ECDC Advisory Forum

Minutes of the Ad Hoc teleconference of the Advisory Forum
Stockholm, 4 November 2015

Contents

Opening and welcome (noting declarations of interest, if any)

1. Andrea Ammon, Acting Director, ECDC opened the session and welcomed all participants.

2. Mike Catchpole, Chair and Chief Scientist, ECDC, noted that the meeting was being recorded, and that apologies had been received from Austria, Belgium, Czech Republic, Denmark, Estonia, France, Lithuania, Luxembourg, Portugal, Poland, Slovakia and the representative of the Standing Committee of European Doctors. There were no declarations of interest made at the beginning of the teleconference.

Item 1. EFSA-ECDC-EURL collaboration agreement on enhancing food and waterborne disease surveillance through molecular typing

3. Johanna Takkinen, Head of Disease Programme, Food- and Waterborne Diseases and Zoonoses, ECDC, presented the document and gave some brief background information before inviting Advisory Forum members to comment on the agreement.

4. Ian Fisher, AF Alternate, United Kingdom, asked for clarification on how Member States would participate and whether it was correct that there would be a single point of contact responsible for data provision in each country. He pointed out a reference error in Article 7, Item 1: 'the agreed dataset (as detailed in Article 8)' however Article 8 related to confidentiality. Furthermore, he suggested it might be appropriate to include WHO in the clause referring to platforms and contacts in the event of human or food alert situations (Article 7, Item 6).

5. Marianne van der Sande, AF Member, the Netherlands, said that her country would be pleased to endorse the agreement, but did not like the idea of restricting data sharing so that everything would have to go through a hub, rather than participants being able to share data and information amongst themselves, as they had been doing to date.

6. Andreas Gilsdorf, AF Alternate, Germany, pointed out that ECDC had not sent the document for review until very late and therefore he had not had a chance to obtain feedback from his national network. The subject matter was also very complex. He was therefore unable to offer advice or endorse the agreement at present and needed more time to review it.

7. Silvia Declich, AF Member, Italy, agreed with the comments by Andreas Gilsdorf and had also not had sufficient time to review the paper or talk to colleagues. She wished to know why it was so urgent to have the agreement endorsed by the Advisory Forum and whether there was a deadline for commenting.

8. Mike Catchpole, Chair and Chief Scientist, ECDC, said that the idea was to take the agreement to the Management Board meeting for approval in two weeks which was why it was being presented to the Advisory Forum first.

9. Johanna Takkinen, Head of Disease Programme, Food- and Waterborne Diseases and Zoonoses, ECDC, responding to comments, said that she fully agreed that visibility and access to data should not be restricted. She explained that this reflected a specific request from the Commission where they were very conscious of data confidentiality issues. The data sharing process would be a stepwise process, starting with limited access during the pilot phase. However data sharing would be promoted and facilitated at EU level to ensure that any relevant investigations were taken forward. With regard to comments by Germany, she apologised for the document not being available earlier but pointed out that the EURL VTEC had been widely discussed with the Commission and that the agreement was between EFSA, ECDC and three EURLs. There was a separate ECDC Member State agreement covering data sharing between ECDC and public health institutes and laboratories so the scope of this agreement was really between the nominated agencies at EU level. Clarifying the urgency, she explained that there had been a kick-off meeting with the veterinary-associated sector on Friday 30 October 2015 and the agreement had been well received, with similar comments to those expressed in the current forum on the extra burden involved, who would have access to what data, confidentiality, etc. The Commission was now waiting for ECDC's Management Board approval of the agreement so they could send nomination letters to the countries. It was hoped that it would be possible to move ahead quickly since the agreement had been under development for two years.

10. Sotirios Tsiodras, AF Member, Greece, asked how ECDC would deal with refusals to share data and whether this would be communicated or publicised.

11. Johanna Takkinen, Head of Disease Programme, Food- and Waterborne Diseases and Zoonoses, ECDC, explained that if there was a refusal to comply with a data request then the country concerned would be contacted and asked to give a legal justification for not releasing the data so in theory it was possible for the data owner to refuse to release to a third party.

12. Mike Catchpole, Chair and Chief Scientist, ECDC asked the AF Member for Greece to put his specific question in writing and send it to ECDC by email as the quality of the telephone connection had made it difficult to catch

the full detail of the question. He noted that the document had taken a long time to produce due to its complexity, the legal discussions and the number of actors involved. It represented the first step in a longer process towards a more open sharing of data however, ECDC was aware from previous discussions in the Advisory Forum that there were concerns about sharing data too widely or moving ahead too rapidly. He asked all AF Members to send any significant concerns to ECDC in writing by Wednesday 11 November 2015 and, in the absence of any definitive objections, the document would be placed on the Management Board agenda for the next meeting on 25–26 November 2015.

Item 2. Proposal for revised data access to TESSy

13. Encarna Gimenez, TESSy User Support Manager, Surveillance and Response Support, ECDC, presented the proposal on a revised policy for access and use of TESSy data and asked for comments from the Advisory Forum.

