

Worldwide standardized education and training in clinical chemistry and laboratory medicine

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Purpose

- Competency-based education
for training laboratory medicine specialists
- Roles
 - IFCC
 - National Societies

Content

- Competency-based education
- Steps for competency-based education
- Some terms and their meanings
 - Milestones
 - Entrustable professional practices (EPAs)
- Implementations
- Competency-based education framework in laboratory medicine
- Roles of the National Societies and the IFCC

Laboratory Medicine

The branch of medicine in which specimens of tissue, fluid, or other body substance are examined outside of the person, usually in the laboratory or near patient sites

Some fields of LM (EU Directive 2013/55/EU for specialists in laboratory medicine, EC4)

- Clinical Chemistry/Immunology,
- Haematology/Blood Transfusion,
- Microbiology/Virology,
- Genetics
- *in vitro* fertilization

Some fields of LM (ACGME Accreditation in US) (2013)

- CP-oriented subspecialties such as
 - blood banking / transfusion
 - chemical pathology
 - hematology
 - medical microbiology
 - medical toxicology
 - medical biochemical genetics
 - molecular genetic pathology

(Genzen JR, eJFCC,2013, eJIFCC2013Vol24No1pp030-036)

Competency-based education

Education models

- Time-based
- Process-based
- Workplace-based
- **Competency-based/Outcome-based**

Competency-Based Education

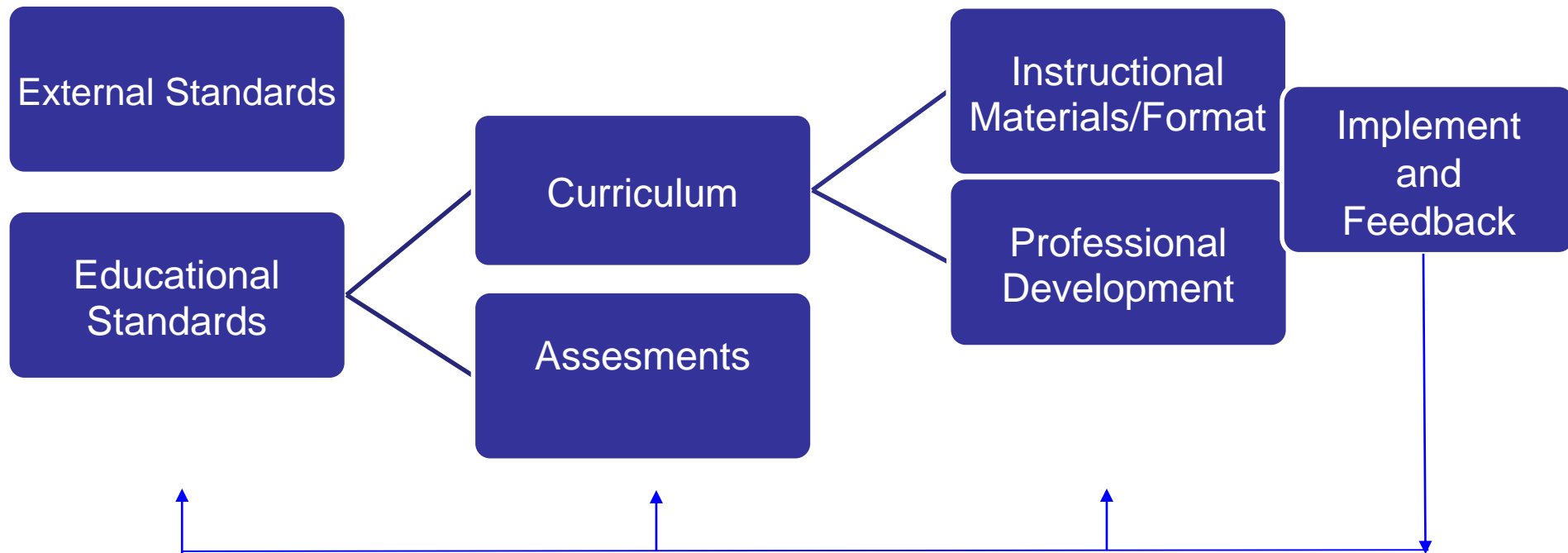
..is an approach to preparing residencies for practice that is fundamentally oriented to graduate **outcome abilities** and organized around competencies derived from an analysis of **societal and patient needs**.

CBE focuses on outcomes of learning

Steps in planning CBE curricula

1. Identify the abilities needed of graduates
2. Explicitly define the required competencies and their components
3. Define milestones along a development path for the competencies
4. Select educational activities, experiences, and instructional methods
5. Select assessment tools to measure progress along the milestones
6. Design an outcomes evaluation of the program.

A Model of CBE



A Model of CBE

What the graduates perform as a proficient laboratory medicine specialists

External Standards

Educational Standards

Curriculum

Assesments

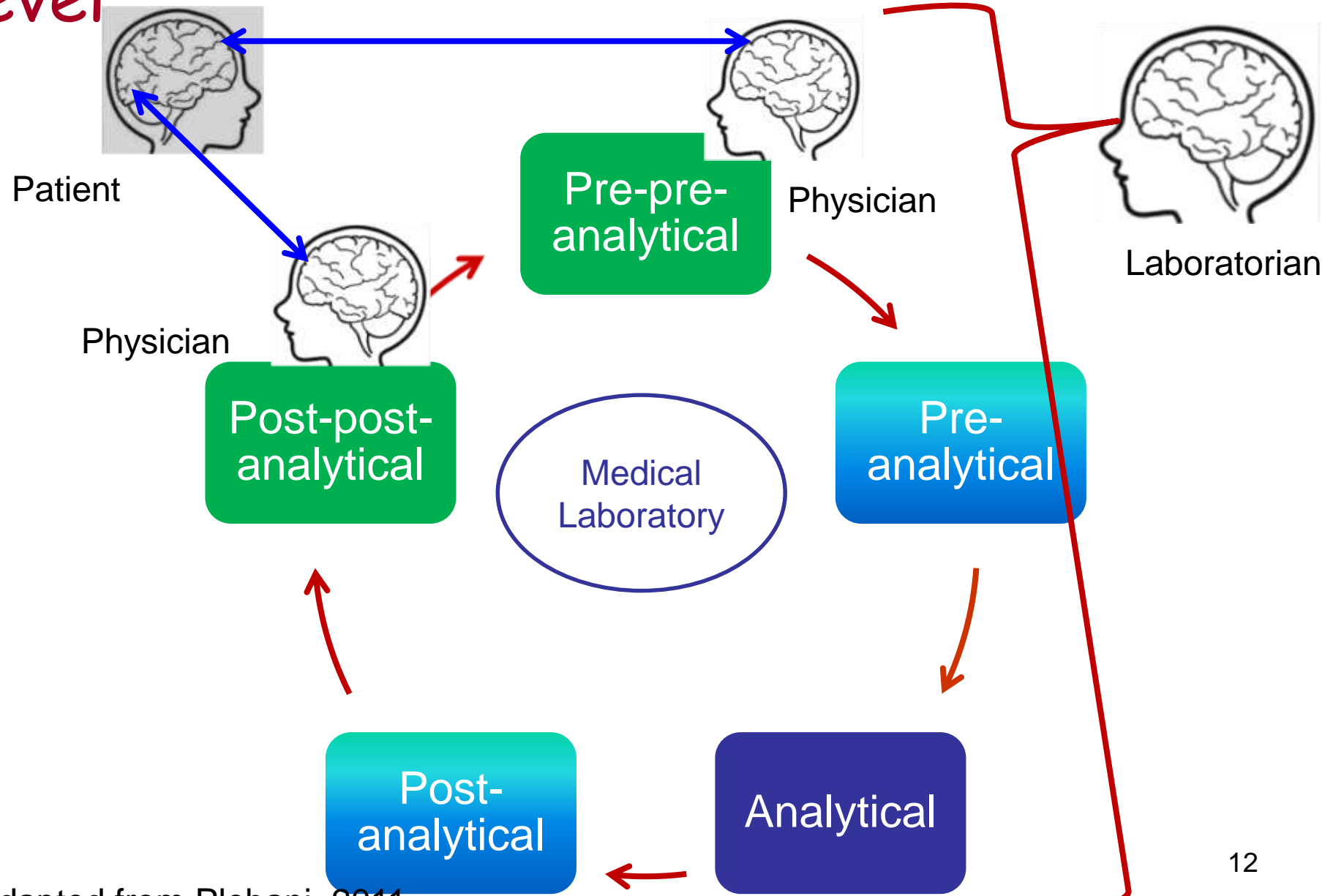
Instruction Materials

Professional Development

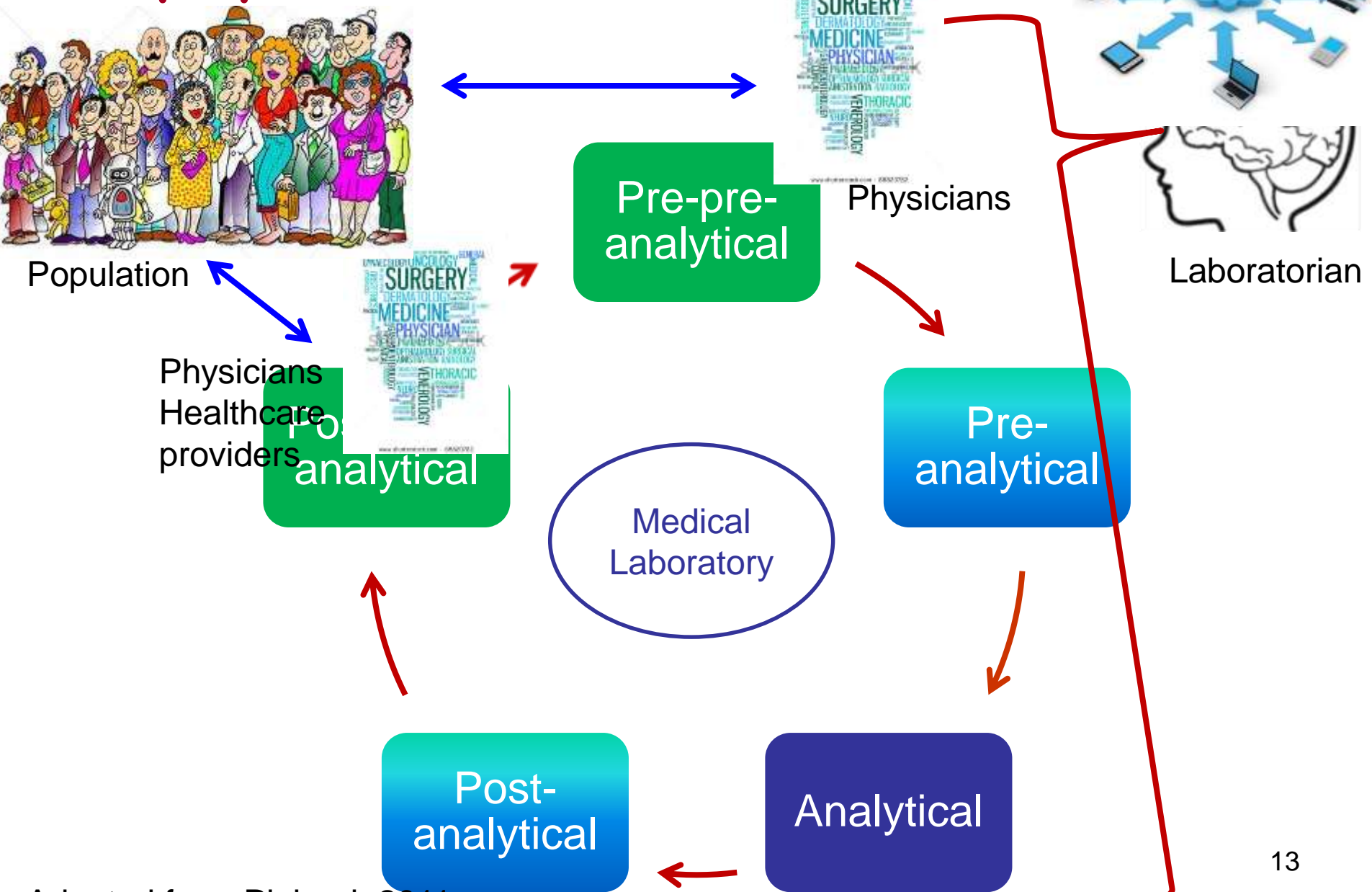
Implement and Feedback



Laboratory responsibility at individual level



At population level



ISO 15189
 4. Management requirements
 5. Technical requirements

A

Organization/Management responsibility
 4.1 Organization and management responsibility
 4.4 Service agreements
 4.15 Management review
Quality management system
 4.2 Quality management system
 4.3 Document control
 4.13 Control of records

