Coordinating Competent Bodies: structures, interactions and terms of reference

Summary:	In order to efficiently work with the EU/EEA Member States the ECDC Management Board has adopted a "One Coordinating Competent Body" approach (MB20) and Terms of Reference for the Competent Bodies (MB21). For each EU/EEA Member State, one Coordinating Competent Body and one National Coordinator, acting as the main entry point for interactions between the country and ECDC, have been identified. This document provides key information on the structures, terms of reference and interactions necessary for the implementation of the one Coordinating Competent Body approach. The document will be updated annually and discussed and agreed with the Coordinating Competent Bodies.
Action:	For discussion and agreement.
Background:	Document AF28/7 Rev.1 – One national Coordinating Competent Body: Structures and terms of reference Document MB 23/16 – One Competent Body for ECDC: Structures and terms of reference Document MB21/10 - Terms of Reference for the Competent Bodies Document MB20/13 Rev.1 - ECDC Work with EU Member States Document MB19/12 - ECDC Work with EU Member States Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004

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Background

1. Based on the ECDC Founding Regulation, the main focus of ECDC's collaboration with the EU/EEA Member States (hereafter referred to as Member States) is through Competent Bodies (CBs), their respective Director's office and their nominated experts. The main mode for ECDC to interact on scientific and technical work with the Member States is within networks and working groups with members being nominated by their respective CB.
2. Over the last years, several initiatives and consultations have pointed out the increasing complexity that developed in the first-years coordination between Member States and ECDC as the Agency grew and its relations with countries intensified.
3. In September 2010, in response to this need for a more streamlined cooperation with the Member States, a Working Group was tasked by the ECDC Director to "develop a clear approach for efficient customer relationships with Member States via Competent Bodies".
4. The conclusions of this Working Group led to the designation of one coordinating competent body (CCB) per Member State, with one National Coordinator, to serve as the point of contact for all communication between ECDC and the Member State on technical and scientific issues. This proposal was endorsed by the ECDC Management Board in November 2010, and followed by the adoption of Terms of Reference (ToRs) for the CCBs in March 2011.
5. In order to reflect this change in all levels of ECDC interactions with countries, additional initiatives were proposed and approved by the Management Board:
    a. To move from the current structure of networks based on ECDC internal areas of work to an approach based on groups of diseases, while preserving a few networks for generic or transversal public health functions.
    b. To define a clear chain of nominations for experts participating in the networks that can always be traced back to the CCBs (and could eventually be managed online by them).
6. In 2011, an ECDC-led Working Group with representatives of eight CCBs was set up to further guide the implementation of the new system. The Working Group developed a draft implementation document, detailing the structures, terms of reference and interactions for the ECDC work with the CCBs and also emphasising the need for simplicity and a step-wise approach in the initial implementation of the system, not to burden the Member States.
7. The draft implementation document was discussed in depth at the ECDC Joint Strategy Meeting in September 2012, and updated according to the input from the Directors and National Coordinators present.

The Coordinating Competent Body structure

Disease work and public health functions

8. The CCB shall be able to address requests for interactions regarding specific communicable disease issues as well as public health functions, therefore resulting in a matrix structure with two dimensions.
9. The disease groups are as follows (grouped by the ECDC Disease Programme):
    a. Antimicrobial resistance (ARHAI Programme)
    b. Antimicrobial consumption (ARHAI Programme)
    c. Healthcare-associated infections (ARHAI Programme)
    d. Emerging and vector-borne diseases (EVD Programme)
    e. Influenza and other respiratory diseases (FLU Programme)
    f. Food- and waterborne diseases and Zoonoses[1] (FWD Programme)
    g. Legionellosis (FWD Programme)
    h. Transmissible spongiform encephalopathy (TSE) (FWD Programme)
    i. HIV/AIDS, STI and Hepatitis B/C (HASH Programme)
    j. Tuberculosis (TB Programme)
    k. Vaccine preventable diseases (VPD Programme)
10. The grouping of public health functions reflects the work of ECDC and its interactions with the Member States, as follows:
    a. Communication
    b. Microbiology
    c. Preparedness and Response
    d. Public Health Training
    e. Scientific Advice Coordination
    f. Surveillance
    g. Threat Detection, EWRS and IHR.