14. Ian Fisher, AF Alternate, United Kingdom, asked whether the peer review group mentioned in Article 6.4, consisting of three national surveillance focal points had already been decided.

15. Marianne van der Sande, AF Member, the Netherlands, asked for clarification on how ECDC would comply with the freedom of information act. She wished to see ECDC taking a more active role in trying to protecting Member State interests in the event of data access requests. She advocated modifying the text to reflect a stronger wording, similar to that seen in the Item 1 document on the management of data on molecular testing of isolates from food-borne pathogens. The Netherlands had gained a great deal of goodwill from data-providing partners by showing them support when any issues had arisen under the freedom of information act. The Item 1 text demonstrated a much more accessible position being taken by ECDC in support of Member States and she wished to see something similar in this proposal.

16. Encarna Gimenez, TESSy User Support Manager, Surveillance and Response Support, ECDC, responding to the question from the United Kingdom on the peer review group policy, said that the policy had been approved in 2009 and then reviewed in 2010–-2011 during an EU wide consultation. Volunteers had come forward to participate in a peer review group but, since no issues had ever arisen, the group had not been activated. A list of those people who had volunteered could be provided if required. Responding to the comment by Marianne van der Sande, she confirmed that it would be possible to look at the wording relating to ECDC's role in support of Member States with a view to strengthening it. However, she pointed out that ECDC had to comply with Regulation (EC) No 1049/2001 of the European Parliament and of the Council dated 30 May 2001 regarding public access to European Parliament, Council and Commission documents, although it could not release personal data unless it was in the public interest or for research purposes, and not to journalists or lawyers.

17. Denis Coulombier, Head of Unit, Surveillance and Response Support, ECDC, added that ECDC was aware that this issue was a concern and had looked into Regulation (EC) No 1049/2001 to see what was feasible. There were exceptions in Article 4 of the Regulation which allowed for data not to be released if there was an issue with data protection, competition or similar. Under the Regulation, ECDC would have two weeks to respond to any request and could refuse to release data on the basis of discussions with a Member State. However, he pointed out that if there was an appeal, this would be reviewed by the EU Ombudsman and ECDC would have to comply with the Ombudsman's final decision. ECDC had been informed by its legal department that in recent judgements and appeals of a similar nature the trend had been to allow free access to data when the request was made and it had been extremely rare for a refusal to be confirmed by the EU Ombudsman, unless very clear criteria were met.

18. Marianne van der Sande, AF Member, the Netherlands, agreed that it was necessary to comply with the Regulation and was in favour of data sharing, but felt that ECDC still needed to make clear its support for the Member States should any issue arise. She was pleased that ECDC would look at the phrasing of the text with a view to taking a more active stand.

Item 3. Public health teams for EU emergency response

19. Denis Coulombier, Head of Unit, Surveillance and Response Support, ECDC, outlined the background to the proposal which had resulted from the response to the Ebola crisis in West Africa. ECDC had participated in discussions with the European Commission's Humanitarian Aid and Civil Protection department (ECHO) on lessons learnt in mobilising the response to Ebola. Under the EU civil protection mechanism it was possible to mobilise EU teams to support third countries during disasters, if requested. WHO had undertaken a similar initiative, to draw up a list of the type of medical teams that could be mobilised internationally to support a country facing a large public health emergency. During discussions in July 2015, ECDC had been asked to come up with proposals on the type of public health teams that could be mobilised to complement clinical or disaster management teams working within civil protection mechanisms. ECDC had prepared and presented a working document based on the idea of mobilising public health response teams as part of international response through ECHO mechanisms. To date, such mechanisms had been utilised to provide funding for NGOS operating treatment units and for mobile laboratories, but not for public health components. The first

step was to highlight the types of teams required. ECDC identified five types of public health response team to correspond to five types of intervention necessary for controlling an epidemic (surveillance and control teams, vaccine-preventable disease epidemic teams; food- and waterborne response control teams; vector-borne disease teams and exit screening teams in affected countries). At the end of an epidemic it might also be possible to mobilise a transition team to be dispatched during the recovery phase to help reconstruct public health services. At this stage, the plan was not very detailed but it had been validated during a Commission meeting of national competent bodies working within civil protection. The next step would be for DG ECHO to prepare a mechanism to mobilise teams in a crisis. ECDC could play a role in identifying the required expertise and act as a facilitator for the mobilisation of the teams. The teams would be coordinated in the field by WHO, or another body if the crisis were to occur in an EU country. ECDC was now seeking advice and comments from the Advisory Forum.

20. Ian Fisher, AF Alternate, United Kingdom, asked whether the teams would come solely from the Member States or whether they would also include ECDC staff.

21. Darina O'Flanagan, AF Member, Ireland, was concerned about the desire to 'pre-nominate' suitable people who would want to go as she was not sure this was feasible. If the purpose was for them to receive advance training then obviously this would be useful. Otherwise, although she was in favour of adopting a more practical approach, she did not think it was not appropriate to identify individuals in advance.

22. Silvia Declich, AF Member, Italy, said that this issue had many implications. Although ECDC had a mandate to produce risk and needs assessments, putting together a public health response team to intervene in third countries was a huge challenge which needed to be examined in relation to the Agency's mission. She suggested that putting together and administering a public health response team may even require a dedicated unit should it become a reality.

