ECDC Advisory Forum

Minutes of the 37th meeting of the Advisory Forum

Stockholm, 26-27 February 2014

Contents

Item 1 – Opening and adoption of the agenda (and noting the Declarations of Interest and Specific Declarations of Interest, if any) *(Documents AF37/2; AF37/3 Rev.1)*

1. Marc Sprenger, ECDC Director, greeted the Members of the Advisory Forum and welcomed them to the Thirty-seventh meeting of the Advisory Forum (AF).

2. Johan Giesecke, Chief Scientist and Chair, welcomed the Members of the Advisory Forum on his behalf and extended a special welcome to Emese Szilágyi, newly appointed Alternate, Hungary and to Nerija Kuprevičienė, Alternate, Lithuania, attending the AF for the first time. The Chair also welcomed Frank Van Loock from the European Commission, Guénaël Rodier from the WHO Regional Office for Europe and Viviane Bremer, Observer, Germany. Apologises had been received from Cyprus, Estonia, Italy, Liechtenstein, Malta, Montenegro, Serbia, the Former Yugoslav Republic of Macedonia and European Patients' Forum.

3. The Chair reminded the participants of the new policy and procedures regarding the Annual and Specific Declarations of Interest and thanked all those members who had submitted their Annual Declarations and the Specific Declarations of Interest for this meeting. He expressed his confidence that all missing declarations would soon be received. No oral declarations of interest were made.

4. The Chair informed the AF that minor amendments had been made to documents AF37/1, AF37/3 and AF37/5, as informed via email correspondence prior to the meeting.

Item 2 – Adoption of the draft minutes of the 36th meeting of the Advisory Forum held in Stockholm (12 December 2013) *(Document AF37/4)*

5. The draft minutes from the Thirty-sixth meeting (12 December 2013) had been previously circulated amongst the AF Members for comments and amendments.

6. Kåre Mølbak, Member, Denmark, said that the paragraph 44 should read 'epidemiologists' not 'immunologists'.

7. Jean-Claude Desenclos, Member, France, said that the minutes should reflect that due to technical problems he could not participate in the discussion until Item 5.

8. Following these amendments, the minutes were approved by the AF.

9. For additional agenda items, Mike Catchpole, Member, United Kingdom, suggested that the Commission should comment on some of the statements made in the now ameliorated documents AF37/1, AF37/3 and AF37/5; Mika Salminen, Member, Finland, said that a response to the revision of Directive 98/79/EC on in vitro diagnostic medical devices should be discussed; Darina O'Flanagan, Member, Ireland, said that a brief discussion on diphtheria antitoxin combined with some additional information from the Commission on the central storage of diphtheria vaccine would be helpful; Franz Allerberger, Alternate, Austria, suggested that the serious lack of rabies vaccine should be added as an agenda item. The AF decided that these items would be added to the agenda, provided that there was sufficient time.

Item 3 – Update from ECDC on the main activities since the last Advisory Forum meeting *(Documents AF37/Info Note 1)*

10. The ECDC Director updated the AF on recent ECDC activities[1], including country visits to Norway and Latvia, meetings at the European Parliament, and an event celebrating the 110th anniversary of the Scientific Institute of Public Health (ISP-WIV) in Brussels.

[1] Item 3 - Update on ECDC main activities (M Sprenger)

11. In the second part of the presentation, which had previously also been given to ECDC staff, the Director shared his vision of ECDC's work in public health. He emphasised ECDC's role as a networking organisation and painted a picture of the challenges that ECDC faces.

12. In the ensuing discussion, the AF predominantly focused on public health funding and the implications of the new Decision of the European Parliament and of the Council on serious cross-border threats to health.

13. Jean-Claude Desenclos, Member, France, said that the next AF meeting should have an extended discussion on the specific implications of the Decision: which parties are involved, what are the implications?

14. The ECDC Director pointed out that the authors of an article published in the Lancet paper concluded that 'the interaction of fiscal austerity with economic shocks and weak social protection is what ultimately seems to escalate health and social crises in Europe'[2]. He promised that he would support any type of investment in public health and would advise against budget cuts, so European public health would eventually rebound to its pre-crisis levels.

15. Sotirios Tsiodras, Alternate, Greece, said that Greek administration denied that the austerity measures had any serious consequences on public health. He cautioned that the correlation between political decisions and health outcomes was a sensitive area. Reversing the negative effects of austerity measures was an area where ECDC is in demand.

16. Mike Catchpole, Member, United Kingdom, acknowledged the added value of ECDC's surveillance efforts. Involving experts around Europe and positioning ECDC as a network organisation was a productive concept. He also emphasised that ECDC had a really important role in risk assessment and that risk assessments could be facilitated by using the Epidemic Intelligence Information System (EPIS) tool in a slightly more proactive way when identifying threats.

17. The Director responded that ECDC already made full use of EPIS, and that ECDC connected with the countries at the first signs of a public health threat. He also assured the AF that draft Rapid Risk Assessments would always be sent first to the experts in the Member States.

18. Denis Coulombier, Head of Surveillance and Response Unit, ECDC, added that the content and scope of Rapid Risk Assessments (RRAs) was not predefined. The format of RRAs was subject to change; for example, 'recommendations' was recently toned down to 'options for mitigation'. He also added, echoing the comment made by Mike Catchpole, that he was happy to hear that ECDC should be more active in EPIS and that the Centre did not necessarily always had to launch a full-fledged, stand-alone RRA.

19. Jean-Claude Desenclos, Member, France, suggested that ECDC should look at the way it produced RRAs, implying that the process had to be adjusted in order to avoid conflicts of missions and competence in an evolving institutional environment following the new decision on cross border threats.

20. The Director pointed out that a technical agency like ECDC should be able to produce an RRA without political interference. ECDC provided 'options for mitigation', a phrase that also expressed mutual respect for the different roles of ECDC and the Commission, with the Commission respecting the quasi-autonomous status of ECDC, which clearly was in the best interest of the European citizen.