P

Resource management

Evaluation / Improvement

4.8 Resolution of complaints
 4.9 Identification and control of nonconformity
 4.10 Corrective action
 4.12 Continual improvement
 4.14 Evaluation and improvement of the management system
 5.6 Ensuring quality of examination results (partly)

ISO 15189: Medical laboratories — Particular requirements for quality and competence

C

laboratories (partly)
 4.7 Advisory services (partly)
 5.4 Pre-examination processes
 5.5 Examination processes
 5.6 Ensuring quality of examination processes (partly)
Post-examination processes
 4.5 Examination by referral laboratories (partly)
 4.7 Advisory services (partly)
 5.7 Post-examination processes
 5.8 Reporting of results
 5.9 Release of results

D

supplies
 5.10 Laboratory information system

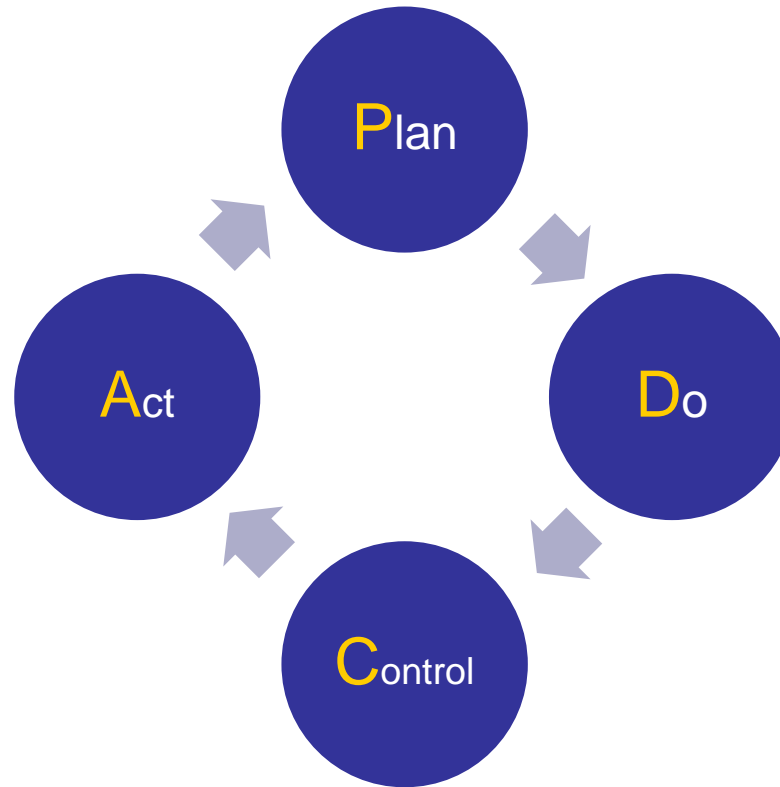
Patient Requirements

Request

Report

Patient Satisfaction

Deming Quality Circle (PDCA)

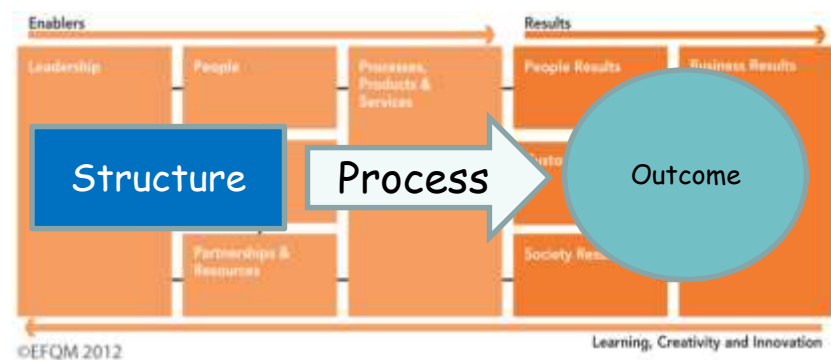


Total Quality Management

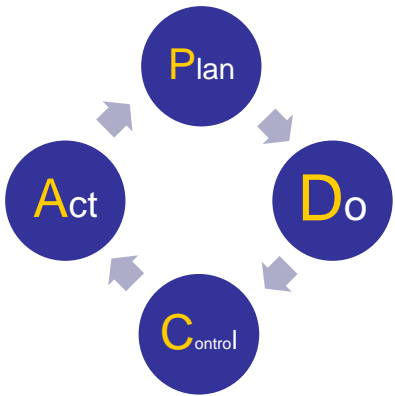
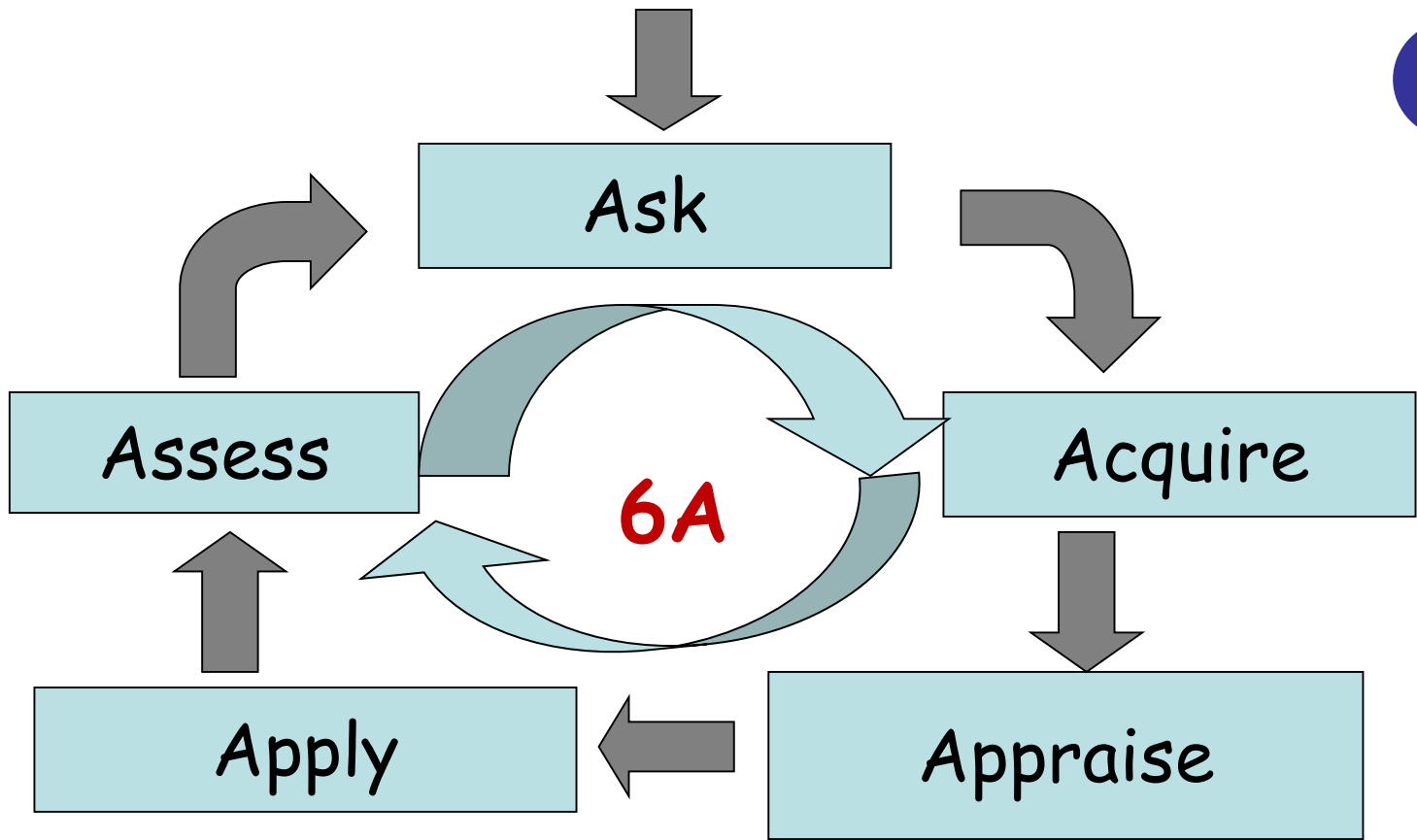
TQM Model (Westgard)



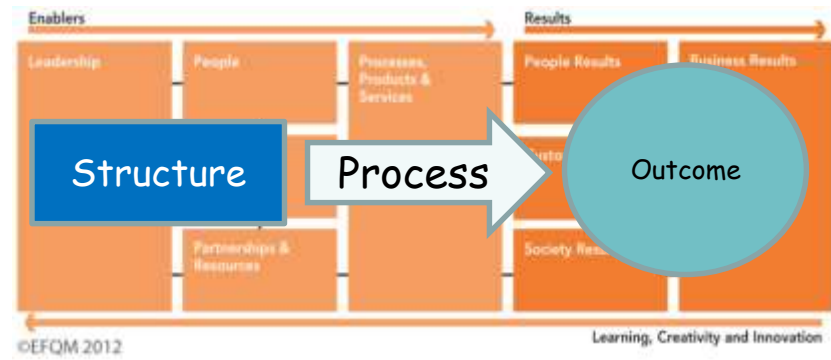
Evidence-based (laboratory) medicine processes



