LABORATORY MEDICINE IN CENTRAL AND EASTERN EUROPE:
CAN WE CATCH UP?

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Summary: Laboratory medicine, as defined by the IFCC and FESCC, is the application of chemical, molecular and cellular concepts and techniques to the understanding and evaluation of human health and disease. At the core of the discipline is the provision of results of measurements and observations relevant to the cause of disease, the maintenance of health and the conversion of these data into specific and general patient- and disease-related information at the laboratory-clinician interface. The discipline is committed to deepening the understanding of health and disease through fundamental and applied research. Furthermore, there are increasing health care expectations and consequently increasing demands of health care resources. Because of the increasing health costs, governments of many European countries have cut health care expenditure, often by decreasing the funding of acute care facilities, closing hospitals, outsourcing services or privatizing health care. Medical laboratories, highly dependent on rapidly changing, expensive and sophisticated technologies, have especially been affected by these policies. Several trends in medical laboratories are developing simultaneously:

· Centralization of diagnostic medical laboratories, rationalization of services, increased emphasis on cost-benefit analysis and cost-effective total patient care, linked to improving outcomes.
· Development of highly specialized laboratories at the interface with research.
· Implementation of point of care technology.
· Development of molecular biology procedures improving diagnosis of infections and inherited diseases.
· Computerization and telecommunication, which facilitates fast communication between laboratory and clinicians.
· Automation and robotics are changing the face of classic laboratories.
· A general trend towards accreditation or certification of laboratories in order to increase and recognize quality and excellence, including consultation services, pre- and post-analytical procedures.

Medical laboratory specialists, whether of medical or non-medical training background, are responsible for comprehensive laboratory services including production of analytical results, consultation with clinicians, management, quality assurance, and computer technology. When possible, they conduct research and training in laboratory medicine. There are considerable differences among countries – in particular between highly developed countries of the European Union and countries of Central/Eastern Europe – in social, economical and health system developments, which affect the practice of medicine. The ultimate goal of laboratory specialists in the Central/Eastern European countries is to catch up with all these processes and also to reduce the gap between east and west in this respect. However, sufficient governmental financial resources are lacking as well. Thus, national laboratory societies bear a higher than ever responsibility in working out and implementing successful strategies, convincing public opinion, political opinion-leaders and the media about the importance of laboratory medicine, a discipline inevitable for successful predictive, preventive and clinical curative medicine.

Key words: CEE countries, European Union, gap, clinical laboratory, service, research, training, quality, responsibility

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Healthcare in the CEE countries after the political transition

Western, Central and Eastern Europe have universal access health care systems. The systems in Central and Eastern Europe (CEE), however, are characterized by historical and continuing underfunding resulting in poor infrastructure and lack of staff incentives. A legacy of the communist concentration on inpatient care is the vast oversupply of hospital beds which continue to take up a disproportionate amount of the already limited healthcare budget – stopping the more cost effective focus on ambulatory care and preventive medicine. The underfunding and inappropriate allocation have led to the development of a secondary healthcare market within the public system, in which the individual patient is often forced to pay from their own pocket to access a theoretically free at the point of delivery service.

The efficiency and quality of care deteriorated, and ultimately the population’s health status worsened. Life expectancy, for example, fell significantly throughout the CEE countries, with the greatest drop occurring in Hungary: 3.5 years from 1970 to 1990. During the same period age-standardized male mortality rates in Bulgaria, Czechoslovakia, Hungary, and Poland increased by 2 to 13 percent, compared with a decline of 12 to 27 percent in Western European countries. Between 1965 and 1989 death rates for males increased by 7 percent in the German Democratic Republic and by 13.1 percent in Hungary. Similar negative trends occurred throughout the Soviet Union as well. A substantial portion of the high death rates can be attributed to the prevalence of noninfectious diseases, such as cardiovascular and respiratory illnesses, cancer, and accidents. Highly cost-effective interventions, such as promoting healthy lifestyles, launching antitobacco campaigns, implementing anti-alcohol regulations, and so on, could have prevented most of these diseases. This clearly indicates the erroneous approach of a health care system that emphasized curative care and the prevention of infectious diseases, yet ignored the noninfectious diseases to which most of the high death rate was attributable, a typical manifestation of non-needs-based planning.

The high mortality rate, along with the economic crisis and high military spending, aggravated the sharp economic downturn that started in the CEE countries in the early 1980s. The mortality rate burdened the region’s economy because of the lost investment in human capital, the increased state medical expenditures, and the more general opportunity cost of lost lives. Thus, not only health care reforms were essential for improving the population’s deteriorating health status, but also for reviving the economy and maintaining of international competitiveness.

From 1995 to 2000, total health expenditure as a percentage of GDP shrank to 5.8 percent in the CEE countries, compared with 8.5 percent of a much higher GDP in the EU. Similarly, total per capita expenditures on health were much lower in the CEE countries and the CIS than in the EU. Over 1995–2000 such expenditures increased from $415 to $900 in the CEE countries, and from $1,680 to $1,920 in the EU.