21. Kåre Mølbak, Member, Denmark, concluded that the new Decision of the European Parliament and of the Council on serious cross-border threats to health would not cause any major changes in the way ECDC works. ECDC's high-quality disease surveillance and its work as a network organisation would not be affected.

22. Fernando Simón, Member, Spain, concurred. The scope of ECDC's work would not change, but the new Decision would probably lend a more specific profile to the role of ECDC.

23. The Director agreed that dealing with serious cross-border health threats was important, but that it would not change the Centre's basic modus operandi. He emphasised that the Centre could quickly adapt to new realities, for example, ECDC was now developing a new TB action plan, which

[2] Karanikolos M, Mladovsky P, Cylus J, Thomson S, Basu S, Stuckler D, Mackenbach JP, McKee M. Financial crisis, austerity, and health in Europe. Lancet. 2013 Apr 13;381(9874):1323-31

used to be a prerogative of the Commission. As far as the EWRS was concerned, he saw the need to redesign some features to meet the new regulations.

24. Karl Ekdahl, Head of the Public Health Capacity and Communication (PHC) Unit, ECDC, explained that two sections of his Unit were prepared to offer support for preparedness and risk communication but that he did not yet know the full extent of the impact of the new Decision on serious cross-border threats to health and that it remained unclear what demands would have to be dealt with by ECDC. The Commission had promised to present a road map to the implementation; in the meantime, his team would attend various preparatory seminars on the topic.

25. Frank Van Loock, European Commission, mentioned that the Commission was currently preparing the reporting template for Article 4 of the new Decision, assessing the consequences on EWRS reporting, and transposing old case definitions under the new framework. He could not commit to any dates as completion depended on external factors. He also assured ECDC that the Commission did not foresee any changes to ECDC's work. Content-wise, there would be no changes. He did, however, anticipate some procedural changes towards consultation, for example, in terms of risk communication or preparedness.

26. Darina O'Flanagan, Member, Ireland, expressed interest to explore the implications of the new Decision on serious cross-border threats to health. For example, expertise on radiological and chemical hazards in Europe was rarely combined with public health competence. At a European level, ECDC could bring this public health dimension to the discussion.

27. Haraldur Briem, Member, Iceland, agreed that the public health aspects of these hazards were not very well known among experts.

28. Aura Timen, Member, European Public Health Association, enquired about the role of learned societies. The Director answered that ECDC initially wanted to establish a comprehensive policy on learned societies but that it had introduced a more pragmatic approach: in the TB, AMR and training programmes, ECDC closely collaborated with learned societies, while in other areas contacts were less relevant and thus more sporadic.

29. Guénaël Rodier, WHO Regional Office for Europe, explained that he was a strong advocate of joint exercises to test health monitoring systems. He also saw a strong operational link between ECDC and the Commission.

Item 5 – Advisory Forum priorities on scientific advice for 2015 Work Programme

30. Andreas Jansen, Head of Section Scientific Advice Coordination, Office of the Chief Scientist, ECDC, reported on the prioritisation of project proposals for the 2015 Work Programme and elaborated on the methodology and results. Graphs and tables summarising the results for all disease programmes are available electronically[3].

31. Jean-Claude Desenclos, Member, France, was disappointed that the participation in the exercise was so low. He considered participation an important task, and he had always assumed all AF members felt the same way. He was, however, disappointed that some disease programme (e.g. the Influenza Programme) had not made the effort to provide a description to any of their projects, which forced him to vote against all influenza projects which is not efficient.

32. Kåre Mølbak, Member, Denmark, emphasised the importance of having more concise descriptions of the individual projects. Also, the number of projects was too high, and fewer options would have made the process easier.

33. Jan Kynčl, Member, Czech Republic, agreed that the lack of detailed information on all five influenza projects was inexcusable. He expressed his amazement that such an error could have passed ECDC's internal revision. He also noted a disparity in style and quality of the provided abstracts/summaries. While some were concise and very well written, others lacked detail and clarity

[3] Item 5 - AF priorities on scientific advise WP2015 (A Jansen)

and offered little more than a proposed 'meeting of experts'. More useful project details would have been helpful.

34. Sophie Quoilin, Alternate, Belgium, thought that the exercise was too time-consuming. It should have been more focused and it would have been helpful if some background had been given on the person or organisation who had suggested the project.

35. Andreas Jansen, ECDC, promised that the selection process would be further fine-tuned, the number of proposals would be reduced, and project descriptions would offer more detail.

36. The Chair pointed out that the ranking was not binding and that Disease Programmes could still reject a project. This, however, was highly unlikely, and a Disease Programme would need very good reasons to reject a high-ranked project.

Item 6 – Scientific advice and risk assessments: update on assessments, reviews and guidance

Item 6a – ECDC's work with Disease Networks (Document AF37/5 Rev.1)

37. Piotr Kramarz, Deputy Chief Scientist, Office of the Chief Scientist, ECDC, reported on ECDC's work with disease networks.[4] He also announced that a second paper will be submitted to the AF in May 2014 which would outline the future work with these networks. ECDC currently coordinates 16 disease networks in total.

38. A recurring theme during the discussion was that some experts in the Member States would be forced to assume too many roles in order to meet ECDC's requirements for the nomination of OCPs (Operational Contact Points) and NFPs (National Focal Points).

39. Irena Klavs, Member, Slovenia, praised the paper on the current state of EDCD's work with disease networks and called it very clear and concise; the fact that the document also outlined the resources at the country level was positively highlighted. At the same time it was pointed out that if all suggested nominations were carried out, some public health officials in the Member States would have to assume too many roles. One way to support Member States would be to raise awareness for public health network functions, for example by talking to the national Ministers of Health. It was also expressed that it would be helpful if ECDC could define the core communicable disease functions that are really needed and provide an estimate of the minimum resources at the country level. Equally helpful would be an annual preview of planned projects (together with an outline of expected benefits) that required Member State participation, e.g. through surveys and questionnaires. The ECDC Director noted that Centre could conduct a 'soft assessment' of the Slovenian situation and provide detailed feedback, if so desired.