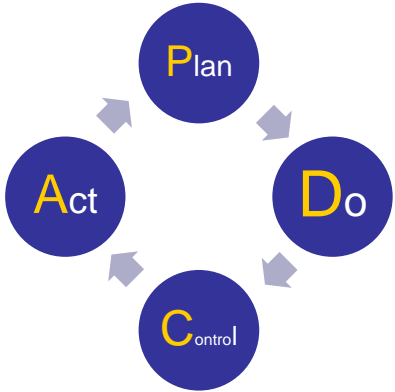
Clinical or Policy Problems



Evidence-based (laboratory) medicine processes in practice



Clinical or Policy Problems



Identify question

Search the evidence

Critically appraise evidence

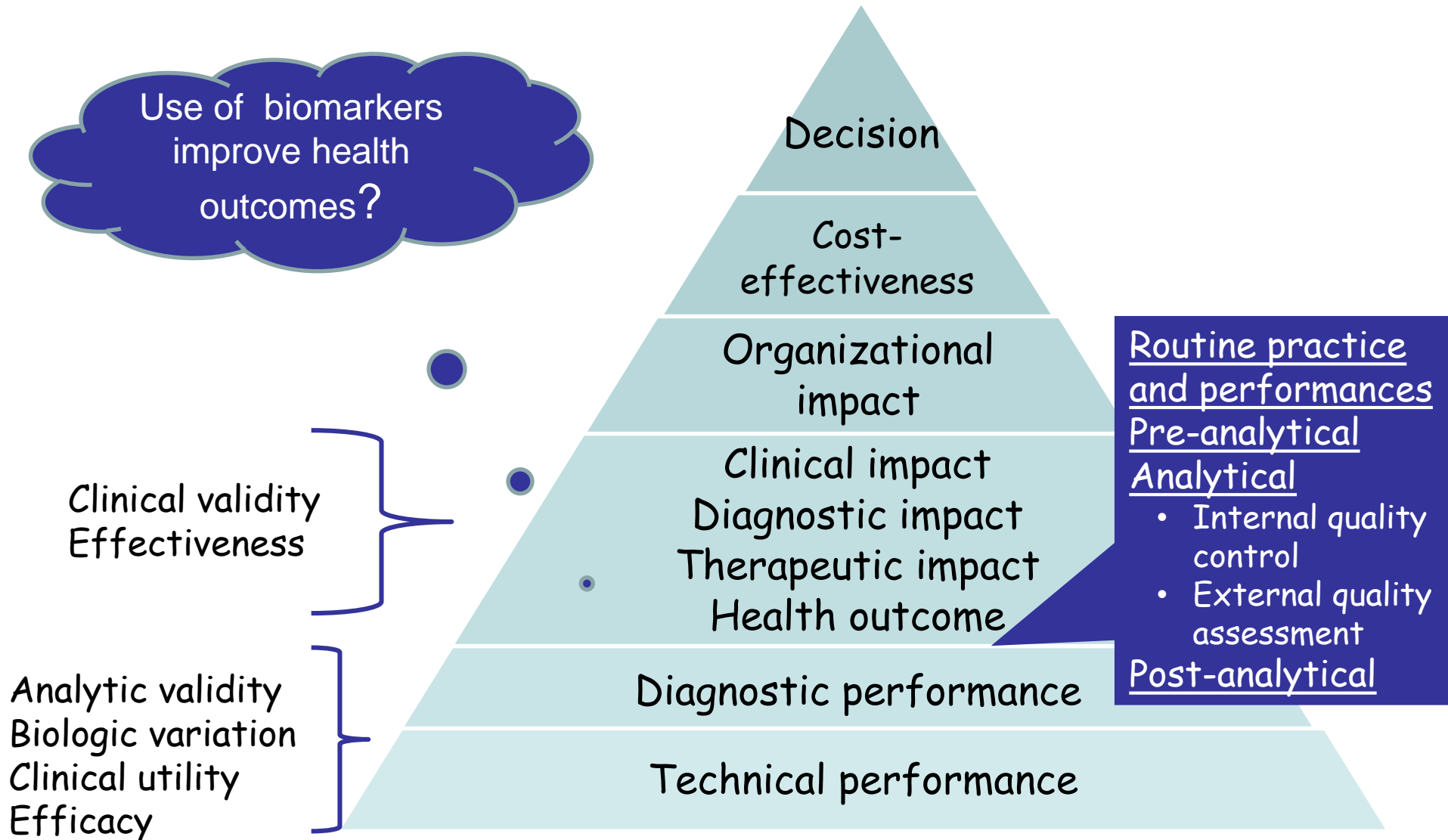
Modify process

Audit practice

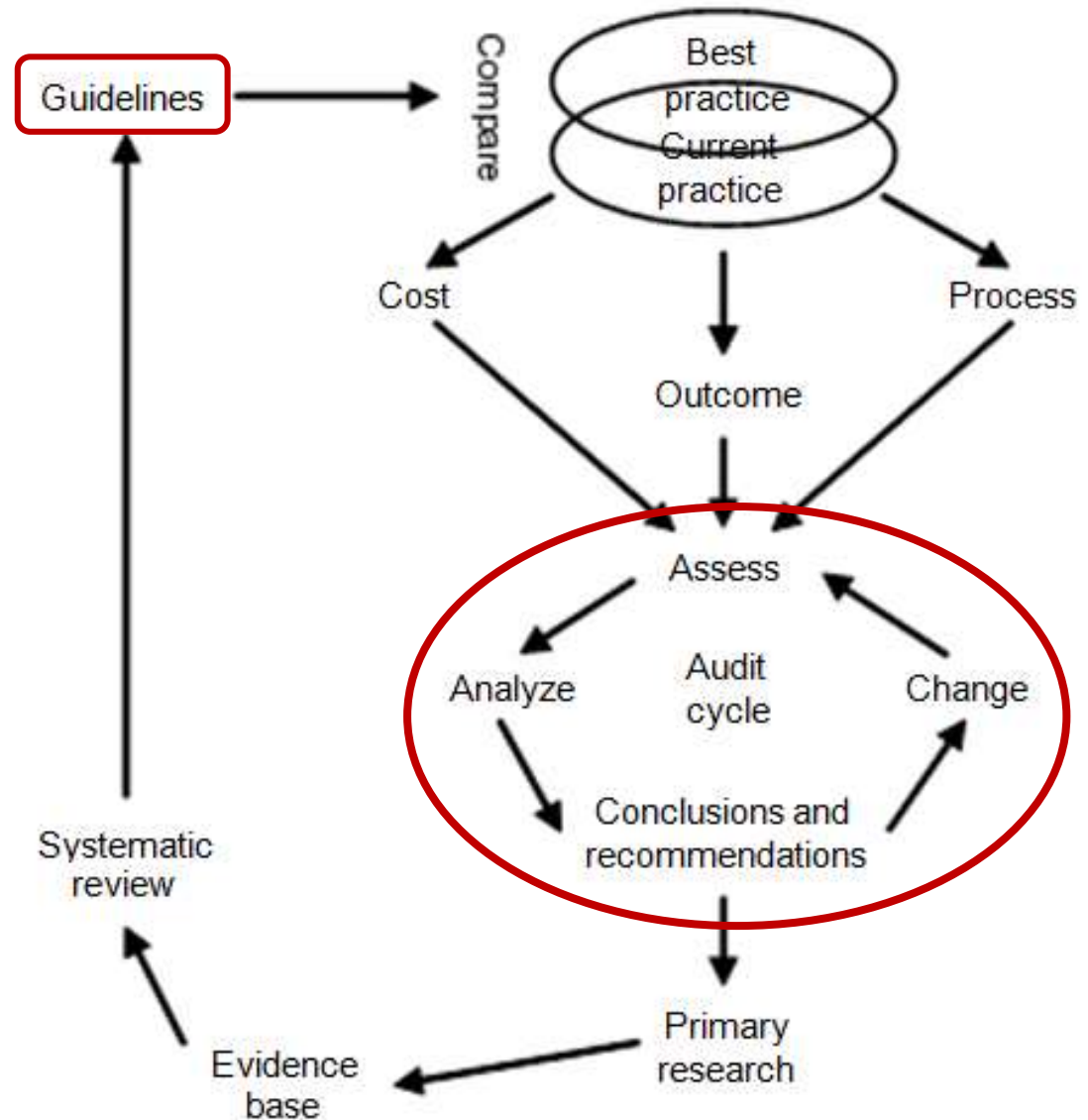
Apply to practice

Health outcome in hierarchy of evidence

Use of biomarkers
improve health
outcomes?

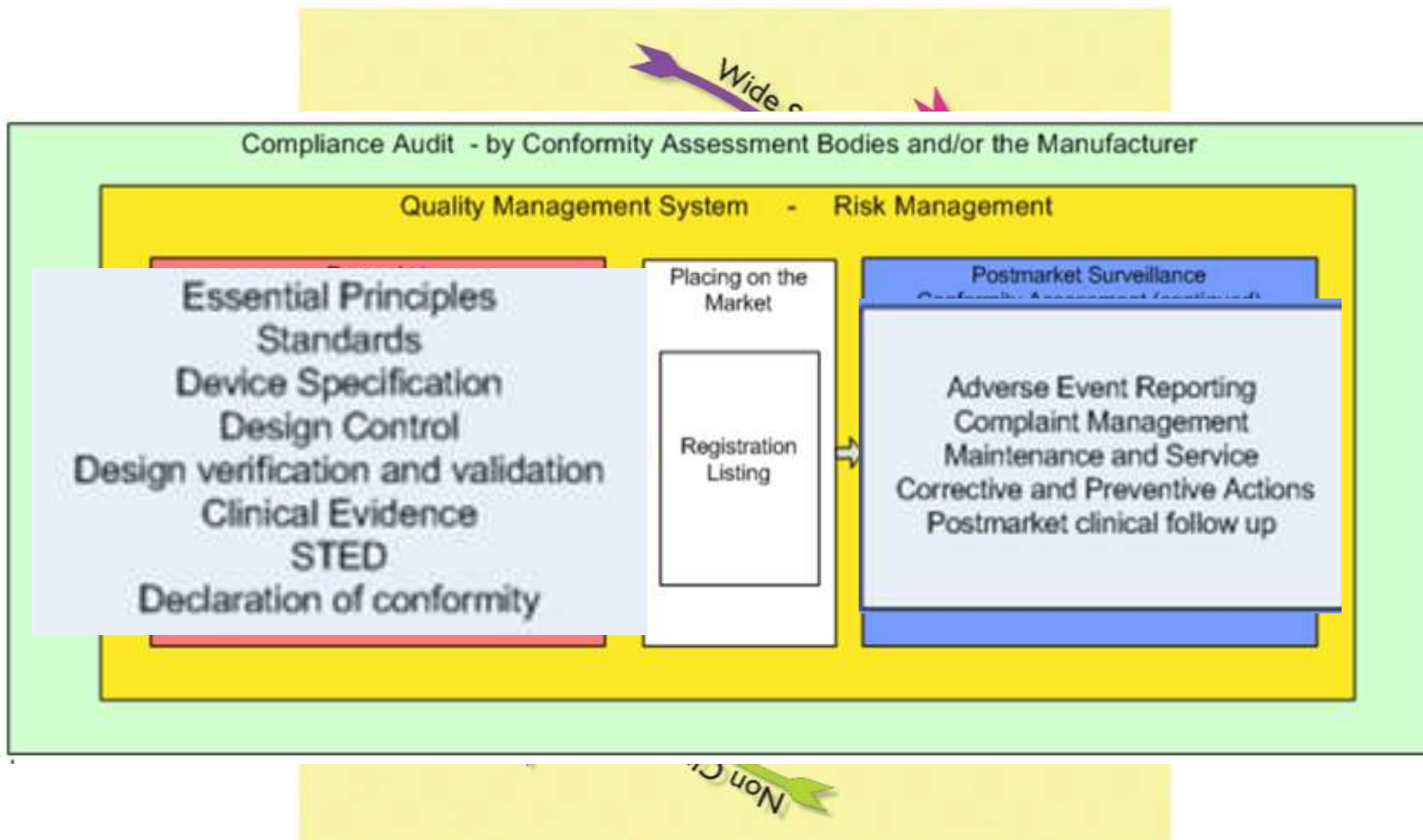


The clinical decision-making loop



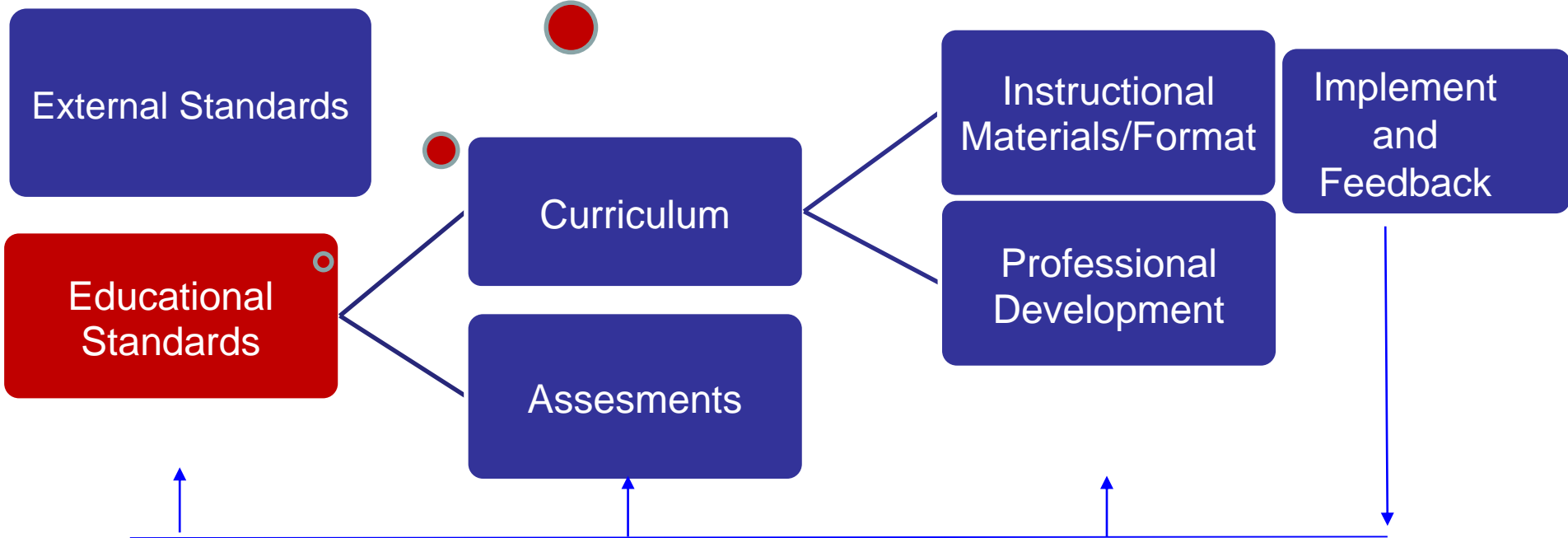
(Collinson PO, Edts. Price CP, Christenson, RH. EBLM Principles, Practice, and Outcomes 2nd Edt. 2007)

