# MODULE 4

# MANAGEMENT AND LEADERSHIP SKILLS IN THE CLINICAL LABORATORY

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**IFCC EMD - Committee on Clinical Laboratory Management (C-CLM)**

# CONTENTS OF THIS MODULE*

- Definitions of Laboratory Management
- Definition of the tasks and skills of laboratory managers
- Healthcare laboratories compared to analytical laboratories
- Effect of recent changes in test kits and instruments on workload of a laboratory manager
- Challenges of being a leader in a healthcare laboratory
- Addressing expectations of patients and healthcare professionals in a world with less visible national boundaries

**) All pictures and images in this module are from Wikipedia, Google search images, unless otherwise noted.*

# LEARNING OBJECTIVES

**By completing this module, participants will be able to:**

- Define their role as laboratory manager in the healthcare system of their country
- Evaluate their skills to counsel other physicians
- Evaluate their skills to counsel patients (*if legal in their country*)
- Participate in postgraduate continuous education activities (such as CME)
- Describe the expectations of stakeholders of the skills and qualities of a laboratory manager; and how to perform formalized feedback (such as surveys, questionnaires, “suggestions, questions, praise and blame”) activities.

# Definition of Laboratory Management

**Management** is the specific organization of tasks and processes.

The verb "**manage**" originates

- from Italian *maggiore* (to handle, especially tools or a horse)
- derived from the Latin words *manus* (hand) and *agere* (to act)
- French word for housekeeping, *ménagerie* is derived from *ménager* ("to keep house"), also encompasses taking care of domestic animals
- Meaning of *manus* is to lead by the hand
- meaning of m*ansion agree* is “to do housekeeping for the proprietor”

current meaning of managing as *to head, to lead, to be in charge of* is a narrowing down of the original meaning

# 12 Tips For Good Management

1) Learn management skills
2) Have a five-year plan for your lab
3) Set clear standards and expectations
4) Optimize your management style for each laboratory staff member
5) Listen to your laboratory staff members
6) Walk around the laboratory daily
7) Learn when to say no
8) Be prepared when small amounts of free time become available
9) Get to know the people at your institution who can help you
10) Get involved in your national (or even international) societies for exchange with peers
11) Attend annual meetings and visit the laboratories of your peers to get an idea of the "state of the art"
12) Celebrate successes with your lab

# Motivation to become a Laboratory Manager

- You chose this profession because you were fascinated with the world around you and wanted to discover on a molecular level the ways in which life exists and to assist other medical workers in the treatment of patients.
- You long to be at the heart of the lab — directing method evaluations, analyzing data, being consultant for medical personnel and patients — but you find yourself caught up in other tasks — ordering reagents, dealing with troubled associates and students, attending yet another committee meeting, anything but lab work.
- You have found that being the head of the lab is more than testing; it is about managing a small business. Lab-management skills, while used every day by lab-specialists, are not directly taught to young apprentices. Rather, they are learned secondhand. While much is to be learned from this follow-by-example approach, it has its limits. We have all heard horror stories of lab managers with poor leadership and organization skills, but how can we keep from becoming a character in one of these stories?

# Laboratory Management should be learned in a Purposeful Manner

- Some laboratory managers are promoted from ranks of technical staff, or are Clinical Pathologists with little management experiences. If an individual has the capacity to learn the science of laboratory medicine, they can learn good complimentary management skills, given the desire and aptitude to do so.
- Management skills are important for career development. Whether you work at the bench or away, the ability to organize your work and supervise those under you is critical.

# 5 Main Categories of Laboratory Management

1. **Planning** allows a laboratory manager to know where the lab is going.
2. **Organizing** is also an important job for a laboratory manager as he or she determines who is in charge of which department and technique, manages the timelines and budgets for multiple departments, and keeps current with research in the fields, technical innovations and expectations from medical community (e.g. guidelines).
3. **Leadership** is extremely important for a lab manager, as it often sets the environment and pace of the lab. Good leadership can inspire laboratory staff members toward productivity and creativity and help members work together.
4. **Controlling** a laboratory involves the evaluation of laboratory staff members and projects progress, and the ability to correct problems as they arise.
5. Know the **legal restrictions** (and advantages) of a healthcare laboratory in your country.

# Laboratory Management: Marketplace Perspective

- Diagnostic laboratories operate in a dynamic environment
- Operational and strategic needs are changing, evolving, and expanding
- Consolidation of facilities and merging of institutions to profit from economies of scale
- Laboratories must be able to readily respond to increases in volume, assay menu changes, and staffing challenges
- Laboratories must be focused on a multitude of short-term goals while not losing sight of what is coming down the road
- Making the right decisions today for staffing, automation, instruments and IT to be prepared for future needs

