IFCC-SCIENTIFIC DIVISION PROJECTS

Pr Philippe GILLERY, MD, PhD
IFCC - Scientific Division Chair

University Hospital and Faculty of Medicine
(UMR CNRS / URCA n°7369)
Reims, France

JCTLM Workshop 2019: Accurate results for patient care
A JCTLM Members' and Stakeholders' Meeting
2nd - 3rd December 2019

ifcc
International Federation of Clinical Chemistry and Laboratory Medicine

IFCC-SD Missions

- **Main mission** : to advance the science of Clinical Chemistry and to apply it to the practice of Clinical Laboratory Medicine
- **Goals :**
  - To develop **reference measurement procedures**
  - To develop **reference materials**
    - ➡ To promote standardization or harmonization of laboratory tests and to improve interpretation of results on **a global basis** (establishment of standards for scientific and technical aspects of good laboratory practice)

IFCC-SD Executive Committee

Name	Position	Country	Term	Time in Office
P. Gillery	Chair	FR	1st	2017 01 - 2019 12
C.M. Cobbaert	Vice-Chair	NL	1st	2017 01 - 2019 12
J. Passarelli	Secretary	US	2nd	2018 01 - 2020 12
B. Das	Member	IN	1st	2018 02 - 2020 12
K. Makris	Member	GR	1st	2017 01 - 2019 12
M. Plebani	Member	IT	1st	2017 02 - 2019 12
J.F. Pierson-Perry	Corporate Member	US	2nd	2018 02 - 2020 12
G. Miller	ICHCLR Observer	US		
I. Young	JCTLM Chair / SD Consultant	UK		
H. Schimmel	JRC Observer	BE		
To be nominated	NIFDC Observer	CN		
C. Burns	NISBC Consultant	UK		
K. Phinney	NIST Consultant	US		

IFCC-SD EXECUTIVE COMMITTEE

Milano, October 2019

7 Committees (theme-oriented)

➢ Nomenclature, Properties and Units (C-NPU) in collaboration with International Union of Pure and Applied Chemistry (IUPAC)	K. Toska (NO)
➢ 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)

16 Working Groups (task-oriented)

Standardization of Haemoglobin A2 (WG-HbA2)	A. Mosca (IT)
Standardization of Carbohydrate-Deficient Transferrin (WG-CDT)	J. Deenmamode (UK)
Standardization of Albumin Assay in Urine (WG-SAU) in collaboration with NKEDP	L. Bachmann(US)
Standardization of Pregnancy-Associated Plasma Protein A (WG-PAPP A)	S. Wittfooth (FI)
Growth Hormone (WG-GH)	E. Lentjes (NL)
Standardization of Insulin Assays (WG-SIA) in collaboration with ADA/EASD	A. Saenger (US)
Standardization of Troponin I (WG-TNI)	R. Christenson (US)
CSF Proteins (WG-CSF)	J. Gobom (SE)
Commutability (WG-C)	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)

IFCC-SD : projects and perspectives

Basis = Strategic plan 2017 - 2019

1. Keep and amplify the high level of involvement of IFCC-SD in the field of standardization / harmonization

2. Keep and amplify the visibility of IFCC scientific activities inside and outside IFCC

3. Prepare the future

Keep and amplify the high level of involvement of IFCC-SD in the field of standardization / harmonization

- **Standardization or harmonization**
  - **Continuation and/or completion of ongoing projects on defined measurands** : see for example the presentation of A. Mosca (WG-HbA2)
  - **Establishment of recommendations regarding metrological traceability** (WG on Commutability - Chair : G. Miller)
- **Picking up measurement priorities :**

  Close cooperation with **ICHCLR** :
  - an ICHCLR observer in SD (G. Miller)
  - SD-Chair member of ICHCLR HOG
- **Identification of new areas of Laboratory Medicine**

  (e.g. Immunology, Pharmacology, Hematology and Haemostasis - see presentation of C. Cobbaert)