Fleshing out the patterns of health care reform across the CEE countries is a complicated endeavor. The health sector cannot be reliably regulated by purely bureaucratic, governmental coordination or by purely market coordination, but must employ a combination of the two. Governments’ ability to achieve a sustainable balance between multiple health sector objectives depends on the development of an appropriate mix of supply-side interventions at the micro (institutional) and macro (system) levels. This mix should increasingly include carefully constrained role for certain market-oriented incentives as well as for traditional regulatory instruments. Viewing the early 1990s as catastrophic for their health care systems, many policymakers have attempted to make too many fundamental changes too quickly. Sometimes new policy decisions have undermined the dependency theory, that is, that every new policy, regardless of how radical a change is designed to bring about, is nonetheless built on a former system. Attempts to build a new system without taking the ramifications of the old into account tend to prove ineffective. Different countries in the region are at different stages of implementing health reforms. Many CEE countries have switched to a system based on social insurance principles. Not only do the countries vary according to how much they have advanced with respect to reforms, but they also vary in relation to the strategies they have chosen. While Bulgaria has privatized almost its entire provider sector, Lithuania has transferred health facilities to local governments, while in Ukraine these facilities still remain the property of the central government. Croatia, which had a fairly decentralized system prior to the 1990s, has attempted to strengthen the central government’s role and has therefore centralized certain aspects of health service provision and financing. In still other countries decentralization is one of the key components of the reforms. Thus, talking about common policy strategies that are appropriate and applicable across the entire region is premature.

There is a reasonable level of clinical competence and training in most of the CEE countries, and in some countries there are world class practitioners in certain specialties. This underlines the conclusion that the main problem regarding the reform of the health sector in CEE is not primarily the medical competence among the healthcare professionals but instead the funding allocations and financial motivation, along with the integration of the different components of health care, in order to provide the best possible care as cost efficiently as possible. This requires appropriate funding mechanisms, integrating public and private contributions.
The following trends can be distinguished in most countries in the region:

Changing method of financing from central budgetary control to centralized insurance-based reimbursement systems.

The gradual introduction of market principles between providers of care and the central insurance fund payers.

An increasing acceptance that the public system will remain underfunded and therefore will be complemented with private funding and insurance.

An increased involvement from employers regarding the health status of their employees.

An increased awareness and demand from the public for an accessible, humane and affordable system.
A gradual increase in life expectancy to Western European levels, which will substantially increase demand for health services.

One of the problems among many in the communist era health care systems of CEE countries was the relatively small amount of funding that was provided by the state to finance health care. This is a legacy that has started to be addressed in some of the countries, most notably in the Czech Republic, but still causes large problems. The lack of funding is compounded by the fact that many of the inputs for health care, from pharmaceuticals to diagnosis equipment cost the same if not more in CEE than they do in Western Europe, and so are a much larger percentage of the funding than in Western Europe. This leaves even less funding in real terms than the headline GDP % dedicated to health care. A clinical laboratory unit costs very much the same to buy in Warsaw, as it does in Hamburg.

The CEE governments have also set as key objectives joining the Euro zone, with the fiscal disciplines that the Maastricht treaty imposes and making their countries tax friendly environments for business investment and entrepreneurs. These objectives are contrary to increasing the allocation of tax revenues to state health care. None of the CEE governments have woken up to these inherent conflicts and problems, and in none of the countries have the governments actively set out to seek private financing for the short fall between state financing and the public’s health care expectations. The most progressive environment for this dual type of system is unexpectedly Lithuania, where private and employer contributions to private health coverage schemes are fully tax deductible and not taxed as a benefit to the employee, and not subject to payroll taxes. In addition, Lithuania has provided an environment that minimizes the hidden taxation of health care services that comes with an exempt value added tax rate, and provided for health care provision to be treated as a zero rated activity. If CEE governments had the insight to really understand the inherent unsolvability of their state health care system’s problems they would be queuing up to follow Lithuania’s enlightened lead.

**Laboratory medicine in the CEE countries**

Laboratory medicine, as defined by the IFCC and FESCC, is the application of chemical, molecular and cellular concepts and techniques to the understanding and evaluation of human health and disease. At the core of the discipline is the provision of results of measurements and observations relevant to the cause of disease, the maintenance of health and the conversion of these data into specific and general patient-
and disease-related information at the laboratory-clini-
cian interface. The discipline is committed to deepe-
ning the understanding of health and disease through
fundamental and applied research. Furthermore, there
are increasing health care expectations and conse-
quently increasing demands of health care resources.
Because of the increasing health costs, governments
of many European countries have cut health care
expenditure, often by decreasing the funding of acute
care facilities, closing hospitals, outsourcing ser-
ices or privatizing health care. Medical laboratories, highly
dependent on rapidly changing, expensive and sophis-
ticate technologies, have specially been affected by
these policies.

Laboratory tests are among the most important
and pervasive aspects of modern medicine. The Co-
lege of American Pathologists estimates that «la-
boratory services drive 80 percent of clinical decisions
from diagnosis through therapy and prognosis.»

