

JCTLM WORKSHOP

SCIENTIFIC WORK & WORKING GROUPS

ESSENTIALS & BASICS

Rudolf M. LEQUIN

**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

ESSENTIALS & BASICS (4)

- 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.

ESSENTIALS & BASICS (5)

- 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 activity (functional; end-point: target product or enzymatic cascade) and 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 RMs 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 RMs and RMPs
 - Compare with prioritised menus of measurands
 - Perform *gap-analysis*
 - *Fitness-for-purpose?* analytical/diagnostic
 - Pure RMs necessary for metrological purposes?
- Matrix RMs 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 RMs and RMPs (3)

“Type B”

- **Surrogates** acceptable?
Analytically and clinically?
- Properties of available RMs? 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 RMs 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