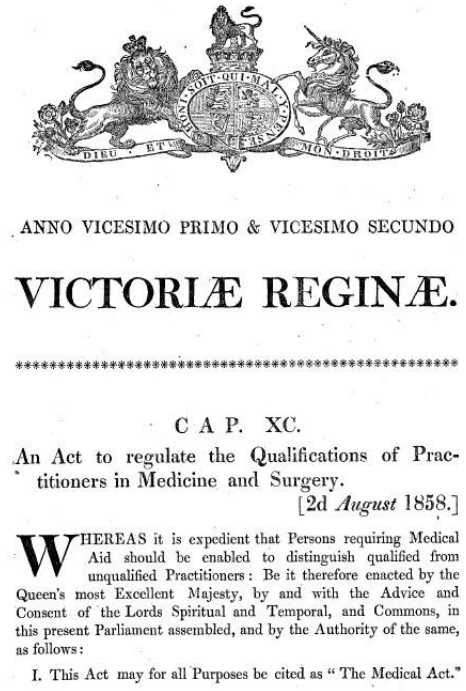
**BUT**

- Clinical laboratories belong to healthcare and must obey the specific legal and ethical limits of healthcare

# Medical Act and the Clinical Laboratory

*Federal legislations to safeguard the patients*

- Restriction of practicing medicine to (licensed) physicians
- Medical Act in most countries include:
  - Diagnosing illnesses
  - Prescribing diagnostic examinations
  - Using diagnostic techniques that are invasive or entail risks of injury
  - Determining medical treatment
  - Prescribing medications
  - Providing clinical monitoring of the condition of patients whose state of health is problematic
  - Providing pregnancy care
  - Conducting deliveries
  - Deciding to use isolation measures

ANNO VICESIMO PRIMO & VICESIMO SECUNDO

VICTORIÆ REGINÆ.

************************************************************

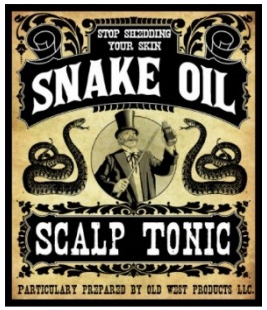
CAP. XC.

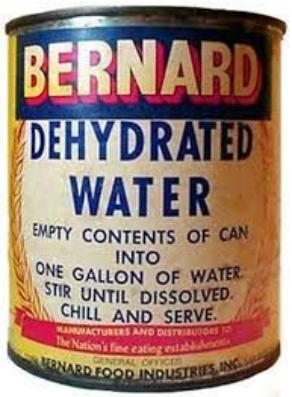
An Act to regulate the Qualifications of Practitioners in Medicine and Surgery.

[2d *August* 1858.]

WHEREAS it is expedient that Persons requiring Medical Aid should be enabled to distinguish qualified from unqualified Practitioners: Be it therefore enacted by the Queen's most Excellent Majesty, by and with the Advice and Consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the Authority of the same, as follows:

I. This Act may for all Purposes be cited as "The Medical Act."




Fighting against quacksalvers – support of evidence based medicine

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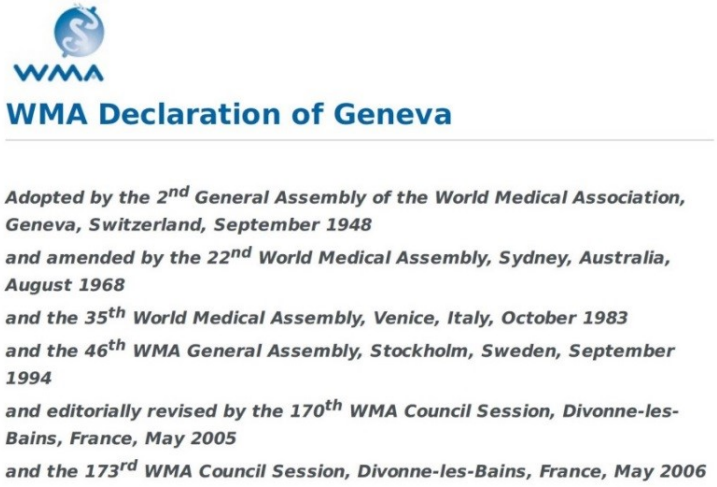
# Healthcare vs. Business/Trade

- Services has to be performed in person, but some can be delegated
- Certain services may not be substituted
- Expansion of medical services not without limits (personal supervision of associates)
- Physician may not expand services by hiring employees (unlike a commercial firms)
- Prohibition of (exclusive) telemedicine
- Critical: (external) IT service provider essential in medical process
- Restrictions on advertising and access to tests
- Special laws for medical data protection
- Special ethical code for physicians

  *(see Declaration of Geneva)*

*primum non nocere, secundum cavere, tertium sanare*



WMA

**WMA Declaration of Geneva**

*Adopted by the 2nd General Assembly of the World Medical Association, Geneva, Switzerland, September 1948*

*and amended by the 22nd World Medical Assembly, Sydney, Australia, August 1968*

*and the 35th World Medical Assembly, Venice, Italy, October 1983*

*and the 46th WMA General Assembly, Stockholm, Sweden, September 1994*

*and editorially revised by the 170th WMA Council Session, Divonne-les-Bains, France, May 2005*

*and the 173rd WMA Council Session, Divonne-les-Bains, France, May 2006*

# The challenge of Defining a Medical Laboratory

No quality assurance criteria need to be applied if laboratory tests are performed by non-health care professionals allowing a free movement of services under the consumer rights directive 2011/83/EU (example from the European Community

> *The Directive on Consumer Rights aims at achieving a real business-to-consumer (B2C) internal market, striking the right balance between a* ***high level of consumer protection*** *and the* ***competitiveness of enterprises****.*

Definition of a medical lab is different across countries (challenging if the same test is performed using animal specimen, food stuff, lifestyle samples and human medical samples!)