National Coordinator, National Focal Points, and Operational Contact Points

11. The overall coordination of the interactions between in the Member State and ECDC is done by the **National Coordinator (NC)** of the national CCB.
12. ECDC will interact closely with the NC on all issues related to the full implementation of the CCB structure. A **NC Coordination Committee**, chaired by ECDC, will advise on and overview the implementation process. The former CCB Working Group will be dissolved.
13. The NC Coordination Committee is selected by the NCs for a period of three years and will work according to specific terms of reference.
14. The NC may identify individuals in the CBs or from other institutions of the Member States as delegated representatives for disease groups, called **Disease Group National Focal Points**

[1] With wildlife zoonoses covered at ECDC mostly under the EVD Programme

(NFPs), and public health functions, called **Public Health Functions NFPs**. The Public health Functions NFPs are meant to cover generic issues, cutting across all the disease areas.

15. The NFPs will play a strategic and coordinating role within their respective area in close collaboration with the NC.
16. The NC, supported and advised by the NFPs, may further identify **Operational Contact Points (OCPs)** with special expertise.
17. The OCPs should meet cooperation needs of a permanent nature, and the number of OCPs should be kept to the minimum level necessary for an efficient cooperation between ECDC and the Member State.
18. Within each disease group there will be specific OCPs for Epidemiology, Microbiology, TESSy Interactions and Response, as appropriate. In the disease groups covering many diseases, there may be a need for several Microbiology and Epidemiology OCPs. Other types of OCPs may be nominated (e.g. Training, Prevention, Monitoring and Evaluation, Entomology), if deemed necessary for an efficient work (see "Nominations" below). It is envisaged that many Member States will appoint the same person for several of the OCPs.
19. For the public health functions, there may not need to be specific OCPs or the number of OCPs in each area is anticipated to be less than for the disease groups. Some OCPs already identified, include OCPs for EPIET and EUPHEM, respectively, under the National Training Focal Point within the training domain, and OCPs for Media and Public Health Campaigns, respectively, within the communication domain.
20. If there is a need to bring in additional Member State expertise on issues that are not permanent in nature, the NC could be asked to nominate a Member State expert for a specific meeting or a time-limited *ad hoc* expert group. This expert would in that capacity not be an OCP.
21. The roles and responsibilities of the NC, the NFPs and the OCPs, as well as of ECDC, will be detailed in specific terms of reference (ToR).
22. ECDC will identify a single contact point and the unit/section/group in the Centre responsible for working with each NFP/OCP.
23. The roles and functions described above (NC, NFP, OCP, and Member State experts) refer to the role of the CCBs representing their Member States for technical and scientific interactions with ECDC.

    However, experts from the Member States could be involved in the work of ECDC under two additional mechanisms.

    a. For specific scientific tasks, such as participation in the *ad hoc* Scientific Panels mentioned in the ECDC Regulation, ECDC will select individual experts according to their scientific knowledge, not according to country representation. Whilst the national CCBs may be asked to suggest such experts, those will – if selected – serve in their individual capacity, not as Member State representatives.[2]

    b. Specific activities in the ECDC work programme may be outsourced through public procurement (calls for tender or calls for proposal) to public health institutions (or consortia of such institutions) in the Member States, and carried out by experts in these institutions. The ECDC relationship with these experts will be entirely based on the signed contracts, and they will not be regarded as Member State representatives.
24. The National Coordinator should be informed whenever an expert from a CB is working with ECDC in any of the above capacities.

[2] Minutes of the Twelfth Meeting of ECDC Management Board, Stockholm, 18–19 March 2008, paragraph 40.