Lifecycle of IVD



A Model of CBE

Define competencies and their components



Competency

An observable ability of a health professional integrating multiple components such as knowledge, skills, values, and attitudes.

Competency Domains (US)

The ACGME/ABMS framework identifies six domains of competence:

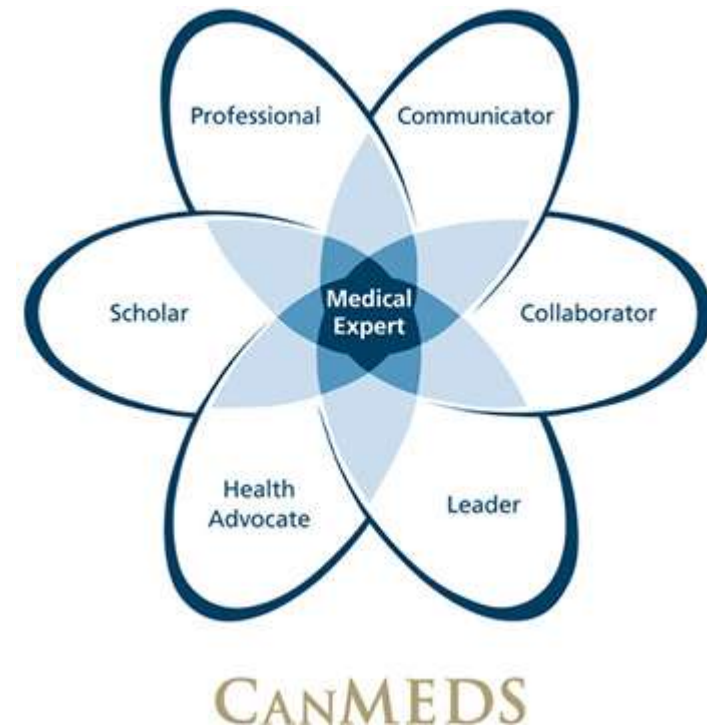
- Patient Care (PC),
- Medical Knowledge (MK),
- Interpersonal and Communication Skills (ICS),
- Professionalism (P),
- Practice-Based Learning and Improvement (PBLI)
- Systems-Based Practice (SBP).

Each domain includes a **set of competencies**.

Competency Domains (Canada)

Royal College of Physicians and Surgeons of Canada (RCPSC) adopted an outcome-based framework of competencies called CanMEDS

- Medical expert
- Communicator
- Collaborator
- Manager
- Health advocate
- Scholar
- Professional



Competency Roles in CBME (Canada)



Role	134 elements	28 key competencies	125 enabling competencies
Medical expert	14	6	27
Communicator	27	5	17
Collaborator	21	2	16
Manager	21	4	13
Health advocate	11	3	14
Scholar	23	4	25
Professional	17	3	14

Competency Domains by different organizations

Institute for International Medical	Deans of Scottish Medical Schools (Scottish Doctor) ¹⁴	U.S. Accreditation Council for Graduate Medical	Indiana University School of Medicine ¹⁹	University of New South Wales Medical school ¹⁵
1. Institution for International Medical Education				
of medicine	social & clinical		guide diagnosis,	clinical sciences
2. Deans of the Schottish Medical Schools				
medical skills	outcomes for	patient care	basic clinical skills	patient assessment
3. US ACGME				
Management of	disease prevention		of health	and disease
4. Indiana University of Medicine				
		improvement	Moral reasoning and	
5. Deans of the Schottish Medical Schools				
6. Canada				

Roles CanMEDs

- Professional
- Medical expert
- Communicator
- Health advocate
- Manager
- Scholar



Consensus Guidelines for Practical Competencies in Anatomic Pathology and Laboratory Medicine for the Undifferentiated Graduating Medical Student

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Competency-based Standards (Australia)



Competency-based Standards

Contents

Unit 1: Collection, preparation and analysis of clinical material

Unit 2: Correlation including

Unit 3: Interpretation

Unit 4: Maintenance

Unit 5: Maintenance

Unit 6: Professional

Unit 7: Responsibility

laboratory

Unit 8: Liaison with

Unit 9: Participation

Unit 10: Contribution

UNIT 1 Collection, preparation and analysis of clinical material

Element

1.1 Ensure the appropriateness of sample collection procedures

1.2 Ensure the appropriateness of specimen reception procedures

1.3 Evaluate specimen suitability prior to analysis

1.4 Determine the priority of laboratory requests (triage) to effectively manage service requirements

1.5 Process specimen utilising appropriate techniques

1.6 Read and validate results Equipment

Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Supplement / Vol. 64 / No. 1

May 15, 2015

Competency Guidelines for Public Health Laboratory Professionals

CDC and the Association of Public Health Laboratories

Competency Guidelines for Public Health Laboratory Professionals

15 competency domains

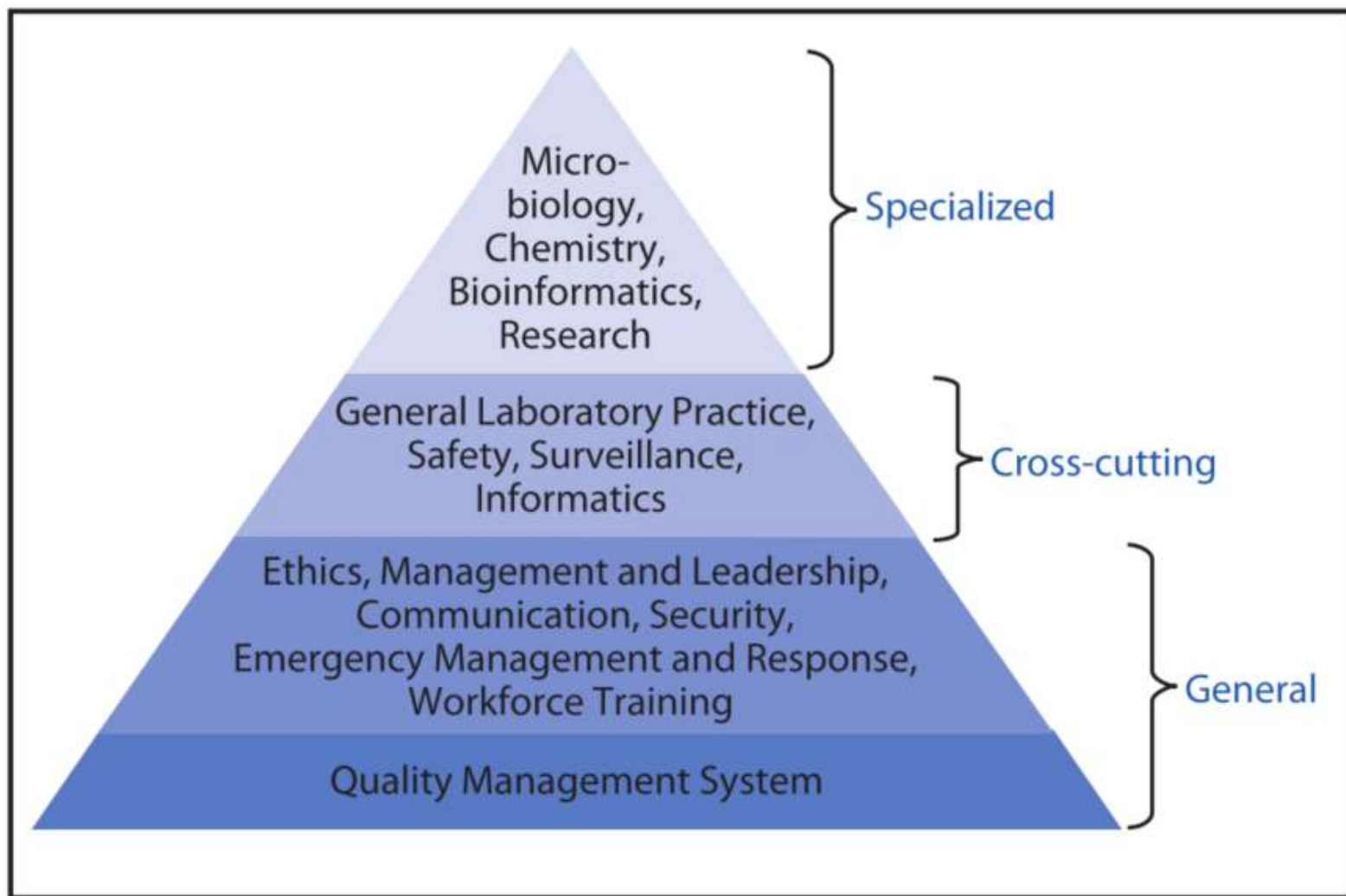
122 competencies

519 subcompetencies

Competency domains for laboratory medicine specialists (15)

1. Quality Management System
2. Ethics
3. Management and Leadership
4. Communication
5. Security
6. Emergency Management and Response
7. Workforce Training
8. General Laboratory Practice
9. Safety
10. Surveillance
11. Informatics
12. Microbiology
13. Chemistry
14. Bioinformatics
15. Research

Schematic of competency domains for public health laboratory professionals



Competency Guidelines for Public Health Laboratory Professionals

Competencies and Skill Domains.....	
Quality Management System Competency Guidelines	
Ethics Competency Guidelines.....	
Management and Leadership Competency Guidelines.....	
Communication Competency Guidelines.....	
Security Competency Guidelines.....	
Emergency Management Competency Guidelines.....	
Workforce Training Competency Guidelines.....	
General Laboratory Practice Competency Guidelines.....	
	Safety Competency Guidelines.....
	Surveillance Competency Guidelines.....
	Informatics Competency Guidelines.....
	Microbiology Competency Guidelines.....
	Chemistry Competency Guidelines.....
	Bioinformatics Competency Guidelines.....
	Research Competency Guidelines.....

