ECDC Advisory Forum

Minutes of the Forty-fourth meeting of the Advisory Forum

Stockholm, 25-26 February 2016

Contents

Opening and adoption of the programme (noting Declarations of Interest and Specific Declarations of Interest, if any)

1. Andrea Ammon, Acting Director, ECDC, welcomed the participants to the 44th Advisory Forum meeting and pointed out that the meeting was being video streamed before giving the floor to the Chief Scientist, Mike Catchpole.

2. Mike Catchpole, Chief Scientist, ECDC, welcomed the participants, in particular, Carlos Matias Dias, newly appointed AF Member for Portugal, Thorolfur Gudnason, newly appointed Observer for Iceland, and Nedret Emiroglu, representing WHO in her new role as Director of Communicable Diseases for Health, Security & Environment at WHO's Regional Office for Europe. Apologies had been received from Estonia, Poland, Romania, Slovakia and the European Public Health Association (EUPHA). He mentioned that Mira Kojouharova, former AF Member for Bulgaria, had informed the secretariat that the previous meeting of the Advisory Forum had been her last before retirement and he wished her well. He also noted that this would be the last meeting attended by Darina O'Flanagan, AF Member for Ireland, and that she would be really missed.

3. Sylvia Declich, AF Member, Italy, and Darina O'Flanagan, AF Member, Ireland, noted that they were involved in the VENICE project, which was mentioned in the preparatory documentation for the group work under Item 14. There were no specific conflicts of interest declared in connection with the agenda.

4. Mike Catchpole, Chief Scientist, ECDC, noted that there had been some slight changes to the programme following the Health Security meeting the previous day (24 February 2016), to make more room for Zika virus issues and the item on training had been removed. There were no proposals for revisions to the agenda and it was accepted.

Adoption of the draft minutes of the 43rd Meeting of the Advisory Forum (10 December 2015) including the Second ad hoc Audio Conference Meeting of the Advisory Forum (4 November 2015) and the Extraordinary Advisory Forum meeting (4 February 2016)

5. Herman Van Oyen, AF Member, Belgium, requested that the extensive comments contributed in writing by his colleague, Sophie Quoilin, AF Alternate, ahead of the AF meeting audio conference on 10 December 2015 be reflected in the minutes for that meeting.

6. Mike Catchpole, Chief Scientist, ECDC gave a short update on actions from the meeting on 10 December 2015: the Joint Action Plan to address the recommendations arising from the Second External Evaluation and the conclusions of the first ECDC Stakeholder Survey would be presented at the Management Board meeting, and updates brought to the AF in future; the Single Programming Document would also be presented to the Management Board, and a paper would be presented to the AF on surveillance processes that afternoon. With regard to the proposed repository for documents produced in other Member States, ECDC would look into this towards the end of 2016. With regard to HIV anti-retroviral resistance, the plan was to capture existing information and not to embark upon molecular-based surveillance until there had been further consolidation.

7. With reference to the ad hoc teleconference on 4 November 2015, he noted that comments by AF members on a collaborative agreement between ECDC and EU reference laboratories had been noted and included in the paper that would be presented to the Management Board. The same applied to a paper on TESSy surveillance and response.

8. With regard to the audio conference on 4 February, a number of AF members noted that they had been unable to connect and requested that this be investigated so that in future the connection could be guaranteed.

9. All three sets of minutes were adopted.

Update from ECDC on the main activities since the last Advisory Forum meeting

10. Andrea Ammon, Acting Director, ECDC, gave a short presentation on the main activities since the last meeting[1].

Update on actions arising from the Second ECDC Joint Strategy Meeting (JSM)

11. Mike Catchpole, Chief Scientist, ECDC, provided feedback on the actions planned in relation to discussions at the JSM held in September 2015, many of which are part of ECDC's Joint Action Plan. He asked for members' reflections on the meeting, any points of accuracy or significant omissions in the minutes and specific advice on the proposed actions.

12. Osamah Hamouda, AF Member, Germany, said the meeting had been very useful, particularly by bringing together people from a variety of different hierarchical levels. It had offered a great opportunity for exchange, between technical and political stakeholders who might not otherwise meet at national level.

13. Darina O'Flanagan, AF Member, Ireland, said that the meeting had offered an opportunity to discuss issues not usually discussed.

14. Jean-Claude Descenclos, AF Member, France, said that the second JSM had been much more successful and well organised. It had successfully brought together ECDC staff, leaders, stakeholders, Advisory Forum Members and Management Board members, which was particularly important as interaction between the AF and the Management Board was limited. The Joint Action Plan was clear and easy to read, however implementation might be more difficult. The horizon scanning discussion and proposal had been good, particularly given the current outbreak of microcephaly linked to Zika virus. It illustrated the point that it was impossible to make predictions and it was therefore useful to think of as many scenarios as possible.

15. Mike Catchpole, Chief Scientist, ECDC, explained that the paper presented to the AF summarised many of the actions directly related to the Joint Action Plan. Updates on the Joint Action Plan would be presented to the AF at future meetings. A template had been developed and would be presented to the Management Board at its next meeting. The Management Board Members had also expressed a wish for the AF to review more of the papers presented to them first and this idea of sequencing papers would be incorporated into the Joint Action Plan. He noted that the horizon scanning had created some interesting discussions because there were mixed views about how ECDC should embark on this. Some Member States were already investing heavily in this area while others were not. ECDC would present a paper later in the year setting out proposals on activities in the area of horizon scanning.

16. Jean-Claude Desenclos, AF Member, France, asked how often ECDC planned to hold joint strategy meetings and when the next one was planned. It would also be useful to look at how to involve stakeholders from different constellations and groups within the Member States.

17. Mike Catchpole, Chief Scientist, ECDC, suggested that it might be useful to set up a preparatory group for future joint strategy meetings similar to that for the AF meetings. This would enable discussion of the range of possible subject, specific theme and invitees.

18. Osamah Hamouda, AF Member, Germany, pointed out that the JSM was already a large meeting and inviting more people would create new challenges.

19. Mike Catchpole, Chief Scientist, ECDC, said that it was a difficult balance to achieve, working with such a large group of stakeholders while ensuring full engagement on a manageable scale.

[1] Update from ECDC on the main activities (A Ammon)

20. Hanne Nøkleby, AF Observer, Norway, agreed that there was a limit to how many people could be accommodated, and therefore having a theme and choosing representatives could be a better solution next time.

21. Andrea Ammon, Acting Director, ECDC, pointed out that, notwithstanding the inclusion of the Management Board for the very first time (during the first morning of Day 1), the number of participants invited to the second JSM had been the same as the inaugural JSM. Still, the scale and complexity of the Working Group sessions (24 in total) differed tremendously from the very first JSM, which was perhaps why the second one was more successful.

22. Mike Catchpole, Chief Scientist, ECDC, reviewing the Joint Action Plan from the JSM, summarised that big data was a good topic for AF discussion; the proposal being that the ECDC website repository for sharing information and national guidance documents should be replicated in other areas as per the ARHAI model (although it was noted that there were problems with the language barrier in accessing documents from other Member States and translation would be beneficial where this was possible); ECDC was supporting the European Commission in developing an options paper on future EU microbiology strategy, and in addition was looking at extending the scope of the EU LabCap report to further areas and moving forward cautiously with the idea of serological surveys as a supplement to other surveillance systems using hepatitis B and C as examples. The Joint Action Plan would be revisited regularly at AF meetings and there would be further opportunities to discuss the issues raised at the JSM.

23. Herman Van Oyen, AF Member, Belgium, referring to page 14 of the Joint Action Plan on the subject of the EU surveillance system reengineering project, asked what was meant by 'removing data where the data quality was poor'.

24. Mike Catchpole, Chief Scientist, ECDC, clarified that his understanding was that if the data quality was poor, it may be necessary to improve it, but if it was not essential, then it was perhaps better to remove the need to collect it.

Update on Epidemic Intelligence

a) Evaluation of EU/EEA Surveillance Systems

25. Phillip Zucs, Acting Head of Section, Surveillance and Response Support Unit, ECDC, presented an update on the evaluation of all enhanced EU/EEA surveillance systems to be undertaken between 2017 and 2020[2].

