IFCC Laboratory Medicine Practice Guidelines

Best Practice Recommendations, Position Papers & Guidelines in Laboratory Medicine

Terms of Reference & Program Roadmap

Program Objectives:
Develop and disseminate best practice recommendations/guidelines in all areas of clinical laboratory medicine and facilitate implementation in clinical laboratories worldwide.

- Terms of reference for this program are provided below, describing the scope and mandate, the process for submission of proposals by IFCC functional groups, guidance document development, review by an IFCC steering group, approval process, and finally publication and dissemination.
- All IFCC Functional Groups will be invited to participate in this program and contribute to development of simple/practical guidelines. However, this is not a mandatory program – not all functional groups need to be involved if rationale is provided that development of such guidance documents is not within their mandate.

Scope & Mandate:
Under this program, IFCC encourages its functional units, which are specialized groups or committees focused on various aspects of clinical chemistry and laboratory medicine, to develop several types of documents to advance the field. These documents are designed to provide guidance, standards, and best practices for laboratory professionals and researchers. Some of the documents that IFCC functional units are encouraged to develop include:

1. **Best practice recommendations**
    - Functional units can create guidelines to establish best practices and standardize procedures in various areas of clinical chemistry and laboratory medicine. These guidelines may cover topics such as:
    - Best practice recommendations on pre-analytical, analytical, or post-analytical phases of the clinical laboratory process (with specific implementation resource e.g., reference, figure, table)
    - Best practice recommend[1]ations on implementation of specific clinical biomarker(s)/assays in clinical laboratory practice (with specific implementation resource e.g., reference, figure, table)
    - Short (5-10 page) documents that can be implemented in day-to-day laboratory service, are user friendly and practical (see draft template below)

2. **Position Statements:**
    - IFCC functional units can issue position statements on important issues and challenges in the field. These statements represent the official stance of the IFCC

on specific topics and help provide clarity and direction to the global clinical chemistry and laboratory medicine community.

3. **Evidence-based Practice Guidelines**
    - Follow a standard methodology for producing guidelines (such as the AACC document https://http://www.aacc.org/science-and-research/practice-guidelines/standard-operating-procedures or the new EFLM proposed methodology)
    - Use the GRADE system to support the recommendations.

[2]

Rationale:

- Most clinical Guidelines are developed by clinical associations/societies with no or minimal consultation with the laboratory medicine community.
- Many existing guidelines developed by organizations such as CLSI are v*ery* detailed/expensive/with limited availability/out of reach of most labs around the world.
- Other practice guidelines developed by others such as NACB/AACC Academy are mostly dated and only a very limited number of guidance documents developed.
- IFCC Executive Board has therefore approved the launch of a new program to develop and disseminate evidence based IFCC Clinical Laboratory Practice Guidelines to support clinical laboratories around the world.
- These guidance documents will provide practical best practice recommendations or formal evidence-based guidelines to laboratory professionals based on information gathered from a wide range of existing reputable clinical guidelines, peer-reviewed publications, and expert consensus.
- All guidance documents will ideally provide specific implementation resources to ensure utility in clinical laboratory practice.
- Given that IFCC is home to leading experts in laboratory medicine, the organization has the knowhow and the expertise to help develop and disseminate these guidance documents.
- Laboratory medicine guidance documents developed by IFCC functional groups will directly contribute to improved quality, standardization and harmonization of clinical laboratory practices around the world.

Target Audience:

1. Clinical laboratory professionals and laboratory services around the world particularly in developing countries including but not limited to IFCC member countries.
2. IVD manufacturers/scientists
3. Governmental and non-governmental institutions involved in laboratory accreditation and quality assurance.

Program Roadmap - Procedures:

1. An **IFCC Taskforce on Laboratory Medicine Practice Guidelines (TF-LMPG)** is being formed to act as a steering group and provide program oversight, and act as a review panel to review proposals received from functional groups.
2. A formal Call for Participation will be issued to IFCC functional groups on October 2, 2023, inviting all IFCC Committees, Taskforces & Working Groups to propose topics related to their field of expertise.
3. IFCC Committees, Taskforces & Working Groups will initially submit potential topics based on their area of expertise to the steering group for review and approval.

