ECDC Management Board
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Update of the position statement of the Commission and ECDC on human pathogen laboratories:

A joint vision and strategy for the future

Background

1. ECDC’s mission is to identify, assess and communicate current and emerging threats to human health from communicable diseases.

2. For our operational mandate, the activities of ECDC in the area of human pathogen laboratories have corresponded to the key points of Article 5 (“Operation of dedicated surveillance networks and networking activities”) highlighted below:

   a) Article 5, point 2 – integrated operation of dedicated surveillance networks of authorities and structures designated under Decision No 2119/98/EC, and

   b) Article 5 point 3 - encouraging cooperation between expert and reference laboratories to foster the development of sufficient capacity within the Community for the diagnosis, detection, identification and characterisation of infectious agents which may threaten public health.

3. In the past five years, ECDC has achieved, together with the Member States, a number of valuable and concrete deliverables in the area of public health microbiology and laboratory collaborations. Most of these activities are based on high-quality clinical and public health microbiological activities undertaken in the EU Member States.

4. In 2010, the Management Board (MB20/14) adopted the “EU Reference Laboratory Networks: a Vision to Strengthen Member State Capacity in Public Health Microbiology”. This vision statement calls for enhancing collaboration and sharing between Member States, to optimise the use of limited resources and fill existing gaps or significant differences in the quality and timeliness of reference laboratory service provision.

5. The networks of collaborating laboratories, coordinated by ECDC in close collaboration with the European Commission, are, according to this vision statement, referred to corporately as “EU Reference Laboratory Networks.

6. The Management Board (MB20/14) raised the issue that for ECDC to realise this vision, commitment is needed for coordination and mutual helpfulness from Member States, the Commission, and other key stakeholders. It stated that the Commission and ECDC have to work even closer together to map and scrutinise their laboratory activities to ensure synergies. Such dedicated
collaboration would eliminate duplication of work that remains since the establishment of ECDC and
the gradual integration of laboratory networking initiatives.

7. To address the above challenges, the Commission and ECDC have worked together to
provide a position paper on “Joint vision of the Commission and ECDC in the area of human
pathogen laboratories in the EU” and to indicate the strategic objectives as well as the respective
roles and priorities to be addressed in achieving these objectives.

8. With a view to promote transparency, the statement includes as an annex a consolidated
picture of the initiatives currently carried out under their respective responsibilities and funded under
their respective programmes and work plans.

9. Following presentation of the Joint vision paper (MB22/8) to the Management Board, a follow-
up report was called by the Board for presentation at MB23, in order to clarify the terminology and
concepts of the document and provide more detailed information on how the strategy will be
developed at operational level (see minutes of MB22, item 5). The present update to the Joint
Position Paper addresses these points.
Definitions and functions

10. In order to have definitions of the terms used in this statement the following definitions are proposed:

a) **Public Health Microbiology**: cross-cutting area that spans the fields of human, animal, food, water and environmental microbiology, with a focus on human health and disease. It requires laboratory scientists with the ability to work effectively across disciplines, particularly epidemiology and clinical medicine. Public health microbiology laboratories, or laboratories with these functions, play a central role in infectious disease detection, monitoring, outbreak response and providing scientific evidence to prevent and control disease. (ECDC; Technical Report 2010.a).

b) **Public Health Microbiology Laboratory**: Any microbiology laboratory serving Public Health functions relevant to communicable disease surveillance, prevention and control.

c) **National Reference Laboratory**: Any laboratory appointed by the National authority as reference structure for specific functions in Member States. This includes the National Reference Microbiology Laboratories serving public health functions. National reference laboratory (NRL)’ and national reference centre (NRC)’ are both commonly used terms across the EU.

d) **Networks of National Reference Laboratories**: Networks established among laboratories appointed by the National authority as reference structure for specific functions in Member States. This includes the Networks of the National Reference Microbiology Laboratories run by ECDC as well as the Networks of WHO reference laboratories.

e) **European Union Reference Laboratory (EU RL)**: EU Reference Laboratories (EU-RL) for specific food and feed hazards and for specific animal diseases established under Article 32 and 33 of Regulation (EC) 882/2004, including those National Reference Laboratories (NRL) designated by the Member States under the mentioned Regulation. These include the 41 EU RL established under Regulation (EC) No 776/2006.

f) **National Microbiology Focal Points (NMFP)**: An ECDC scientific advisory forum of experts called the National Microbiology Focal Points. The NMFPs are nominated through the Management Board members by the national authorities of EU/EEA Member States on the basis of their ability to function both as strategic and technical partners to ECDC in the area of Public Health microbiology.

11. Together with the National Microbiology Focal Points, the European Centre for Disease Prevention and Control (ECDC) has developed a consensus definition of ‘Public health microbiology’ as above (point 10a). They have recognised a number of core functions as crucial elements for reference microbiology laboratories (e.g. reference diagnostics, reference material resource, scientific advice, collaboration on research and monitoring, capacity for participating to alert and response activities (ECDC; Technical Report 2010.a).

