



MEETING REPORT

Ensuring quality in public health microbiology laboratories in the EU: Quality control and areas in need of strengthening

Stockholm, 9-10 September 2009

1 Executive summary

One of the fields of work covered by the European Centre for Disease Prevention and Control (ECDC) is scientific advice on communicable diseases, including microbiology and laboratory issues. ECDC carries out its microbiology activities in close collaboration with the Member States. To facilitate this process, the Member States officially nominated representatives – National Microbiology Focal Points (NMFPs)¹ – who provide technical and strategic input on overarching questions in microbiology. Together with ECDC, the NMFPs developed an agreed definition of ‘public health microbiology’ (PHM)² and performed a survey to:

- collate the knowledge and information on microbiology laboratory systems and structures in the EU and EEA/EFTA countries; and
- to identify areas of work that would provide an European added value.

In order to interpret the section of the survey dedicated to laboratory quality issues, ECDC organised an ad hoc NMFP consultation group meeting with key experts in this field. The goal of the meeting was to gain an overview of international and national systems of quality assurance, of how these are implemented in EU Member States, and to identify obstacles and challenges.

During the meeting, representatives from national and international quality assurance organisations explained the relevant systems and structures currently in place, and the participating NMFPs elaborated on the quality assurance systems that are used in their countries. Commonly used technical terms in the field of quality assurance were reviewed, and the challenges and obstacles in developing and maintaining quality systems were discussed. The participants agreed that ECDC could provide European added value in the area of quality assurance by

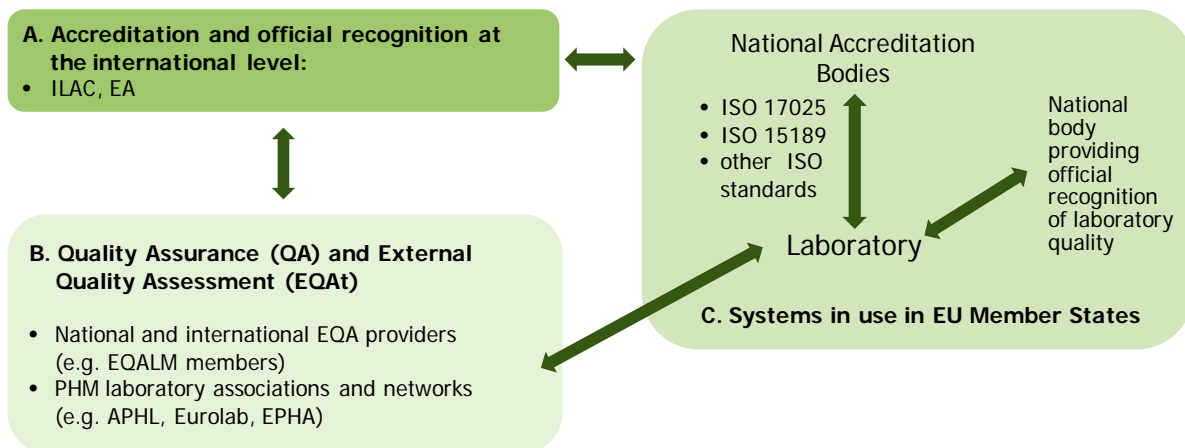
¹ http://ecdc.europa.eu/en/activities/microbiology/Microbiology%20Documents/0711_MIC_GeneralStrategy_ECDC_Cooperation_with_Lab.pdf

² Public health microbiology was defined by the NMFPs as a cross-cutting area that spans the fields of human, animal, food, water, and environmental microbiology, with a focus on human health and disease.

reinforcing collaboration, stimulating the exchange of good practices, and by providing relevant information resources.

2 Laboratory quality systems and structures

Figure. Overview of structures and systems for ensuring quality in public health microbiology laboratories – summary (see Annex for abbreviations)



2.1 Accreditation and official recognition

'Accredited once, accepted everywhere.'

The official accreditation of PHM laboratory services recognises a laboratory's professional competence and provides an official indication of high-performance standards to the general public and authorities. National Accreditation Bodies (NAB) are performing accreditation along accepted international standards, including ISO 17025 and ISO 15189 (Figure, C), two key standards for medical laboratories. The European co-operation for Accreditation (EA) and the International Laboratory Accreditation Cooperation (ILAC) are organisations that ensure international consistency in the accreditation process, as expressed by the principle 'Accredited once, accepted everywhere'.

2.2 Quality Assurance (QA) and External Quality Assessment (EQAt)

'A healthier world through quality laboratory practice.'

In order to support the efforts of PHM laboratories in their efforts to maintain a consistently high quality level of performance, various national and international organisations have been established (Figure, B) which provide networking and training opportunities as well as technical support. During the meeting, the representative from the Association of Public Health Laboratories (APHL) gave useful insights into the wide range of training programmes and materials the APHL found successful in promoting a culture of quality in US public health laboratories. Organisations with a similar scope of services are active in the European context, e.g. Eurolab or the European Public Health Association.

The ISO standards mentioned above require that laboratories regularly participate in External Quality Assessment (EQAt) and Proficiency Testing (PT) to ensure their testing performance and competence. Such assessments are conducted by national and international EQAt/PT providers, e.g. UK NEQAS or EQUALM (European Committee for External Quality Assurance Programmes in Laboratory Medicine, an international organisation for providers of external quality assurance schemes) (Figure, 1 B).

