Slovenská Zdravotnícka Univerzita

LABORATORY MEDICINE

NOTES ON LECTURES AND SEMINARS FOR POSTGRADUATE STUDENTS



Gustav Kovac
Anna Porubenová
and
Jozef Glasa, Lubomir Danisovic, Pavel Blazicek, Michal Farkas,
Michal Ondrejcak, Daniel Kuba, Monika Drakulova, Jan Trupl
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RAABE



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Gustav Kovac

PREFACE

College textbook

- prepared for students of postgraduate specialization studies in laboratory medicine, clinical biochemistry – physicians and laboratory diagnosticians, for whom we provide this study.

Goal

- to create a comprehensive system of knowledge about laboratory diagnostics from the perspective of a physician/laboratory diagnostician working in a clinical laboratory and at the same time collaborating with clinicians.

This requires knowledge and practical skills in

- pathophysiology
- laboratory methodologies
- the clinical course and manifestations of diseases

all from the perspective of the clinical laboratory.

The text is divided into 11 chapters

- Clinical Laboratory
- Molecular pathology
- Clinical Chemistry
- Urine and body fluids
- Cytogenetics
- HLA
- Hematology
- Coagulation
- Clinical Microbiology
- Immunopathology
- Transfusiology

Each chapter is divided into three sections

- Introduction
- Laboratory context
- Clinical context

In the introduction

- we focus on the pathophysiological nature of the problem, we look at the typical pathophysiological features and characteristics of the diseases, so that the student has a clear idea of what we are talking about
- without knowledge of the pathophysiological principles, you can't make any progress in laboratory diagnostics

In a laboratory context

- the range, categories, types and especially the principles of laboratory procedures and methodologies used in the clinical laboratory, including instrumentation and information technology
- the laboratory context is the essence of laboratory diagnostics and is therefore the main focus and concentration on the subject

In a clinical context

- we focus on the symptomatology and syndromology of diseases and their relationship to the results of laboratory tests – i.e. the indication and interpretation of laboratory parameters in the diagnosis, differential diagnosis and monitoring of individual diseases
- we recommend using the clinical context as a basis for clinical consultation. Without ensuring communication between the clinical laboratory and the clinic, there is no reliable laboratory diagnosis

Laboratory diagnostics
- cannot be carried out in isolation,
- but always only in a clinical context – in direct contact in the diagnosis, differential diagnosis, therapy or monitoring of a specific clinical case

This is the problem of physicians and laboratory diagnosticians
who work in the clinical laboratory,
- the clinical laboratory represents the interface (cutting edge) between the clinical and the laboratory,
- providing laboratory results for clinicians is the foundation of a clinical laboratory's existence,
- rational indication and qualified interpretation of laboratory tests is the other side of the coin, without which it is impossible to ensure quality laboratory diagnostics
- bridging this gap between the clinic and the laboratory is the main mission of physicians and laboratory diagnosticians working in the clinical laboratories
- knowledge and experience are essential to master the communication between clinic and laboratory
- the biggest risk in performing this task is the high workload and the resulting slippage into routine

Laboratory medicine
- attempts to bridge the aforementioned issue

In the presented undergraduate textbook
- with a defined focus and scope
- it is not possible to discuss all the tests that can be performed in the clinical laboratory
- nor all aspects of their indication and interpretation

We have drawn on more than 30 years of experience and focused on only the most important ones from our point of view.

In conclusion, we would like to point out that
- errors in laboratory diagnosis whether due to
- non-compliance with a laboratory procedure (faulty laboratory examination)
- incorrect choice of laboratory parameter (indication)
- or its incorrect evaluation (interpretation),

can lead to serious harm to the patient or even death

Gustav Kovac

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1.
CLINICAL LABORATORY

Gustav Kovac
Anna Porubenova
Jozef Glasa

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1.1 NOTES ON GENERAL MANAGEMENT PRINCIPLES