# Current Challenges of the Medical Act

- ***Delegation*** of some defined procedures to other professions (mainly due to financial restraints or by a shortage of skilled professionals)
- ***Substitution*** of the work primarily reserved for physicians

Consequences for the necessary skills, both from the perspective of the laboratory manager as well as from the perspective of the laboratory personnel!

# Skills Necessary for the Management of Laboratory

Is equivalent to the stakeholders' perspective for expectations of a laboratory manager.

Stakeholders perspectives those of:

- Patients
- Laboratory personnel
- Other healthcare workers
- Hospital administration
- And in some cases governmental bodies

# Skills of Laboratory Manager

- Manual skills

- Applied science
  (Biochemistry, Biology, Physics, IT)

- Theoretical and applied knowledge
  (Medicine, Mathematics)

# Perception of Necessary Skills Dependent on the Profession of the Laboratory Manager

**Challenge:** There are differences across different countries not only in the designation of the different professions but also in the number, and proportion of distinct professions operating in laboratory medicine including

- "Clinical Pathologists" (summarizing all physicians with a medical license and formal postgraduate specialization in laboratory medicine, aka physician laboratory medicine specialists)
- "Scientific Biomedical Specialists" (non-medical laboratory medicine specialists with a university degree such as a master's degree or diploma **and** formal postgraduate specialization in laboratory medicine)
- "Non-scientific Biomedical Technologists" (laboratory medicine specialists without university degree or with a bachelor's degree)

Please note:

- the tasks of persons with a master' degree but **without** formal postgraduate specialization differs between countries
- In some countries a partial medical license can be given to scientific biomedical technologists

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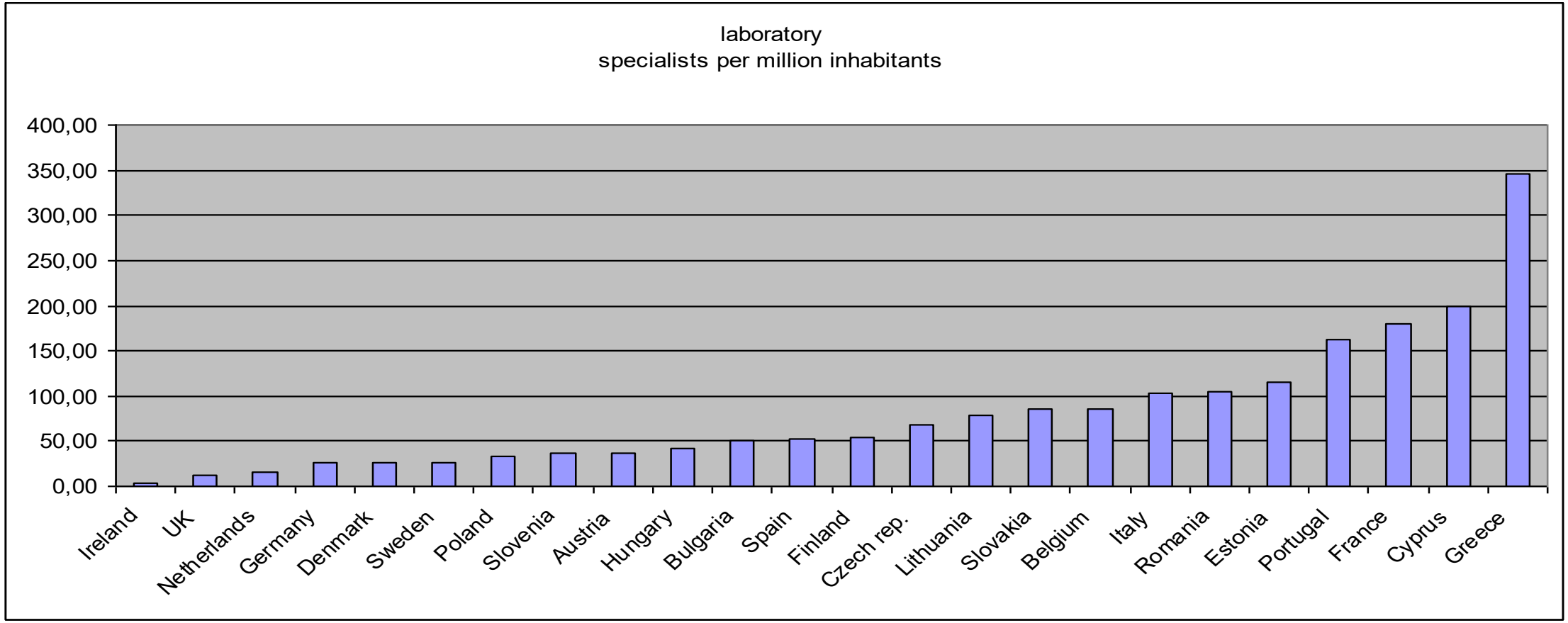