Competency Guidelines for Public Health Laboratory Professionals

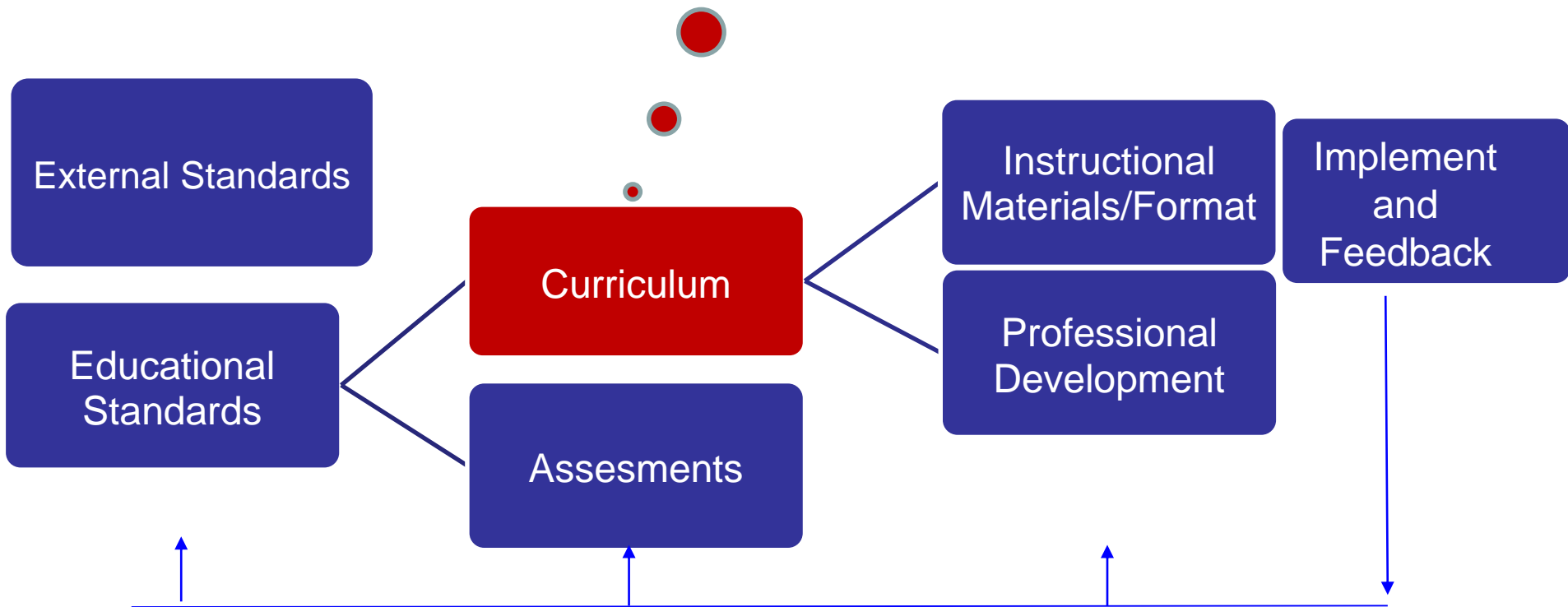
Example

TABLE 1. Public health laboratory competency guidelines: Quality Management System (QMS) domain

QMS 1.00. Organization: ensures that the laboratory's organizational structure is committed to achieving and maintaining quality*				
Subcompetency	Beginner	Competent	Proficient	Expert
QMS 1.01. Commitment to quality	Describes quality concepts and good professional practice	Demonstrates actions consistent with quality concepts and good professional practice	Sustains laboratory quality management system (QMS)* processes and procedures to ensure good professional practice	Oversees the development of policies,* processes,* and procedures* for review and maintenance of the QMS
QMS 1.02. Organizational structure	Identifies the laboratory's organizational structure that ensures quality	Explains how the laboratory's organizational structure ensures quality	Manages organizational structure to ensure quality	Coordinates organizational structure to ensure the QMS is well-integrated into all levels of laboratory operations

A Model of CBE

Define competency
Components?
Knowledge, skills and
attitudes



Competency components

Competency: An observable ability of a health professional, integrating multiple components such as

- knowledge
- skills
- values
- attitudes

Laboratory Medicine (AU)

- Laboratory Medicine Scientist (Bachelor of Science)
(<http://www.murdoch.edu.au/Courses/Laboratory-Medicine/>)
- Master of Laboratory Medicine
(<http://www.studyat.uwa.edu.au/courses/92530-master-of-laboratory-medicine---coursework-and-dissertation>)
- PhD in Medical Laboratory Sciences
(<http://www.healthcarestudies.com/PhD-in-Medical-Laboratory-Science/Australia/RMIT-University/>)
- Basic Pathological Sciences (Royal College of Pathologists)
- Chemical Pathologists and Scientists
(<http://www.aacb.asn.au>)

Training in Laboratory Management and the MBA/MD in Laboratory Medicine

Box 2. Laboratory management curriculum in laboratory medicine training

Trainees should learn to develop the following skills and competencies:

Organizational and leadership skills

Skill level I

The fundamentals of human behavior in organizations (eg, management structure and function, the structure of differing practice settings)

Interpersonal skills to effectively manage, lead, and motivate others

The role of ethics in medical and managerial decision making

The different responsibilities of pathologists, administrators, and technologists

The relationships between pathologists, hospitals, and staff (eg, contracts, decision making, negotiation)

The environment of patient-oriented and ethical service

The organization of the clinical laboratory (eg, preanalytic processes, the structure of analytic units, postanalytic reporting)

Skill level II

Understand human resource systems (eg, recruitment, re performance measurement)

Financial skills

Skill level I

The fundamentals of financial data collection and financial statement analysis

The budgeting process for operational planning, managerial control

How to properly assign current procedural terminology

Skill level II

Assess the need for new laboratory instrumentation (eg, financial justification)

The nature and behavior of costs in the laboratory (eg, tax accounting)

The applicable forms of reimbursement for pathologists in clinical laboratories (eg, Medicare, managed care, health insurance)

How to monitor, effectively influence, and manage laboratory in a health care organization

Regulatory skills

Skill level I

The accrediting agencies relevant to laboratory certification and licensure

Participate in at least one CAP self-inspection event

The "test complexity" model of Clinical Laboratory Improvement Amendments (CLIA) (ie, high complexity, moderate complexity, waived, physician-performed microscopy)

Understand the compliance requirements for laboratories (eg, CLIA, the model compliance plan of the Office of the Inspector General)

Understand the patient privacy and electronic data security

How to use quality control principles (eg, delta checks) in detecting preanalytic, analytic, and postanalytic errors in the laboratory

The principles of postanalytic result processing and information delivery (ie, medical informatics)

Skill level II

The principles involved in the determination of test reference intervals

How to choose, use, and monitor the performance of reference laboratories

Adapted from Smith BR, Wells A, Alexander CB, et al. Curriculum content and evaluation of resident competency in clinical pathology (laboratory medicine). *Am J Clin Pathol* 2005;117:16-21.

Laboratory management curriculum in laboratory medicine training

- Organizational and leadership skills
- Financial skills
- Regulatory skills
- Quality assurance, quality control, pre- and postanalytic management

Current curriculum in laboratory management at the University of Utah

Box 3. Current curriculum in laboratory management at the University of Utah

Introduction to management principles

Human resources management

Financial management

Operations management

Quality, regulatory compliance, and risk management

Pathology practice characteristics and contracting

Political advocacy

Strategic planning

Business development

Marketing, advertising, and promotion

Outreach development

Sales management

Current curriculum in medical informatics at the University of Utah

Box 4. Current curriculum in medical informatics at the University of Utah

Overview and introduction to medical informatics

Excel spreadsheets

Statistical analysis

Sensitivity and specificity

Likelihood ratios

Assay comparison, linear regression, and nonlinearity

Reference intervals

Data-mining

Improving test ordering and interpretation

Cost-effectiveness analysis

Bioinformatics in clinical research Information technology security

Laboratory information systems

Laboratory information technology management

Image analysis

Public health reporting

Use of the internet (eg, PubMed, e-mail, social issues)

Hospital information systems and the electronic medical record

EC4 Syllabus for Laboratory Medicine

- Core knowledge, skills and competencies
 - I. Basic knowledge requirements
 - II. Indications for laboratory medicine procedures
 - III. Influence of collection and storage of specimens
 - IV. Analytical principles and techniques
 - V. Analytical evaluation of laboratory methods
 - VI. Clinical evaluation of laboratory methods
 - VII. Case-related medical evaluation of laboratory tests
 - VIII. Clinical training
 - IX. Research and development; audit
 - X. Laboratory management and quality assurance

Medical Biochemistry specialist training syllabus (Our Department)

Laboratory safety

General laboratory principles and techniques

Information technology

- Laboratory Information System (LIS)

- Hospital Information System (HIS)

Biochemistry in health and disease

Method development, validation and verification

Quality Management

- Internal quality control

- External quality assessment

- Proficiency schemes

Medical Biochemistry specialist training syllabus (Our Department)

Clinical laboratory management

- Pre-analytical processes

- Analytical processes

- Post-analytical processes

- Standard operation procedures

- Risk management

Skills

- Decision for analytical techniques

- Decision for instruments

- Data management

- Interpretation

- Outcome analysis

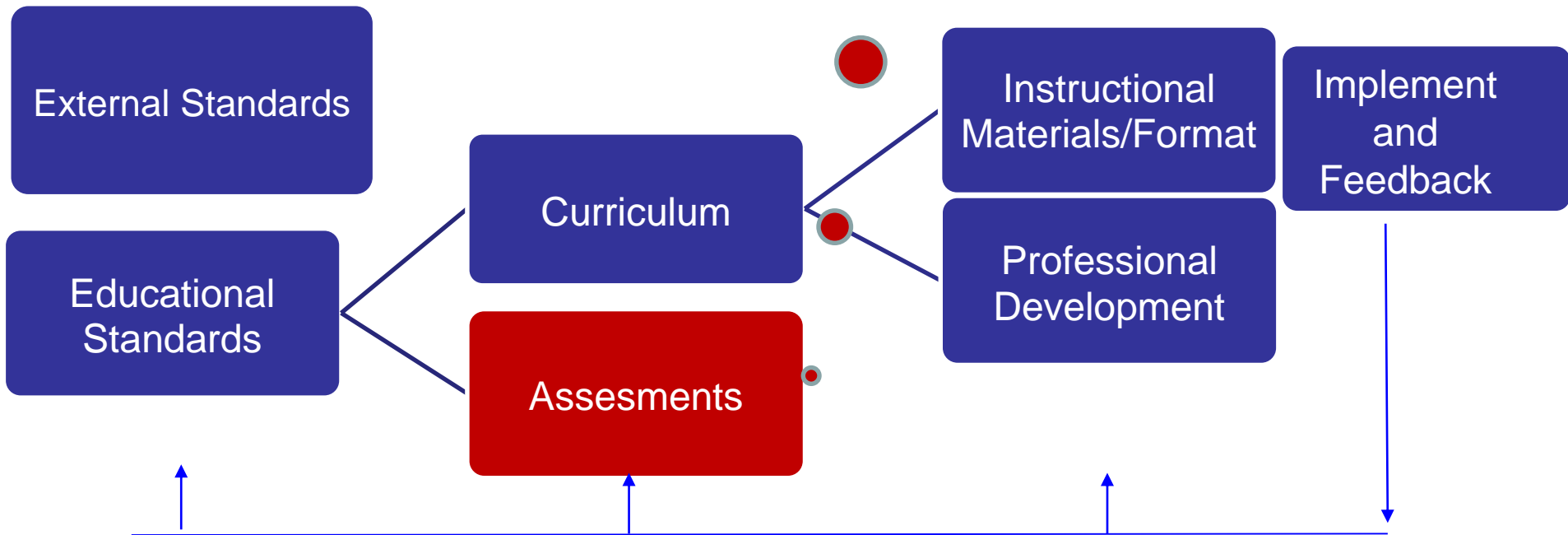
- Managerial skills

Medical Biochemistry Specialist Training Syllabus (Our Department)