TOPICS

- **General management principles**
- **Fundamentals of clinical laboratory management**
- **Clinical laboratory business management**
- **Safety in the clinical laboratory**
- **Interpretation of laboratory tests**
- **Information systems in the clinical laboratory**
- **Ethics in laboratory medicine**
- **Conclusions to the clincal laboratory**

DEFINITION

Management
- is an activity by which a manager achieves his/her goals through the work of other people

Job description of the manager
by Fayol
- planning
- organising
- motivating
- coordination
- check

by Mintzberg
- decision-making
- informing
- working with people

Planning and control

Stages/process
- strategy – formulation of the intention
- tactics – definition of objectives
- operative – specific tasks

Objectives
- short-term (operational) – days to weeks
- medium-term (tactical) – weeks to months

long-term (strategic) – months to years

Planning techniques
- milestones – e.g. tasks are set and reviewed weekly – a process suitable for project planning and implementation
- key events – recording them in the calendar (meeting dates) – a process suitable for planning/recording routine events – as they come
- networked – connecting milestones and key events into one whole – project and current events complement each other

Check
- the process of evaluating inputs, processes and outputs
- based on the feedback loop, we find out whether we have achieved the set goals

Motivation

Meeting needs,
which can be arranged hierarchically from the lowest to the highest level
- physiological (hunger)
- security (occupation)
- group (religion/politics)
- leadership (leading place)
- higher order (culture/charity)

Factors of dissatisfaction
- the main function of money is to remove dissatisfaction
- a good salary removes dissatisfaction, but does not motivate you to perform at a high level

Factors of motivation
- career progression
- gaining recognition
- the satisfaction of your own work

Team

Team
- is a group of workers, optimally numbering 5 – 7, working towards a common goal

Stages of team building
- forming (forming)
- storming (confrontation)
- norming (norming)
- performing (activity)

Roles of individual team members
- head
- explorer
- monitor
- worker
- finisher
- maintainer of team spirit

Problems in the team's activities
- *cycling* – poor communication with the environment + concentration on solving own problems + loss of sense of reality
- *scapegoat* – when failures occur, there is a need to personalize the cause of the failure

Change management

Drivers of change
- economic
- social
- technolgical
- political

Change
- occurs when the balance between the driving and braking forces is disturbed
- always provokes resistance

To overcome the change, it is possible to use
- education
- communication
- coercion
- support
- handling
- negotiation
- Engaging

It is important to evaluate
- where we came from
- where have we got to
- how we got there

Selection of staff

Staff shall be selected on the basis of
- analysis and job description
- specifications of personal characteristics
- questionnaires (indicative selection)
- by personal interview

Once a worker has been selected, it is essential in the long term to pay attention to
- development – education and training
- performance evaluation – feedback

Leadership and management styles

A leader
- motivates
- innovates
- introduces changes
- changing the organisation's activities for the better

The manager is the administrator
- maintains the status and activities of the organisation at a high level

Management styles
Autocratic
- the leader decides alone

Democratic
- the head decides on the basis of majority

Laissez fair
- the manager shall leave the staff to their own discretion and, if necessary, shall intervene as they see fit

No management style can be said to be ideal
- it's more about adapting the style to the specific circumstances
- if tasks need to be completed quickly or workers are not very educated, an autocratic style prevails
- if there is enough time and the workers are educated, the democratic style prevails

Organisational structure

Organisational structure ("organisational spider")
- represents the division of the organisation into individual departments and divisions
- reflects the nature of the organisation's activities

Division of the organisation
- is conditional on the division and description of work

There is always a natural conflict embedded in the organisational structure between
- centralisation (where the ultimate consequence of this trend is cost reduction)
- and decentralisation (where the ultimate consequence is an increase in quality) of activities, products and services
- ultimately, it is a question of finding the right balance between centralisation and decentralisation for the specific situation

Organisational culture

Organisational culture
- is the sharing of the values, beliefs and traditions that prevail in the organization
- it's about relationships – how things are done and how problems are solved

Types of organisational cultures
- *centralist* – a web with one centre – the chairman decides – an example is a political party