26. Herman Van Oyen, AF Member, Belgium, said that what was needed was a better understanding of the situation in the individual Member States. The evaluation needed to focus more on variations in data collection and interpretation. It was easy to standardise laboratory techniques, but not to understand how data was collected, on measles for example. Ideally, the outcome should be for the consolidated data to provide a better understanding of the situation on a Europe-wide basis.

27. Jean-Claude Desenclos, AF Member, France, inquired whether generic terms of reference would be defined from a European perspective before outsourcing the project, and whether specific issues needed to be addressed. He wished to know how the evaluation would be used and how it would influence policy. He proposed that an independent advisory group on EU surveillance be set up to assist ECDC in drafting recommendations for the call for tender.

28. Mika Salminen, AF Member, Finland, supported the proposal by the AF Member for France regarding an advisory body. Although ECDC was not planning to look at national surveillance systems, he argued that EU data was based completely on national systems and it was therefore necessary to analyse national system contributions to the EU system. He suggested comparing data provided by systems with ECDC data requests to see how well they were matched. Timeliness was also important, given that in some cases data were now over two years old.

29. Jan Kynčl, AF Member, Czech Republic, pointed out that the number of staff in Member States was quite limited, and if these people were involved in an extensive surveillance system evaluation

[2] Evaluation of EU/EEA Surveillance Systems (D Coulombier)

activity, it could affect the production of data. It was also important to consider what would be done with the results of the evaluation – the systems were different across Europe and the results would be heterogenous. He suggested that the funding for this project could be better used elsewhere, particularly when support was needed at the national level for other important issues.

30. Frank Van Loock, European Commission, emphasised the need to look at efficiency and the EU added value in the evaluation, and to try to find synergies across the different systems. At the JSM, there had been some reflection on the internal use of data at ECDC, and this should be part of the equation. Many improvements had already been made to the way in which data was being analysed, but ECDC could possibly also look at how to make better use of tools. He also advocated involving EPIET fellows in the surveillance evaluation project.

31. Nedret Emiroglu, WHO Regional Office for Europe, informed AF members that discussions were ongoing within WHO governing bodies linked to reform and the capacities of Member States. WHO was working with ECDC on this issue and it could have an impact on the evaluation in question. The idea was to place a greater obligation on the Member States for external assessment of core capacity under the IHR which included many elements in the surveillance systems. The issue would be discussed at the World Health Assembly in May. There was a possibility that each country would be asked to make an independent assessment every four or five years and a joint evaluation tool was being developed for this. WHO was working with ECDC's Country Preparedness and Support Section to ensure that the various systems could communicate with one another as this would probably become one of the requirements of the annual reporting which would replace self-assessment under the IHR.

32. Paul Cosford, AF Member, UK, agreed with the idea of setting up an advisory group and also felt that the timescale was too long. With regard to how the outputs would be promoted and used, he hoped that in addition to being able to draw consistent information from all countries, it would also be possible to extract information on trends for outbreak and response work, which would be very useful.

33. Anders Tegnell, AF Member, Sweden, reiterated the need to focus on the usefulness of the project and ECDC' activities in this area because many people felt that it was an extra burden rather than offering added value. He pointed out that many of the networks had been evaluated over time and it could be useful to look at what had already been done. He also liked the idea of a coordinating or advisory body to streamline the process.

34. Isabel Noguer Zambrano, AF Alternate, Spain, said that she also welcomed this initiative although she hoped that the timeframe could be shortened. She agreed that it was difficult to evaluate surveillance systems without taking national systems into account. Another aspect was the link between surveillance and public health action and she wished to see this part of the questionnaire developed further. She requested clarification regarding the operational contact point to be consulted – whether this was at country level or EU level - and how these people would be involved in the operation.

35. Sylvia Declich, AF Member, Italy, agreed with the other comments made. She also pointed out that although there was an agreed methodology for indicator-based surveillance, there was none for event based surveillance, and she wondered whether there were plans to develop one. She also wondered how it would be possible to encompass recent developments, for example the burden of communicable disease represented by migrants, when the data available did not have the necessary variables to stratify for this. Europe needed to take into account the changes in its structure and population and to stratify for other variables.

36. Osamah Hamouda, AF Member, Germany, strongly agreed with the need for an advisory body since this was one of ECDC's areas of core business. It was necessary to be clear about what was being evaluated – was it ECDC´s role and the TESSY data or was it surveillance more generally, in which case it was not possible to leave out national surveillance systems. It was hard to imagine how the quality of the data could be evaluated without looking at national systems to a certain extent. He suggested that if the evaluation was limited to the core functions of ECDC then the timeline could be condensed. He wondered if previous evaluations done in the networks could be reused. He also pointed out that the qualification of the contractor would be a crucial factor. It would be difficult for someone outside of the system to understand how it functioned.

37. Denis Coulombier, Head of Surveillance and Response Unit, ECDC, responding to comments and questions, said that the specification had not yet been drawn up and the scope was still being discussed so Members' comments would be very useful and the Advisory Forum could probably have a

role in the proposed advisory body. He pointed out that the focus was not on ECDC surveillance but on European surveillance. ECDC did not plan to ask the consortium to come up with the methodology but would specify the objectives very clearly. The overall objective was to decrease the burden on the Member States. He had taken note of the point made by the AF Member for the Czech Republic, and confirmed that it was not ECDC's intention to overburden the whole surveillance system in a given country. With respect to the timeline, he noted that most Members wanted to move more quickly but felt that this would be a challenge. Since this type of evaluation was only carried out once every 10 years it needed to be done properly to get the full perspective. He hoped it would be possible to bring the draft of the requirements back to the AF meeting in May 2016 and thanked the participants for their useful comments.

b) Zika virus

38. Denis Coulombier, Head of Surveillance and Response Support Unit, ECDC, opened the floor for discussion on the Zika virus, proposing that the focus should be on the content of ECDC's risk assessment, with particular emphasis on the case definition, surveillance protocols and advice for returning travellers in relation to sexual transmission. Other areas proposed for discussion were: blood and sperm donations and the risk of further international spread, the link to vector surveillance; balancing proportionality of travel advice with a precautionary approach and a possible screening strategy for pregnant symptomatic/asymptomatic women returning from affected countries. With regard to the causal relationship between Zika virus and microcephaly, he pointed out that there was enough evidence to strongly consider a relationship although discussion was still ongoing on the magnitude. A WHO spokesman had recently said that Zika should be considered the culprit until proven innocent, and this was the working hypothesis adopted by ECDC.

39. Paul Cosford, AF Member, UK agreed that this was the right approach. In the UK they believed that the situation merited being taken seriously and they were currently watching for increases in microcephaly in other countries (e.g. Colombia) in order to confirm or disprove the link.

40. Jean-Claude Desenclos, AF Member, said that it was important not to forget the chemical exposure element, particularly since pesticides were used extensively in the affected areas and such substances could have serious adverse effects during early pregnancy. With reference to magnitude, he had recently seen results from an as yet unpublished study from French Polynesia indicating that the risk of an adverse outcome for foetuses exposed to Zika virus was only linked to exposure during first trimester of pregnancy, but that the magnitude of risk could be as high as 1%.

41. Osamah Hamouda, AF Member, Germany, pointed out that according to experts in Germany responsible for registration of birth defects, the background incidence of microcephaly was not as low as believed. In South America they had a good registration system but most of the new registrations were based on anecdotal evidence and there was also no clear definition of microcephaly so it was necessary to proceed cautiously.

42. Herman Van Oyen, AF Member, Belgium, pointed out that microcephaly itself was not a disease. In Brazil the number of premature births and caesarean sections was high and there was a strong reporting bias. It was therefore necessary to make a critical appraisal of the situation and adopt a basic epidemiological approach to investigating it.