Some examples

IFCC-SD : Thematic refocusing

Committee on Bone Metabolism (C-BM)

Chair : E. Cavalier (BE)

- **2019 : Establishment of Committee on "Bone Metabolism" (C-BM), formed by the joining of the already existing Working Groups:**
  - Standardization of Bone Markers Assays (WG-BMA) in collaboration with IOF
  - Parathyroid Hormone (WG-PTH)
  - Vitamin D Standardization Program (WG-Vit D)Terms of Reference

- **Terms of Reference**
  - Standardize PTH assays
  - Standardize or harmonize bone markers assays
  - Standardize vitamin D metabolites assays

IFCC-SD : News topics - Pharmacology

Working group on Immunosuppressive Drugs (WG-ID)

Chair : C. Seger (CH) - established in 2018

- **Terms of Reference**
  - Establishment of **candidate reference procedures and reference materials** for immunosuppressive drugs
  - Definition of the the **need for harmonization or – if feasible – standardization** of measurement services
- **Current projects**
  - Establish and communicate the regulatory framework
  - Measurement comparison aimed to assess the state of art
  - Production of reference materials and establishment of reference methods to be listed in the JCTLM database

IFCC-SD : New topics - Cancer

Working group on Fecal Immunochemical Testing (WG-FIT)

Chair : S. Benton (UK) - established in 2017

- **Terms of Reference**
  - To harmonise and/or standardise **analysis of haemoglobin in faecal samples by immunochemistry (FIT)**, including pre-analytical phase
  - To establish **EQA** and 3rd party **IQC** programmes
  - To determine impact of **assay interference of Hb variants** and other factors
  - To determine the **feasibility** of developing reference materials and/or commutable calibrators

- **Current projects**
  - Identification of a suitable reference material and assessment of commutability for all available laboratory quantitative FIT methods
  - Review of all FIT EQA programmes currently available globally

IFCC-SD : New topics - Proteomics

Working group on Apolipoproteins by Mass Spectrometry (WG-APOMS)

Chair : C. Cobbaert (NL) - established in 2017

- **Terms of Reference**
  - To achieve **standardization of a panel of clinically relevant serum apolipoproteins** (apo) A-I, B, C-I, C-II, C-III, E and apo (a) with traceability to SI
  - To evaluate clinical performance and clinical utility of such panel(s)
- **Current projects**
  - Define the **analytes / measurands** intended to be measured
  - Development of **primary and secondary reference materials**, including evaluation of commutability (to be JCTLM listed)
  - Development of an **LC-MS/MS-based reference method**
  - Assessment of the **performance of commercially available** apolipoprotein assays
- **Future Projects**
  - Evaluation of **clinical performance and utility** of the multiplexed apolipoprotein test (**EFLM** working group on Test Evaluation Criteria)

IFCC-SD : New topics - Inflammatory markers

Working group on Standardization of Procalcitonin Assays (WG-PCT)

Chair : V. Delatour (FR) - established in 2018

- **Terms of Reference**
  - Develop and validate a **reference measurement procedure** for PCT absolute quantification by ID-MS
  - Document and understand the **variability of results** provided by the different commercially available PCT assays
  - **Evaluate** the **need for standardization of PCT assays and its feasability**
  - **Perform** standardization of PCT assays, if needed and feasible.

- **Current projects**
  - Production of **commutable EQA** materials designed to assess comparability of commercially available PCT assays
  - Production and characterization of **candidate primary calibrators**
  - Development of a **candidate reference method** for absolute quantification of PCT by IDMS

A new area : metrological traceability of medical devices

- **Working group on Continuous Glucose Monitoring (WG-CGM)** Chair : Dr Guido Freckmann (DE)
- CGM devices used for monitoring "blood glucose" on a continual basis (data obtained from a small electrode under the skin transmitted to a receiver)
- CGM systems are more and more often used by patients with diabetes : immediate and permanent information (contrary to blood markers)
- **Time in Range (TiR)** : absolute time (or percentage of time) a person with diabetes spends in certain pre-defined concentration ranges : **new "biomarker" of glycemic control ?**