- *bureaucratic* – the structure of a power pyramid where everyone has a place, rights and responsibilities – an example is the government and ministries
- *matrix* – there is a blending of management structures in the soap of the "x" and "y" axes – an example is a university hospital – the x-axis follows the hierarchy of teaching, the y-axis follows the hierarchy of the provision of curative and preventive activities (this culture is the most suitable for development, but suffers from the problem of loyalty)
- *club-like* – there is no superiority and subordination – everything works on the basis of the principle of chance – examples are artists and scientists

Outdoor environment

Outdoor environment

- the space in which individuals and organisations are found (the internal environment)

External environmental factors

- competition
- market
- Sociology
- technology
- policy
- economy

Their basic characteristic is that

- we cannot determine them,
- but we have to adapt to them

1.2 NOTES ON CLINICAL LABORATORY MANAGEMENT

1.1.2 NOTES ON COSTS

- ***Strategies***
- ***Fiscal system***

Strategies
- outdoor and indoor environment

Fiscal system
- financial decision-making
- outsorcing vs buying, leasing reagent rental analytical equipment

The role of the laboratory diagnostician
- Medical priorities, planning, management/control , anticipation (technology and external environment)

Problems
Fundamental problems
- regulation
- hidden costs
- information system

Cost control
- Automation
- prevention of additional costs
- eficiencia
- Budget

Laboratory costs
Direct costs
- wages
- reagents
- blood (unpredictable nature of costs + costs of communicable disease testing)
- tests that cannot be carried out in the laboratory due to the absence of an analyst or expert
- capital investments: purchase, leasing, rental, special contracts

Indirect costs
- indirect (material, wages, other) = overhead
- marketing
- Administration

Fiscal system

Chart of accounts
Results
- assets = liabilities + principal
- income – expenditure = net income (profit or contribution)

NOTES TO PROFIT AND LOSS

Contributional margin
- the difference between the price of the examination and the variable cost of the examination

Contribution and profit margin
- profit (net income) = income – expenses
- contribution = income derived from tests produced by the laboratory – costs for which the laboratory is responsible

Impact of "contribution" on the pricing process
- competition, government regulations, other restrictions, treaty restrictions

Managerial responsibility and "contribution margin"
- for market expansion, select only those examinations that will have the most positive impact on the "contributional margin"

BUDGET NOTES

Principles
Financial plan in EUR + targets
- projection of the strategy into the operational plan
- operational plan and budget

Projection:
- workload
- estimation of resources
- estimate of direct costs
- calculation of indirect costs
- Balance of income and costs

Budget analysis
- where resources are consumed
- how quickly resources are consumed
- estimation of the causes and their link to the place where the costs are incurred

Departmental budget analysis and allocation of costs to individual sections
- allocation of costs of general functions between posts
- laboratory department budget
- laboratory example

NOTES ON THE CLINICAL CONTEXT

Definitions
- the role of accounting is to measure, report and control the inputs and outputs of the laboratory

Financial accounting
- presents a point of view for the purpose of presentation to the external environment of the company

Management accounting
- ("responsibility accounting" = responsibility for costs incurred per unit of output = viewpoint from "inside" the firm)
- The smallest unit that can be costed is the product (product)

Cost categories for determining operational costs
- variable, fixed, semi-fixed
- direct, indirect

Accounting for examination and laboratory services
- wages
- Material
- indirect costs

Accounting focused on diagnosis categories
- allows you to calculate the cost of each category of diagnosis
- the basis is the cost of 1 test for each spectrum test provided by the laboratory

Activity-based accounting
- linking the consumption of fiscal resources to the places where the costs are generated
- direct costs
- indirect costs

The role of accounting in variance analysis
- a comparison of the actual variation (deviation) from the planned budget
- explanation (identification of the cause) of the deviation
- corrective measures

Pricing of examinations: a "buy or sell" decision
Strategies
- communication at all levels
- comparative strategy
- cost strategy
- strategy based on intuition
- knowledge and understanding of the market, regulation and competition
- large companies: pricing leaders
- ethics must prevail in some situations