43. Denis Coulombier, Head of Surveillance and Response Support Unit, ECDC, agreed that co factors such as pesticides could not be excluded and that microcephaly was not a disease but a measurement (as stated in the ECDC risk assessment). He informed the AF that ECDC had agreed with the US CDC to have a liaison officer from ECDC in Atlanta since the US CDC was extremely active in Brazil, Venezuela and Colombia in providing support for studies currently being carried out.

44. Robert Hemmer, AF Member, Luxembourg, said that his institute was advising travellers to the affected regions to use Permathrin to spray their clothes and insect repellents with higher concentrations of DEET. He wondered whether there was any evidence that this might have a similar effect to use of pesticides.

45. Niklas Danielsson, Senior Expert, Communicable Diseases, Surveillance and Response Unit, ECDC, pointed out that the first signals from Brazil came from a reliable and stable system. In Brazil they were currently trying to investigate all cases which was why so little information was available as

yet. So far around 30% of the cases notified as microcephaly cases had been confirmed, with 11% of them also having confirmed Zika virus infection. Results were expected by the end of April.

46. Hervé Zeller, Head of Disease Programme, Emerging and Vector-borne Diseases, ECDC, said that in Colombia they had started investing all pregnant women at national level in December and the first indications from ultrasound investigations could be available by end of March or beginning of April although the results of studies would not be available until the end of May. However, Zika virus infections were being detected by PCR and it is important to consider the preliminary findings with caution. There were currently 5 000 pregnant women under surveillance in Colombia.

47. Isabel Noguer Zambrano, AF Alternate, Spain, said that she was having difficulties obtaining information on Guillain-Barré Syndrome (GBS) and births in Spain, highlighting the problems of linking information from communicable disease surveillance systems and non-communicable disease registries.

48. Paul Cosford, AF Member, UK, said that he had received information that day from the UK's emerging zoonotic infection team of a first announcement in Colombia of a pregnancy with a probable Zika virus infection in the amniotic fluid. He pointed out there was a tendency to overeact and create a climate of fear. It was therefore important to be able to give clear, accurate, professional advice without making assumptions.

49. Niki Paphitou, AF Member, Cyprus, asked whether a proactive approach was warranted in the countries around the Mediterranean where the vector could be present and whether some form of recommendation could be provided on vector control if this was not premature.

50. Denis Coulombier, Head of Surveillance and Response Support Unit, ECDC, responded that ECDC was not in a position to make recommendations on this type of regulation and that there was a huge discrepancy between the approach in the US and Europe. ECDC's preparedness group was currently working on a plan which would be useful for those countries at risk, where conditions could soon be ripe for the vector.

51. Darina O'Flanagan, AF Member, Ireland, referring to the case definition, said that it did not mention exposure, just the symptoms of rash, fever and neuralgia. It was so sensitive as to be rendered meaningless and there were no epidemiological criteria. There were many people who might consult a doctor with a rash but have been nowhere near South America. She also pointed out that asymptomatic cases were still important as it was not yet known whether people who were asymptomatic could end up being affected if they became pregnant or whether they could transmit the virus to the mosquito.

52. Hervé Zeller, Head of Disease Programme, Emerging and Vector-borne Diseases, ECDC, said that this issue reflected ongoing discussions within WHO as to what constituted an endemic area. Travel advice on PHE website:

Condom use for 6 months for infected male travellers returning from Zika-affected area. For asymptomatic male travellers returning from Zika affected areas contraception is advised to prevent pregnancy and condom use for 28 days, and for 6 months for men with symptoms.

One suggestion was to use the term 'receptive areas' but more discussion was needed.

53. Osamah Hamouda, AF Member, Germany, also supported the idea of deleting the possible case as it was meaningless.

54. Jean-Claude Desenclos, AF Member, France, said that exposure criteria were required and that it did not make sense to test people who had not travelled to an affected area unless their sexual partner had recently returned from one.

55. Denis Coulombier, Head of Surveillance and Response Support Unit, ECDC, suggested that removing the possible case definition would avoid any confusion.

56. Kåre Mølbak, AF Member, Denmark suggested that there should be two definitions, one for use in relation to Zika-endemic countries and another for non-endemic countries. In Denmark the main concern was pregnant women and they were testing a great many asymptomatic women returning from affected areas. He did not think that clinical criteria would be relevant for the situation in Denmark but in an outbreak situation this might be different.

57. Paul Cosford, AF Member, UK, said it was important to distinguish a case definition from criteria for laboratory testing. He believed that the possible case definition should be deleted. He did not think

it was realistic to test asymptomatic people but one major concern was whether the virus was present in semen and this was causing problems in UK for the compilation of their travel advice.

58. Jaap van Dissel, AF Member, Netherlands, said he favoured a more operational definition and a case classification in accordance with follow-up. For example, there could be a case definition for pregnant women detailing follow-up upon return from an affected area. Case definitions should also be linked to countries however, there were still differences between the country lists produced by ECDC, WHO and US CDC. It was also important to look at whether a country had had previous exposure to the Zika virus and whether there was any herd immunity. In the Netherlands there were many travellers returning from Caribbean destinations but there was no point testing them all as they had probably been exposed.

59. Robert Hemmer, AF Member, Luxembourg, pointed out that the symptom of a 'rash' in the case definition was not very specific and a clearer indication of the neurological symptoms was also required.

60. Darina O'Flanagan, AF Member, Ireland, pointed out that ECDC's protocol was not in the Zika library on the AF extranet and had not been sent to the competent body for surveillance.

61. Osamah Hamouda, AF Member, Germany, wondered if it would be useful to include GBS and microcephaly in the clinical criteria.

62. Isabel Noguer Zambrano, AF Alternate, Spain, said that some criteria for testing would be very useful, given the current anxieties with over 300 cases having been tested in laboratories across Spain to date and many unnecessarily. With regard to clinical criteria, in Spain they had included fever in their protocol, and also the fact that chikungunya and Dengue needed to be ruled out. With regard to epidemiological criteria, there was a risk that the definition would miss autochthonous cases which was a concern in Spain.

63. Hervé Zeller, Head of Disease Programme, Emerging and Vector-borne Diseases, ECDC, commenting on the algorithm for testing, said that pregnant women were high priority, although if the vector was not present then this could be low priority. The first draft of the algorithm would be circulated to the Member States shortly for clarification. With regard to the case definition for chikungunya and Dengue, ECDC had proposed to the Commission the wording 'any person meeting the clinical and epidemiological criteria were classified as possible cases' so for both of these diseases the definition of possible cases existed.

64. Nedret Emiroglu, WHO Regional Office for Europe, said that WHO had an interim case definition and different recommendations for endemic and non-endemic countries. It did not have a possible case definition but was working on this.

65. Denis Coulombier, Head of Surveillance and Response Support Unit, ECDC, said that the experience from Ebola was that reporting of cases in the media was usually quite reliable and quicker than waiting for confirmation. With regard to case definitions, it was not a problem if a case definition within a country was different to that at EU level, however if it was decided to report at EU level it would be necessary to have consistency. With regard to the inclusion of neurological symptoms and pregnancy in the case definition, ECDC had decided not to include these on the basis that any pregnant woman or anyone showing neurological symptoms coming from the affected area should be tested anyway. The list of variables in the surveillance protocol (which had not yet been circulated) asked for information on gestational term of pregnancy, neurological signs and other relevant information.

66. Darina O'Flanagan, AF Member, Ireland pointed out that some of the first autochthonous cases could be in visitors to Europe and she would want to report these cases but did not know where to report them. She wondered if ECDC planned to send out some instructions for reporting.

67. Denis Coulombier, Head of Surveillance and Response Support Unit, ECDC, said that such cases should be reported in TESSy and not to EWRS. ECDC was planning to have an atlas for Zika similar to that for Ebola.

68. Jean-Claude Desenclos, AF Member, France, said that this would involve a great deal of work for France due to it having overseas territories in the Caribbean. France was already planning reinforced surveillance involving *Aedes albopictus*. If an outbreak or autochthonous transmission occurred in the EU and France had to add Zika to Dengue and chikungunya, he was not sure that it would be possible to do this in real time.

