IFCC Scientific Division
Report to Council
Durban (South Africa), October 2017

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

- Mission and objectives
- SD : structure and operating
- Strategic plan
- Recent achievements
IFCC SD

- Mission and objectives
IFCC SD

Mission: 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
Traceability (based on ISO 17511)

Primary Reference Material
(pure substance)

Secondary Reference Material
(matrix)

Mfr Working Calibrator

Mfr Product Calibrator

SI unit
Reference Procedure
(e.g. IDMS)

(calibrator)

Mfr Selected Procedure

Mfr Standing Procedure

Routine Procedure

Patient sample results are equivalent to the reference procedure results

The SD roadmap to Heaven!
IFCC SD
Working in Partnership

- IFCC Divisions
- Corporate members
- Metrology institutions
- Governmental bodies and non-Governmental organisations
- Other professional bodies
- Clinicians and clinical organisations
IFCC SD

- Mission and objectives
- SD : structure and operating
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<tr>
<th>Name</th>
<th>Position</th>
<th>Country</th>
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<td>P. Gillery</td>
<td>Chair</td>
<td>FR</td>
<td>1st</td>
<td>2017 01 - 2019 12</td>
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<td>C.M. Cobbaert</td>
<td>Vice-Chair</td>
<td>NL</td>
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<td>2017 01 - 2019 12</td>
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<tr>
<td>J. Passarelli</td>
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<td>US</td>
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<td>K. Makris</td>
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<td>T. Nobori</td>
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<td>M. Plebani</td>
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<td>J.F. Pierson-Perry</td>
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<td>G. Myers</td>
<td>JCTLM Chair / SD Consultant</td>
<td>US</td>
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<td>H. Schimmel</td>
<td>JRC Observer</td>
<td>BE</td>
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<td>C. Burns</td>
<td>NISBC Consultant</td>
<td>UK</td>
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<td>K. Phinney</td>
<td>NIST Consultant</td>
<td>US</td>
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SD - Executive Committee (SD-EC)
SD - EC in Athens (June 2017)
Scientific Division

Committees

Theme orientated

Appointed Chair plus four/five elected members among nominees from national societies and/or corporate members

Working Groups

Task orientated

Appointed Chair plus unlimited members

Corresponding members nominated by the national societies
SD Committees

- Nomenclature, Properties and Units (C-NPU) in collaboration with International Union of Pure and Applied Chemistry (IUPAC) - R. Flatman (AUS)
- Molecular Diagnostics (C-MD) - D. Payne (US)
- Traceability in Laboratory Medicine (C-TLM) - L. Siekmann (DE)
- Reference Intervals and Decision Limits (C-RIDL) - Y. Ozarda (TR)
- Standardization of Thyroid Function Tests (C-STFT) - L. Thienpont (BE)
- Harmonization of Autoimmune Tests (C-HAT) - J. Sheldon (UK)

*Newly created*
SD Working Groups

- Standardisation of Haemoglobin A2 (WG-HbA2)  
  A. Mosca (IT)

- Standardisation of Carbohydrate-Deficient Transferrin (WG-CDT)  
  J. Wielders (NL)

- Standardisation of Albumin Assay in Urine (WG-SAU) in collaboration with NKEDP  
  L. Bachmann (US)

- Standardisation of Pregnancy-Associated Plasma Protein A (WG-PAPP A)  
  S. Wittfooth (UK)

- Growth Hormone (WG-GH)  
  E. Lentjes (NL)

- Standardisation of Insulin Assays (WG-SIA) in collaboration with ADA/EASD  
  A. Saenger (US)

- Standardisation of Troponin I (WG-TNI)  
  R. Christenson (US)

- Parathyroid Hormone (WG-PTH)  
  C. Sturgeon (UK)

- CSF Proteins (WG-CSF)  
  K. Blennow (SE)

- Standardization of Bone Marker Assays (WG-SBMA)  
  H. Morris (AU)

- Commutability (WG-C)  
  G. Miller (US)
SD Working Groups

Newly created

- Immunosuppressive Drugs (WG-ID)  
  L. Langman (US)

- 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)
IFCC SD

- Mission and objectives
- SD: structure and operating
- Strategic plan
IFCC - Scientific Division
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
1. Keep and amplify the high level of involvement of IFCC-SD in the field of standardization / harmonization