40. Mike Catchpole, Member, United Kingdom, said he struggled to get to the core of the disease network issue. Disease networks were initially surveillance networks, but what are they now? What is the purpose of these networks? The paper implied that the disease network's remit had moved beyond surveillance. If the disease networks are now predominantly 'expert networks', was there really added value in these expensive network meetings? Some things are done more efficiently through correspondence and at scientific conferences. In conclusion, the UK representative expressed that the Centre still owes the AF an answer on what was the real purpose of these networks.

41. Anders Tegnell, Member, Sweden, appreciated the paper as a review of the history of ECDC's disease networks and a report on their current status. However, this should not keep the AF from critically evaluating the role of the networks, and if the evaluation was negative, corrective steps should be taken. The Swedish representative also expressed that he would like to see a clearer structure on nominating members and expressed deep hesitation about the OCP level. The procedure forced the Member States to accept a structure that might not suit them and that would, for example, hurt resource-strapped countries as they would not be able to create new jobs to fill all functions.

[4] Item 6a - ECDC work with Disease Networks (P Kramarz)

42. Jurijs Perevoščikovs, Member, Latvia, said it would be helpful if people with expertise in clinical issues would be included for some diseases. With regard to the nomination of FPs in Latvia, he said that it would be difficult to meet ECDC's demands.

43. Jan Kynčl, Member, Czech Republic, compared the networks before and after the establishment of ECDC. Under the auspices of ECDC, some networks seemed to suffer from over-coordination. Also, some of the rules and requirements as ECDC describes them did not take into account the specific structures in the various countries.

44. Mika Salminen, Member, Finland, said that in he had some doubts about expanding the number of people involved. He added that disease-specific programme managers did not exist in Finland, where this was considered a dated model. With regard to the network meetings, he had a positive opinion; all meetings he visited were extremely productive. As other AF members, he supported a critical evaluation process for all 16 disease networks. This could be done through the AF or externally.

45. Fernando Simón, Member, Spain, emphasised the difference between OCPs and experts. While OCPs are experts in their fields, they are also representatives of their countries. Experts, at least theoretically, are not bound by national loyalties and are independent.

46. Sophie Quoilin, Belgium, Alternate, said that one of the major roles of ECDC was to develop networking capacity. Unfortunately, the way ECDC developed this capacity was marred by a top-down approach.

47. Darina O'Flanagan, Member, Ireland, noted that some of the networks have thrived while others have floundered. An external evaluation would be helpful.

48. Kåre Mølbak, Member, Denmark, Franz Allerberger, Member, Austria, and Darina O'Flanagan, Member, Ireland stressed the positive aspects of the disease networks. Small countries particularly benefited as networks increased the options to develop effective peer interchange.

49. The ECDC Director acknowledged the high number of network meetings but also said that in general getting input from participants was valuable; he agreed, however, that the number of meetings needed to be discussed.

50. Piotr Kramarz, ECDC, noted that in case the countries were overburdened by the number of requested nominations, they could simply not nominate. Member States were under no obligation to nominate FPs or OCPs. It was also pointed out that the upcoming paper scheduled for May would address the role and purpose of networks, define the future of the networks and make suggestions for alternatives to the old lab-driven structure.

Item 6b – Update on the process of delivery of scientific advice at ECDC

51. As requested during the Thirty-fourth AF meeting, the Forum was updated on ECDC's approach to scientific advice.[5]

52. The AF agreed that their input should be sought on the formulations of the questions for the public consultation.

Item 6c – Update on ECDC policy to join consortia

53. Johan Giesecke, Chief Scientist and Chair, stated that ECDC would retain the old procedure which specifies that ECDC would not join any consortium as partner. ECDC will, however, serve on scientific committees or advisory boards, but would stop short of becoming a full partner.

54. Jean-Claude Desenclos, Member, France, expressed his astonishment that ECDC, in a reversal of its former stance, now categorically ruled out – without prior discussion in the AF – serving in a consortium or preparing a call for tender.

[5] Item 6b - Delivery of scientific advice at ECDC (A Jansen)

Item 6d – Progress on the IMI ADVANCE project

55. Piotr Kramarz, Deputy Chief Scientist, ECDC, reported on the Centre's role in the IMI ADVANCE project in which ECDC is currently the leader of Work Package 7. Other organisations involved in the IMI ADVANCE project include RIVM/CIb (full partner status), Statens Serum Institute (full partner), WIV-SIP (collaboration on Work Packages 1, 3, 4 and 5), Hungary's National Center for Epidemiology (associated partner, contributions to Work Packages 4.6, 7, 7.1), and the Hellenic Centre for Disease Control & Prevention (associated partner).[6]

56. Kåre Mølbak, Member, Denmark, pointed out that Work Package 5 (proof-of-concept studies for benefit/risk monitoring) was the most important. Overall, consortium work remained difficult as consortium participants are extremely heterogeneous and communication remains difficult. The consortium's approach was called to be over-ambitious because it tried to cover too many topics; however, it is hoped that the current a-little-bit-of-everything approach could be changed to a more specific one.

57. The majority of the AF agreed that regular updates on ADVANCE would be helpful.

58. Jean-Claude Desenclos, Member, France, noted that France had always been opposed to the participation of ECDC in the IMI project, despite considerable pressure to join and that the difficulties that were pointed out in the discussion were to be expected.

59. Fernando Simón, Member, Spain, commented that IMI ADVANCE was important because it could be seen as a continuation of certain tasks previously covered by I-MOVE. Unfortunately, vaccine effectiveness seemed to be a minor objective. This was rather unfortunate because this season's influenza vaccine and its low effectiveness – despite the fact that all strains circulating in Spain were included – demonstrated the need for reliable research in this field.

60. Sophie Quoilin, Alternate, Belgium, saw a similar quandary. Public health experts promote vaccination but lack relevant information, for example on long-term vaccination effects. The re-emergence of mumps and pertussis in Belgium raised questions which IMI ADVANCE could perhaps solve. Belgium's main motivation to join the project was to look for answers on vaccination.