2.3 Systems in use by Member States

'Commitment, not just compliance.'

The NMFPS³ explained that Member States were aware of the importance of quality assurance systems, but also that countries use different legislation when certifying PHM laboratory quality (Figure, C). Differences between international standards for PHM laboratories (e.g. ISO 17025, ISO 15189) and the respective national standards were pointed out. These differences relate to requirements for:

- participation in EQAt rounds – mandatory vs. recommended rounds and frequency of rounds;
- internal audits;
- laboratories that want to perform reference functions;
- documentation;
- equipment; and
- QA management and QA managers.

The participants explained that ISO 15189 accreditation of PHM laboratories services leads to improvements in the laboratory management and quality assurance (QA) activities (e.g. documentation) and helps to identify systematic errors and thus increase reliability and reproducibility. However, irrespective of whether or not a laboratory is licensed according to national criteria or is ISO 15189 accredited, the participants emphasised that there is a need for commitment to quality practice and that one should look beyond mere compliance with legislation.

It was also discussed that the field of QA uses technical terms for which there is no comprehensive, freely available glossary, which often leads to an incorrect use of terms. Therefore, collecting and defining frequently used QA terms (from an EU perspective) appears to be a project which ECDC could support.

3 Obstacles and challenges for PHM laboratories

The following issues were discussed:

- Financial constraints: implementation of QA systems requires significant financial resources, dedicated personnel and time.
- Education: there is a need for proper training for QA managers.
- Information: low awareness of existing international quality standards and of the positive impact they have on QA practice.
- Support from the laboratory management levels: an engaged management is needed to support the implementation and maintenance of QA systems; there is a need for evidence-based advocacy to allocate funds to QA.
- Facilities and staff safety: low awareness of how the lack of good QA practice and proper facilities can impact staff safety.
- Size of laboratories and number of services performed: small laboratories performing a few tests might not be able to afford accreditation of their activities (balancing output and needs/costs).

4 Next steps

In order to address the identified obstacles and challenges, ECDC could provide technical support to PHM laboratories. These initial activities could establish and maintain good practice as a means of ensuring quality:

- Information resources: providing a comprehensive and easy-access glossary of terms in the field of QA. The translation of the glossary into all official EU languages will be explored.

³ Participating NFMPs were selected for this ad hoc consultation group meeting based on the survey results for (1) requirements for official recognition of laboratory quality; (2) requirements for the development of QA manuals and schemes; and (3) identified needs in the field of quality assurance.

- Information exchange: ECDC could assist Member States in learning from each other or from relevant organisations by sharing good practice and information on how to ensure quality in PHM laboratories.
- Studies/Analysis: ECDC could further review and analyse the needs for improving laboratory practice by consulting the NMFP forum or by establishing active collaborations with public organisations/networks that perform regular EQA schemes. Such exchanges could help ECDC to identify specific areas that would provide European added value by strengthening the performance of the Member States' PHM laboratories (e.g. methods harmonisation, twinning arrangements and training initiatives).

Annex

Abbreviations

APHL	Association of Public Health Laboratories
EA	European co-operation for Accreditation
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EFTA	European Free Trade Association
EQA	External quality assurance
EQALM	European Committee for External Quality Assurance Programmes in Laboratory Medicine
EQAt	External quality assessment
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
NAB	National accreditation body
NMFPs	National Microbiology Focal Points
PHM	Public health microbiology
PT	Proficiency tests
QA	Quality assurance
UK NEQAS	United Kingdom National External Quality Assessment Service

Agenda of the meeting

Wednesday, 9 September 2009

13.00 – 14.00	Lunch
14.00 – 14.45	– Welcome and introduction to ECDC – Meeting objectives Amanda Ozin (head of section for Scientific and Technical Advice and Knowledge Services, ECDC)
14.45 – 15.45	Session 1: 'Accreditation and official recognition' Chair: Polya Vutova Máire Walsh, ILAC Marianne Edman Falkensson, EA
15.45 to 16.15	Coffee Break
16.15 to 17.45	Session 2: 'Quality assurance and external quality assessment' Chair: Adoración Navarro Torne Karen Breckenridge, APHL Christine Walton, EQALM Christine Walton, UK NEQAS
17.45 to 18.30	Discussion 'Definitions in the field of quality assurance' Chair: Amanda Ozin
19.00	Dinner

Thursday, 10 September 2009

09.00 to 10.15	Session 3: 'Quality assurance systems in use' Chair: Daniel Palm Jaana Vuopio-Varkila, NMFP Finland Iva Christova, NMFP Bulgaria Waleria Hryniewicz, NMFP Poland
10.15 to 10.30	Coffee break
10.30 to 12.00	Discussion Chair: Polya Vutova – Current situation (road map) – Obstacles and challenges (implementation and maintenance) – Next steps (future directions)
12.00	Lunch

List of participants

Máire Walsh	International Laboratory Accreditation Cooperation (ILAC)
Marianne Edman Falkensson	European co-operation for Accreditation (EA)
Karen Breckenridge	Association of Public Health Laboratories (APHL)
Christine Walton	European Committee for External Quality Assurance Programmes in Laboratory Medicine (EQALM)
	United Kingdom National External Quality Assessment Service (UK NEQAS)
Jaana Vuopio-Varkila	National Microbiology Focal Point – Finland
Iva Christova	National Microbiology Focal Point – Bulgaria
Waleria Hryniewicz	National Microbiology Focal Point – Poland