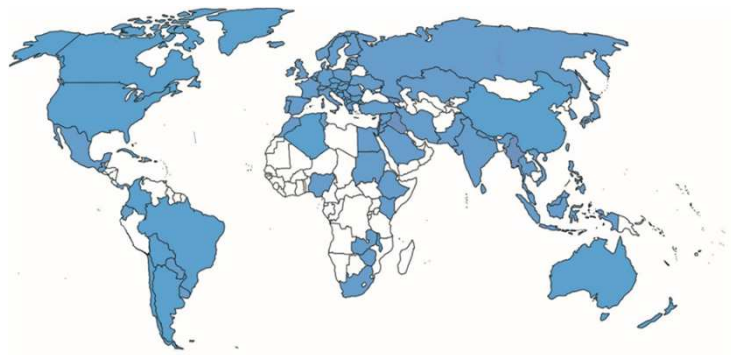


Need for metrology to support standardization activities of the IFCC Scientific Division

Philippe Gillery, MD, PhD
University Hospital of Reims, France
Chair, IFCC - Scientific Division



IFCC : International Federation of Clinical Chemistry and Laboratory Medicine



45,000 Laboratory specialists
93 Full members & 17 Affiliates

www.ifcc.org

The IFCC is a worldwide, non-political organization for Clinical Chemistry and Laboratory Medicine. Among its aims:

- 1. Establishing global standard setting in collaboration with other international organizations;**
2. Supporting its members through scientific and educational endeavour;
3. Providing a series of congresses, conferences and focused meetings in order for laboratory medicine specialists to meet and present original findings and best practice.

Challenges for Healthcare Delivery

- Increasing patient expectations
- Growing rates of chronic diseases
- Ageing of the population
- Increasing costs of medical advances
- Limited growth of healthcare budgets



IFCC : Worldwide approaches

Quality clinical laboratory practice to meet clinical requirements

- Uniformity of optimal medical practice is key to financially sustainable healthcare systems
- **Accurate or comparable laboratory results** allow clinicians to follow international practice guidelines on the basis of the same data from which they were derived

IFCC - Scientific Division (SD) : Missions

To advance the science of Clinical Chemistry and to apply it to the practice of Clinical Laboratory Medicine

- By **identifying technical innovations** and diagnostic strategies and assisting the transfer of these to the profession
- By promoting the **standardization of laboratory tests** and the **comparability of patient results** through the **development of reference measurement systems**, or **harmonization activities where this is not currently possible**
- By **establishing standards** for scientific and technical aspects of **good laboratory practice**



Reference Measurement Procedures and Materials



7 IFCC-SD Committees (Theme-oriented)

- Nomenclature, Properties and Units (C-NPU) in collaboration with International Union of Pure and Applied Chemistry (IUPAC) Y.B.L. Hansen (DK)
- Molecular Diagnostics (C-MD) P. Ahmad-Nejad (DE)
- Traceability in Laboratory Medicine (C-TLM) A. Kessler (DE)
- Reference Intervals and Decision Limits (C-RIDL) Y. Ozarda (TR)
- **Standardization of Thyroid Function Tests (C-STFT)** H. Vesper (US)
- **Harmonization of Autoimmune Tests (C-HAT)** J. Sheldon (UK)
- Bone Metabolism (C-BM) E. Cavalier (BE)