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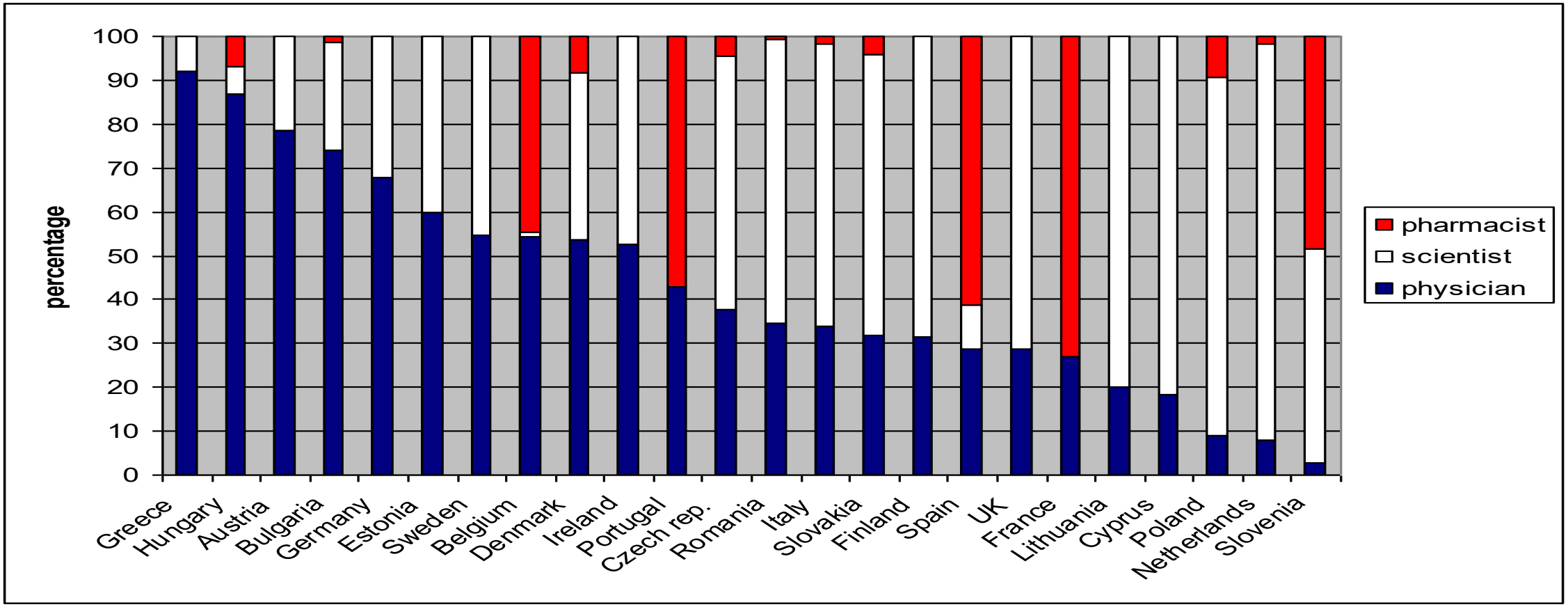


# The Medical Act in the Medical Laboratory and Necessary Skills

- Complex processes in a medical laboratory could be dissected in many small segments of work ("Taylorismus")
- Many of these small segments could be performed from persons who are trained for this particular work (irrespective of educational background)

***BUT:***

Medical practice –irrespective of the discipline -- requires both the ***science of medicine*** (i.e. detailed knowledge of anatomy, physiology and biochemistry as well the underlying diseases and their treatment) and the ***craft (or art) of medicine*** (i.e. competence in its applied practice including the Social Sciences)

# Specific Situation of Laboratory Medicine

Medical discipline with the second most patient contacts (after General Practioners)

- Results of laboratory tests trigger many medical decisions
- Majority of laboratory tests performed are time-critical

**BUT:**

- Personal encounters of laboratory personnel with patients are infrequent
- Laborator testing is sometimes regarded as a ***commodity*** (no acknowledgement on services received), not an individually-tailored medical service
- Difficulty to reach intensive personal involvement of associates with patients

# Shift from Manual Workload to Counseling in Last Decades

Focus has shifted from the analytical phase to the preanalytical and post-analytical phases.