69. Denis Coulombier, Head of Surveillance and Response Support Unit, ECDC suggested that in this scenario only autochthonous cases would need to be reported in real time.

70. Niki Paphitou, AF Member, Cyprus, pointed out that the testing of cases was expensive and therefore in areas where the vector was present testing large numbers of people would represent a significant financial burden. She wondered if there could be a designated laboratory to which specimens could be sent for testing.

71. Jean-Claude Desenclos, AF Member, France, said that in 2015 France had had an outbreak of Dengue and had done an analysis of the outbreak which could be useful for preparedness planning with Zika.

72. Thorolfur Gudnason, Observer, Iceland said that it did not make sense for Zika to become a notifiable disease and that it would be more appropriate to make severe complications, such as microcephaly or GBS notifiable. It was also important to know who to test.

73. Denis Coulombier, Head of Surveillance and Response Support Unit, ECDC, said that they were not recommending that every returning traveller should be tested, but that positive cases should be notified. Making available the algorithm and testing guidelines would help to clarify here. He also confirmed that the male partners of pregnant women would also be included in the testing criteria.

74. Jurijs Pervoščikovs, AF Member, Latvia, asked whether it was necessary to report a case in a pregnant woman that had not been confirmed but just had an epidemiological link.

75. Denis Coulombier, Head of Surveillance and Response Support Unit, ECDC confirmed that only confirmed cases should be reported and not those under investigation.

76. Sylvia Declich, AF Member, Italy, said that the procedure between the Health Security Committee and the Advisory Forum relating to case definitions needed to be refined.

77. Denis Coulombier, Head of Surveillance and Response Support Unit, ECDC pointed out that the Commission usually adopted an interim case definition until the official one had been agreed. He was also of the opinion that it would be beneficial for the case definition to be discussed with the national focal points before it was taken to Health Security Committee.

78. Mika Salminen, AF Member, Finland, pointed out that the AF were supposed to advise on issues related to surveillance and that the AF should be informed and have a chance to comment any proposals were put to the Health Security Committee. With regard to surveillance he pointed out that there was a significant difference in the situation between the northern and southern parts of Europe and Zika did not constitute a long-term threat to pregnant women in the north. He therefore wondered what the surveillance data would be used for in the future.

79. Mike Catchpole, Chief Scientist, ECDC, said that ECDC was looking at ways to ensure that it shared documents with the AF on the extranet and engaged with the AF during preparations for Health Security Committee discussions.

80. Niklas Danielsson, Senior Expert, Communicable Diseases, Surveillance and Response Unit, ECDC, summarising the information available on sexual transmission, said that previously there had been two documented cases of sexual transmission. Two days before the meeting a further report on the CDC Health Alert network reported 14 suspected cases of transmission in the US, all associated with men returning from affected areas and all having had symptoms of disease.

81. Anders Tegnell, AF Member, Sweden, said that one of the main concerns with the Zika virus outbreak was in relation to blood donors. He asked what type of advice should be given on the donation of blood, sperm or plasma, particularly in terms of the timeframe.

82. Denis Coulombier, Head of Surveillance and Response Support Unit, ECDC said that the ECDC risk assessment covered this. It advised special caution for pregnant women with regard to substances of human origin but otherwise that the decision should be taken on an individual risk-specific basis. Normally it was 28 days deferral for persons who were symptomatic.

83. Paul Cosford, AF Member, UK said that they were recommending no blood donation for six months and if the female partner of a male traveller to a Zika affected area was pregnant, condom use was advised during travel and for the duration of the pregnancy. In the absence of reliable data it was necessary to at least try and give consistent advice.

Travel advice on PHE website: Condom use for 6 months for infected male travellers returning from Zika-affected area. For asymptomatic male travellers returning from Zika affected areas contraception is advised to prevent pregnancy and condom use for 28 days, and for 6 months for men with symptoms.

We know that there are discrepancies between HPE (in line with CDC recommendations) and ECDC which is in line with WHO.

84. Jaap van Dissel, AF Member, Netherlands, said that the current advice from the US CDC was to use a condom for six months which was completely out of proportion with reality. Many people travelled to Thailand and Indonesia, and he felt that the advice needed to be more realistic and consistent. The advice in the Netherlands for returning travellers regarding use of condoms and deferring blood donations was one month for both. They wished to dispel the idea that Zika was a sexually transmitted disease.

85. Niklas Danielsson, Senior Expert, Communicable Diseases, Surveillance and Response Unit, ECDC, agreed that advice on timelines for a man having unprotected sex with a pregnant woman should be the same as for sperm donation but pointed out that at present it was thought that infection to foetuses occurred via transplacental transmission and not at the time of conception. ECDC advice in the risk assessment was to defer blood donation for 28 days after return.

86. Jean-Claude Desenclos, AF Member, France, agreed that the advice on this issue should be consistent. In France they had imported cases from overseas so with recommendations of this type it was a question of implementing guidelines. It was important to consider the message being communicated and not to give the impression that they were only interested in protecting the metropolitan area.

87. Kåre Mølbak, AF Member, Denmark, did not understand why so much emphasis was being placed on condom use. There appeared to be a misunderstanding whereby Zika was thought to be a sexually transmitted disease and it was important that this misconception was dispelled.

88. Nedret Emiroglu, WHO Regional Office for Europe, giving an update from WHO, said that the guidance on blood donation, dated 18 February, recommended deferral for 28 days and refraining from sex for up to four weeks but did not specifically advise use of condoms. A number of WHO guidelines were being issued that day, including one on GBS and one on breastfeeding. A research group was currently working on laboratory algorithms and it was hoped this would be ready at the beginning of March.

89. Isabel Noguer Zambrano, AF Alternate, agreed that all documents should have the same periods and give the same guidelines. In Spain the virus had been detected in semen but the potential for transmission depended on the viral load and there was no information available on this yet. Spain was also advising the use of condoms but she agreed that it was important to be cautious about the advice implying that Zika is primarily a sexually transmitted disease.

90. Darina O'Flanagan, AF Member, Ireland, said that in the context of planning a family, the issue was not about use of condoms, it was about picking a safe time for conception.

91. Jean-Claude Desenclos, AF Member, France, felt that the issue was more about how to protect pregnant mothers during the first trimester of pregnancy. It was more important to recommend to women planning pregnancy to postpone it and ministries were not doing this. He also noted that blood for transfusions was now being tested in the French overseas territory of Martinique.

92. Denis Coulombier, Head of Surveillance and Response Support Unit, ECDC said that prevention advice was currently being given to returning males but perhaps the emphasis should be switched to prevention of pregnancy instead of prevention of sexual transmission.

93. Paul Cosford, AF Member, UK, said that there was not enough information to know at which stage the virus was most dangerous so it was assumed that it was during early pregnancy. There was evidence that the virus could be present in the semen of an infected male for up to 64 days. In the UK the most specific precautionary approach possible was being taken. His agency had selected six months as the appropriate period because it fitted around advice regarding blood transfusion in association with malaria. However, the situation for asymptomatic men was as yet unknown. The question was

what evidence was available to prove that the risk for asymptomatic persons was less than that for symptomatic persons. The debate seemed to suggest that the period could be cut to 28 days for asymptomatic persons. The UK advice for symptomatic persons was to refrain from sex for six months but he wondered whether in the case of pregnant partners it should be nine months to cover the whole duration of pregnancy. He recognised that differences among countries in advice currently being given was a cause for concern, and noted that this was true for the UK with respect to areas in which its advice was out of sync with many other partners around the table.

94. Denis Coulombier, Head of Surveillance and Response Support Unit, referring to an upcoming research meeting between WHO and the Pasteur Institute, asked anyone who would be attending to convey to the meeting organiser the need for research into the epidemic parameters having an impact on public health measures.

95. Mike Catchpole, Chief Scientist, ECDC, said that this was clearly not the end of the discussion and that ECDC would move forward with the idea of setting up a working group on this issue. He asked members to email him if they were interested in participating in the working group.

96. Jean-Claude Desenclos, AF Member, France, offered to host a technical meeting on preparedness and response to the appearance of *Aedes albopictus* at his institute as any such meeting would send a strong message.