Nominations

25. Within the Member States, the tasks and responsibilities are cascading down from the NC to the NFPs and further to the OCPs.
26. The nominations of NFPs and OCPs are the responsibility of the NC, and the NC will always have the possibility to change the nominations, for example if the delegation of tasks is not working out in a satisfactory way or the responsibilities of a nominated individual changes. It is anticipated that in many smaller Member States several NFP and/or OCP functions may be delegated to the same person.
27. It is not necessary for all roles of NFPs and OCPs to be nominated. Neither does the NC need to appoint different people for all the roles.
28. If the lower levels have not been appointed (or are unavailable), the responsibility to ensure that the tasks are carried out rest with the upper level (NC for NFP responsibilities and NFP for OCP responsibilities). There is always a possibility for the NC to appoint an alternate for an NFP or OCP.
29. When a need arises to have a new type of OCP in a network, the Network Coordination Committee makes a proposal, including draft ToR and envisaged interactions. The proposal will be discussed in the NC Coordination Committee, and if approved, ECDC will ask the NCs to nominate the requested OCPs. The ToRs should as much as possible be generic to fit more than one network.
30. Once a person has been nominated, additional personal information needed from that person (e.g. declaration of interest, signature of confidentiality forms) will be addressed directly by ECDC to the nominated person and not channelled via the NC.

ECDC Disease and Public Health Networks

31. The Disease Group NFPs and OCPs constitute the **ECDC Disease Networks**, and the Public Health Functions NFPs and OCPs constitute the **ECDC Public Health Networks**.
32. The ECDC Networks will progressively cover all aspects of ECDC work within their respective area. The disease networks will thus have several functions beyond surveillance, with OCPs for Epidemiology, Microbiology, TESSy Interactions and Response, as appropriate.
33. To reflect the matrix structure, the Microbiology Network will consist of the NFPs for Microbiology and the OCPs for Microbiology in all the Disease Networks, likewise the Surveillance Network will consist of the NFPs for surveillance and the OCPs for epidemiology microbiology (when appropriate, e.g. for laboratory based surveillance) and TESSy interactions in all the disease networks.
34. For each network there will be a smaller (maximum 10 members) **Network Coordination Committee** (currently called Coordination Group) from among the network members (NFPs and/or OCPs), mirroring both the broad scope of expertise in the network and its geographic diversity.
35. The Network Coordination Committee is elected by its member for a period of three years.
36. The Network Coordination Committee will appoint a chair among its members and work closely with Centre in between the full network meetings, advice on urgent matters and contribute to the agenda of the regular network meetings.
37. Depending on the nature of work (and for the Disease Networks the number of diseases covered), the architecture of the networks will differ in its details between the networks.
38. The network members may organise themselves in **permanent or *ad hoc* working groups**, **task forces** and **sub-networks** as best fitting the needs within the network.
39. The frequency of meetings with the full networks and working groups, task forces and sub-networks within the networks will be decided by ECDC based on needs and economic