61. Darina O'Flanagan, Member, Ireland, voiced concerns about the project, especially the involvement of the industry. She also pointed out that competence on vaccination issues was largely with public health institutes, as was demonstrated in Finland where the National Institute for Health and Welfare investigated a possible nexus between Pandemrix and narcolepsy cases and produced convincing results. On the other hand, research based on large-scale databases could not provide satisfying answers as data often were dubious and definitions wobbly.

62. Piotr Kramarz, ECDC, pointed out that the aim of IMI ADVANCE was to create a blueprint for the evaluation of vaccine effectiveness, and that the project was not a continuation of I-MOVE. He also acknowledged that the public-private interaction within the project was problematic.

Item 6e – Update on the 'Burden of Communicable Diseases in Europe' project

63. Alessandro Cassini, Expert, Burden of Disease and Forecasting, Office of the Chief Scientist, ECDC, presented the results of the 'Burden of Communicable Diseases in Europe' (BCoDE) project that aims to estimate the impact of 32 selected diseases and to choose a suitable composite health measure, including sequelae and interventions.[7] Following an extensive literature review, outlined and tested methodology, ECDC created a software and user-friendly toolkit for burden estimation. The BCoDE study allows assessment of the comparative impact of infectious diseases. ECDC plans to include BCoDE estimates in its next Annual Epidemiological Report. Any Member State that is willing to participate will get the necessary support from ECDC.

64. Jean-Claude Desenclos, Member, France, thanked ECDC for the update on the project. He wondered if it makes sense in a broad public health view to only do this for infectious diseases.

[6] Item 6d - Progress on IMI ADVANCE Project (P Kramarz)
[7] Item 6e - Update on BCoDE (A Cassini)

65. Hanne Nøkleby, Member, Norway, declared that Norway would be very interested in participating.

66. Darina O'Flanagan, Member, Ireland, expressed her interest to participate, provided that Ireland would get the necessary support (resources).

67. Mika Salminen, Member, Finland, expressed definite interest to take part in the project and was pleased that it is compatible with the work carried out by WHO.

68. Anders Tegnell, Member, Sweden, stressed that showing the potential of burden of disease was very important work.

69. Franz Allerberger, Alternate, Austria, confirmed the importance of the project, given the interest on estimates from politicians. He wondered if participation could be limited to sub-topics such as food and water-borne diseases as this would lower the burden for countries to take part in this exercise. Austria would highly appreciate to do so.

70. ECDC responded that looking at specific diseases only would absolutely be possible.

71. Jan Kynčl, Member, Czech Republic, noted that this work is very important, it was however advised to be careful with the wording, especially as far as prioritisation goes, because prioritisation could imply that the other diseases would be diseases without a problem.

72. Kåre Mølbak, Member, Denmark, stated that Denmark would be happy to continue to collaborate with ECDC on this project. He stressed the importance to communicate uncertainty of figures as this would be based on allot of assumptions. Countries would have to agree on this.

73. Viviane Bremer, Observer, Germany, expressed a note of caution. For Germany, the indicators did not really work and colleagues in Germany have advised to go ahead with this cautiously.

74. ECDC Director welcomed the idea of visualising the burden in hard figures. He also pledged to provide the evidence behind it.

75. In conclusion, ECDC agreed that there is a need to express the uncertainties. But it would be important to do the exercise to see where the necessary data is lacking. The Centre could also arrange country visits in order to help as regards to resources. An incidence-based approach for long-term diseases would serve as basis which gives a better idea of disability-adjusted years (DALY). Cost and cost-effectiveness would also be considered.

Item 4 – Update on the Greek Presidency of the European Union

76. Sotirios Tsiodras, Alternate, Greece, provided an update on the Greek EU Presidency (January–June 2014).[8]

Results of the Working Group Sessions

Working Group A: Criteria for review of the IMI ADVANCE Project outcomes

77. Jaap van Dissel, Member, Netherlands, presented the results of the Working Group (WG).[9] The presentation focused on the review of the IMI ADVANCE electronic platform and addressed concerns about the heterogeneity of the various database formats, the cost of databases, the robustness of the database, and the ownership of data.

78. The WG developed a set of review criteria, ranging from added value to risk management planning. A comprehensive list is available in the presentation. The group also offered a list of

[8] Item 4 - Greek EU Presidency (S Tsiodras)
[9] Working Group A

'suggested proofs of concepts', for example influenza vaccination in pregnancy and the safety of HPV vaccination.

Working Group B: Future development of the organisation of the European Conference on Applied Infectious Disease Epidemiology (ESCAIDE)

79. Franz Allerberger, Alternate, Austria, reported results for WG B.[10]The Group stated that the aims and objectives of ESCAIDE were now clearly defined. Participation of southern and eastern Member States was low, involvement of national public health institutes should be boosted (preferably by holding the conference every other year outside of Sweden), and Academia seemed underrepresented.

80. Mike Catchpole, Member, United Kingdom, said that he was initially in favour of the rotation, but had since changed his view as holding the conference in Stockholm gave it a clear identity.

81. Darina O'Flanagan, Member, Ireland, said that it was difficult for staff in countries on the periphery to get travels approved. Holding the conference outside of Sweden gave people a chance to attend.

82. The ECDC Director noted that there were cheap ways to travel to Stockholm, for example Ryanair. He added that he would like to see that ESCAIDE also covered cross-border aspects.

83. The Chair informed the AF that the 2014 deadline for ESCAIDE submissions had been moved to 23 May 2014.

Working Group C: The PRECEPT project on grading of evidence is running

84. Aura Timen, Member, European Public Health Association, reported for WG C on the PRECEPT project on grading of evidence.[11] The PRECEPT framework structures existing methodology in order to deal with complex problems: identifying single questions, systematic reviews, bias assessment, evidence grading, summarising evidence. The WG assessed the suitability and applicability of this methodology to public health, listing a series of pros and cons which can be found in the group's presentation.

Item 7 – Epidemic intelligence: update on recent threats in the EU

Item 7a – Human infection with avian influenza A viruses, China

85. Pasi Penttinen, Head of Programme Influenza and other Respiratory Viruses, Office of Chief Scientist, ECDC, provided an overview of the current situation regarding avian influenza A virus outbreaks in China.[12] ECDC published a Rapid Risk Assessment on 26 February 2014.