- Communication skills
- Role in the hospital management
- Procurement
- Standardization, certification, accreditation
- Good clinical laboratory practices
- Evidence-based of laboratory medicine
- Teaching skills
- Organization of Meetings
- Research and development skills
- Lifelong learning

A Model of CBE

Define milestones along a development path for the competencies



Milestones

A milestone is a

behavioral descriptor that marks a level of performance for given competency

- The levels of milestones are defined based on the Miller's Pyramid

(derived from the ACGME Milestones Project)

Assessment in Competency-Based Education

Miller's pyramid

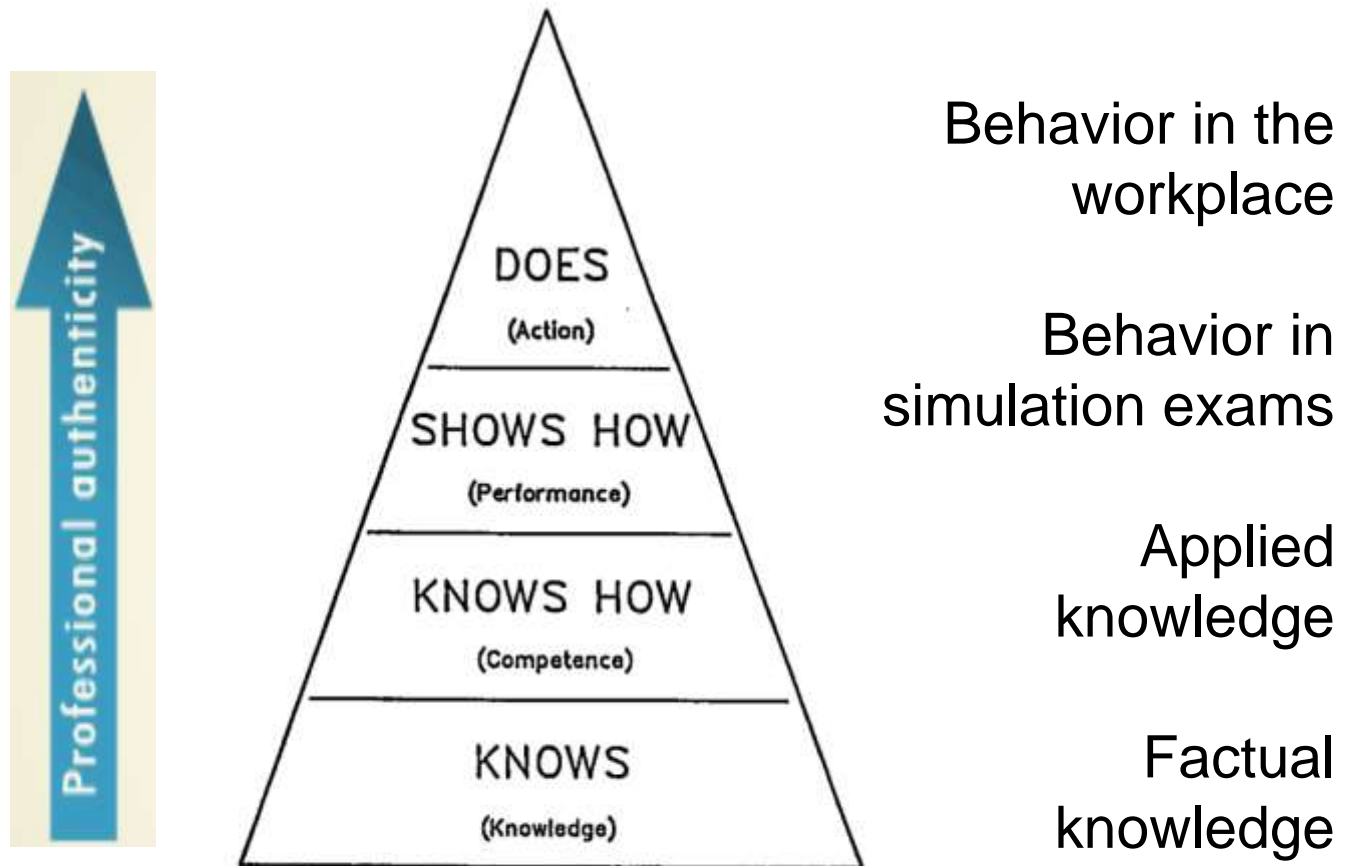


Figure 1. Framework for clinical assessment.

Milestones Levels

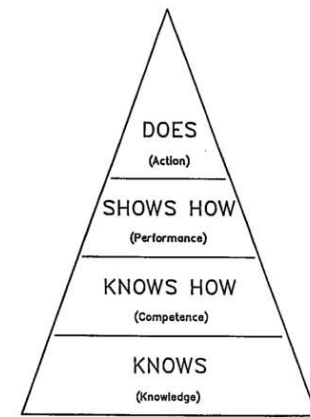


Figure 1. Framework for clinical assessment.

Level 1: **Novice: Don't know what they don't know** training fellow

Level 2: **Advanced beginner: Know what they don't know** but is not yet

Level 3: **Competent: Able to perform the tasks and roles of the milestone discipline – restricted breath and depth** fellowship.

Level 4: **Proficient: know what they know and don't know** demonstrates the milestones targeted for fellowship. This level is designed as the graduation target.

Level 5: **Expert: know what they know** performance targets set for fellowship and is demonstrating aspirational goals which might describe the performance of someone who has been in practice for several years. It is expected that only a few exceptional fellows will reach this level.

Pathology and Laboratory Medicine (USA) (2016)

Pathology

 Requests for Changes in Resident Complement

Program Requirements

 Currently In Effect

 Approved but not in Effect until 2016


Milestones

 Pathology

 Forensic Pathology

 Blood Banking/Transfusion Medicine

 Neuropathology

 Pediatric Pathology

 Hematology Pathology

 Medical Microbiology

 Chemical Pathology

 Cytopathology

 Molecular Genetic Pathology

 Dermatopathology

 Clinical Informatics

 Selective Pathology

<http://www.acgme.org/acgmeweb/tabid/142/ProgramandInstitutionalAccreditation/Hospital-BasedSpecialties/Pathology.aspx> (2016)

The Chemical Pathology Milestone Project

A Joint Initiative of

The Accreditation Council for Graduate Medical Education

and

The American Board of Pathology



Milestones Levels

Chemical Pathology Milestones Project

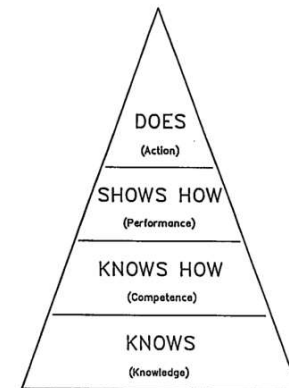


Figure 1. Framework for clinical assessment.

PC1 — Consultation				
Level 1	Level 2	Level 3	Level 4	Level 5
<p>Understands the role of the consultant in chemical pathology</p> <p>Observes and assists in the consultation</p> <p>Able to use the EMR and other electronic resources to obtain clinical and disease information</p>	<p>Performs clinically useful consultation in a timely manner</p> <p>Prepares full and complete consultative reports with faculty guidance</p>	<p>Effectively communicates consultative recommendations and action plans</p> <p>Develops a portfolio of consultations</p> <p>Independently prepares full and complete consultative reports</p>	<p>Effectively teaches consultation skills</p> <p>Competently and independently performs consultation during regular working hours and while on call</p>	<p>Proficient in chemical pathology consultations (including those involved in complex clinical scenarios)</p> <p>Proficient in consultation regarding complicated patient evaluations</p> <p>Demonstrates expertise at the level expected of a subspecialist in chemical pathology</p>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:				Not yet achieved Level 1 <input type="checkbox"/>

Selecting a response box in the middle of a level implies that milestones in that level and in lower levels have been substantially demonstrated.

Selecting a response box on the line in between levels indicates that milestones in lower levels have been substantially demonstrated as well as **some** milestones in the higher level(s).

Milestones

The CBD^{1,2} Competence Continuum

By introducing a competency-based medical education model to resident training and specialty practice, the CBD initiative will break down specialist education into a series of integrated stages — starting at transition to discipline and moving through practice. The CBD Competence Continuum provides a quick look at the new stages which begin upon entry into a discipline-specific residency following the attainment of the MD designation.

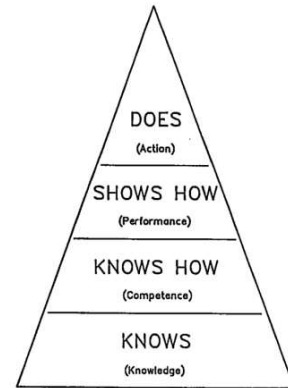


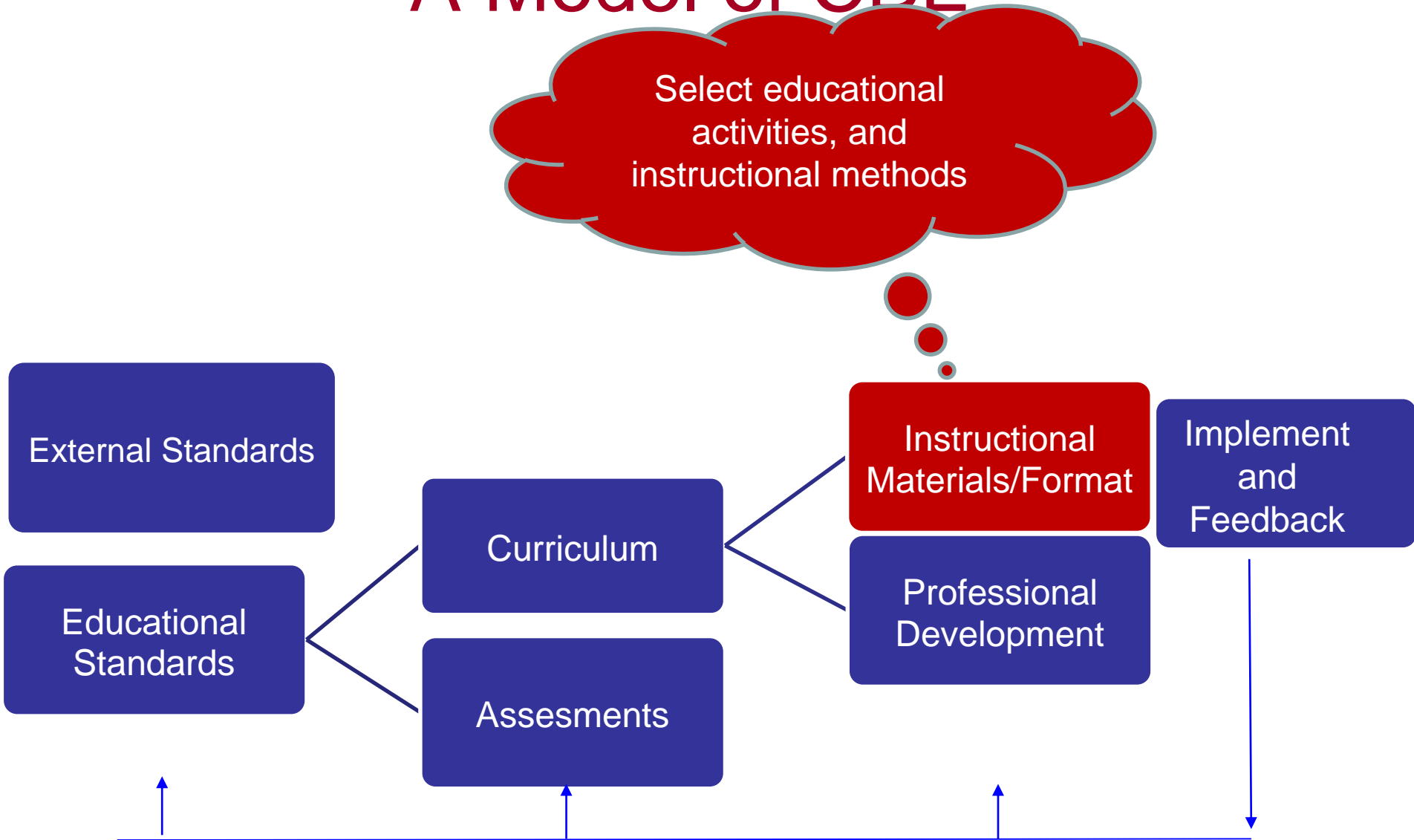
Figure 1. Framework for clinical assessment.