Economic basis for setting prices or charges
- example of price analysis

Selling price
- covering direct costs
- covering a realistic estimate of indirect costs
- the provision of a satisfactory profit

Billable examination
- only if it is reimbursed, it generates income

Methods of calculating prices or charges
- profit maximisation
- return on invested capital
- conversion costs
- contribution margin
- standard costs
- direct costs
- total costs
- relative value

Make or buy decision
- consider the quality of the examination offered
- compare the cost of in-house testing with the cost of outsourcing
- medically necessary TAT statute
- evaluate consultation skills and clinical insight
- estimate logistics problems

The breaking point
- break-even point = fixed expenses + expected profits/revenue – variable expenses

"Management and prevention" of costs
Causes
- Prerequisites
- the output of the examinations is directly proportional to the clinical requirements
- costs are directly proportional to the output of the laboratory tests, provided that the maximum eficiency point is not exceeded and compliance with regulatory and quality requirements does not require additional procedures
- constant indication of inputs without reduction of outputs escalates the cost of the examination

- lack of information on clinical needs
- lack of education on rational indication
- increasing workload
- how to reduce unnecessary costs

Notes on solutions

Adequate education
- providing assessments of the quality and adequacy of the indication

Pareto principle (80/20 rule)
- focus on the most frequently indicated examinations

Managerial control through interpretive commenting on results
- cumulative findings, educational comments

Managerial control of the indication of optimized diagnostic clusters
- fewer resources used on the one hand and unchanged quality of outputs on the other

Management control using the support of "indicator leaders"
- clinical leaders influence indication behaviour

Reducing the importance of the indication of "multitest profiles"
- repeated examinations, reflex testing

Providing higher eficiency in automated areas of the laboratory
- ill-considered choice of automatic analysers

Stricter budget monitoring
- 80% of the most commonly used tests are underestimated

Acquisition of eligible chapter equipment
- purchase – leasing – response rental – special terms and conditions
- Workflow optimization is the main reason for the acquisition of automated analyzers
- A new analyzer in the context of legacy workflows is not an asset
- Consolidation of jobs
- Reduction of downtime
- Replacement of existing equipment
- Reduction of staff
- Cost of the examination carried out
- Cost of a new instrument

Workflow notes

Cost analysis

Purchase

Analytical technique and equipment

Key factors
- the benefit of each capital expenditure
- net future increases in profits/savings (cash flow)
- the useful life of the investment (depreciation)

Important factors
- the number of patients who will benefit
- degree of benefit to patients
- the demographic characteristics of the patients who will benefit
- benefit for the "parent" organisation

Key elements
- duration of the project
- original capital investment
- annual operating costs
- present value of expenditure
- average annual savings

- number of patients examined
- age of patients examined
- average cost per patient examined
- intangible benefit

Lease/rental agreement
- a remedy against technological obsolescence
- depreciation is calculated on the basis of historical cost

Cost of 1 contracted examination (reagent rental)
- the analytical technology provider provides: reagents, consumables automated data processing, installation, training, maintenance and other requirements – excluding manpower
- the owner is burdened with the cost of labour
- the analytical technology provider shall establish a fixed cost per test including control materials and calibrators
- advantage: avoiding depreciation as well as fixing fixed and variable costs for a period of 5 years

Conclusions

- cost-benefit analysis

Measuring laboratory productivity
- productivity types

Types of laboratory productivity
- worker productivity
- productivity of automatic equipment
- clinical productivity
- workload productivity

Improving fiscal productivity
- in most cases it covers wages and overemployment

1.3 NOTES ON BUSINESS MANAGEMENT

TOPICS
- **Diagnostic specialisations**
- **The clash of medical culture with technological innovation**
- **The impact of medical technologies**
- **Flexibility, adaptability and alternatives**
- **Merging and merger shock**
- **Management skills**
- **Legislative factors**
- **Government inaction**
- **Compliance**
- **Balance medicine and business**
- **Supporting the value of the laboratory**
- **Managing patient outcomes**
- **Case reports: evidence-based medicine and rational indication**
- **Significance: pathological and normal results**
- **Specificity and sensitivity**
- **Diseases**
- **Lege artis**
- **Leadership, relationships , business**
- **Information management**
- **Total cost management**
- **Managerial responsibilities and profit**
- **Utilisation**
- **Productivity**
- **Revenue**
- **Profit**
- **Price**
- **Risk**
- **Reimbursement management**
- **Summary and conclusions**