12. Reliable capability of diagnostic and reference microbiology laboratory service is pivotal for ensuring adequate surveillance of communicable diseases and monitoring of drug resistance in human pathogens. It is also a prerequisite for enabling preparedness for future threats caused by emerging pathogens and epidemic disease, from local to global levels, as required under the provisions of the International Health Regulations (IHR, 2005).

13. In keeping with the EU Health Strategy stating that “The Charter of Fundamental Rights recognises citizens’ right of access to preventive healthcare and the right to benefit from medical treatment”, every Member State should have access to routine and emergency diagnostic and
reference laboratory services to detect, identify, characterise and subtype human pathogens of public health significance, either locally or through cooperative agreement.

14. Currently, reference microbiology services for human pathogens in the EU are the remit of Member States health authorities through their National Reference Laboratories according to national provisions. In 2010, ECDC published the results of mapping survey of National Reference Laboratories and public health microbiology resources in the Member States. The survey indicated, as expected, heterogeneity in the mandate, nomination process and organisational models for delivering reference microbiology functions (ECDC; Technical Report 2010.b).

15. Since 1999, in recognition of the need for EU coordination of response to cross-border health threats caused by communicable diseases, Decision 2119/98/EC and its implementing measures link public health authorities in the EU Member States and the Commission in order to coordinating EU-wide surveillance and the early warning and response (Commission Decision 2000/57/EC) to health threats caused by communicable diseases of relevance for the European Union.

16. Concerning the European Union surveillance of communicable diseases the networks previously known as Disease Specific Networks and further on Dedicated Surveillance Networks (DSN) allowed building and consolidating systems for surveillance of selected communicable diseases, prioritized on the basis of provisions under Decision 2119/98/EC. The large part of these DSNs had an important microbiology component including National Reference Laboratories covering specific diagnostic needs, like for E.coli and Salmonella (ENTER-NET), Legionella pneumophila (EWGLI-NET) and human influenza (EISS). Since 2005 a gradual process of transfer of DSNs from the Commission to the ECDC was started and as of October 2011, 16 DSN have been already transferred and operative. These networks are regularly providing surveillance data to TESSy (the surveillance instrument put in place by ECDC) and their microbiology component is notably essential. In addition to the surveillance data the National laboratories actively involved in providing the data to TESSy allow additional activities like external quality assessment schemes for human pathogens and laboratory training schemes on diagnostic testing, antimicrobial susceptibility testing and molecular typing. A number of ECDC funded project (see annex) make possible the outsourcing of part of these activities to Member States.

17. Concerning the Union early warning and response (Commission Decision 2000/57/EC) to health threats caused by communicable diseases since 1999 the networks of the National Reference Laboratories have been proved of pivotal importance in helping a coordinated response to these threats. The involved laboratories were part of the previous DSN system or of the networks currently responsible for the Union surveillance of communicable diseases and run by ECDC. Coordination mechanisms are managed by the Commission on a case by case base and appropriate actions have been implemented by the highest possible expertise available to address the need of the specific events, including support, when indicated and possible, from laboratories under the remit of veterinary and food and feed legislations, know as EU RL. Summary of the events dealt under provisions of Decision 2119/98/EC, including those which needed specific support actions in the field of laboratory coordination, are available in the three Reports from the Commission to the European Parliament and to the Council covering the activities of the Early Warning and Response System in the years 2002-2007. The activation of the network of an EU Reference Laboratories to respond to the E.coli epidemic in Germany is a recent example.

18. Under Decision 1350/2007/EC, the Commission supports actions to develop strategies and mechanisms for responding to health threats from communicable diseases, including high-quality diagnostic cooperation between Member States laboratories; the work on the setting up of a network of Community reference laboratories; the further strengthening of risk management capacity and the preparedness and planning for health emergencies; the development of cooperation and improvement of existing response capacity and assets, including mobile laboratories to deploy rapidly in emergencies.
Joint vision of the Commission and ECDC in the area of human pathogen laboratories in the EU

The position statement is intended to provide the joint vision of the Commission and the European Centre for Disease Prevention and Control (ECDC) in the area of human pathogen laboratories in the EU and to indicate the strategic objectives as well as the respective roles in achieving these objectives.

The Commission and ECDC work together:

1) To help and support Member States to comply with the EU legislation on communicable diseases under Decision 2119/98/EC of the Council and of the European Parliament, in order 1) to implement surveillance at EU level and 2) to coordinate the response to severe health threats of cross border impact caused by communicable diseases;

2) To help and support Member States to strengthen the capacity and assure the quality of EU public health microbiology functions, through reinforcing the networks of national reference laboratories to cover the different areas under the current legal obligations and to reliably inform surveillance and epidemic intelligence of communicable diseases;

3) To assure coordination and sustainability of the public health microbiology functions which have been consolidated or developed by the Commission and ECDC over the time and by the currently existing funding mechanism, namely the Health Programme 2008-2013 and the other Union Programmes;

4) To address recent challenges and needs expressed by the health authorities in Member States, notably by the Community Network for surveillance and control of communicable diseases, by the Health Security Committee and by the Management Board and Advisory Forum of the ECDC, building on the experience gained in the last years;