¹ Competence by Design (CBD)

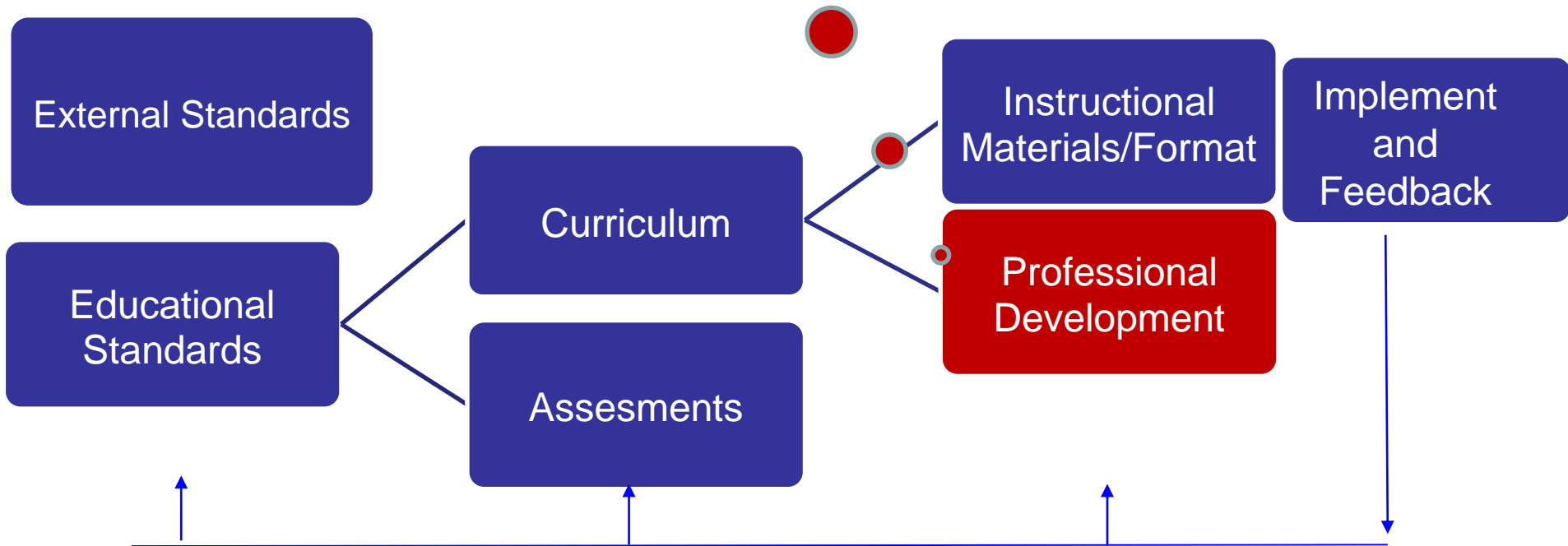
² Milestones at each stage describe terminal competencies

A Model of CBE



A Model of CBE

Select assessment tools
to measure progress
along the milestones



Decisions for level of supervision

Entrustable Professional Activities (EPAs)

The entrustable professional activity (EPA) concept allows faculty to make competency-based decisions on the level of supervision required by trainees.

Entrustable Professional Activities (EPAs)

«Core unit of professional work that can be identified as a task to be entrusted to a trainee once sufficient competence has been reached»

- EPAs are not an alternative for competencies, but a means to **translate competencies into clinical practice**
- Competencies are descriptors of **specialists**
- EPAs are descriptors of **work**

Entrustable Professional Activities (EPAs)

TABLE 2 GUIDELINES FOR FULL ENTRUSTABLE PROFESSIONAL ACTIVITIES DESCRIPTIONS

1. Title	Make it short; avoid words related to proficiency or skill. Ask yourself: Can a trainee be scheduled to do this? Can an entrustment decision for unsupervised practice for this EPA be made and documented?
2. Description	To enhance universal clarity, include everything necessary to specify the following: What is included? What limitations apply? Limit the description to the actual activity. Avoid justifications of why the EPA
3. Required Knowledge, Skills, and Attitudes (KSAs)	
4. Required KSAs	
5. Information to assess progress	
6. When is unsupervised practice expected?	
7. Basis for formal entrustment decisions	

➤ Which competency domains?

Milestones

Required Knowledge, skills, attitudes

Syllabus-Curriculum

Standards, Books, Legislations

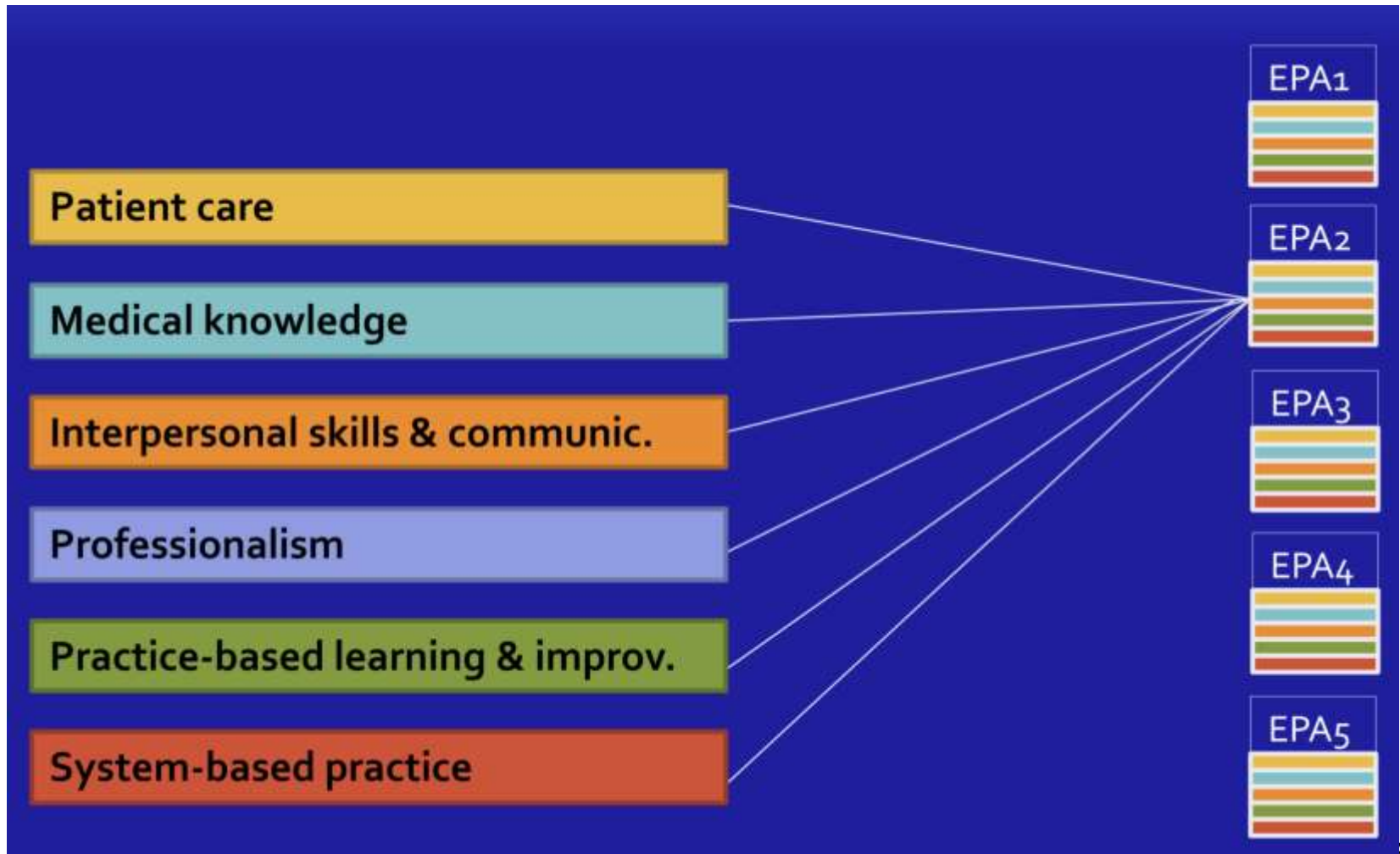
EPAs usually require multiple competencies in an integrative, holistic nature.

	EPA1	EPA2	EPA3	EPA4	EPA5
Patient care	++	++		+	++
Medical knowledge	+	+	++	+	
Interpersonal skills & communic.	++	++	++		+
Professionalism	++	+	+	++	+
Practice-based learning & improv.	+	++		++	+
System-based practice		++	+		++