86. In its risk assessment, ECDC outlined two main scenarios: a widespread transmission in poultry with occasional spill-over to humans or a pandemic scenario with a new strain with near to no immunity in the human population. China is currently in the late stage of its influenza season. ECDC's threat assessment concludes that the risk of transmission of influenza A(H7N9) in the EU is currently low. The cases of H10N8, H6N1 and H9N2 were possibly detected due to enhanced surveillance. The risk assessment also outlines options to reduce the risk of importation of cases to Europe, further transmission in Europe and options in case of a possible pandemic.

[10] Working Group B
[11] Working Group C
[12] Item 7 - EI Session - Avian influenza A in China (P Penttinen)

87. Robert Hemmer, Member, Luxembourg, inquired if ECDC could elaborate on virus presence in poultry on Borneo following the importation of a case to Malaysia. ECDC responded that it is currently not aware of any cases in animals or humans in Malaysia stressing that the case in Malaysia was in fact imported from China.

88. Anders Tegnell, Member, Sweden, expressed his appreciation of ECDC risk assessments and asked if ECDC planned to continue publishing risk assessments in this area.

89. Mike Catchpole, Member, United Kingdom, pointed out that the big threat was assortment of the virus and the risk of infection of migrating birds, making virus monitoring in China and monitoring of birds specifically important. The question was raised what ECDC could do and achieve in this respect internationally. ECDC replied that at this point influencing by professional means would be the only viable option due to lack of funding.

90. Kåre Mølbak, Member, Denmark, expressed his wish for ECDC to go ahead with its work on this and was wondering if the current scenario might just be the tip of iceberg.

91. Sophie Quoilin, Alternate, Belgium, appreciated ECDC's risk assessment. Regarding national preparedness plans it was inquired if ECDC considered doing general preparedness plans for influenza. ECDC responded that it is moving to generic preparedness planning. ECDC is working on this but this is seen as a very long-term process. The best tools would indeed be national plans and it seems like time well invested to update them for influenza preparedness planning.

92. Aura Timen, Member, European Public Health Association (EUPHA), wanted to know what ECDC's opinion on post-exposure prophylaxis as best practice would be. ECDC replied that this was very difficult to answer. ECDC is not in position to recommend specific actions to countries but could provide the evidence. However, for this particular strain (A(H7N9)), there is currently very little evidence to work on. The United Kingdom have done some work around this and the respective references can be found in the new ECDC assessment.

93. Guénaël Rodier, WHO Regional Office for Europe, congratulated ECDC on its work and wondered what was known from animal side (e.g. OIE). ECDC responded that it is closely monitoring the reporting of the respective partner organisations.

94. Sotirios Tsiodras, Alternate, Greece, enquired if an update on serological information was planned. ECDC responded that some papers on serology in humans have been published.

Item 7b – Zika virus infection in the Pacific and Chikungunya in the Caribbean

95. Niklas Danielsson, Senior Expert in Communicable Diseases, Surveillance and Response Support Unit, ECDC, updated the AF on the current outbreaks of Zika virus infection in the Pacific and chikungunya virus in the Caribbean.[13] Both viruses share the same vector and show a similar clinical picture. Both emerged during on-going dengue outbreaks in the affected areas. Chikungunya started in the French part of St Martin in December 2013 and has since spread very quickly from island to island and has now reached South America (New Guiana). It seems likely that chikungunya will become endemic in the area which might in turn increase risk for importation to the EU given that the Caribbean are an all-year holiday destination for EU citizens. Eight Caribbean islands are currently affected.

96. The Zika outbreak in French Polynesia started in October 2013. Unusually high rates of neurological and autoimmune complications like Guillain-Barré syndrome have been associated with this Zika outbreak.

97. Both outbreaks are occurring in EU overseas countries and territories with different levels of diagnostic capabilities and support from EU Member States.

98. Jean-Claude Desenclos, Member, France, thanked ECDC for the update. He added that France worked with modellers on the current outbreak that had also worked on La Reunion outbreak (during the chikungunya outbreak in 2005/2006). The tendency in St Martin seems to be that the

[13] Item 7 - EI Session - Update on ongoing vectorborne outbreaks (N Danielsson)

chikungunya outbreak is plateauing right now. It has been shown that temperature is a parameter to consider and longer transmission has to be expected. It was also stressed that in the French department of the Caribbean and Guyane dengue surveillance experience is exceptional. He disagreed with the notion that chikungunya and zika infection are indistinguishable when diagnosing. In addition, to put the two outbreaks into perspective in Polynesia, the dengue outbreak is going down while the Zika outbreak was peaking. In some of the Caribbean, this dengue outbreak has been the longest ever. While ECDC noted that maybe in the Caribbean it is possible for chickungunya to become endemic, he indicated that this did not happen in La Reunion. He suggested to ECDC to be more careful with a statement on endemic potential. He also mentioned that the modelling exercise done in France suggested that the initial chikungunya cases were found quite early, particularly in Saint-Martin suggesting that surveillance the French Caribbean was quite sensitive. He also questioned if instead of looking at specific diseases like chikungunya, dengue or zika the discussion should be generalised on the topic of arboviruses transmitted through Aedes aegypty and/or albopictus. It also indicated that the access to diagnosis in the Caribbean is very good and that ECDC has to handle wording in this sensitive area with care.

99. Herve Zeller, Head of Programme for Emerging and Vector-borne diseases, Office of Chief Scientist, ECDC, responded that modelling for the current outbreak in the Caribbean is slightly different as the vector in question comes from Asia instead of Africa, leaving very few tools to control the situation. Options to reduce the risk of infection are known. ECDC also acknowledged that there is seasonality and stressed that there is currently no evidence that chikungunya might become endemic in the Caribbean but that the possibility could not be ruled out either. Current concern is that chikungunya has reached South America. ECDC is looking closely at the U.S. CDC and PAHO (Pan American Health Organization) to obtain a clear picture, but raised concerns regarding vector control at local level. This is why ECDC supports training at local level in the Caribbean based on the lessons learnt during the dengue outbreak on Madeira in 2012. One of the main points to look at would be to understand why people do not use repellents and to identify possible errors in public messages.