INTRODUCTORY REMARKS

Diagnostic specialisations

Overview
- the health care system may have forgotten , perhaps never realised and appreciated the importance of the diagnostic laboratory to health care
- medical diagnostic technologies are the method of choice
- physical examination and other subjective methods are replaced by quantitative measurements
- new generation POCT
- Medical technology segment: laboratory medicine and other clinical in vitro diagnostic technologies generated the largest volume of sales in medical technology in 1988
- interacting forces: ambulatory care, prevention and reliance on objective data

Outpatient care and prevention requires more laboratory tests
- decentralisation: transfer of care from hospitals to outpatient clinics
- diagnostic support for specialisations
- costly medical diagnostic laboratories
- increasing obligation for preventive examinations in chronically ill elderly patients

Emphasising primary care
- the decline in the importance of medical specialties and the rise in the importance of primary care
- compulsory preventive screening for diabetes, prostate cancer and breast cancer

Providers increasingly trust objective findings (medical technology) more than clinical findings

- the average doctor's time per patient is 20 minutes or less
- medical decisions need to be made immediately
- Laboratory support cannot be remote but must be fast, easy and reliable (POCT)
- reliance on objective data

Medical culture, technology, innovation

- a culture shift in the delivery of medical care
- the value of a medical and diagnostic laboratory
- new and dynamic technologies with research support

The impact of technology

- medical diagnostic technologies increase the cost but also the speed of the diagnostic process
- however, these are necessary steps in making medical decisions

Marketing dynamics

- Medical diagnostic technologies represent the largest segment within the medical hospital cost industry
- the average cost of a laboratory test is: 0.03 – 0.05 USD
- but the use of its result by providers affects : 0,7 – 0,8 USD
- the following health care
- 80% objective patient data

Pressure to increase the specificity and sensitivity of tests without increasing costs

- laboratory testing with the highest possible diagnostic specificity and sensitivity is a prerequisite for good medical practice
- this has an impact on costs
- research is part of the medical diagnostic technology industry

Delaying reimbursement for new examinations

- FDA approval 1 – 2 years
- waiting for AMA recognition 1 – 2 years
- current list of examinations: eligible examinations (CPT-4 letter) 1 – 2 years

The paradox of high costs and price controls by insurers

Payments are controlled by a third party

- insurance companies
- Payers
- healthcare management organisations

Experts are worth something

- 90 000 Kč (Germany for a doctor starting out)
- 60 000 CZK (CR specialist)
- 30 000 CZK (Czech starting doctor)

Flexibility, adaptability, alternatives

- during chaos, a leader must have more than one strategy to ensure survival in the noise and confusion of battle: flexibility and adaptability

Mission is no longer a determinant of cost

- altruism no longer has an effect

Diagnostic laboratory in the role of a competitor

- the hospital's expertise is based on a professional and time basis
- continuous erosion of the median price of a single test by out-of-hospital laboratories: $28 – $23
- esoteric examinations become routine
- complexity is increasing
- the practice of global accounting is eliminated

Integrated delivery systems, decentralisation and networks

- the need to reduce costs and increase value and quality of care
- coordination, integration and consolidation is the answer
- educational initiatives: explaining why this is necessary
- some (not all) of the staff want to be involved in planning and decision-making

Creative directors and managers face these barriers:

- lack of understanding that a new external environment has been created
- lack of understanding and merit of integration

- fear of loss of influence after integration
- constant emphasis on the central operating unit as a decisive factor