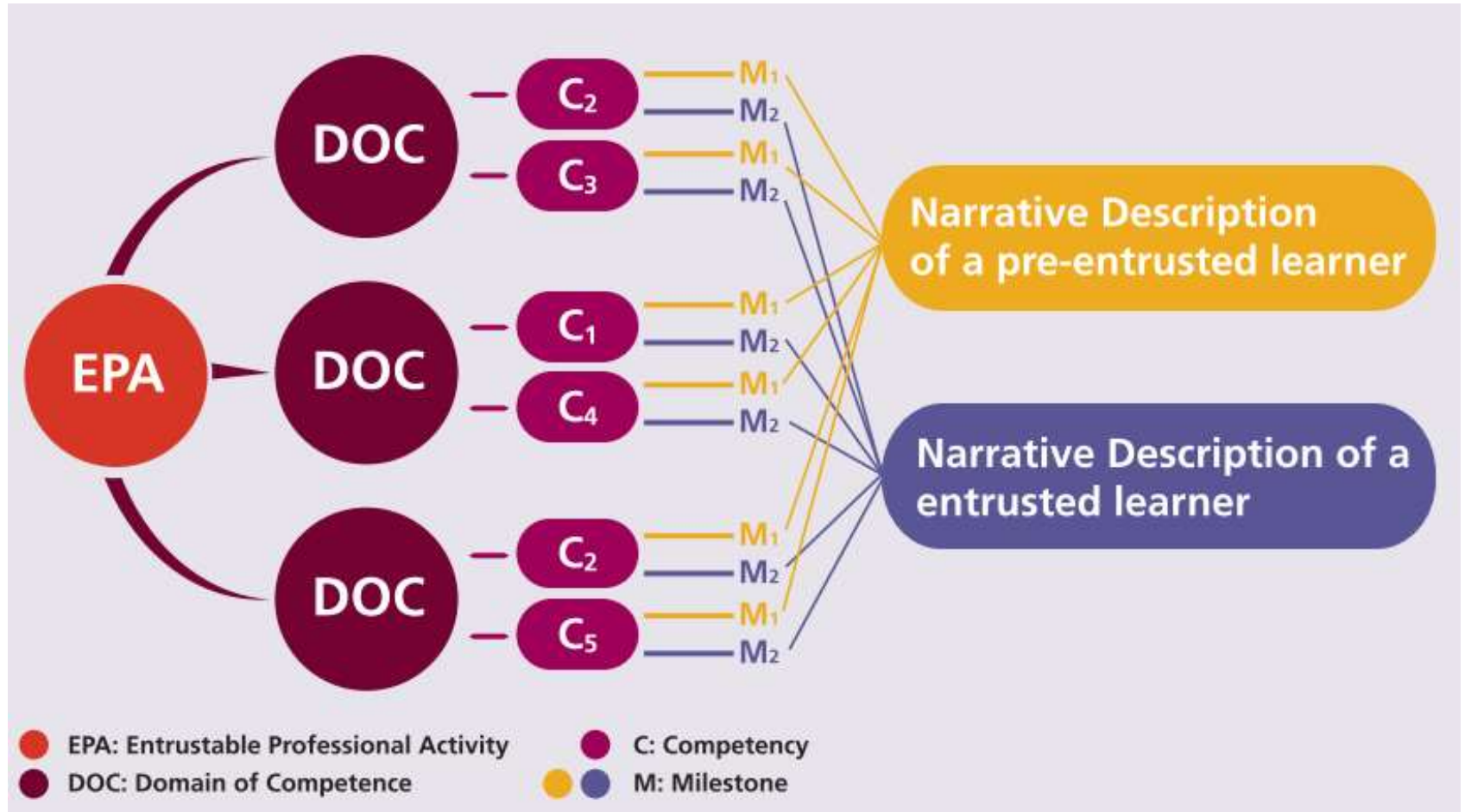
Assessment based on EPAs

competencies inferred

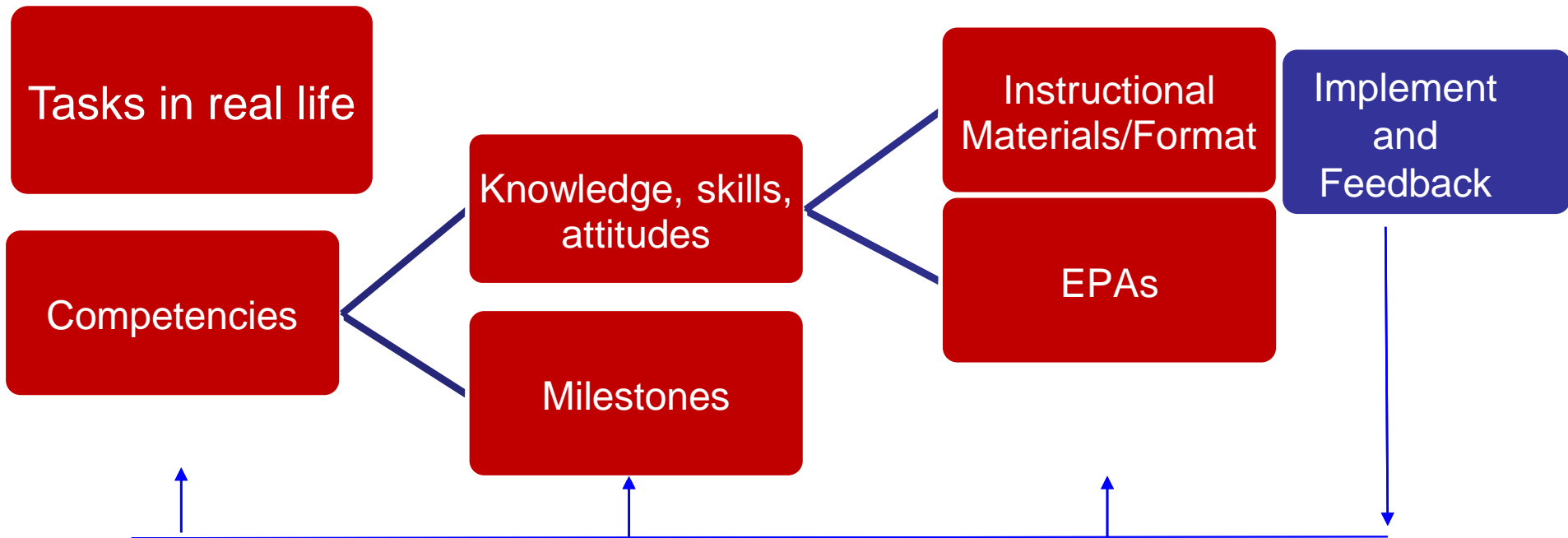
EPAs require proficiency in several competency domains



EPA, Competency and Milestones



Linking EPAs to competencies

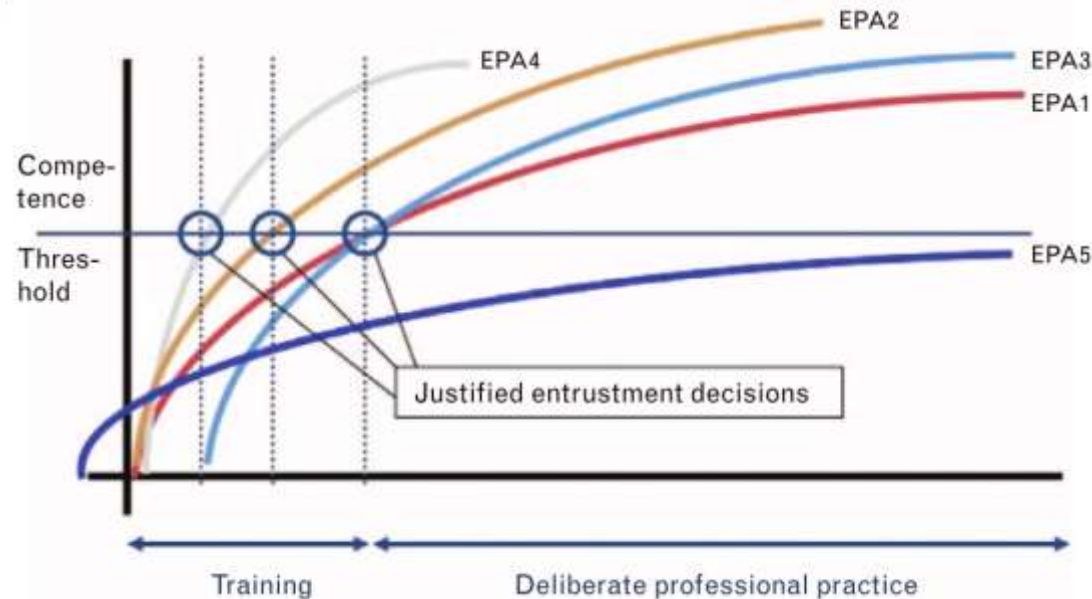


Competences; Milestones and Entrustable Professional Activities (EPAs)

Growth of competence over time



Competency curves of one trainee



7-item format of EPA description

1	Title of the EPA
2	Specification and limitations
3	Most relevant domains of competence
4	Required experience, knowledge, skills, attitude and behavior for entrustment
5	Assessment information sources to assess progress and ground a summative entrustment decision
6	Entrustment for which level of supervision is to be reached at which stage of training?
7	Expiration date

Example EPA description

1	Verification of the new analyte
2	Includes: perform verification experiments, estimate of related measures, decide if it complies the requirements
3	X QMS X Patient care X Medical Knowledge X Communicator
4	Knowledge: basic knowledge of laboratory statistics, analytical and clinical performance characteristics; which guidelines used ... Skill: skill in using necessary laboratory devices to perform verification experiments; computer skills and related statistical analysis; searching best evidence ... Attitude and behavior: professional communication with the clinician, and related IVD vendor ... Experience: done at least 5 times
5	Literature presentation; case-based discussions; real life experiments
6	Supervision Level: Level 4 proficiency level
7	Expiration: optional

To empowerment of laboratory medicine specialists

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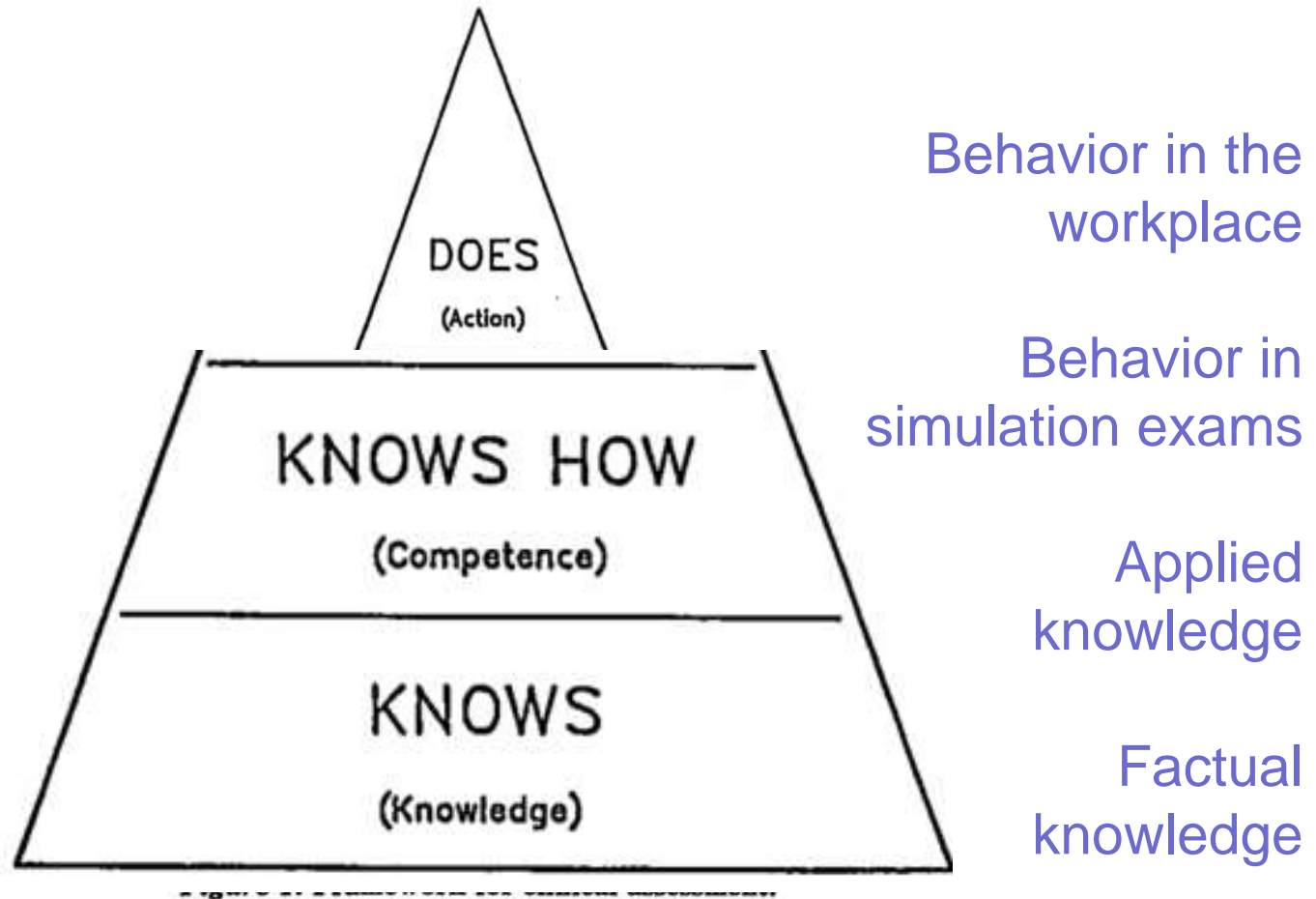
- IFCC
- National societies
- National board exams
- IFCC: Worldwide assessment models
 - Tests or exams in digital media

A consensus curriculum for laboratory management training for pathology residents

Ten **The most common** **Management Topics Covered**

Topic	% of Programs
Quality assurance	51
Laboratory inspections	51
Regulatory affairs and accreditation	48
Test validation	43
Billing and compliance	40
Risk management	37
Test cost assessment	37
Capital equipment purchasing	37
Financial management and accounting	34
Leadership and management	32

Exams can be for



- National board exams
- IFCC: Worldwide assessment model

Worldwide standardized education and training in clinical chemistry and laboratory medicine

- challenging
- can be improved or harmonized by establishing an assessment modules based on the first two proficiency steps of the Miller's Pyramid
- competency-based education approach

Thank you very much for your attention
Greetings from Pamukkale/Denizli