23. Andreas Gilsdorf, AF Alternate, Germany said that it was good to have a structured approach and that this was useful for Member States if they were thinking of becoming more active on an international basis. However, he had doubts about whether to call the groups 'teams' and believed the emphasis was on functions rather than teams, since the composition of the groups would differ for each crisis.

24. Sotirios Tsiodras, AF Member, Greece, agreed with the comment from Germany.

25. Denis Coulombier, Head of Unit, Surveillance and Response Support, ECDC, responding to the question from the United Kingdom, said that the teams would not be restricted to individuals from the Member States and that the idea was to mobilise expertise across the European Union. At the start of an outbreak ECDC staff might be sent as a rapid response group if it was not possible to mobilise Member State expertise quickly enough, although the idea was for ECDC to facilitate mobilisation. If Member States had their own teams it would be possible through the proposed mechanism to mobilise and coordinate the response more quickly at EU level. Answering the concerns expressed by the AF Member for Ireland, he agreed that it was not possible to have a list of all those experts who could be mobilised. The idea was more to be able to identify quickly the experts most suitable for mobilisation rather than maintaining a registry of all those who could be mobilised. He pointed out that some of those mobilised would be logisticians or data administrators rather than public health experts and they would possibly be easier to identify. Answering the question from the AF Member for Italy relating to ECDC's mandate and contributing to the teams, he explained that the ECDC's Founding Regulation did in fact allow for ECDC to provide technical support to Member States facing outbreaks upon request. The proposed mechanism would be developed in collaboration with ECDC's governing bodies and the Management Board would be consulted, as had been the case during the Ebola outbreak, especially if this implied the redirecting of resources or priorities. He pointed out that when an international public health emergency was declared under the International Health regulations countries were obliged to provide this type of international public health support anyway. ECDC had worked with DG ECHO on a typology and the details could be added later, following consultation with Member States. With regard to use of the term 'team' he explained that one of the requirements was for the groups to be autonomous and not necessarily have to rely on local support in the affected country. The idea was that the teams or groups mobilised would have all the necessary support functions – data management, logistics, communication support etc. – and these could all be predefined. In many instances the teams could fit into a pre-established structure on the ground. However he agreed that referring to the groups as teams did not make sense in relation to what they had experienced in Guinea during the Ebola crisis.

Any other business

26. Andreas Gilsdorf, AF Alternate, Germany, raised the difficulties with the training needs assessment sent to the Member States for completion. It had been impossible to complete the assessment for Germany despite many meetings and the timeline being extended. He wondered whether other countries were experiencing similar problems and asked for the issue to be placed on the agenda of the next AF meeting for discussion and to help with interpretation.

27. Marianne van der Sande fully supported the request from Germany, stating that it was impossible to give meaningful answers in the questionnaire with so little guidance available. The questionnaire did not reflect the reality in countries and the answers would not provide the input required by ECDC.

28. Darina O'Flanagan, AF Member, Ireland, agreed with comments by other AF Members and pointed out that the late addition of EUPHEM and microbiology has complicated matters further.

29. Mike Catchpole, Chair and Chief Scientist, ECDC, agreed that this issue needed to be placed on the agenda of the AF meeting in December and that it underlined the importance of having a dialogue with the Advisory Forum on an ad hoc basis. He also apologised for the late delivery of papers for the teleconference and assured that provision would be more timely for the next meeting.

30. Sylvia Declich, AF Member, Italy asked about the status of the IMI call which had been discussed at the last ad hoc teleconference on 14 September 2015.

31. Mike Catchpole, Chair and Chief Scientist, ECDC, said that the dialogue with IMI was ongoing and that there was no clarity on timelines.

32. Andrea Ammon, Acting Director, ECDC, added that the dialogue with IMI and vaccine producers was still ongoing to see if they could comply with ECDC proposals. If the responses were positive it was expected that the call would be launched in December. The Advisory Forum's views had been reflected very clearly and if there was any disagreement ECDC would revert for further discussion.

33. Mike Catchpole, Chair and Chief Scientist, ECDC thanked all the AF Members for their input at the teleconference and hoped to see many of them at ESCAIDE the following week.

Annex: List of participants

To be added by Governance

Annex II: List of Participants

Member State	Representative	Status
Bulgaria	Mira Kojouharova	Member
Croatia	Sanja Kurečić Filipović	Member
Germany	Andreas Gilsdorf	Alternate
Greece	Sotirios Tsiodras	Member
Hungary	Ágnes Csohán	Member
Ireland	Darina O'Flanagan	Member
Italy	Silvia Declich	Member
Latvia	Jurijs Perevoščikovs	Member
Netherlands	Marianne van der Sande	Member
Spain	Isabel Noguer	Alternate
United Kingdom	Ian Fisher	
Observers		
Iceland	Thorolfur Gudnason	Member
Norway	Hanne Nøkleby	Member
European Commission		
DG SANTÉ	Frank Van Loock	
	Andrea Schwarz	