- Well-being of the patient by
  - **counseling** of other physicians and patients
  - In **selecting** adequate tests
  - **Interpreting** the results by the Clinical Pathologist
- Reason for the different perception of the necessary skills of a laboratory manager from **higher standardization**
- **Evolution in the laboratory**
  - Supply of test kits
  - Advances in technology
  - Advances in instrument design

*Clinical Chemistry* 50:12
2415–2458 (2004)

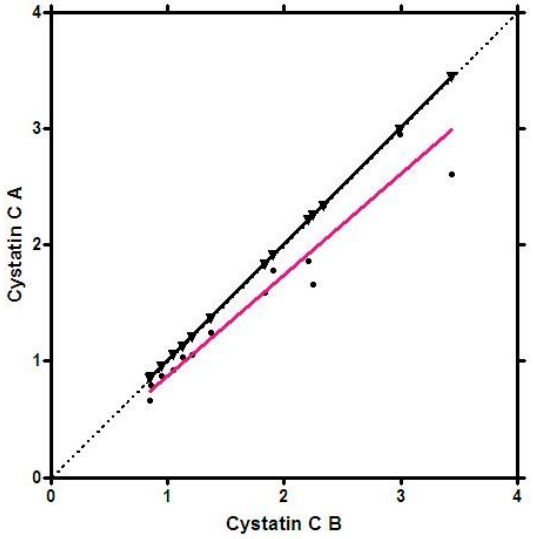
# Shift from manual workload to Counseling in Recent Decades

IVD-companies offer nearly perfect diagnostic systems for many areas of the clinical laboratory. Technical chores such as:

- Preparation of reagents
- Tedious adjustments of instruments

previously regularly performed by highly qualified professionals in the laboratory and overseen by the laboratory manager nearly completely shifted to IVD-companies

- With use of CE/FDA marked reagents, even many tasks of test evaluation need no longer be repeated by Clinical Pathologist but can be relied on evaluation performed by IVD-companies.




| | |
|---|---|
| Best-fit values | |
| Slope | 0.8702 ± 0.02691 |
| Y-intercept | 0.0000 |
| X-intercept | 0.0000 |
| 1/slope | 1.149 |
| 95% Confidence Intervals | |
| Slope | 0.8121 to 0.9283 |
| Goodness of Fit | |
| Sy.x | 0.1927 |
| Is slope significantly non-zero? | |
| t | 32.34 |
| DF | 13.00 |
| P value | < 0.0001 |

J Lab Med 2015; 39(1): 26–69 DE GRUYTER

*On 19 September 2014, the current version of the "Guideline of the German Medical Association on Quality Assurance in Medical Laboratory Examinations" was published. It featured an introduction by the German Medical Association.*

**Revision of the "Guideline of the German Medical Association on Quality Assurance in Medical Laboratory Examinations – Rili-BAEK"**

FDA
clinical validity

CLIA
safety and effectiveness of test system

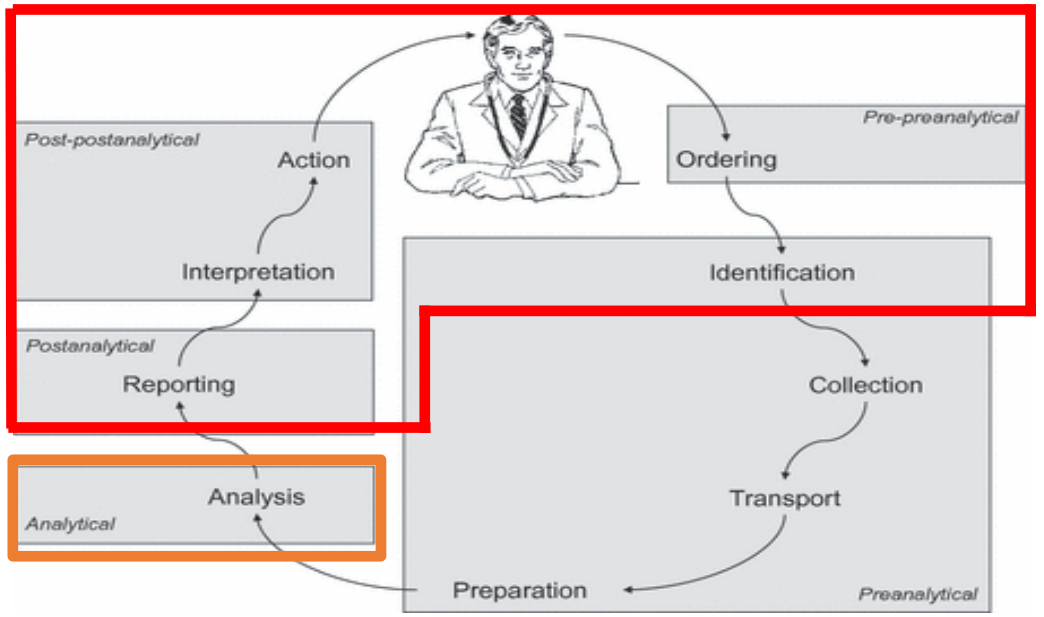
# “Brain-to-Brain Loop”

*in-vitro* testing process was named “Brain-to-Brain Loop”