97. Denis Coulombier, Head of Surveillance and Response Support Unit, ECDC, gave a brief summary of the discussions on the Zika virus:

Process of developing assessment:

- Share information and ensure discussion with the AF ahead of discussions in the Health Security Committee.
- Structure the input of the AF and competent bodies in the scientific work concerning Zika through a dedicated platform (e.g. AF extranet)
- Keep strong links with WHO.

Causality of the link between Zika infection and adverse pregnancy outcome/neurological complications:

- Consensus on the role of Zika infections in the genesis of these complications although alternative aetiologies should still be considered, along with cofactors.
- ECDC should focus attention on areas where developments could provide more insight on the link (e.g. Colombia, more recently affected by Zika, and the possible emergence of complications).

Magnitude of the link between Zika and adverse pregnancy outcomes:

- Indication that it could mainly play a role for infections in the first trimester of pregnancy, and be around 1% of magnitude for infected pregnant women at this stage of pregnancy
- ECDC should remain very critical as regards the information available on the proportion of microcephaly cases.
- ECDC should consider the impact of a strong reporting bias when estimating the magnitude of the link with adverse pregnancy outcomes.

Assessment:

- ECDC should list the unknowns in its assessments.
- ECDC should be explicit about the uncertainties surrounding the evidence on which its options are based.

Advice/Response:

- Focus attention on the risk to the foetus from infected mothers.
- Stress the importance of considering sexual transmission in the context of preventing risk for foetuses.
- Align the timeframe used for various advice in ECDC documents.

Case definition:

- Avoid confusion between case definition for surveillance and algorithms for case-ascertainment and laboratory testing.
- Consider whether a 'possible case' definition is needed, and whether it should be attached to 'area suitability' criteria.
- Consider the possibility of a case definition for endemic areas and for non-endemic areas.
- Align with other stakeholders the list of areas and countries to be considered for the epidemiological criteria.

Laboratory issues:

- ECDC laboratory algorithm to be ready in next few days.
- Surveillance protocol.
- Consider immediate notification of confirmed cases in receptive areas of the EU only for the first autochthonous cases in the event of a local transmission.

Preparedness:

- Consider scenarios for the establishment of local transmission in EU countries within the European continent.
- Review regulations on pesticides and in particular DEET.
- Communication:
- Align various ECDC documents (e.g. FAQ and risk assessment).
- Focus attention on sexual transmission and the associated risk to foetuses and adverse pregnancy events.

Research:

- Input at the upcoming WHO and Pasteur research meeting – need for research into the epidemic parameters that have an impact on public health measures (e.g. transmission or duration of presence of replicable virus in semen with asymptomatic cases).

Scientific advice: update on assessments, reviews and guidance

a) Results of the 2015 IRIS Prioritisation Exercise and the way forward

98. Helena de Carvalho Gomes, Senior Expert, Evidence-based Public Health, Office of the Chief Scientist, ECDC, gave a short presentation on the results of the exercise performed in 2015, the possible way forward and the timeline for the IRIS exercise 2016[3], following which the floor was opened for comments and questions.

99. Hanne Nøkleby, Observer, Norway, said that she had not received any proposals or responses after sending out the questionnaire. She suggested contacting those involved directly. She pointed out that the more topics there were, the longer it would take to complete the questionnaire and the less inclined people would be to answer which is why it would be good to restructure the number of proposals.

100. Anders Tegnell, AF Member, Sweden, suggested selecting the areas that were most relevant as some were not necessarily within the EDCDC mandate. He proposed that the ideas could be reviewed first by ECDC to remove some of the unrealistic ideas first and make the exercise simpler. He also believed that if people understood the relevance of the exercise more it might help to get them on board.

101. Jaap van Dissel, AF Member, Netherlands, said that perhaps there was some concern that the disease networks were not equally strong in every EU country and it was necessary to achieve a better balance somehow while keeping everyone linked in. He thought that the AF should still be kept in the loop via the focal points but both options were possible.

[3] IRIS results and way forward (H de Carvalho Gomes)

102. Robert Hemmer, AF Member, Luxembourg, agreed that the AF should be kept in the loop as AF members would raise the scientific questions that others did not consider. Other bodies could be brought in but the AF needed to remain involved.

103. Jean-Claude Desenclos, AF Member, France, said that the declining figures were a worrying signal. The idea of a two-step approach was a good idea but he was not sure if the technical people were the most appropriate for the network. The idea behind scientific advice was to facilitate decision taking for those involved in policy-making so it would be good for them to be more involved in the process. The specific function of the AF was to prioritise the giving of advice based on science and evidence and perhaps there was another more appropriate source could be found to participating in step 1.

104. Mika Salminen, AF Member, Finland, also regretted the low response rate but felt that it was difficult to see where the responses ended up in the work plan. In the future he hoped this could be improved so that it would be possible to track how the advice was used. He was in favour of more topics but also preferred to keep the AF involved. He supported the idea of vetting unrealistic ideas and doing some preparatory work to make the others more comparable.

105. Kåre Mølbak, AF Member, Denmark suggested that the low response rate could be remedied by arranging the exercise as a working group at the Advisory Forum which would ensure responses. However it would require more editing and preparation first.

106. Jan Kynčl, AF Member, Czech Republic, was surprised by the low response but suggested it could be due to the lower quality of the proposals for consideration. He agreed with the proposal by the AF Member for Denmark that this could be discussed in working groups at an AF meeting.

107. Herman Van Oyen, AF Member, Belgium, said that it was necessary to find the appropriate people with an overview and knowledge of the systems and the whole process. With a broader strategic vision and by tackling more strategic issues it would be possible to adapt over a period of around five years.

108. Mike Catchpole, Chief Scientist, ECDC suggested that it might be possible to undertake the working group exercise at the May AF meeting or at least reflect back on how ECDC was thinking of changing the strategy. He thanked the members for their comments.

b) Estimating the impact of communicable diseases on population health: the BCoDE toolkit

109. Alessandro Cassini, Expert, Antimicrobial Resistance and Healthcare-associated Infections, Surveillance and Response Support Unit, ECDC gave a short presentation on the BCoDE toolkit[4], following which the floor was opened for general discussion.

110. Darina O'Flanagan, AF Member, Ireland, congratulated ECDC on a tremendous conclusion and fantastic work. In terms of public health priorities it was obvious that healthcare-associated infection (HAI) was where the focus should be. She advised that we disseminate to health technology assessment (HTA) focal points in the European Commission and Member States.

111. Jean-Claude Desenclos, AF Member, France, said that it was a nice application. He asked whether there were plans to use it to assess the burden of disease that can be avoided through interventions and what the distribution would be in each country. He also wondered whether the tool could be used in other areas such as environmental, non-communicable disease, etc.

112. Alessandro Cassini, Expert, Antimicrobial Resistance and Healthcare-associated Infections, Surveillance and Response Support Unit, ECDC, said that the next step would be to allow for the user to build outcome trees and to design an open library and a platform where people could share their models online.

113. Mika Salminen, AF Member, Finland said that the toolkit had a lot of potential and was a very positive new development. He also pointed out that it could be used for cost-effectiveness studies (CEA).

[4] BCoDE –Burden of Communicable Diseases in Europe (A Cassini)

114. Kåre Mølbak, AF Member, Denmark congratulated ECDC on the project and thought it should be used as a research tool because of the uncertainties associated with some diseases. One important next step would be to highlight the areas where more research was needed for the future.

115. Frank Van Loock, European Commission, echoed the comments made by all other colleagues and also thanked the Member States for providing the data. He welcomed the fact that antimicrobial resistance was high on the list for future models. It could also be beneficial for enlargement countries, to compare what was being done in the EU with what they had, and for educational purposes. He suggested that the tool and the information available could be communicated more widely and wondered what the next step would be. He also suggested that the tool could benefit research on prevention strategies, for comparing different epidemiological settings and expressed the need that the disease models are continuously improved.