100. Mike Catchpole, Member, United Kingdom, agreed with France, particularly on the point of endemic potential in the Caribbean.

101. Kåre Mølbak, Member, Denmark, pointed out that there is no risk for Greenland regarding vector-borne diseases.

102. Jaap van Dissel, Member, Netherlands, inquired whether there would be a risk assessment now that the chikungunya outbreak has reached South America.

103. Ana Maria Correia, Alternate, Portugal, noted that the vector that transmits dengue has been present in Madeira since 2005 and during the 2012 outbreak cases were importation to the EU mainland. Now the situation on the island is calm with no risk for European tourists.

104. Frank van Loock, European Commission, was wondering what support or message could be provided to the countries affected by the outbreak, including communicating the assessment.

105. Darina O'Flanagan, Member, Ireland, was looking for advice to put out on the national website and was wondering how realistic the common and current advice to wear long-sleeve shirts and long trousers, etc., would be for a holiday destination like the Caribbean.

106. Denis Coulombier, Head of Surveillance and Response Support, ECDC, stressed that EU Overseas Countries and Territories (OCT) have been affected by outbreaks in different ways in the recent past. Before the European summer season and the accompanying uptake of vector activity in Europe, this has to be kept in mind given that the first Zika virus cases were imported to Europe.

107. Niklas Danielsson, ECDC, stated that the Centre is well aware of differences between OCT. Main question regarding the chikungunya outbreak in the Caribbean would be, how effective vector control is. He wondered if for mainland Europe rapidly detected importation could be key.

Item 8 – What should be the next steps for ECDC's work on polio?

108. Elizabeth Bancroft, Visiting Scientist, Office of the Chief Scientist, presented on polio and polio activities.[14] The following discussion mainly circled around the use of OPV versus IPV and the role of environmental surveillance (sewage testing).

109. According to Elizabeth Bancroft, ECDC feels that in certain limited outbreak situations, there is evidence to use OPV, for example in areas with good hygiene and good vaccination coverage. In general, however, ECDC is in harmony with WHO that IPV is the vaccination of choice.

110. Mike Catchpole, Member, United Kingdom, said that the UK was the last Member State to actually dispense with its stocks of OPV, as its strategy would be focused on IPV. He wondered whether there was really robust evidence from Israel to change the current stance on IPV/OPV.

111. Jaap van Dissel, Member, Netherlands, noted that 200 000 people in the Netherlands refused to get vaccinated (the last polio outbreak was in 1992). Oral vaccine would be used in an outbreak in a susceptible population; the rest of the population would receive IPV. Both vaccine types were stockpiled in the Netherlands, he added.

112. Mika Salminen, Member, Finland, said that his country used environmental surveillance as the main tool and that Finland acknowledged its limitations. Also, the representativeness of environmental surveillance had never been properly assessed, but with the help of an EPIET fellow, there should soon be some answers to this question. AFP surveillance would not work in Finland, he continued, because the signal-to-noise ratio was simply too low.

113. Fernando Simón, Member, Spain, doubted the benefits of environmental surveillance and whether it was really worth the expenditure in time and money. He also criticised the routine further characterisation of enteroviral sequences because its representativeness was rather poor. If, however, there was a system with better algorithms, Spain would be interested.

114. Anders Tegnell, Member, Sweden, said that Sweden's first choice was IPV, and even in an outbreak situation he would be worried to run an OPV campaign.

115. Robert Hemmer, Member, Luxembourg, inquired about the availability of vaccines and vaccine stocks.

116. The AF was informed that in case of an outbreak, all EU/EEA Member States would have access to the global OPV stockpile managed by WHO and UNICEF for emergency use; OPV stockpiling for emergency use in the EU/EEA was not encouraged because of limited supply and shelf-life.

117. Mira Kojouharova, Member, Bulgaria, added that the Bulgarian Ministry of Health tried to purchase IPV-containing quadrivalent vaccine. The vaccine could not be obtained on the market, which caused problems with unvaccinated refugees. She also said that improving rates in undervaccinated populations should be one of the main priorities.

118. Darina O'Flanagan, Member, Ireland, asked whether the risk had increased so much that Member States now needed to engage in environmental surveillance or AFP surveillance. Answering her own question, she pointed out that the risk had not increased as there had always been traffic from endemic countries. The level of increased risk did not justify additional surveillance measures.

119. Jurijs Perevoščikovs, Member, Latvia, said that his country could not purchase IPV monovaccince for Latvia on the market. He added that Latvia had been engaged in environmental surveillance for a long time and that 20% of all sewage samples were enterovirus positive.

120. Sophie Quoilin, Belgium, Member agreed that the risk was not higher than before. She also saw no reasons to step up surveillance or initiate environmental surveillance in Belgium.

121. Guénaël Rodier, WHO Regional Office for Europe, said that Syrian immunisation had been very good up until the outbreak of the civil war. He also said that low-cost IPV was available through

[14] Item 8 - Update on polio activities (E Bancroft)

UNICEF and that OPV was only licensed in those EU/EEA countries where it was produced for export (Belgium, France and Italy), and in Bulgaria and Poland where trivalent OPV was licensed.

122. The AF was informed that countries needed to take early action regarding licensing to ensure availability of OPV. The European Medicines Agency has a pivotal role in facilitating licensing options for OPV for those Member States currently with no licensed OPV product.

123. Elizabeth Bancroft addressed the various comments by pointing out that IPV remains the routine vaccination of choice, while OPV was being phased out as part of routine vaccination plans. In an outbreak among a vaccine-naïve population, ECDC would suggest OPV; one case of polio would already be considered an outbreak. Also, ECDC was not promoting environmental surveillance; instead, ECDC wanted to learn more, collect evidence, calculate the costs (e.g. of sending samples to reference laboratories), provide facts so Member States could take an informed decision. However, environmental surveillance could be helpful, but finding the perfect sampling scheme was difficult.