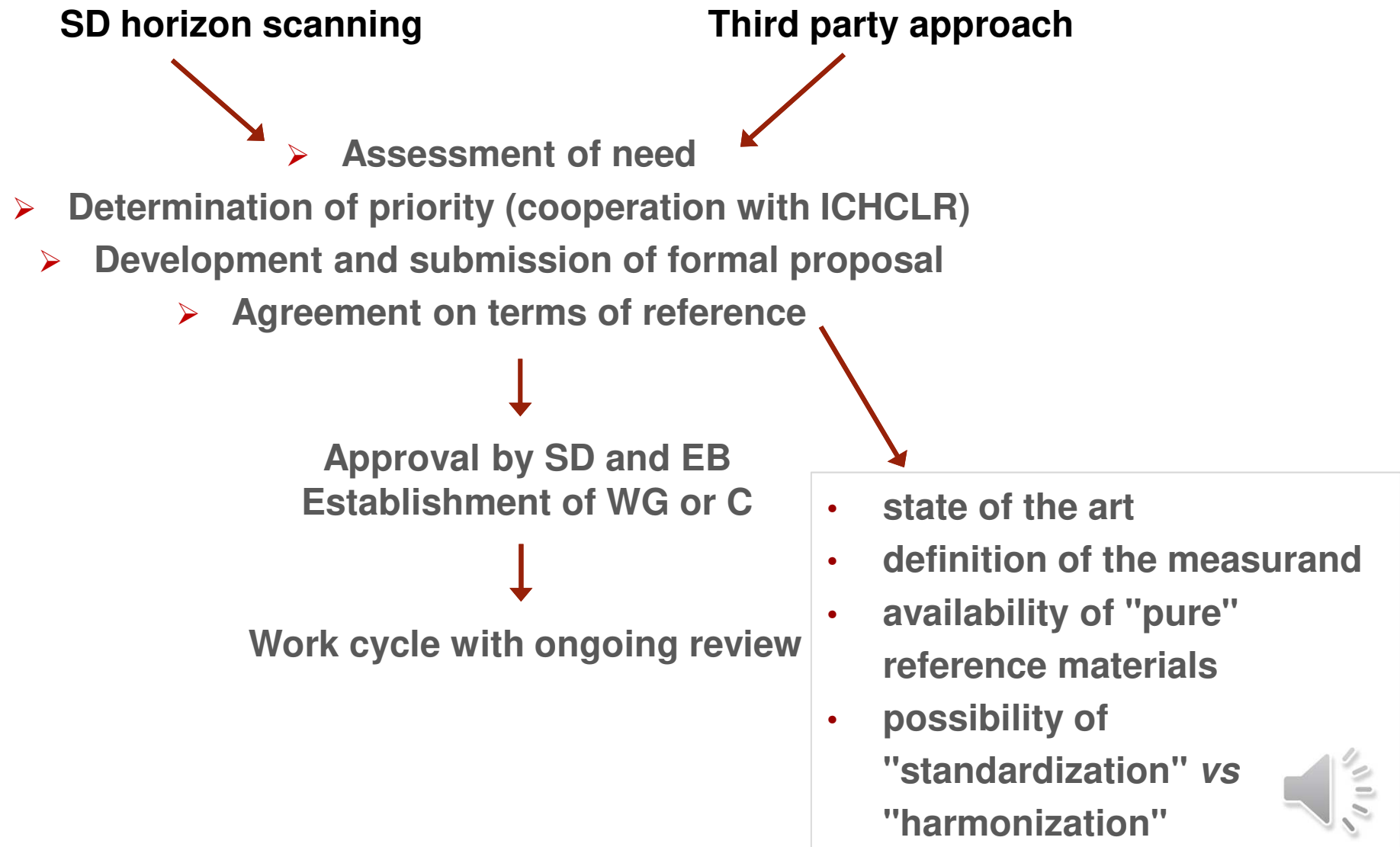


17 IFCC-SD Working Groups (Task oriented)

- **Standardisation of Haemoglobin A2 (WG-HbA₂)** A. Mosca (IT)
- **Standardisation of Carbohydrate-Deficient Transferrin (WG-CDT)** J. Deenmamode (UK)
- Standardisation of Albumin Assay in Urine (WG-SAU) in collaboration with NKEDP J. Seegmiller (US)
- Standardisation of Pregnancy-Associated Plasma Protein A (WG-PAPP A) S. Wittfooth (FI)
- Growth Hormone (WG-hGH) M. Vos (NL)
- Standardisation of Insulin Assays (WG-SIA) in collaboration with ADA/EASD M. Steffes (US) & J. Seegmiller (US)
- Standardisation of Troponin I (WG-TNI) R. Christenson (US)
- CSF Proteins (WG-CSF) J. Gobom (SE)
- Commutability in Metrological Traceability (WG-CMT) G. Miller (US)
- Immunosuppressive drugs (WG-ID) C. Seger (CH)
- **Apolipoproteins by mass spectrometry (WG-APO MS)** C. Cobbaert (NL)
- Pancreatic enzymes (WG-PE) D. Grote-Koska (DE)
- Fecal Immunochemical Testing (WG-FIT) S. Benton (UK)
- Cell free DNA and related biomarkers (WG-cfDNA) R. van Schaik (NL)
- Standardization of Procalcitonin assays (WG-PCT) V. Delatour (FR)
- Continuous Glucose Monitoring (WG-CGM) G. Freckmann (DE)
- Development of a Reference Measurement System for sustainable PT/INR Standardization C. Cobbaert (NL)



Main drivers for setting up of a SD working party ?



Specificity of Metrology in Laboratory Medicine

2 pillars

- Use of methods traceable to highest order RMPs : **Best quality**
- Interest of patient : **Our reason to live**

NOT JUST "METROLOGY FOR METROLOGY" !

**Efforts in fields
unrelated to patient
care are useless !**

When full metrological
standardization schemes cannot
be established **another solution
must be considered**
(*e.g.* harmonization)

Necessity of **close
collaboration** between
Metrology and Laboratory
Medicine



To standardize (or to harmonize)

- Many assays have been standardized (or harmonized) in the last decades
 - ✓ Simple parameters : glucose, creatinine, cholesterol
 - ✓ Enzymes
 - ✓ Peptides, hormones, proteins :
 - TSH (IFCC-C-STFT)
 - FT4 (IFCC-C-STFT)
 - CDT (IFCC-WG-CDT)

But the number of medical tests requiring standardization or harmonization remains enormous !