CGM : facts and challenges

- Measurement of glucose concentration in **interstitial fluid** ➡
  Use of smart **algorithms** to predict the actual blood concentration

- No standards or established metrics to describe accuracy of CGM systems.
  CGM values cannot easily be traced to higher order materials of methods (measurement in interstitial fluid)

- Successful application of TiR : glucose concentration measured by CGM are treacable and different CGM systems provide comparable results for TiR

WG-CGM (established in july 2019)

- **Terms of Reference**
  - Establish **traceability** of glucose values obtained by CGM to materials and methods of higher metrological order,
  - Establish **metrics** for the evaluation of the analytical performance of CGM,
  - Work with ISO on a **new CGM guideline** (analogous to ISO 15197) to establish standardized procedures and acceptance criteria for CGM.

- **Current projects** (July 2019)
  - Propose **means suitable for establishing the traceability of** glucose values obtained by CGM to materials and methods of higher metrological order according to ISO 17511, including definition of **adequate compartment(s)** for reference samples (capillary, venous),
  - Find **procedures suitable** for assessment of **analytical performance** of CGM systems,
  - **Define metrics and corresponding minimum acceptance criteria** for the analytical performance of CGM systems.

Keep and amplify the visibility of IFCC scientific activities outside IFCC

- **Reinforced relations with partners involved in standardization** : BIPM and NMIs, manufacturers, clinical societies, other scientific societies

A major goal : Why ?

- Successes in standardization : **but** :
  - How many tests ? Relatively few
  - How many have still to be standardized / harmonized ? Many !
  - **How many tests are actually standardized in clinical practice ?**

    Few of them, even though IFCC reference methods and materials have been established or produced

There are obstacles / barriers / pitfalls in standardization

- **Standardization is not only a technical issue for specialists and involves many stakeholders involved in different fields**
  - Analytical aspects and prioritization
  - Scientific concepts / clinical attitudes
  - Economical aspects / commercial strategies
  - Regulatory frameworks

  …. which all can be obstacles / barriers / pitfalls

- **A successful implementation in routine laboratory medicine and clinical practice must involve**
  - scientific societies (IFCC and partner socieites)
  - clinical societies
  - regulatory agencies
  - patients

  …. from the beginning !

Two major goals for IFCC and its partners

- **Avoid duplication of efforts** and ensure **synergy** (*e.g.* IFCC - academic laboratories - NMIs)
- Overcome **reservations** and **obstacles** (manufacturers, clinical societies, regulatory bodies)

Actions are needed !

Actions are in progress in IFCC-SD !

- **Reinforced contacts with NMIs and BIPM** (MoU)
- Common **strategy** between **IFCC and ICHCLR**
- **Collaboration with other scientific societies** in standardization approaches (ADA, ISTH, IOF, IATDCMT)
- **Identification of practical obstacles to standardization** and possible solutions associating all stakeholders

➡ Project of a **specific seminar** for concretely « designing the future »

IFCC / ICHCLR Workshop in 2020 :
"Barriers to global standardization of clinical laboratory testing: reference materials and regulations"

http://seoulstandardizationworkshop.org/

International Consortium
for Harmonization of Clinical Laboratory Results

IFCC International Federation of Clinical Chemistry and Laboratory Medicine

Workshop Announcement

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

29-30 May, 2020 - SEOUL, KOREA

IFCC WorldLab SEOUL 2020

Immediately following IFCC WorldLab 2020 - http://www.seoul2020.org/2020/home

This workshop will address the barriers to implementing global metrological traceability of clinical laboratory methods. Differences in country or region specific reference materials and regulatory requirements are barriers to standardization. ISO standards with JCTLM certified reference materials, reference measurement procedures and protocols provide tools for global standardization. Workshop topics will address technical and regulatory issues, impact of new biomarkers and technologies, approaches to prioritization of tests for standardization, and conclude with issuing recommendations for improved approaches to achieve globally standardized patient test results.