Item 9 – Framework Action Plan to Fight Tuberculosis in the European Union

124. Marieke van der Werf, Head of Programme on Tuberculosis (TB), Office of Chief Scientist, ECDC, presented on ECDC's plan to assess whether the Framework Action Plan and the monitoring framework need to be updated including planned methods and consultations.[15]

125. Darina O'Flanagan, Member, Ireland, pointed out that elements of the plan would have to target the different situations regarding TB incidence in the countries across Europe and high incidence of TB in marginalised groups like prisoners. She pointed out that the current ECDC document is being taken seriously. To assess whether it needs updating or how it is used, ECDC should ask countries if they use it.

126. Fernando Simón, Member, Spain, stressed the importance of sub-regional analysis and differentiation between European transmission and imported infections. It would also be important to address migrant issues. While Europe has seen a decline in incidence it shouldn't be too satisfied with that but should instead continue in its elimination efforts.

127. Sotirios Tsiodras, Alternate, Greece, mentioned that NGOs as very important stakeholder should be involved in the process to decide whether the Action Plan needs to be updated.

128. Jaap van Dissel, Member, Netherlands, asked about links to the work done by the World Health Organization (WHO) in this area in order to avoid duplication of work.

129. ECDC responded that it is very well aware of WHO's work as ECDC was/is actively involved in it. Based on this work ECDC wants to critically asses if there is a need for an update of the Action Plan. Social determinants shall be addressed in the process although it has yet to be decided how this could be done. One of the challenges will be to cover the whole EU in the plan given the different patterns of high and low incidence of TB across Europe.

130. Franz Allerberger, Alternate, Austria, expressed his concern about TB as Austria sees more and more that patients with multidrug-resistant TB come to Austria and authorities do not know who is responsible for their treatment. As a result, patients fall out of the system without minimum care, probably partially due to austerity measures. There is a need to secure minimum treatment.

131. Aura Timen, Member, EUPHA, stressed that a breakdown of services due to austerity measures gives the chance to work more closely together.

132. ECDC Director highlighted the importance of a broad approach. He inquired about the duration of the assessment process and the planned end product. Marieke van der Werf, ECDC, responded that the end product of the assessment would be presented to the EU Commission.

133. Frank van Loock, European Commission, stressed that there was a need to identify the areas where an update of the Action plan is needed. The question would also be if there are needs beyond public health. The need to take it forward on a policy level would include steering an EU-wide Action

[15] Item 9 - Framework Action Plan to Fight Tuberculosis (M van der Werf)

Plan with inter-service input. For a new Action Plan, endorsement on a political level would be needed and the end product of the ECDC assessment would have to address the questions raised in this debate.

134. Ana Maria Correia, Alternate, Portugal, wondered how ECDC plans to involve the TB network in the Action Plan.

135. The Chair summarised that the AF agrees to the plan to develop a plan for assessing the need for a new Action Plan to fight TB in the EU.

Item 10 – Final report on commissioned evaluation of the surveillance of severe influenza in Europe *(Document AF37/6)*

136. Julien Beauté, Expert in Respiratory Tract Infections, Surveillance and Response Support Unit, ECDC, presented on the final report on the commissioned evaluation of the surveillance of severe influenza in Europe.[16] The first attempt to monitor severe influenza cases at EU level was made during the 2009 pandemic influenza. ECDC's weekly influenza overview (WISO) is based on the data that comes from input gathered since 2010. Heterogeneity of systems across Europe hinders any significant value on European level. The example of federally organised systems like in the U.S.A. shows that this is more meaningful. ECDC's proposal currently includes the following options: drop surveillance work; proceed with current strategy aiming at improvement; proceed with current system but restrict severe influenza surveillance to intensive care units (ICU) in hospitals or establish new surveillance system based on EU network of sentinel hospitals.

137. Fernando Simón, Member, Spain, pointed out that Spain provides information on severe cases to ECDC. The objective should not be to know the number of cases but rather to understand differences or a change in behaviour of influenza viruses. While it would help to know incidence this would not be paramount. In the 2013/2014 season, influenza attracted a lot of media attention in Spain even though it was a rather quiet season. He stressed again that there was no added value for Europe to know the numbers of infections but to get an idea of the behaviour of the virus. He suggested sentinel countries.

138. Jean-Claude Desenclos, Member, France, congratulated on an extremely good report done by someone competent. However, one weakness was the analysis of the European value. It was suspected that the interviews should probably have been done with other people. ICU option looked like the only viable option. It was doubted that ECDC would be able to harmonise surveillance across Europe. France would vote against a sentinel system. Proper mitigation would require knowledge of the number of severe cases. Ideally all over Europe. It was suggested to set a reasonable target (5 to 10 years) for a new system rather than having something in place rapidly.

139. Mike Catchpole, Member, United Kingdom, praised a very nice report. However, the report did not talk enough about purpose of e.g. early warning or detection of severe cases. This would be far better met through ICUs than sentinel systems, particularly in early stages of a season/epidemic.

140. Jan Kynčl, Member, Czech Republic, agreed with France and the United Kingdom. The Czech Republic has national influenza surveillance in ICUs only. The advantage of this would be a harmonised system of who is brought to the ICU and this might make it easier to compare. Limitations in national systems were acknowledged and seen as a reason to discontinue with the current European overview. Using a sentinel system in hospitals would be interesting option but again this would provide a divers picture across Europe. It was perceived that it might be possible to establish task groups.

141. Florin Popovici, Member, Romania, thanked the authors for an excellent report. However, the report would not describe all the efforts in the countries regarding budget and staff in order to keep surveillance in place. The current system proved very useful. Severe acute respiratory tract infection (SARI) surveillance system would help to understand what goes on in terms of severe influenza cases as it would allow getting a picture of how different strains are evolving or are absent. Regarding options, hope were expressed that ECDC could convince countries to have their own surveillance

[16] Item 10 - Evaluation of severe influenza surveillance in Europe (J Beaute)

systems, maybe with task groups as mentioned by Jan Kynčl. While a sentinel system might be worth thinking about, the criteria mentioned in the report might not be applicable.