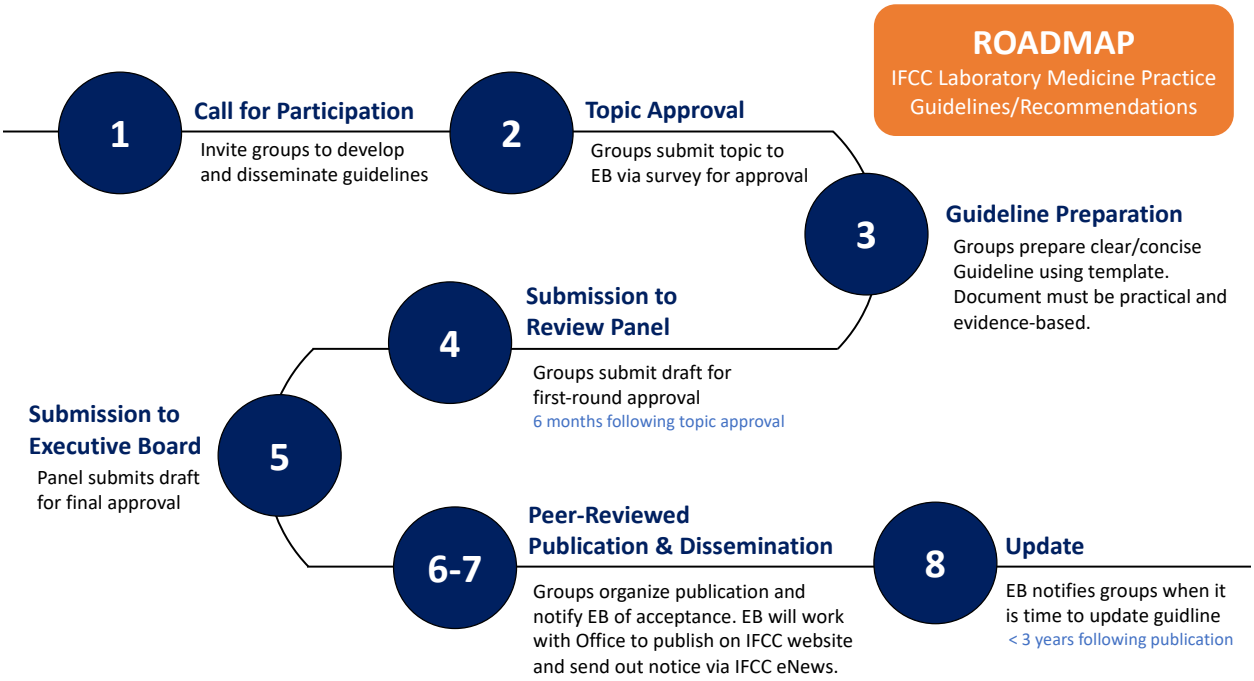
   Key Criteria for selection of topics:
   - Topics in all aspects of Preanalytical/Analytical/Postanalytical phases
   - Topics related to clinical laboratory implementation of clinical biomarker(s)
   - Basic and advanced topics/recommendations/guidance documents eligible
   - Emphasis given to those essential tests as defined by WHO.
   - Priority should be given to topics related to application of new/emerging clinical biomarkers.
   - Functional groups should identify what is out there and assess need before selecting topics for guideline development.
   - Topics selected should address unmet needs. A needs assessment may be required by the functional group through surveys of IFCC national societies and/or clinical laboratories to identify key areas of interest.
   - State of assay standardization/harmonization should be considered.
   - Comments should be included on cost effectiveness/affordability when recommending implementation of new biomarkers.

4. Following topic approval, IFCC Committees, Taskforces & Working Groups will develop guidelines based on their area of expertise. In most cases, this will also involve consultation with published clinical guidelines and with international experts (other clinical laboratory scientists, clinicians, industry partners, etc.). All documents/recommendations/guidelines must be:
   - Clear and concise
   - Organized according to IFCC LMPG template or other similar templates.
   - Conflict of interest statements be included to ensure no commercial bias.
5. IFCC Committees, Taskforces & Working Groups will submit final draft documents to IFCC Steering Committee/Review Panel, along with suggested journal, for review and first-round approval. This should occur within 6-12 months following topic approval.
6. The IFCC Steering Committee/Review Panel will review and also organize peer review from experts in the field to vet the proposed topic. The panel will ensure guidelines meet all conditions set out in the terms of reference.
7. IFCC LMPG Taskforce will act as a Steering Committee/Review Panel and will forward their recommendations on guidance documents to the IFCC Executive board for final approval.
8. Following guideline approval, IFCC Committees, Taskforces & Working Groups will organize peer-reviewed publication. IFCC Committees, Taskforces & Working Groups

should notify IFCC Executive Board once guidelines are accepted for publication. A consultation phase may be required in some cases before finalizing the document(s)

Publication and Dissemination:

- IFCC TF-LMPG will liaise with IFCC Office to publish guidelines on the IFCC website and send out notice to IFCC community via eNews.
- IFCC TF-LMPG will send out notice to the IFCC Functional Group when it is time to update guidelines, no later than 3 years following initial publication.
- Best Practice Recommendations/Guidelines may also be translated to other languages with collaboration of IFCC national societies to ensure wide-spread dissemination and implementation globally.
- To manage this process, IFCC will maintain a list of proposed and approved topics. This timeline can also be used to track timeline/progress for approved topics.
- An electronic database of IFCC clinical and laboratory practice guidelines will also be developed and linked to the IFCC website and made freely accessible.



Draft Template – Best Practice Recommendations

Introduction/Rationale

Introduction to committee/taskforce and their overall focus

E.g. "The IFCC [insert committee/taskforce name] is focused on [insert focus]."

Statement on topic, aim(s), and significance of the recommendations

E.g. "In this report, the [insert committee/taskforce name] provides recommendations on [insert topic here]. The overall aim of this report is to bring latest clinical [guidelines/evidence/expert consensus] on [insert topic here] to laboratory practice. Implementation of these recommendations will help support [insert significance here]."

Brief background on topic

Brief description on how recommendations were developed (guidelines, publications, expert consensus)

Box 1. IFCC [insert committee/taskforce name] recommendations for [insert topic].
Recommendation 1: [insert brief statement of recommendation] Recommendation X: [insert brief statement of recommendation]

Recommendation 1

Brief statement of recommendation

E.g. "We recommend [insert recommendation]."

Summary of supporting evidence

E.g. general evidence (guidelines, publications, expert consensus), advantages, limitations

Details of recommendation

E.g. specific suggestions, considerations

Recommendation X

Brief statement of recommendation

E.g. "We recommend [insert recommendation]."

Summary of supporting evidence

E.g. general evidence (guidelines, publications, expert consensus), advantages, limitations

Details of recommendation

E.g. specific suggestions, considerations

Implementation

Table/Figure

E.g. visual aid to summarize how recommendations can *specifically* be applied in laboratory practice including algorithms

Resources

E.g. reference to existing aids that are considered gold standard to aid in implementation in laboratory practice[3]