Loop runs from clinical question over selecting the adequate test(s) and obtaining the patient’s sample over to the analytical process and to the post-analytical steps with determining medical treatment, prescribing medications and other substances, providing clinical monitoring of the condition of patients, providing pregnancy care and deciding to use isolation measures –

typical elements of Medical Act

**With the exception of very few tests, it is obvious that all other tests need medical interpretation**



# Medical Interpretation

- Medical interpretation goes far beyond “normal – abnormal test result” and – as a part of the Medical Act – has to be done by a physician.
- Physician not only knows the limits of the analytical part (i.e. the testing process) but also experienced in the consequences of a certain test result in context of
  1. other diseases
  2. certain therapies and
  3. clinical course of the disease
- These tasks can be done by a medical laboratory specialist focused on certain specialties of Clinical Pathology only (such as Endocrinology or Hemostasieology)

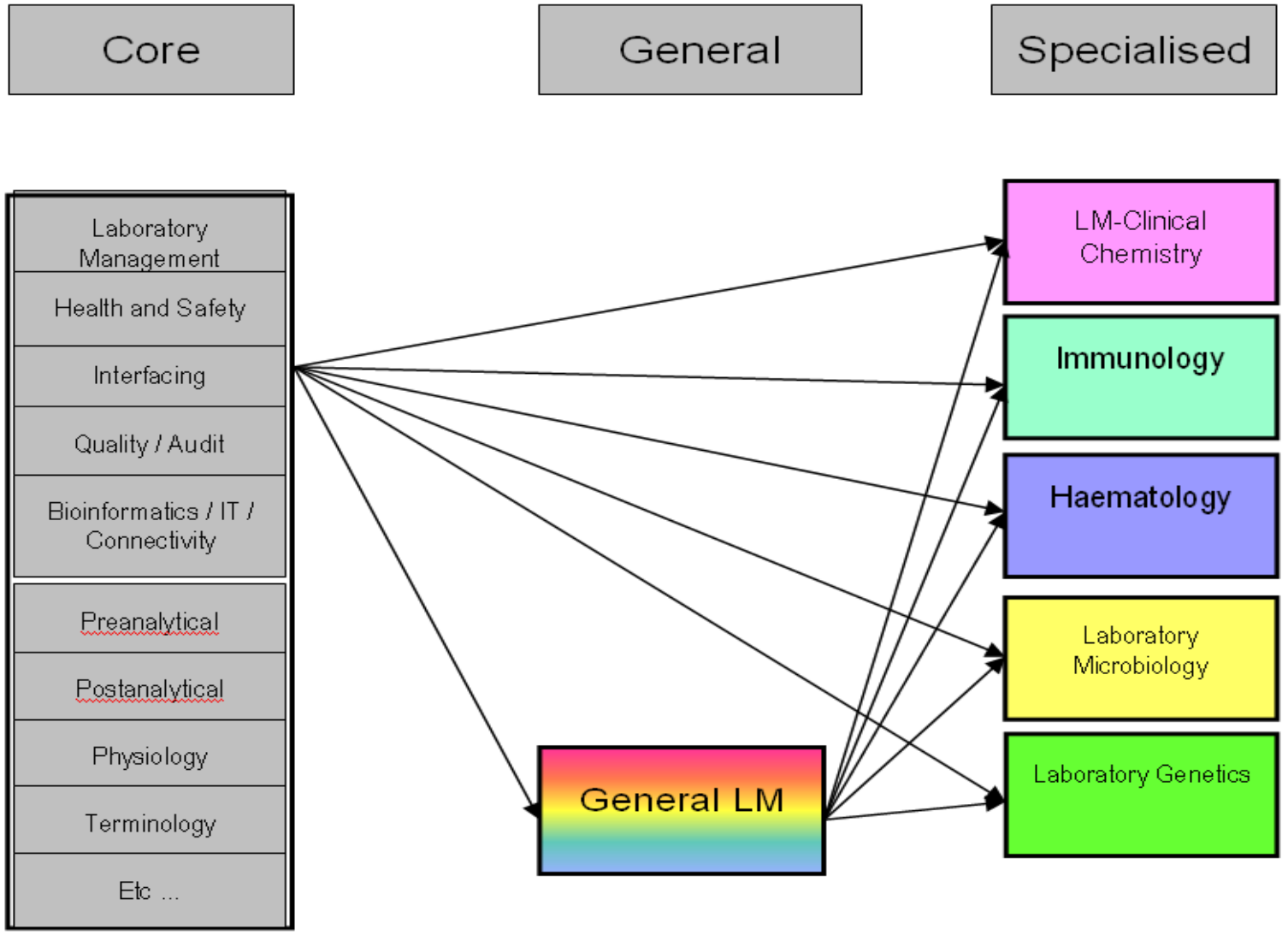
**OR**

- by a medical laboratory specialist covering all subjects of in vitro testing (i.e. Hematology, Clinical chemistry, Immunology, Laboratory Genetics and often Microbiology)