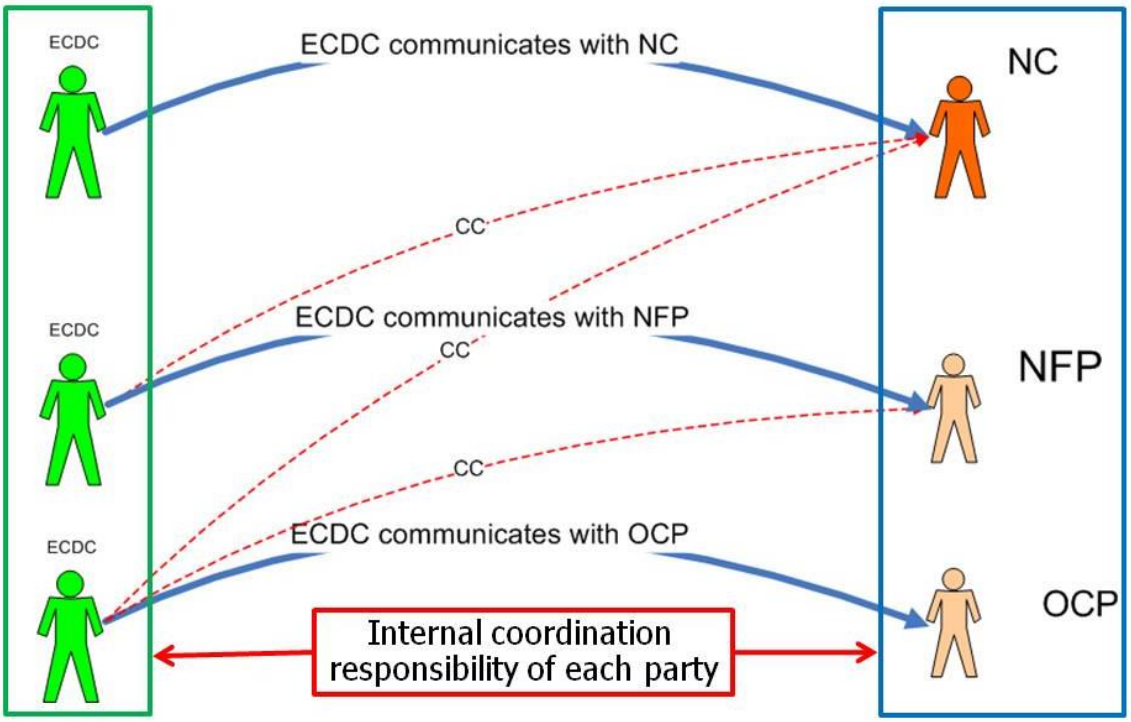
constraints. ECDC and the Network Coordination Committee could decide to invite observers to these meetings as best meeting the network needs.

Coordination within the Member States

40. To ensure a smooth coordination of work, the NFPs and OCPs within a Member State will need to liaise closely with the NC and other relevant NFPs and OCPs, but the exact nature of this coordination is left to each country to decide.

Interactions between ECDC and the Coordinating Competent Bodies

41. Interactions between ECDC and the CCBs will principally be at three levels, corresponding to the nomination levels described above:
    a. **High-level relational and coordination interactions** between ECDC and the CCBs will be at the level of the **NC**, following necessary and appropriate consultation in the country.
    b. **Strategic and overarching interactions** related to a specific disease group or public health function will be at the level of the **NFPs**, following necessary and appropriate consultation in the country.
    c. **Technical and operational interactions** related to specific area within the domains of a disease group or public health function will be at the level of the **OCP**, following necessary and appropriate consultation in the country.
42. By delegating roles and responsibilities (to NFPs and OCPs), the NC also delegates the interactions with ECDC that follow with these roles and responsibilities.
43. All interactions will be based on the ToR for specific functions in the structure (NC/NFP/OCP).
44. In all interactions, ECDC will define at the beginning of the email who (NC/NFP/OCP) is the recipient of a specific message.
45. To facilitate coordination within the Member States, the NC will always be copied in the interactions between ECDC and NFPs/OCPs in the Member States and the NFPs will always be copied in the interactions between the ECDC and the OCPs within his/her domain.
46. Further to this, it will be the responsibility of the Member State to decide on how the consultation processes within their country will be organised.
47. ECDC will set up a similar internal system to ensure the corresponding coordination within the Centre. When this is in place, only those that have been appointed within ECDC to communicate with the CCBs at the three levels will be allowed to do it.
48. In specific areas, notably concerning data exchange and clearance related to ECDC surveillance activities (mainly related to TESSy), the interactions are more complex and are gradually being developed as needed. In the ongoing implementation of the new CCB structure they will be critically revised and simplified whenever possible as to fit the general structure of interactions as much as possible.
49. To provide a full overview, ECDC is gradually compiling a list of the interactions needed to efficiently work with the Member States through the CCBs.



Principles for main interactions between ECDC and the CCBs.

