernsthaften Krise der gesamten Laboratoriumsmedizin führen. Die Gründe liegen unter anderem in der verminderten Zusammenarbeit von Klinikern und Labormedizinern, zunehmender Zentralisierung der Durchführung von Labortests und der Entwicklung minimalinvasiver Techniken, die auch ohne direkte Kontrolle oder Aufsicht durch Laborpersonal angewendet werden. Dem drohenden Niedergang der Laboratoriumsmedizin kann durch gesteigertes Bewusstsein gegenüber den neuen Entwicklungen in klinischen Labors sowie eine Re-Professionalisierung der Labormediziner entgegengewirkt werden. Neue Ressourcen müssen geschaffen werden, um junge Ärzte für die Laboratoriumsmedizin zu gewinnen, die Rolle der labormedizinischen Fachärzte wieder zu stärken und ihre aktive Beteiligung an der Entwicklung, Anwendung und Überwachung innovativer Diagnosesysteme zu fördern. Es steht ernst um den Patienten; es liegt in unseren Händen, ihn wiederzubeleben.

Schlüsselwörter: Beruf; innovative Technologien; Laboratoriumsmedizin; Professionalisierung; Stellen.

Introduction

Laboratory medicine is a basic part of semeiology. Results of laboratory testing are an integral part of the complex clinical decision-making process, influencing medical diagnoses and therapies. Medical laboratories have undergone changes in organization, complexity and participation in decision-making for treatment and patient

management over recent years, with increased precision and accuracy of test results allowing improved clinical and economic outcomes [1]. Such substantial progress was made possible worldwide by developments in technology, informatics and computer science, by the introduction of laboratory automation and automated pre-analytical and analytical platforms, by improved testing procedures and controls, and by compliance with systems of quality management, such as certification and accreditation. This transformation of laboratory medicine, which outwardly appears to be attractive for health professionals looking for a stimulating job where research results and relevant clinical applications merge, seems to be less appealing at present. In fact, an increasing shortage of skilled laboratory professionals is evident worldwide, especially in community hospitals and in independent laboratories, particularly large reference laboratories [2]. In the United States, although the US Department of Labor estimates that 14,000 new medical laboratory professionals will be needed annually up to 2012, less than 5000 students are graduating every year [3]. Although increasing automation and the introduction of innovative biomedical and information technologies will have an unknown impact on the type and number of clinical laboratory workers needed to maintain or improve diagnostic and productive efficiency, the dispro-portion between vacancy rates, job growth and de-creased vocations is expected to bring the whole field of laboratory medicine to a serious crisis in the very near future, not only in the United States, but also in most Western countries, particularly in Europe. In general, most professionals in charge have not seriously considered the constant reduction in the number of post-graduate students qualifying in the two principal sub-disciplines of laboratory medicine (clinical biochemistry and clinical pathology) over the past decade, as documented by the scarce number of reports on this topic. This impending shortage of professional vocations apparently clashes with the high educational profile required for laboratory science practitioners [2] and the enormous progress achieved in quality improvements throughout the whole testing process [1], both of which should portray the laboratory profession as more attractive and satisfying. This situation raises two main issues: i) what are the causes, and ii) how much have laboratory professionals contributed to this situation? Indeed, difficulties in student recruitment, the high cost of training programs combined with shrinking revenues for hospital laboratories, low wages relative to other health careers, and the lack of career growth and opportunity might have contributed to this situation [2]. Nevertheless, some other factors can be identified.

The clinical interface

Appropriateness in ordering and interpreting results of laboratory testing is an inalienable component of every physician's clinical background, and is characterized by both her/his cumulated experience and updated scientific knowledge. Nevertheless, the number and complexity of tests added to analytical panels are continually increasing in the laboratory setting. On the one hand, this represents a solution to the never-ending requirements for innovative and more efficient tests aimed at supporting both diagnostic insights and relevant therapeutic effectiveness. On the other hand, this situation requires increased feedback between clinicians and laboratory professionals [4]. The relationship between clinical laboratory specialists and physicians should be viewed as a tight partnership, where both the parties communicate efficiently in the interests of both patients and healthcare providers [1]. Depending on a wide series of factors, among which either being scientifically and authoritatively skilled or customarily holding a consultant position appears prominent, the contribution of professional laboratory advice regarding the attitude of physicians in ordering tests and in interpreting diagnostic results differs widely among and within countries. There is general awareness that the involvement of laboratory specialists in clinical audits and their participation in reviewing and discussing clinical cases is often modest, due to either a limited number of available and/or sufficiently skilled personnel or the growing demands placed on modern laboratories. However, a third suggestion should not be ruled out: in some cases, limited and mistaken perceptions of jobs and responsibilities hinder laboratory staff from actively participating in the clinical decision process. There are increasing requests for guidelines for appropriate and effective laboratory investigation, along with clinical and economic outcome measures for test utilization. In this respect, laboratory specialists should be increasingly focused on their role as skilled "clinical consultants". The increased sense of confidence resulting from improved analytical quality and processes leaves more space and time for laboratory professionals to intervene up- and downstream of testing procedures, and could drive more satisfying professional growth and a reaffirmed professional identity. The "run the instrument only activity", an expression often used by some clinicians until recently to depict the activity of laboratory professionals, should be firmly refuted with solid evidence of clinical and scientific competency.