# Skills of Generalists vs. Specialists in Laboratory Medicine

- Depending on local situations medical laboratory **specialists** and medical laboratory **generalists** can counsel adequately.
- Advantages of generalists: expert of in vitro diagnostics who oversees the whole test spectrum in Clinical Pathology – but skills have to cover the whole spectrum of laboratory medicine
- In certain situations in particular very complex patients / university hospital setting, two or even more laboratory specialists might be more appropriate for optimum treatment of patient
- Academic Biomedical Specialists often participate in clinical rounds and share their advice, similar to nurse consultants or pharmacist consultants. In hospitals with clinical rounds, there is long tradition of sharing knowledge between different professions with mutual respect.
- Extensive social skills are needed from the laboratory manager so that all professions involved can give input to the benefit of the patient while legal issues such as accepting different responsibilities of the professions involved have been taken into account

# Syllabi of Laboratory Managers (Generalist vs. Specialist)



# Legal Issues of Substitution

Laboratory Manager has to be aware of legal issues which are currently absolute ***roadblocks*** to move certain areas of laboratory medicine to nonqualified practitioners or lay persons:

In particular

- **Blood transfusions**
- **Genetic testing**
- Dealing with **contagious diseases** in many countries are restricted to physicians only
- Certain diagnostic kits can only be exclusively obtained by a physician's **prescription**

# Skills and Qualities Needed as a Laboratory Manager

- Wide array of improvements in the last years in:
  - **Preanalytical processes** (such as electronic orders, diagnostic pathways, barcode coding of primary samples, robot-assisted aliquoting, permanent temperature control of reagents and samples, automatic checks for clots, hemolysis, lipemia and icterus)
  - **Analytical processes** (in particular by using highly standardized techniques with low Intra- and inter-assay variation)
  - **Post-analytical processes** (such as auto validation and sending reports electronically directly in the health record)
- Improvements and time savings allow many Clinical Pathologists to spend less time with the analytical processes.
- Allow assigning more of their time being a partner to the other physicians (and to patients) for selecting and interpreting laboratory tests and advising therapies.

# Skills and Qualities Needed as a Laboratory Manager

Extensive practical and theoretical medical expertise are essential for these tasks, with a special focus on

1. Medical knowledge
2. Practical experiences
3. Laboratory management skills

and less than in previous times on analytical techniques.

Changed perception of the necessary skills of laboratory manager by stakeholders

# Skills and Qualities Needed as a Laboratory Manager

However, despite many technological improvements

- **Manual work can be still the cornerstone of a laboratory manager** in some specialty testing such as in:

- Cytology
- Malaria microscopy
- Microbiology
- Hemostasieology
- Complex toxicology testing
- Autoimmune disease testing

# Necessary Skills Dependent of Healthcare System

Basically, patients` well-being should be universally definable situation complicated due to federal systems of healthcare:

Heterogeneous healthcare systems, as well as the different allocation of resources e.g. to laboratory medicine in different countries, result in differences in role of physicians, and scientific biomedical specialists and non-scientific biomedical technologists in the medical laboratory.

# Necessary Skills Dependent of Laboratory Size and Test Menu

Definition of the necessary skills of laboratory manager is dependent on size and kind of the laboratory:

- complexity and the volume of testing differ markedly between laboratories
- level of direct intervention by the clinical pathologists is different between laboratories of differing sizes and in different countries personal contact between clinical pathologists and patients occurs on a regular basis in some countries and is rare or even non-existing in other countries

# Necessary Skills Dependent of Local Settings

- Healthcare and Medical Act challenged by the **increasing specialization in medicine** as well as the increasing percentage of **part-time employees**

(when the Medical Act was defined there was perception of a single one polyvalent physician (“personal physician”) being responsible around the clock of his/her patients, working by himself without or with only little assistance from coworkers)

- Challenge arises when position of a laboratory manager is split between two part-time employees
- Good social skills are necessary to demonstrate as well the unique personalities of both part-time laboratory managers as to allow the mutual compensation for each other

Detailed knowledge of anatomy, physiology and biochemistry

Knowledge of underlying diseases and their treatment

Practical skills in laboratory work (e.g. Microscopy)

Applied practice in medicine including the Social Sciences

Continuing efforts in research

Basics of economical knowledge and of legal issues

Continuing efforts in development (including CPD and CME)