Supporting information systems

50. To support the nomination process and the interactions between ECDC and the CCBs, ECDC is now further developing an on-line tool (CRM), which will include details on all institutions, persons and roles within the CCB structure, as well as the interactions linked to these roles.
51. Through the CRM, the NCs will also have full access to all nominations from his/her country and be responsible for keeping the list of nominations updated.
52. The CRM will automatically ensure that messages between ECDC and the CCBs reach the right person, with appropriate other persons copied. The system will also keep a record of all interactions.
53. The CRM will fully support the grouping of nominated persons (NC/NFP/OCP) in networks, sub-networks, working groups and task forces as needed.
54. To support the day-to-day technical communications between the ECDC and the NCs/NFPs/OCPs, a specific extranet will be set up for each network. Subsections of these extranets may be reserved for the work of the various working groups and sub-networks within that domain.
55. Access to the extranets and other ECDC information systems, e.g. EPIS and TESSy will be linked to specific roles within the CCB structure. Once a named person has been assigned a specific role (NC, NFP or OCP) in the CRM, the system will ensure that this person will also get access to all relevant ECDC information systems and extranets, linked to that function.
56. In the beginning the system will include a limited set of interactions. New interactions will gradually be implemented in the system as needed.

Governance and terms of references

57. The details governing the implementation of the structure of ECDC relations with the CCBs (this document with annexes) will be updated on a regular basis and the changes agreed with the CCBs in annual meetings.
58. In between these meetings, the NC Coordination Committee will make interim decisions on structures and terms of references under this framework.
59. The NC Coordination Committee will further decide on the detailed interactions, and facilitate a smooth implementation of the system, including guiding the development of CRM.
60. Terms of reference have been developed for the NC and the NFPs, detailing the responsibilities of these functions and ECDC, respectively. The ToRs for the NFPs consist of a generic part common for all NFPs and a part, specific for each NFP. Gradually ToRs will also be developed for the OCPs.
61. Any request from ECDC for an OCP in a new area should first be discussed in the NC Coordination Committee and the need and ToR agreed before ECDC could ask for nominations. If the NC Coordination Committee disagrees with ECDC, all NCs will be consulted.
62. Generic ToRs have also been developed for the Network Coordination Committees, and specific ToRs will be developed for any working group and sub-network within the disease and public health networks.
63. All agreed ToRs are annexed to this implementation document.

Implementation

64. The nomination process of the national CCBs and NCs is completed.
65. Since October 2011, the NCs are being copied in on all interactions which are taking place in the ECDC various areas of work.
66. Following the agreement of this implementation document and the updated terms of reference of the NC and NFPs, the Member State will need to (re)appoint the NFPs in all areas.
67. The NCs will also be asked to (re)appoint OCPs as soon as their ToRs have been developed. Pending finalisation of all the specific OCP terms of reference, ECDC will continue to approach the presently nominated Member State experts.
68. The CRM tool for Member State nominations of NFPs and OCPs will be available to all NCs in 2013.
69. By the end of the first quarter of 2013, the new structure should be fully operational.

Evaluation

70. The meeting of the CCBs 2011 suggested evaluating the new structure after one year. This is foreseen to take place in 2014 in order to improve further the interaction between ECDC and the Member States through the CCB.

List of Annexes

1. Terms of Reference for the **National Coordinator** in the Coordinating Competent Body in EU/EEA Member States.
2. Terms of Reference for ECDC **National Focal Points for Disease Groups** in EU/EEA Member States.
3. Terms of Reference for ECDC **National Focal Points for Public Health Functions in** EU/EEA Member States.
4. Terms of Reference for ECDC **Operational Contact Points for Disease-Specific Interactions** in EU/EEA Member States.
5. Terms of Reference for ECDC **Operational Contact Points for Public Health interactions** in EU/EEA Member States.
6. Terms of Reference for ECDC **National Coordinator Coordination Committee**.
7. Terms of Reference for ECDC **Disease Network Coordination Committees**.