- Continuation and/or completion of ongoing projects
- Picking up priority measurements from the harmonization consortium (ICHCLR)
- Identification of new areas
  - Molecular biology and Proteomics
  - Other areas of Laboratory Medicine (Immunology, Pharmacology, Hematology)
    - Automimmune tests (WG C)
    - Drugs (WG-ID)
    - Immunochemical fecal Hb testing (WG-FIT)
1. Keep and amplify the high level of involvement of IFCC-SD in the field of standardization / harmonization (continued 1)

- Committees: Keep a sustained activity in these theme – oriented groups of major strategic interest for IFCC
  - C-NPU: Links with other international organizations (IUPAC)
  - C-MD: Creation of an IFCC network / identification of new tests / new diagnostic strategies
  - C-TLM: Maintenance of IFCC networks (eg HbA$_{1c}$)
  - C-RIDL: Establishment of reference values worldwide
  - C-STFT: Important advances in standardization / harmonization and clinical outcomes
1. Keep and amplify the high level of involvement of IFCC-SD in the field of standardization / harmonization (continued 2)

- Working groups: Carefully check the creation / evolution / productivity of WGs on specific tasks for limited lifetime
  - Near to achievement: WG-CDT, WG-HbA\(_2\) (reference procedures and/or materials)
  - New scientific items: *eg* WG-PAPPA, WG-CSF, WG Apolipoproteins by MS
  - Collaborative WGs: *eg* WG HbA\(_2\) (ISTH), WG-SAU (NKPED), WG-SIA (ADA/EASD), WG-BMA (IDF)

- Ensure a dynamic process
  - WGs to close and/or transform
    - Task ⇔ theme: WG-HAT ⇔ C-HAT
    - New WGs on specific application: WG-cMSP (general reflexion ⇔ specific applications) (*eg* apolipoproteins)
2. Keep and amplify the visibility of IFCC scientific activities inside and outside IFCC

- Active participation in all IFCC and regional federation meetings
- Systematic preparation of a special issue in the official IFCC journal every 2 to 3 years (last achievement: 2016 in CCA)
- Participation in scientific meetings of clinical societies in areas covered by SD (eg endocrinology, immunology, cardiology)
- Participation and reinforced relations with partners (BIPM, NMIs, WHO), focussing on specific expertise areas of SD (eg HbA₂ for WHO)
2. Keep and amplify the visibility of IFCC scientific activities inside and outside IFCC (continued)

- Increased interactions with other IFCC divisions or task forces for identifying new markers suitable for standardization / harmonization, in cooperation with corporate members (importance of clinical relevance and interest for effective implementation of the tests in laboratories)
  
  \[e.g.\] Markers of diabetes (AGEs): C-EUBD (EMD)]

- Participation in IFCC structural changes: ensuring synergy with the newly created Emerging Technology Division
3. **Prepare the future**

- Focus SD activities on new areas of clinical chemistry and laboratory medicine (eg molecular biology, proteomics)
- Select and involve new members in SD Cs and WGs (key actors getting older or retiring, new skills required in new areas of interest).
- Promote the involvement of young scientists in SD activities with EB support
- Ensure the maintenance of IFCC networks (cf C-TLM).
IFCC SD

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- Recent achievements
IFCC SD
Some key achievements

- More than 150 scientists and clinicians from all IFCC regions involved as members of Cs / WGs
- SD symposia at most major international congresses
- Bergmeyer conferences (Tumor markers - 2016)
- Key publications (Special issues in IFCC Official Journal)

2016 : CCA special issue
CLINICA CHIMICA ACTA

International Journal of Clinical Chemistry and Diagnostic Laboratory Medicine

Special Issue
Current contributions of the IFCC Scientific Division to standardization

Guest Editors:
P. Gillery
I.S. Young
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Committees

Update on activities
Committee on Nomenclature, Properties and Units : Robert Flatman (AU)

- **Current Projects**
  - Transfer of the NPU generic database to IFCC site: help and advice on training the future IFCC NPU database manager(s) in relation to the installation, updating and management of the database, and on its relationship with other national versions.
  - Mapping of the IFCC-IUPAC laboratory coding system to SNOMED CT.
  - Securing and structural updating of information in the NPU coding system and its environment.
  - Development of an international vocabulary for nominal examinations in scientific communication.