Information and registration: http://seoulstandardizationworkshop.org/

Presented under the auspices of

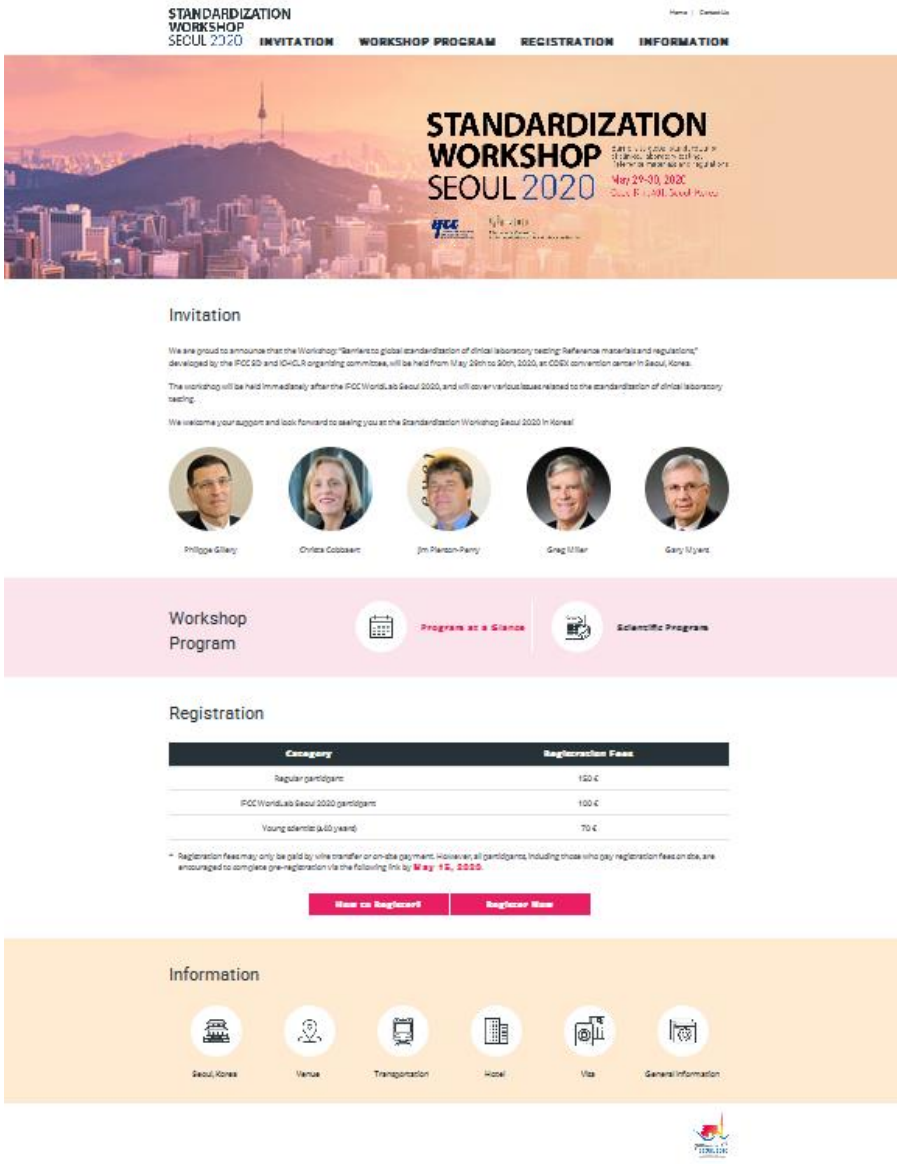
IFCC International Federation of Clinical Chemistry and Laboratory Medicine

International Consortium for Harmonization of Clinical Laboratory Results

IFCC WorldLab SEOUL 2020

JCTLM Accurate results for patient care

Unrestricted



Add in your agenda !

SD-EC - Thank you

Thank you !