116. Hanne Nøkleby, Observer, Norway, congratulated ECDC on the toolkit. She wondered if there was any way in which the tool could be used to illustrate a counter-factual history and highlight what would happen if infectious diseases were not being tackled.

117. Mike Catchpole, Chief Scientist, ECDC, said that the example given in the presentation by Alessandro Cassini of the measles outbreak provided some of this evidence.

118. Anders Tegnell, AF Member, Sweden, agreed that it was important to be able to show what would happen if work was not being done on infectious diseases. He also commented that the use of the word 'prioritisation' was very political and suggested that 'ranking' would be better.

119. Alessandro Cassini, Expert, Antimicrobial Resistance and Healthcare-associated Infections, Surveillance and Response Support Unit, ECDC, said that he was working with ECDC colleagues from the preparedness group to integrate their tools in order to provide more interpretation.

120. Isabel Noguer Zambrano, AF Alternate, Spain thanked ECDC and said that the tool was very helpful for calculating mortality and disability in a European context. In Spain the tool was being used on epidemiological training courses. She pointed out that burden of disease was widely used as an introduction for papers but not as a tool for planning or prioritisation.

121. Sylvia Declich, AF Member, Italy, said that in Italy they were going to use the tool to assess the burden of vaccine-preventable disease. She asked whether ECDC was thinking of updating the literature review behind the trees. She also stressed that the assumptions behind the tool should be made very clear to people using it and they should be advised to consult with experts to prevent it being misused.

122. Alessandro Cassini, Expert, Antimicrobial Resistance and Healthcare-associated Infections, Surveillance and Response Support Unit, ECDC, pointed out that the tool was available to everyone as it had been financed with EU citizens' money. He thanked the AF members for their support and positive input and would update the tool with a new version the following week.

123. Mike Catchpole, Chief Scientist, ECDC, explained that Item 10d) ECDC Advisory Forum - future ways of working was not a discussion item but was simply to inform the AF that Isabel Oliver, AF Alternate for UK would be taking over from Darina O'Flanagan in the Advisory Forum preparatory working group.)

Update from Public Health Capacity and Communication Unit

ECDC Country Support Strategy

124. Irina Ljungqvist, Senior Expert, Country Preparedness Support Public Health Capacity and Communication Unit gave a short update on ECDC's Country Support Strategy[5].

125. Frank Van Loock, European Commission, said that the Commission had been very pleased to see the proposal and noted that at the JSM the new Director General had alluded to the fact that this was an important area for strengthening of activities. Frank van Loock was interested in the twinning

[5] ECDC Country Support Strategy (I Ljungqvist)

process but needed to understand it better. He also wished to have more information on how the outcomes of processes would be measured.

126. Jurijs Perevoščikovs, AF Member, Latvia, thanked ECDC for its support in organising a meeting in Riga on TB between five of the most affected European countries. A number of areas had been identified where the countries could work together with help from ECDC.

127. Irina Ljungqvist, Senior Expert, Country Preparedness Support Public Health Capacity and Communication Unit, referring to the twinning process, said that the idea was to twin those countries that were willing to share experience with those countries that had a specific need – for example in the area of outbreak experience. ECDC would act as the broker and facilitate interaction. It was hoped that those Member States who were interested would be able to help shape the dialogue. In addition to process indicators there would also be results indicators and outcome indicators and the strategy would be further refined.

128. Mike Catchpole, Chief Scientist, ECDC, pointed out that there were other areas where twinning had been successful such as in microbiology.

Update on Vaccine-Preventable Disease Programme

129. Lucia Pastore Celentano, Head of Disease Programme, Vaccine-Preventable Diseases, Office of the Chief Scientist, ECDC, gave a short update[6], following which the floor was opened for comments and questions.

130. Kåre Mølbak, AF Member, Denmark, said that from Denmark's perspective the most challenging issue was the declining coverage of the HPV vaccine due to safety concerns as this was now reaching the level of a public health crisis. Compared with the uptake for MMR given at the same age, only around one third of those eligible were accepting the vaccination. The issue needed to be prioritised and work was needed on communication. Communication materials needed to be made available to empower medical personnel to enter into a dialogue with those eligible for the vaccine.

131. Jean-Claude Desenclos, AF Member, France echoed these sentiments. In France data on vaccine coverage showed a similar rapid decline and a study had been commissioned to investigate 14 potential complications, with one of the main findings related to GBS. As a consequence of the debate in France HPV, which had been a mandatory vaccine, could end up not being mandatory anymore and evidence was needed to tackle this.

132. Darina O'Flanagan, AF Member, Ireland, agreed with her colleagues, pointing out that experience with false claims concerning MMR and autism had shown how important it was to provide evidence to maintain confidence in national vaccine systems. For this reason if one issue had to be selected for prioritisation she would choose HPV.

133. Sylvia Declich, AF Member, Italy, noted that the four points given as long-term goals were all very relevant and she would suggest making them medium-term instead. With regard to HPV and vaccine hesitancy, she pointed out that there were other issues embedded in this and it was necessary to investigate these in order to understand the crisis.

134. Herman Van Oyen, AF Member, Belgium suggested that the burden of disease toolkit would be the ideal tool to demonstrate to the anti-vaccine movement the effect of non vaccination over time.

135. Isabel Noguer Zambrano said that Spain supported the initiative and had identified vaccine coverage, effectiveness, security and outbreaks as priorities. Spain also strongly supported the initiative for working with hesitant populations and was considering translating some of ECDC's documentation to make it available to the general population.

136. Jurijs Perevoščikovs, AF Member, Latvia, said that the two most important issues were vaccine safety and efficiency. He needed evidence-based answers to demonstrate how vaccination was efficient and safe and more analytical information about the situation in Europe. He suggested using existing databases to obtain more information in order to improve communication on immunisation. In Latvia there was also a need for scientifically-based information on procedures for those having missed vaccinations under the national immunisation schedule.

[6] Update on Vaccine-Preventable Disease Programme at ECDC (L Pastore Celentano)

137. Robert Hemmer, AF Member, Luxembourg, agreed with colleagues' comments on the issues of vaccine safety and efficacy. With regard to the debate about mandatory versus non-mandatory vaccination, he pointed out that the only vaccine that had ever been mandatory in Luxembourg had been smallpox yet his country had one of the highest vaccination coverage rates in Europe. Luxembourg would also welcome an expert opinion on the zoster virus vaccine which had been under discussion there recently.

138. Jaap van Dissel, AF Member, Netherlands, proposed taking up the issue of standardising national immunisation schedules again as harmonising to the least intense schedule could help with vaccine hesitancy. It would also be a good way of checking data as national institutes were often reliant on industry for evidence.

139. Anders Tegnell, AF Member, Sweden agreed that it would be useful to collect and pool experience from all EU Member States because this issue was a ticking time bomb. However, mandatory vaccination was very much a national issue that depended on the country.

140. Paul Cosford, AF Member, UK said that it was very important to understand public opinion and the views of healthcare workers on this issue. In the UK vaccines had recently been introduced against zoster, rotavirus and seasonal childhood flu and they would be very interested in evaluating the results of these introductions. He also believed it was important to detect gaps in vaccine research to better prioritise in the future.

141. Thorolfur Gudnason, Observer, Iceland, said that there were two main issues for focus: maintaining coverage by addressing vaccine shortages in the national programme with guidance from ECDC and dealing with scepticism, perhaps by having a common platform where people could ask questions about side effects, etc.

142. Hanne Nøkleby, Observer, Norway, supported the comments made by the AF Member for Denmark. In Norway although HPV coverage was still gradually increasing the slightest incident could change the situation so that it became similar to that in Denmark. Mandatory vaccination was very much a national issue which depended on the country and it should be kept that way. She encouraged ECDC to continue to focus on vaccine shortages.

143. Frank Van Loock, European Commission, pointed out that ECDC was not alone in its work on this issue and might be able to get help from others partners and players involved in this issue, such as the European Medicines Agency and the Health Technology Assessment.