Committee on Molecular Diagnostics : Debs Payne (US)

- **Current Projects**
  - Establish an International Network of IFCC Reference Centres in Molecular Diagnostics
  - Develop a checklist for technology transfer from development to clinical laboratory testing
  - Standardise formats for reporting of molecular diagnostic results
Committee on Traceability in Laboratory Medicine: Lothar Siekmann (DE)

- **Current Projects**
  - Organization of IFCC Ring Trials for reference laboratories

Reference Intervals and Decision Limits: Yesim Ozarda (TR)

- **Current Projects**
  - Conduction of a new study to compare alternative approaches (conventional and big data) for the determination of reference intervals
  - Creating a website to provide the reference intervals obtained from the global study for practice of Evidence Based Laboratory Medicine
  - Preparation of a publication on the distinction of Reference Intervals and Clinical Decision Limits
Committee Thyroid Function Tests
Linda Thienpont (BE)

- Current Projects
  - Recalibration of FT4 and TSH assays after the Phase IV method comparison studies on clinically relevant samples: is intended as technical standardization/harmonization process, by which FT4 assays will become traceable to the conventional reference measurement procedure based on equilibrium dialysis (ED) isotope dilution-liquid chromatography-/tandem mass spectrometry (ID-LC/MS/MS), TSH assays to the statistically inferred all-procedure trimmed mean (APTM).
  - Measure a FT4 and TSH panel of each 120 American apparently healthy volunteers with the recalibrated assays; measure the FT4 panel also with the conventional reference measurement procedure; use the data as proof-of-concept for standardization of FT4 and harmonization of TSH by demonstrating that the traceable assays can use a common reference interval; use this as a basis for further elaboration of the reference intervals by the IVD manufacturers.
  - Get into contact with all involved stakeholders for benefit-risk analysis in preparation of the implementation of the standardized/harmonized assays.
  - Promotion of the concept of Traceability in Latin America
A new Committee : C-HAT
Harmonization of Autoimmune Tests
Joanna Sheldon (UK)

- Terms of reference
  - To evaluate what are the main causes of variability for a number of diagnostically critical autoantibodies.
  - To identify autoantibodies where a common calibrator could reduce the inter-assay variability
  - To identify or produce commutable materials that could be used as interim calibration material for autoantibody assays.
  - To produce well-characterised pure antibody preparations with known concentration and identity and use these to transfer values to a matrix preparation.
  - To evaluate the impact of new reference material on the variability of autoantibody tests and identify areas where further harmonisation would improve diagnostic accuracy.
Working groups

Examples of recent achievements
Standardization of CDT (WG-CDT)
Chair : Dr Jos Wielders

- Public health problem: Alcohol abuse / abstinence among top 5 causes of disease / disability
- CDT: Carbohydrate deficient transferrin: clinical and forensic alcohol biomarker
- Strategic approach
  - Establishment of standardization scheme (RMP, reference materials, network of reference laboratories)
  - Implementation of reference system
- Reference Measurement Procedure established and IFCC approved
  - Measurand and target analyte for standardization: Disialotransferrin
  - Method: HPLC with photometric detection (approved)
  - Reference materials: serum based (approved)
  - New thresholds (decision limits: 2.0%)
- Outcome: "Standardized % CDT$_{IFCC}$ Units"
  (general use: 01 July, 2018)
Standardization of HbA₂ (WG-HbA₂)
Chair: Prof. Andrea Mosca (IT)

- Public health problem: Thalassemia
- Strategic approach
  - Establishment of standardization scheme (RMP / reference materials / networks)
  - Ensuring implementation and comparability of HbA₂ values
  - Collaboration with ICSH
- Candidate reference measurement procedure: HPLC - ID-MS/MS
  - Peptide mapping
  - Calibration: HbA₀ and HbA₂ materials / traceable to SI
  - Recombinant ¹⁵N-labelled Hb used as internal standards
- Certified reference materials: in preparation (JRC)
- Network of reference laboratories: in constitution (3 worldwide)
Development of New Projects

SD horizon scanning

Assessment of need
Development and submission of formal proposal
Agreement on terms of reference

Approval by SD and EB
Establishment of WG or C

Work cycle with ongoing review

Third party approach
SD in Durban
Scientific Division:
A tool for every IFCC member:
becoming involved in the work of SD

- Apply for positions on SD or C’s
- Become a corresponding member of a C
- Become a member of a WG
- Propose a new WG or C
- Promote young scientists

Thank you!