142. Anders Tegnell, Member, Sweden, acknowledged that this topic represents a complicated area. Sweden managed to set up an ICU surveillance system which works quite well and works for the country. He, however, missed the aim for an EU system. Maybe difference for admittance amongst countries might hamper comparison. He expressed clear hesitance to move towards EU-wide harmonisation as it might not be worth the effort. Before considering this, the added value would need to be clarified.

143. Darina O'Flanagan, Member, Ireland, reported that Ireland has an ICU surveillance system and denominator with admittance to hospital which would be a good thing to have. She also stressed the importance of ICU in the framework of hospitals.

144. Mika Salminen, Member, Finland, reported that Finland is setting up an ICU surveillance which has already proved useful in 2014. He did not consider it valuable to have a separate new surveillance system for Europe which would bypass national systems.

145. Kåre Mølbak, Member, Denmark, stressed the importance of having a system in place. But he also stressed the importance to respect choices between ICU or hospital surveillance. He considered it possible to go with a harmonised approach.

146. Fernando Simón, Member, Spain, clarified his previous statement that he favoured a system with sentinel countries, not sentinel hospitals.

147. Julien Beauté, ECDC, wondered if there could be a filter at ECDC level. Countries could of course have their national system but from EU perspective it would not be enough to just list cases given that ECDC would like to provide early warning. It was acknowledged that most participants had expressed a preference for the ICU option.

148. The Chair concluded the session with the task for ECDC to clarify European value of European influenza surveillance.

Item 11 – Update on risk and behaviour-based communication

149. Karl Ekdahl, Head of Public Health Capacity and Communication Unit, ECDC, presented on ECDC's work in the field of risk and behaviour-based communication.[17] ECDC feels that the existing evidence gap in this area has been filled and that ECDC has provided an extensive overview of the capacities and the work that has been done in this area in Europe. Some of the research done has also fed into the work around European Antibiotic Awareness Day. Support to national health campaigns has mainly been achieved through development and provision of communication toolkits.

150. Mike Catchpole, Member, United Kingdom, complimented on the priority list. A fair amount of work on antimicrobials has been done and is on-going in the UK, so it would be worth touching base with the UK on this topic. He congratulated ECDC on its work in this area and stressed the importance of further engagement in the countries.

151. Mira Kojouharova, Member, Bulgaria, reported that Bulgaria was one of the pilot countries for the guidance tool to help enhance vaccination uptake. Evaluation of the project was successful among practitioners. She encouraged ECDC to keep this work up. However, it would take more time to have evaluation of results to see if an uptake in vaccination coverage among Roma children was indeed achieved.

152. Fernando Simón, Member, Spain, complimented on a very nice list of achievements.

153. Florin Popovici, Member, Romania, agreed with Bulgaria as Romania was another pilot country for the vaccination tool. It would take some time to measure the actual impact of the tool and Romania would need further support.

[17] Item 11 - Update on risk and behaviour-based communication (K Ekdahl)

154. Anders Tegnell, Member, Sweden, stressed the need for evidence-based work, so point three (Basic hygienic measures in the home and in the community, with a focus on respiratory and gastrointestinal hygiene) might be challenged in that respect.

155. Aura Timen, Member, EUPHA congratulated ECDC for very impressive work in such a short while. She was looking forward to co-operate and disseminate this work to frontline physicians.

156. Karl Ekdahl, ECDC, remarked that the Competent Body structure might be a bit problematic as national partners might not be the ones to implement ECDC work in this area. It was clear from comments that work on vaccine uptake should continue. ECDC will try to find the necessary funding.

157. ECDC Director stressed the importance of the right channels. This work needs to be channelled through the right groups to reach those in need.

Item 12 – Update on second external evaluation of ECDC

158. Andrew Amato, Head of Programme HIV/AIDS, Sexually Transmitted Infections and Viral Hepatitis, ECDC, reported on the current state of ECDC's external evaluation following the intervention of the ECDC Management Board (MB) in 2013. An inception report of the Economisti Associati was received on 30 December 2013. Interviews with AF members are considered very important for ECDC to ensure thorough evaluation. Data collection will run until June 2014. On 6 June 2014, the contractors will send their interim report to the ECDC MB. In August 2014, the final external evaluation report is scheduled to be available, which would allow sharing with the Advisory Forum in September (pending approval by the ECDC MB).

Item 13 – Update from the European Commission

159. Frank van Loock, European Commission, presented the views of the European Commission. Following the Council Recommendations and the influenza pandemic in 2009, the Commission has a firm desire to see severe influenza covered and would very much welcome ECDC working on this.

160. He also gave a brief update on the topic of in vitro diagnostics, mainly pointing out that there are thorough consultation processes within in the Commission for any new initiative, and also in the proposed revised in-vitro diagnostics directive. . Once the internal document is finalised, the Council and the Parliament examine the proposal, but from here onwards, the influence of the Commission is limited. Should countries or AF Members discuss certain matters, it was suggested to contact respective Member of the European Parliament or Attachés. As far as data protection issues are concerned, there exists an exemption clause for communicable diseases although concerns persist about research that is not purely conducted for surveillance reasons.

161. It was acknowledged that the joint procurement agreement signifies a major change now that the finalisation and ratification stage have been reached in several countries. Influenza vaccines will likely be the first ones to be affected by this new agreement before any other process starts.

162. Johan Giesecke, Chair, recognised that the AF meeting might not be the correct forum to voice concerns but still encouraged it.

163. Mike Catchpole, Member, United Kingdom, remarked that the main point was on data protection as Member States might be able to collect less data under the new rules and this in turn might also affect ECDC's work.

Item 14 – Any other business

164. As there was no other business, the meeting was adjourned. The Chair thanked all the participants for the valuable input. Special thank you was extended to the ECDC Corporate Governance team for their professionalism and excellent arrangements. The next AF meeting is scheduled for 13 and 14 May 2014.