5) To assure an efficient and rapid link between the assessment and management processes at EU level in an efficient and sustainable way with the view of responding in a coordinated way to outbreaks and severe threats caused by communicable diseases;

6) To consider the options and feasibility of creating EU reference laboratories or EU reference functions to cover specific issues which are so far partially or not covered at EU level, and for which potential risk of vulnerability has been identified, notably in the area of the rare or dangerous pathogens;

7) To strengthen the Union laboratory capacity and improve surveillance and preparedness to the global health threat of antimicrobial resistance in human pathogens and immunological aspects in the field of vaccine preventable diseases;

8) To strengthen synergy with other initiatives in the area of laboratory capacity and networking implemented by other Commission services, notably the European External Action Service (EEAS), DG DEVCO, DG ENTR, DG MOVE, and DG RTD;

9) To help Member States to implement the International Health Regulation (2005) through the development of core capacities of EU added value;

10) To support the implementation of the laboratory components of the EU Chemical Biological and Radio Nuclear (CBRN) action plan;

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11) To address the international dimension involving closely the WHO, the Global Health Security Initiative (GHSI) notably through its Action Group (GHSAG) and its Laboratory Network (LN).

The Commission, in close cooperation with the Member States and the ECDC will:

1) Monitor the implementation of the EU legislation on communicable diseases, including the specific laboratory functions related to detection, characterisation of human pathogens toward surveillance and support to outbreak response;

2) Develop the legal and organisational framework of the future EU reference laboratories for human pathogens on the basis of the highest expertise currently available in the EU as the specific situations will require;

3) Coordinate measures requiring the activation of laboratories in the EU in order to manage the public health response to cross-border health threats caused by communicable diseases, including events of potential international concern or deliberate release of dangerous pathogens;

4) Formalising mechanisms to establish sustainable EU cooperation between Member States for EU reference laboratory services on the basis of potential available options;

5) Continue to support public health laboratory functions through the existing funding mechanism, namely the Health Programme 2008-2013 and the other Union Programmes, including the ECDC work programme;

6) Continue to address the international dimension of the laboratory networking through the active collaboration with WHO and the Global Health Security Initiative (GHSI) with the main view to provide Member States with an efficient capacity to respond in a coordinated way to severe cross border health threats which involve an international dimension.

ECDC will encourage cooperation between experts and reference laboratories, in order to foster the development of sufficient capacity within the Union for the diagnosis, detection, identification and characterisation of infectious agents which may threaten public health.

ECDC will support Members States and the Commission in the following areas:

1) Integrated epidemiological and laboratory surveillance of communicable diseases;

2) Integrated epidemiological and laboratory support to investigation and assessment of cross-border epidemic diseases or outbreaks of illness of unknown origin which may spread within or to the Union, at the request of the Commission or the Member States;

3) Laboratory contribution to epidemic intelligence for the assessment of emerging communicable disease, emerging pathogen or pathogen of unusual virulence or antimicrobial resistance and immunological aspects in the field of vaccine preventable diseases;

4) Coordination of EU-wide networks of national reference laboratories for communicable diseases;

5) Encouraging collaboration between expert and reference laboratories;

6) Appraising, building and fostering laboratory capacity and capabilities through training and crossborder technical cooperation agreements;

7) Supporting quality assurance schemes for laboratory techniques.
The Commission and ECDC in order to ensure synergy and avoid duplication and overlapping of initiatives will:

1) Maintain transparency through close communication and further develop mutual consultations at project planning stage by regular teleconferences and face-to-face meetings;

2) Provide the Member States the appropriate information in case of specific issues to be addressed by surveillance and response to communicable diseases with a view to have a clear picture of the mutual tasks and responsibilities of the ECDC and the Commission;

3) Have regular consultation with the Member States on the development of the laboratory strategy, work plans and activities at the Management Board, Advisory Forum and National Microbiology Focal Points meetings;

4) Update their website with information concerning the activities and initiatives implemented in the field of EU coordination of laboratory networks and functions.

Next steps in the development of key areas of work in public health microbiology

The Commission will:

1) Continue the reflection process with the ECDC, the Member States, the funded projects and the involved services on the set-up of EU reference laboratories and functions, including development of possible options;

2) Develop the framework for EU reference laboratory support for emerging cross-border threats and support mechanisms for a referral system.

ECDC will:

1) Appraise laboratory capacity of MS and EU laboratory functions for priority diseases, pathogens, antimicrobial drug resistances and vaccine-induced immune protection;

2) Continue strengthening the capacity of disease specific EU networks of national reference laboratories and training programmes in public health microbiology;

3) Develop a strategy for integration of molecular typing in communicable disease surveillance and epidemic intelligence;

4) Develop a strategy for strengthening surveillance and alert systems for antimicrobial resistance of human pathogens in close collaboration with the EFSA to facilitate integrated surveillance across the human and animal health sectors.

The ECDC updated public microbiology strategy (2012-2016) was developed to outline the implementation of the above next steps by ECDC and submitted for consultation on 28 September 2011 in a joint meeting of the Advisory Forum and National Microbiology Focal Points (AF27/Working Group).