144. Lucia Pastore Celentano, Head of Disease Programme, Vaccine-Preventable Diseases, Office of the Chief Scientist, ECDC, confirmed that the HPV vaccine was among ECDC's priorities and it was currently working on guidance. They were also aware that safety was an issue and ECDC was collaborating closely with the European Medicines Agency on this issue. An expert opinion would be published soon on the rotavirus vaccine. With regard to comments on how to better share information on vaccines, ECDC was trying to set up a platform and once this was up and running all stakeholders would be invited to contribute. There was also an idea in the pipeline of developing an e-learning training course on tackling vaccine hesitancy to provide support to healthcare workers.

Update on the ECDC Migrant Task Force

145. Maarit Kokki, Head of Section, International Relations, Director's Office, ECDC, gave a short presentation of the Task Force activities to date[7], following which the floor was opened for discussion.

146. Jan Kynčl, AF Member, Czech Republic pointed out that this issue did not just relate to the health of migrants, there was also a clear risk to European citizens and hospitals due to the spread of antibiotic resistance. Healthcare workers needed to be made more aware of this fact and antibiotic resistance should also be a focus of the work in this area. He suggested that ECDC could recommend that vaccinations were offered to healthcare workers and social care workers supporting migrants free of charge.

[7] Update on the ECDC Migrant Health Task Force (M Kokki)

147. Jean-Claude Desenclos, AF Member, France, said that it would be good to gain some insight from some of the most affected countries by having a correspondent in each country. This was particularly relevant because field experts did not necessarily have experience of migrant health and the problems were in areas other than infectious disease. With regard to the risk of migrants bringing about an infectious disease outbreak in Europe, he did not believe that this was a major risk, however hospital-associated diseases or TB could be more of a problem.

148. Sylvia Declich, AF Member, Italy, welcomed the work being done by ECDC in this area. There were two different categories associated with migrant health – long-term migrants and newly-arrived migrants. The most relevant topic associated with migrants was probably TB. She suggested that in future ECDC would have to implement some sort of medium-term project to monitor migrant health and countries needed to think about introducing variables into their surveillance to better understand this issue. Recent studies in Italy had shown the main problems in terms of healthcare coverage were associated with migrants who had been in the country for under five years.

149. Herman Van Oyen, AF Member, Belgium, noted that in his country there was no investment by the government in migrant health and it was voluntary organisations that were dealing with the issue. Belgium was no different to many other countries in Europe where there was no interest in investing in such issues. It was therefore good to have support from ECDC to increase public awareness of the issue of migrant health.

150. Isabel Noguer Zambrano, AF Alternate, Spain agreed with France that the problem went far beyond infectious diseases. Although ECDC's mandate was based around infectious diseases it was also important to see this issue from a broader public health perspective.

151. Anders Tegnell, AF Member, Sweden said that there were two different areas associated with the issue of migrant health in Sweden. Firstly there were problems with reception centres and secondly there was the burden on healthcare facilities in the long term, which was what Sweden was currently experiencing. Experience in Sweden had shown that migrants did not spread diseases such as TB to other groups because they did not integrate. It was, however, difficult to know if they were being targeted in the right way and at the right time in terms of public healthcare and vaccination programmes. It was therefore important to look at the long-term consequences. ECDC had made a good start but there was still an enormous amount of work to do.

152. Nedret Emiroglu, World Health Organization, said that a meeting had been organised in Rome in 2015 on migrant health which had issued an outcome document highlighting the fact migrants did not pose a threat in terms of communicable diseases. The issue would be discussed at the World Health Assembly in May which would bring it into the spotlight again.

153. Osamah Hamouda, AF Member, Germany agreed with comments by France and Sweden regarding the differences in approach for the short-term and long-term. ECDC needed to make recommendations in the area of migrant health that went beyond the recommendations for the national population and Member States could then try and incorporate these into their national healthcare services, particularly with regard to antibiotic resistance and vaccinations. He suggested that ECDC could look at data on infectious diseases among migrants to see what diseases, if any, were occurring and posed the greatest risk.

154. Maarit Kokki, Head of Section, International Relations, Director's Office, ECDC, thanked the Members for their comments. Responding to comments on antimicrobial resistance she said that ECDC had guidance for travellers returning from countries outside of the EU and this would be updated. With regard to the point on the immunisation of healthcare personnel working with migrants, she would take this idea forward to the Vaccine-Preventable Disease programme. She liked the idea of having a correspondent or contact in each country and would propose this to the Task Force. She confirmed that ECDC was working on both mid-term and long-term issues related to migrant health. With regard to the collection of data on variables and diseases, these issues had already been taken up by the Task Force. The screening process she had mentioned related to migrants already in EU countries so it was more of an assessment of health needs for migrants and this was now ongoing. With regard to the collection of data from migrants' health assessments upon arrival in the EU, ECDC had had discussions with the International Organization for Migration and the Commission because there were several instruments available for this. ECDC was looking at how the information could be used and where and when it was obtained.

Influenza Vaccine Effectiveness studies proposal (IMI2 JIVES)

155. Maarit Kokki, Head of Section, International Relations, Director's Office, ECDC, gave a short update on the proposal[8], which was followed by a general discussion.

156. Jean-Claude Desenclos, AF Member, France said that some of the issues were still unclear for him. In France there was increasing vaccine hesitancy and confidence was an important issue. The IMI2 JIVES proposal was linked to the evaluation of the effectiveness of a vaccine for which public funding was available at national or EU level, thus creating a market. He did not see how he could advise ECDC or France's Management Board representatives on this issue without having further clarification of ECDC's role in a programme where industry was playing a major role. He had asked for clarification of this several times but had still not seen any evidence of how it would work. It was particularly important because ECDC also advised national institutes from the Member States.

157. Kåre Mølbak, AF Member, Denmark supported the concerns of the AF Member for France. His institute in Denmark had had mixed feelings after having entered ADVANCE and this proposal looked similar. Funding in kind from industry meant that industry would be involved and there would be issues that it would be difficult to raise. His concern was provoked by the current crisis in Denmark associated with immunisation and one third of the female cohort having decided not to be vaccinated with HPV. This type of network would not provide a solution. The timing was not good and the in-kind funding from industry needed to be reconsidered.

158. Isabel Noguer Zambrano, AF Alternate, Spain had a more positive view of the project and pointed out that the pharmaceutical companies would not have an influence in the decision-making role. It was good that countries were being given the opportunity to take part in this initiative which could perhaps eventually go beyond influenza to look at a new platform to evaluate other vaccines.

159. Jaap van Dissel, AF Member, Netherlands, pointed out that there was already collaboration going on with industry through HORIZON 2020. It would perhaps be better to explore how to ensure that multiple industries were involved and a diverse range of countries. He also advocated the establishment of some form of governance or advisory body to oversee.

160. Mike Catchpole, Chief Scientist, ECDC, referring to the issue of a code of practice, said that he agreed it was necessary and ECDC had been working on this, but it was not yet complete. With regard to Kåre Mølbak's point on ADVANCE, he noted that the concerns expressed went beyond industry being present at the meetings and moved to a new level which would need to be reflected on. He was also very aware of the effect that the collaboration might have on public opinion.

161. Maarit Kokki, Head of Section, International Relations, Director's Office, ECDC, thanked the members for their comments. She agreed that the timing was inappropriate and hoped that ADVANCE would be further developed before JIVES got going. Referring to the governance models proposed by the Member for the Netherlands she suggested that this would come during the second phase of negotiations and therefore would of course be further discussion within the Advisory Forum before entering the second phase. Referring to the comment on HORIZON 2020 and industry involvement, she noted that at the request of the Commission ECDC was currently preparing a document for the Management Board on its role industry-funded projects and this would be presented to the Advisory Forum when it was ready. She agreed that the platform could be extended to look at other effectiveness studies in the longer term at the European level.

162. Andrea Ammon, Acting Director, ECDC, noted that the area of risk assessment was one of ECDC's core business areas and all Member States needed to assess the effectiveness of the influenza vaccine. Although this was perhaps not the ideal way to do it, the IMI proposal would combine various interests and they would be represented in one place. According to her understanding from previous discussions, the pre-requisites for ECDC being able to join were that industry would have no decision-making power in the analysis and design of the study or the primary publication. Rather than expressing additional concerns at this stage she suggested going back to the conditions of the original discussions in September and using them as a basis for deciding whether to go forward.