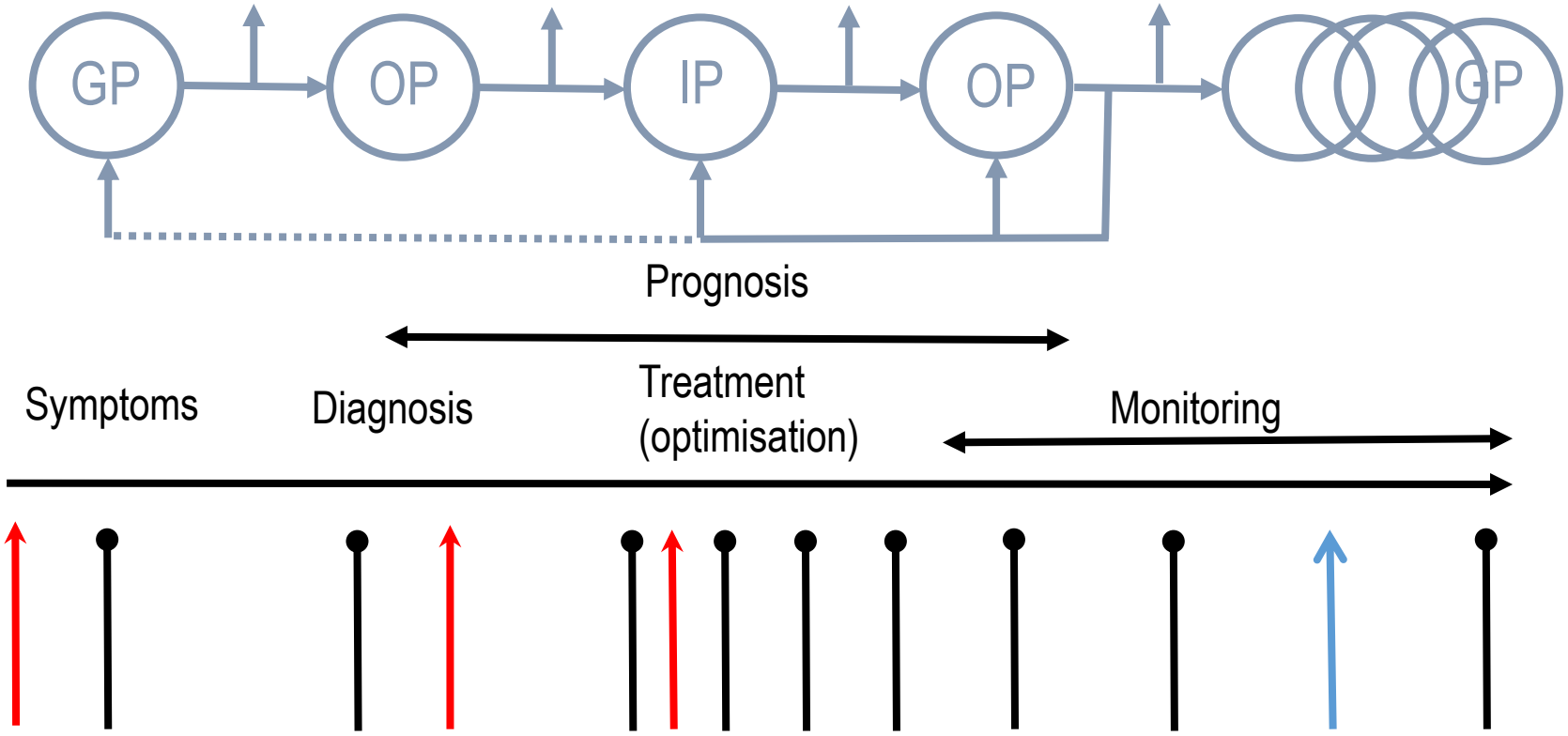
Continuing efforts in innovation and technology

Good medical practice

# Direct Access of Patients to Biomedical Specialists (Non-Medical Laboratory Specialists)

- Patients not interested in result of a certain laboratory test but want to get the answer what (medical) consequences of the test results incur to them
- Test results without medical interpretation are without use
- Unethical to offer laboratory testing without qualified medical post-analytical interpretation
- Patient's safety relies on medical knowledge / skills of the non-medical laboratory specialist (oxymoron)
- Invasive sampling (like phlebotomy / bone marrow puncture / spinal tap) precedes testing process
- For sampling physician's supervision or even the direct sampling by the physician is mandatory (except for saliva and urine)

# Laboratory Testing is Used Under Different Settings for Precise Medical Decisions



# Direct Access of Patients to Biomedical Specialists (Non-Medical Laboratory Specialists)

- Definition of the skills necessary for a laboratory manager in countries with direct patient access is very challenging
- In particular, legal issues make it nearly impossible to impose definitions for the necessary skills.
- To hit on an expedient: limited setting in which non-medical laboratory specialist with proof of the necessary knowledge and skills are allowed to run a specialized laboratory (such as basic clinical chemistry tests only, doing capillary blood counts only, doing malaria smears only)
- Comparable situation to a registered nurse who is allowed to perform a small spectrum of medical services (performing vaccinations or prescribing certain drugs)

Evidence Based Medicine

Healthcare

Lifestyle

Lab Tests

POCT

DTCT

Animal testing, Food testing

Commercial lab testing


# How to Maintain Necessary Skills

## Willingness of life-long learning

- In many countries, formal programs such as CPD (continuing professional development) and CME (continuing medical education) track the scope and the success of the participation in such a program
- In countries with voluntary CPD/CME programs only, laboratory manager has to participate in such programs out of her/his own personal initiative

# SUMMARY

- In last decades high level of standardization of the tests used in clinical laboratory and improvements of the IVD vendors
- Less effort is needed now for the analytical processes than previously
- Skills of the Clinical Pathologists have to focus more on fundamental contents of the Medical Act, i.e. the diagnosing and the counseling of physicians and patients
- Ongoing adoption of the syllabus for post-graduate education in Clinical Pathology as well as of life-long learning by CPD-CME programs to ensure high standards and achieve the patients' wellbeing