Clin Chem Lab Med 2018; 56(10): 1598–1602

DE GRUYTER

Opinion Paper

Christa Cobbaert*, Nico Smit and Philippe Gillery

**Metrological traceability and harmonization of medical tests:
a quantum leap forward is needed to keep pace with globalization
and stringent IVD-regulations in the 21st century!**

<https://doi.org/10.1515/cclm-2018-0343>

Received April 4, 2018; accepted April 5, 2018; previously published
online May 7, 2018



Standardization / Harmonization of tests : a challenge !

- A process involving **many stakeholders** with **different objectives and cultures**
- A process revisiting old procedures, establishing reference methods / materials, and implementing the new procedures
- A process potentially leading to changes
 - ✓ in obtained values, result expression and reporting
 - ✓ in manufacturers' procedures
- A process **with potential (sometimes unexpected) consequences**
 - ✓ at the **clinical level** (change of units / decision limits)
 - ✓ at the **manufacturers' level** (difficulties to set up new traceability chains, to comply with regulations)



Risk of non practical application !



What is needed for a successful standardization ?

- A rationale in public health
- A controlled scheme of standardization
- **A unified approach (laboratory professionals and manufacturers, at the least)**
- A sustainable standardization system (networks of reference laboratories)
- A successful implementation in routine laboratory medicine and clinical practice, involving **all partners, not only lab med people and metrologists !**



- Clinicians
- Scientific societies



- Patients



- Academic laboratories
- Clinical laboratories
- NMIs
- IFCC



- Manufacturers
- EQA providers



- Ministries
- Health regulators

Stakeholders involved in standardization



Interactions of IFCC with NMIs

- IFCC believes that **a global approach** is necessary involving :
 - ✓ Partners directly involved in standardization (BIPM, NMIs, WHO)
 - ✓ Regulators
 - ✓ Professional / Scientific Societies and Academies
 - ✓ Individual Laboratory Professionals
- Current situation :
 - ✓ Involvement of NMIs in some Cs / WGs
 - ✓ WGs chaired by NMI scientists (e.g. WG-PCT)
 - ✓ Attempt of coordination between SD Cs / WGs and NMI projects
 - ✓ **MoU signed between IFCC and BIPM in 2020**
- Near future :
 - ✓ More systematic involvement of NMIs in review / management of projects



IFCC-SD Executive Committee

Name	Position	Country	Term	Time in Office
P. Gillery	Chair	FR	2nd	2020 01 - 2022 12
C.M. Cobbaert	Vice-Chair	NL	2nd	2020 01 - 2022 12
G. John	Secretary	UK	1st	2021 03 - 2023 12
B. Das	Member	IN	2nd	2021 01 - 2023 12
K. Makris	Member	GR	2nd	2020 01 - 2022 12
M. Plebani	Member	IT	2nd	2020 01 - 2022 12
M. Rottmann	Corporate Member	DE	1st	2020 03 - 2022 12
R.D. Josephs	BIPM Observer	FR		
L. Deprez	European Commission/JRC Observer	BE		
I. Young	ICHCLR Observer	UK		
G. Miller	JCTLM Chair / SD Consultant	US		
C. Burns	NIBSC Consultant	UK		
Y. Zhen	NIFDC Observer	CN		
K. Phinney	NIST Consultant	US		



Major messages

- **Need for metrological traceability in Laboratory Medicine :**

↳ **Thus Metrologists** must be involved
but they cannot work alone in the field of Lab Med

↳ Clinical aspects must be brought by **Health Professionals**
..... **who need** metrological expertise

- **Necessity to involve all stakeholders in order to overcome all problems**
- A major concern : **Regulations** around the world

↳ **A forthcoming workshop in your agenda**





JCTLM Members and Stakeholders biennial meeting and workshop

Overcoming challenges to global standardization of clinical laboratory testing: reference materials and regulations

A workshop organized by the IFCC Scientific Division, the International Consortium for Harmonization of Clinical Laboratory Results (ICHCLR) and the Joint Committee for Traceability in Laboratory Medicine (JCTLM)

Dates: 6-10 December 2021

Location: Virtual sessions

Format: Two 2-hour discussion sessions on three separate topics with a final combined session to develop workshop recommendations

Workshop goals:

The workshop will develop and publish recommendations how the laboratory medicine community can address challenges related to reference materials and to country and region specific regulations to more effectively achieve standardized results on a global basis.

Organizing committee: Philippe Gillery, Christa Cobbaert, Greg Miller, Gary Myers, Joe Passarelli, Robert Wielgosz, Ian Young, Elvar Theodorsson





JCTLM Members and Stakeholders biennial meeting and workshop

Overcoming challenges to global standardization of clinical laboratory testing: reference materials and regulations

Session 1: What are the needs and logistical challenges for standardized results?

Session 2: What are the challenges for CRM producers?

Session 3: What are the challenges to meet regulatory requirements in different countries or regions?

Session 4: Develop workshop recommendations for publication and follow up actions

<https://www.bipm.org/en/committees/jc/jctlm/wg/jctlm/2021-12-06>



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Editorial

IFCC Scientific Division: A conductor of standardization in laboratory medicine



The standardization adventure is still in progress !

Thank you !