Innovative technologies

Point-of-care testing (POCT) is defined as testing at or near the site of patient care, wherever that medical care is needed. Thus, the term POCT is virtually synonymous with immediate response, primarily because of the related need to act in a life-threatening setting, such as myocardial infarction, or to provide immediate warning in the ongoing management of a chronic disease, such as diabetes or oral anticoagulant therapy. There is evidence that each of these clinical contexts might positively influence the use of healthcare resources, decreasing thera-

peutic turnaround time and improving clinical efficiency and outcome for patients [5]. Besides the definition of POCT, the very location of POCT devices implicitly means that the participation of laboratory professionals, either for implementation and utilization of these efficient diagnostic instruments or for data validation and interpretation within clinical decision-making, is reduced or even absent. In some circumstances, most POCT applications are not under the direct control or supervision of laboratory staff. Therefore, appropriateness of test utilization, integrative strategies, clinical algorithms, care paths, performance maps and supervision of test results, are frequently removed from the traditional role of laboratory professionals. Although it is not difficult to predict increasing success for these systems, it should be highlighted that their major point of weakness is constitutional. POCT is not necessarily performed by laboratory staff, but by other members of the healthcare system or by consumers themselves, who might purchase materials at a drug store, then perform the test and interpret the data themselves [6]. Therefore, auto-referential and static quality management is connatural to these systems, and is intrinsically rigid to modify and/or to improve. On the contrary, quality management is mainly a dynamic and organized duty, performed in loco and continuously monitored and adjusted by laboratory professionals at various levels of hierarchy. Thus, if a malfunctioning POCT instrument is identified by clinical users, only a reduced set of actions can be carried out before requesting help from the laboratory. Thus, a malfunctioning POCT instrument that is not identified because of difficult communications or other causes might lead to unpredictable outcomes for patient health.

In any case, the availability of POCT devices and relative test panels is constantly expanding and physicians are increasingly attracted by their practical advantages, which often involve some attenuation or, at worst, severance of the clinical-laboratory interface. As some physicians struggle with the increasing quality demands in the extra-analytical phases of laboratory medicine, which is actually the predominant cause of variability in test results [7], it is expected that a large proportion of conventional testing re-sources will be allocated to extra-laboratory facilities, leading to a substantial decrease in the demand for laboratory personnel. Owing to increased numbers of analyzers, more expensive reagents and difficult comparability and/or transferability of POCT results to the routine laboratory, these devices might suffer from several practical disadvantages, such as incorrect handling and/or maintenance by poorly trained clinical staff, unsuitable calibrations and/or quality controls, and a lack of cost-effectiveness [8]. In these cases, appropriate functioning and monitoring of POCT devices require implementation of a quality system through educational policies on their use and efficient programs for quality assessment. Laboratory professionals are in an ideal position to sustain knowledgeable information on the most appropriate application and monitoring of these diagnostic systems within patient care. This is a tangible opportunity for the future that might present new professional opportunities, entailing new areas for participation of laboratory professionals within the clinical decision-making process.

Diagnostics is increasingly a multitask process. Laboratory medicine is also becoming a multidisciplinary science, involving cellular and molecular immunology, autoimmunity, immunogenetics, immunochemistry, immunopathology, immunology of infectious diseases, tumor biology and virology, membrane biochemistry, molecular biology, and pathobiology. Developing more versatile protocols and affordable instruments for specific analytic tasks is becoming possible through recent progress in the area of micro-arrays, proteomics, microfluidics and lab-on-a-chip-type devices. There are enormous potential diagnostic applications for these minimally invasive tech-niques, including cancer, cardiovascular and neuromuscular diseases, organ transplantation and infertility [9, 10]. Owing to high throughput, high quality, and simplified collection and processing procedures, these innovative technologies have became pervasive and continue to grow in prevalence, not only in clinical laboratories, but also in extra-laboratory contexts, because, in analogy with POCT devices, they can easily be managed by non-laboratory professionals. Although several innovative diagnostic micro- and nanotechnologies have high applicability to the field of laboratory medicine, there is still open debate on appropriate settings for these devices. Nevertheless, widespread implementation within diagnostic or therapeutic protocols still requires validation, optimization, laboratory quality control and assurance for competency, which are still the responsibility of laboratory professionals.

