JCTLM WORKSHOP
SCIENTIFIC WORK & WORKING GROUPS

ESSENTIALS & BASICS

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Friedrich II “ der Große”
(1712 – 1786)

“ Jedermann kann auf seiner façon selig werden “
ESSENTIALS & BASICS (1)

- Contribution to the Health system
- Follow existing Standards i.e. ISO and CEN

Presentation of Reference Measurement Procedures (EN 12286/ ISO 15193)

Description of Reference Materials (EN 12287 / ISO 15194)

Metrological traceability of values assigned to calibrators and control materials (EN/ISO 17511)

Metrol. traceability catalytic concentration of enzymes (EN/ISO 18153)

Requirements for Reference Measurement Laboratories (ISO 15195)
Particular requirements for quality and competence (ISO 15189.2)
ESSENTIALS & BASICS (2)

• Within the existing work of Medical Laboratory:

Select work items on the basis of priorities of **diseases**

Consultation with Medical Professional Community?
ESSENTIALS & BASICS (3)

• In Laboratory Medicine some 600 to 800 ( > 1000) quantities/substances examined, i.e. measured or determined
The results of examination for only some 100 quantities are traceable to SI ("type A") quantities are well-defined / homogeneous measurands are in many cases well-defined for example: electrolytes / metabolic products / steroids/thyroid hormones etc.
• The results of examination for a large group (~600) are *not traceable* to SI, but to arbitrary units e.g. WHO IUs (“type B”)
  - the substances are heterogeneous (glycosylation and peptide/protein heterogeneity)
  - the substances in RMs are often well characterised
  BUT: the measurand in virtually all cases is unknown
  - discrepancy between component(s) in RM and measurand
ESSENTIALS & BASICS (6)

- Virtually all RMs of these ("type B") substances are surrogates for the measurand

- RMPs: rigorously distinguish between measurements based \textit{activity} (functional; end-point: target product or enzymatic cascade) and \textit{reactivity} (structural; binding or no binding)
Priority Setting (1)

- Within the existing arsenal of parameters examined by the medical laboratory:

Classify the diseases perceived to be the most important ones (global/regional)
Consider: prevalence – incidence – morbidity – mortality
Priority Setting (2)

• Determine the *test menu* of all measurands for each prioritised disease, including routine clinical chemistry, liver function tests etc.

• Consider the purpose of diagnosis and/or monitoring of therapeutic measures
Availability RM and RMPs (1)

- List of top-priority measurands menus based on top-priority diseases

- For each and every measurand, consider definition of the component(s), for “type A” as well as for “type B” (metrological requirement)
Availability RMs and RMPs (2) “Type A”

- Listing of available RM and RMPs
- Compare with prioritised menus of measurands
- Perform gap-analysis
- Fitness-for-purpose?
- Pure RM necessary for metrological purposes?

- Matrix RM necessary, including commutability?
- Value assignment to matrix RM: which RMP? Metrological/clinical criteria?
- Uncertainty according to GUM?
- Prepare list of work items for “type A” measurands; ranking
Availability RM and RMPs (3) “Type B”

- **Surrogates** acceptable? Analytically and clinically?
- Properties of available RM? Measurand defined? Analytical and diagnostic/monitoring aspects?
- Clarification of Traceability chain

- Value assignment? Activity or reactivity procedure?
- RMP available? Candidate for International conventional RMP?
- Need for matrix RM? Commutability/transferability
Availability RM[s and RMPs (4) “Type B”

- Uncertainty according to GUM
- ranking

- Prepare list of work items for “type B” measurands
Networks

- Credentialing applicant laboratories:
- Compliance with ISO 15195 (or ISO 17025)? Accreditation required?
- Competence and capability
- Participation in International Key Comparisons under the aegis of CIPM
- Participation in IFCC networks
- Personal, proven expert and expertise
WORKING GROUPS

Proposal #1
- WG priority-setting
- WG availability
- RMs, RMPs, and RMLs
- WG reference systems for “type A”
- WG reference systems for “type B”
- WG networks – expert labs

Proposal #2
- WG priority-setting + availability
- RMs, RMPs, and RMLs + reference systems for “type A” + reference systems for “type B”
- WG networks – expert labs