Europe has an opportunity now to increase
spending on in vitro testing in order to raise standards
of health and ensure effective treatment in health care.
This opportunity arises due to the following factors:

Concerned individuals in the general population are
learning (often via the Internet) about the informa-
tion that in vitro tests can provide regarding risks of
disease, state of health and effectiveness of treat-
ment. Health policy must open up to the popular de-
mand for information that is developing.

New technologies such as genetic testing will have a
positive impact on health and the shift towards pre-
vention of disease. Apart from informational value in
individual decisions about health and life style,
getic testing will allow selection of patients to suit
existing drugs that may have unacceptable side
effects in the general population as well as selection
of new drugs to suit patients that have the necessary
receptors on which the drugs exert effects.
Health Technology Assessment is being used to
assess the medical utility of health care technologies
in given clinical situations. In vitro testing provides
objective information is an essential element in HTA.
However, it is important that HTA is not misused out-
side the medical application in health care to deny
access to technologies that give individual benefit.

The existing low regional expenditure on in vitro tes-
ting compared with the US and Japan, must be
increased to ensure that the diagnosis is correct, that
the treatment given is monitored for effectiveness
and to increase the weight of preventive medicine in
health policy.

Modernization and increases in health care spending
in Central and Eastern Europe and the need to
emphasize diagnosis in these countries will provide
steady increases in the amount of in vitro testing in
these countries.

Globalization of commerce and tourism and other
larger scale enterprises (e.g. in agriculture) increase
the risk of spread of diseases. The IVD industry is the
major supplier of tests not only for human medicine,
but also veterinary, food and environmental tests. It
is vital that a viable IVD industry exists to respond
quickly to new threats (as it did for HIV testing).

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LABORATORIJSKA MEDICINA U CENTRALNOJ I ISTOČNOJ EVROPI: MOŽEMO LI JE DOSTIĆI?

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Kratki sadržaj: Laboratorijska medicina, kako je definišu IFCC i FESCC, je primena hemijskih, molekularnih i celularnih pristupa i tehnika za razumevanje i procenu zdravlja i oboljenja kod ljudi. Srž discipline je obezbeđivanje rezultata merenja i posmatranja odgovarajućih uzroka oboljenja, odrzavanje zdravlja i prevođenje ovih podataka u specifične i opšte informacije koje se tiču pacijenta i oboljenja u komunikaciji laboratorija-žičačar. Disciplina je orijentisana potpunom razumevanju zdravlja i oboljenja primenom fundamentalnih i primenjenih istraživanja. Ovo zahteva ulaganje velikih materijalnih sredstava kako bi se postigli željeni ciljevi. Zbog povećavanja troškova lečenja, vlade mnogih evropskih zemalja su smanjile potrebne izdate za zdravstveno zbrinjavanje, što ide preko zatvaranja bolnica i privatizacije istih. S druge strane medicinske laboratorije u velikoj meri zavise od visoko sofisticirane tehnologije. Iz navedenih razloga u medicinskih laboratorijama istovremeno se razvijaju sledeći pravci:

- Centralizacija dijagnostičkih medicinskih laboratorija, racionalizacija službe,
- Razvoj visoko specijalizovanih laboratorija koje se oslanjaju na istraživanje,
- Primena »point-of-care« tehnologije,
- Razvoj procedura molekularne biologije, što poboljšava dijagnozu infektivnih i naslednih oboljenja,
- Komputarizacija i telekomunikacija sa poboljšavanjem brze komunikacije između laboratorije i kliničkih odeljenja,
- Automatizacija i robotika menjaju lice klasične laboratorije,
- Opštav stvarna akreditacije ili sertifikacije laboratorija da bi se povećao kvalitet uključujući sve faze rade, pre- i post-analitičke procedura i konsultacije.

Medicinski laboratorijski specijalisti, bilo da su medicinske ili ne-medicinske orijentacije su odgovorni za celokupan rad laboratorijske službe uključujući izradu analitičkih procedura, konsultacije sa kliničarima, menadžment, osiguravanje kvaliteta i komputarizaciju tehnologiju. Kad god je to moguće u laboratorijama treba da se odvijaju istraživanje i edukacija iz oblasti laboratorije medicine. Postoje očigledne razlike između pojedinih zemalja i to naročito visoko razvijenih zemalja Europske zajednice i zemalja Centralne i Istočne Evrope i to u socijalnom i ekonomskom pogledu što utiče na razvoj i primenu medicine. Iz ovog razloga cilj laboratorijskih specijalista u ovim zemljama je da dostignu željeni napredak kako bi se razlike između zapada i istoka umanjile. Međutim, nedostatak finansijskih sredstava ograničava ovaj napredak.

Ključne reči: CEE zemlje, Evropska zajednica, razlike, klinička laboratorija, služba, istraživanje, edukacija, kvalitet, odgovornost

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Received: October 10, 2003
Accepted: March 9, 2004