Centralization of laboratory testing

Laboratory automation (LAS) and information (LIS) systems have been introduced to many clinical laboratories since the early 1990s. These technological advances have had a tremendous impact on the whole testing process, allowing the development and implementation of high-throughput analytical platforms and modular systems [1, 11]. Political changes in national healthcare systems, which included reorganization of healthcare delivery, have forced the cutting of costs for laboratory testing, promoting an expanding trend towards consolidation. A suitable opportunity to achieve this goal is the centralization of laboratory testing, which is now allowed by efficient and powerful interfaces between LAS and LIS. Thus, for both economic and quality opportunities, outsourcing plans for centralization are being developed worldwide, creating newly integrated healthcare delivery systems that encompass laboratory networks and centralized core laboratory facilities. Thus, large test volumes are processed with minimal human intervention, leading to a lower need to enroll and train specialized staff. The

immediate economic benefits are evident; a centralized laboratory generally has reduced working expenses, resulting in a much more cost-effective process than contracting many small, private laboratories. The quality supervision of only one or a few large laboratories is much easier than for several smaller laboratories. Nevertheless, a policy under which the financing and delivery of laboratory resources are combined in large non-profit or for-profit organizations that have a broad range of laboratory resources might result in what many fear to be the "deprofessionalization" of laboratory medicine practice [12].

Conclusions

Laboratory medicine is constantly struggling with managed care, political and public health issues. Changing healthcare scenarios and cost-containment policies have profoundly influenced the reality of laboratory medicine over the past decade. After the successful consolidation of laboratory analyses for more than 30 years, advances in analyzer miniaturization and LAS are leading to an apparent paradox, where separate though concurrent developing policies coexist: monolithic core laboratories process large test volumes on the one hand, and small POCT and other innovative technologies are focused on a rapid response to targeted needs in small quantities on the other [13]. The final result will be a substantial compression of resources on the whole, following an evolution that seems already appointed and justified for both economic and clinical reasons. However, laboratory specialists should play an active part in this process and their role should change flexibly to prevent an otherwise inevitable professional decline. For clinical laboratories to remain competitive in the marketplace through the next two or three decades, previously unachievable levels of efficiency appear to be mandatory. We think that a substantial agreement, not excessively constraining laboratory resources, could be signed with health managers by proposing an attractive balance between greater levels of diagnostic efficiency and throughput, the silver bullets that could allow the rebirth of laboratory medicine. This would ultimately reduce expenditure without being detrimental to patient benefits. The question remains as to how further efficiency can be achieved in a field where no room for improvement seems to be left. This is a hard task that must primarily involve new educational approaches.

Education of laboratory science practitioners in innovative activities and major responsibilities is thus the second magic approach that could allow more efficient reallocation of both human and economic resources. However, this represents the more complex part of the solution, involving quite a radical change in the way laboratory activity has customarily been conducted. Focus can be scattered in various directions. A starting point would be an improvement in the information extractable from analytical data through continuous collection and storage of individual results, corrected for both analytical bias and variability and referred to shared reference intervals, to allow complete data transferability [14, 15]. This is a very efficient and politically agreeable approach, as it might permit a significant reduction in repeat tests, leading to budget savings without affecting the efficiency and clinical effectiveness of laboratory medicine [16].

Moreover, a metrologically correct measurement system and units should be implemented, at least for the most important groups of analytes [17]. In addition, each laboratory should be involved in active collaboration for the more advanced clinical activities deployed in its setting. For example, where an onco-hematological service is present, the laboratory should take advantage of this by providing, besides traditional analytical and morphological results, a suite of features able to both improve diagnostic accuracy and allow subsequent follow-up of patients [18]. Such an activity involves knowledge of the clinical applications of molecular biology, a field that presents consistent opportunities for laboratory professionals to develop as specialists or skilled consultants. Similar opportunities are available in several medical and surgical specialty services. Challenges are also offered by proteomics, which, besides genomics, probably represents the most immediate field of interest for both laboratory and clinical diagnosis. Clinical proteomics can be considered more than a challenge for the laboratory, as it involves not only analytical and molecular knowledge, but also bioinformatics expertise. The translational significance that lies behind proteomics studies and applications is able to profoundly transform the way the diseases are diagnosed and treated on an individual basis, leading to so-called personalized medicine. Some of the major benefits of the Human Genome Project include improved insights into human health and disease, identification of new drug targets and, eventually, a breakthrough in healthcare management through the creation of personalized databases [19]. Nanobiotechnology applications are able to both manipulate single cells and extract data that have the potential to be incorporated into clinical laboratory diagnosis [20]. Academic health centers and research laboratories, which are constantly faced with these new diagnostic challenges, will have increased demands for professionals with new interests and skills. An additional field of interest is the partnership between clinical laboratories and the biotechnology industry. Mutual interaction and cooperation in the discovery and development of clinical chemistry tests, analyzers and novel investigation fields will open up new areas of interest for the clinical laboratory science profession.

In such an evolving scenario, the role of scientific societies, in particular the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), is strategic for leading the renovation process, to track the route and guide the changes towards re-professionalization of laboratory scientists. This will require new spaces and

resources to attract young professionals to this wonderful profession. We must be aware that vocations are influenced by personal preferences and knowledge, by the environment in which learning and practice occur, and by the feedback provided within the environment itself. The "patient" appears to be in a serious condition; it is in our hands to let him be reborn.

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