Lack of understanding in the central operating unit of the objectives of integrated health care delivery
- loss of geographical concentration of the operational unit
- lack of qualified staff
- failure to identify key moments of integration
- inappropriate information systems
- lack of demographic data on the population receiving care and their needs
- the key elements necessary for building an integrated system
- in integration, the integrated organisation remains intact

Shock of change of owners and mergers

- in mergers and amalgamations, one entity absorbs the other with fundamental changes in organisational structure, culture
- the reason for changes in the laboratory are changes in market requirements in regulations

Management skills

- the dual role of a leader: business and medicine

Key considerations for transformation management
- Supporting staff in implementing the necessary steps in the shift
- managing people in the context of transformation
- encouraging new ways of thinking

Technomanagement
- traditional management methods rely on manipulation: getting people to do what management wants
- technimanagement focuses on the needs of the individual and
- Management skills consist of selecting the means and preparing the environment within which each staff member will align his or her own goals with those of the organization
- The organization gains control of the process by providing staff who express interest with the opportunity to integrate their personal goals with organizational goals, extend this to co-workers, and present this group as an example that gives reassurance to the staff, the organization (financially), and at the same time improves the quality of health care
- success in the management of a complex medical technology organisation lies in the recognition of appropriate methods as well as existing constraints
- management cannot be squeezed into one equation

Balanced Budget Act 1997

Legislation

- negative implications and operational changes for laboratories
- medical necessities
- decrease in reimbursements
- invitations to tender for the provision of examinations
- screening: diabetes, cervical, prostate, breast cancer

Clinical Laboratory Improvement Act

The inaction of the government (of the USA, but also of ours)

- massive organisational changes in laboratories within healthcare management organisations
- occupational medicine and occupational safety protection
- regulations
- training
- overview
- cost
- fraud prevention
- reimbursements
- the government rejected the position of clinical laboratories that they cannot be held responsible for the rational indication of laboratory tests

The greed and misjudgment of a minority has caused the federal government to be unstoppably hyper-reactive in preventing and detecting fraud:

Compliance

- crime
- audits
- programs
- officials

- additional administrative costs
- laboratory directors need to plan for the additional costs of providing the above

Balance: medicine and business

- health care becomes significant and visible
- 100,000 deaths are caused by medical failures annually in the US, according to a National Academies finding
- electronic information link between the laboratory and the provider is the most important factor influencing the safety of healthcare

Supporting the value of the laboratory

- efforts should be made to be a partner to clinicians and government
- the future of the laboratory depends on how valuable clinicians and the government consider it to be
- the clinical laboratory must be involved in programs that increase value with clinicians and government

NOTES ON THE LABORATORY CONTEXT

Leadership, relationships, business

- the external environment of the laboratory – the clinical interface area is based on 4 basic pillars that the medical director must consider and master

Leadership

- transforming external and internal changes, trends and forces into daily practice: how to get subordinates to do it

Motivate subordinates to participate in training activities that address this

- be familiar and knowledgeable with experts in legislation
- look for information beyond the usual references

Communication

- a laboratory professional is traditionally considered a scientist, less so a manager or politician
- for a business professional, conflict and conflict of interest is a normal part of his professional practice
- laboratory management requires a new quality based on the hybridisation of medical and business knowledge and skills

Policy

- negative view: a politician is a person who gains power and influence by using methods that discredit the value system
- a positive view: the art and practice of managing public affairs
- the laboratory leader must realize that he or she lives in a political system and must behave in a way that ensures compensation for himself, the laboratory and the laboratory staff
- it is necessary to manage both inward policy (integration and consolidation) and outward policy (public funds) and their acquisition

The laboratory professional must be skilled in

- protecting patient rights
- forming alliances with other laboratory professionals
- be a vocal and effective advocate for the highest quality healthcare

HUMAN RESOURCES

Information management

Primary(active databases

- the interface between the clinic and the laboratory should be provided electronically
- database connectivity

Secondary (passive) databases

- workload
- codes
- verification of the provider's diagnosis
- financial accounting
- compliance
- accreditation