[8] Influenza Vaccine Effectiveness studies proposal (IMI2 JIVES)-update (M Kokki)

163. Jean-Claude Desenclos, AF Member, France, agreed but said that the conditions had not been set out clearly in the presentation. Moreover, evidence was required if the Advisory Forum was to be able to advise ECDC on this issue and at the political level.

164. Herman Van Oyen, AF Member, Belgium, said that any risk assessment needed to take account of the risk of not participating. He also stressed that the governance structure should demarcate more strongly the limitations placed on industry representatives when participating in meetings for example. He believed that everyone had the same ideas but it was necessary to be explicit in how they were stated.

165. Mike Catchpole, Chief Scientist, ECDC, understood that having the conditions set out clearly in the text – which would come out in April – was a prerequisite for ECDC involvement and if this condition could not be met then ECDC would be unable to participate.

166. Jaap Van Dissel, AF Member, Netherlands, pointed out that all the vaccines being used in the EU were registered by EMA, which was a body partially funded by industry and the studies that the Member States used to make their policies were all 100% industry-based so it was difficult to avoid this paradox.

167. Jean-Claude Desenclos, AF Member, France, was not against exploring the possibility but pointed out that this was different to previous practice – it involved the authorisation for use of a vaccine in a national setting as part of a national programme and he felt strongly that industry had no role to play here. The decision would have to be taken completely independently.

Advisory Forum Working Group session: Opportunities, challenges and the potential role for ECDC in supporting the work of the National Immunisation Technical Advisory Groups (NITAGs) in reviewing evidence on vaccines and vaccination policies

168. The Advisory Forum heard feedback from the three working groups presented by the rapporteur, Darina O'Flanagan [slides].

Working Group A (Chair Osamah Hamouda)

Working Group B (Chair Sylvia Declich)

Working Group C (Chair Darina O'Flanagan)

169. In response to the first question as to whether the working groups would support ECDC's role in leading this scientific collaboration, there was widespread agreement that the groups would support this. Group B felt ECDC had to be cautious in collaboration with the NITAGs as they were covered by different types of legislation depending on the country. Group C felt it was important that ECDC should facilitate but that it should be careful when defining its specific role. It would also be necessary to collaborate with WHO in this area because it had already done a great deal of work in this area.

170. With regard to the model of collaboration currently under discussion with NITAG representatives, everyone agreed that it would be good to share the work plans and agenda but not to impose the priorities. Group C thought other domains of collaboration could be working on the social acceptability of vaccines and combating vaccine hesitancy.

171. With regard to reviewing evidence and scientific literature it was felt that this could be further elaborated once the network was up and running. Group B thought there could be issues with ownership and the commissioning but this could be worked out at a later stage.

172. There was a great deal of discussion on mathematical models and it was agreed that basic generic mathematical models that could be adapted to Member States' specific features would offer significant added value and be very useful.

173. With regard to Question 3b on levels of collaboration, most people agreed that the low level was probably already available through VENICE and the high level required further resources. The most suitable level seemed to be the medium one, moving to the higher level later.

174. In answer to Question 3c as to whether the IT platform should be Sharepoint at ECDC or outsourced, there was a general consensus in all three groups that ECDC should host the platform in the end, with differences throughout the process.

175. Responding to Question 3d on the composition of the Steering Committee and the terms of reference, it was felt that ownership of products and networks should be agreed but that established networks should be used rather than creating new ones. The coordinator or moderator would not necessarily have to be the NFP for VPD, it could be competent body but it would also be important to remember to include WHO and DG SANTE.

176. With regard to Question 4 on how the network could be integrated into the VENICE III infrastructure, further comments were invited from the floor.

177. Anders Tegnell, AF Member, Sweden said that a NITAG could not exist in Sweden as there was a law preventing it and public agencies did the work that the NITAG would do. NITAGS were not homogenous structures and differed considerably from country to country, making it difficult to know who ECDC would be collaborating with and supporting. He felt it would be more sensible to simply support countries. His main concern was who the network was for and how it differed from existing networks.

178. Mika Salminen, AF Member, Finland, agreed that the structures were diverse. Finland had a NITAG but similar to the situation in Sweden, it was the public health institute that provided the background material discussed within the NITAG. He also did not think it would be appropriate to have a new network since the NFPs for VPD were already there to facilitate this type of work. VENICE was one possibility among many but it should be the purpose that decided the model to be used rather than a network that was looking for new tasks.

179. Osamah Hamouda, AF Member, Germany, said that as Germany was hosting the VENICE network he had participated at the last meeting in Berlin in December 2015 and had the impression that the participants had a very positive view of the network. Having the public health institutes provide the ground work for the NITAG was one of the ways in which duplicate work could be prevented and resources pooled. It would be a shame to lose the momentum in the VENICE network.

180. Herman Van Oyen, AF Member, Belgium said that in his country the NITAG was the Health Council that provided information on vaccine schedules and vaccines available on the market. He advised against creating new networks as this could become very complicated and he believed that it was better for each country to use their NFP and to see how they could organise best in their own setting using the existing structure.

181. Sylvia Declich, AF Member, Italy felt that there was a need for the improved collaboration or coordination of the work of NITAGs as vaccines were being brought out regularly and it made no sense for countries to repeat work already done. The way the network should be set up, through the competent body or the VPD network, was up to the individual country. The VENICE platform was available but so was the EPIS forum so there were different options. Italy had used the information placed on the EPIS forum a couple of years previously in connection with meningococcal disease. She would prefer to start collaborating at the middle level with the idea of going further in the future.

182. Paul Cosford, AF Member, UK, said that in principle the members agreed but the language was getting in the way. Basically they should avoid duplication where possible without impinging upon one another's processes. He was in support of the idea so long as it supported those working in the area to avoid duplication. The description of the VENICE structure made it sound as though it was new although it was not, which he advised caution with the use of language.

183. Frank Van Loock, European Commission, said that the Commission was concerned by a process engaging the national authorities or technical advisory groups without asking the Member States. The process would have to be formalised at a later date with the Member States. NITAGs advised on costs, expenses and vaccine policy yet there other groups within the Commission working in these areas so it was vital to avoid duplication. However, overall the Commission was not opposed to the idea, provided that these caveats were taken into account.

184. Lucia Pastore Celentano, Head of Disease Programme, Vaccine-Preventable Diseases, Office of the Chief Scientist, ECDC, said that it would be very useful to compare the results of this discussion

with the discussions at the Berlin meeting of VENICE in December 2015. The Berlin meeting was interesting because NFPs for VPDs and the NITAG representatives were both in attendance and what was clear was that there was no desire to set up a new network or duplicate existing work on either side. ECDC's main motivation was to support the NITAGs by providing them with more streamlined information to help them take decisions. Under ECDC's mandate there was a platform available and the NFPs, who could often provide the secretariat for the NITAGs. Discussions on how to set up the NITAGs, capacity building, and other aspects were for WHO. ECDC would limit its scope to the area of scientific advice. She thanked the participants for their input to the discussions.

Any other business

185. Darina O'Flanagan, AF Member, Ireland, thanked the Advisory Forum for giving her the opportunity to say how much she had enjoyed working with them all. She had been involved since 1998 working on the ESCON committees with the Commission long before ECDC came into existence. It had been great to be able to collaborate with the AF Members and hear about how they had all had to grapple with similar issues to her own in Ireland. She had always learned so much from listening to the others around the table and it has been fantastic to watch ECDC grow and see what it had achieved over the past decade. The Agency was a great resource for the Member States and they really appreciated it. She hoped that ECDC would continue to work closely with the Advisory Forum and involve it in discussions. At the Advisory Forum meetings it was possible to be more frank in the discussions than in other more formal forums. She thanked the AF Members and wished them well for the future.

186. Andrea Ammon, Acting Director, ECDC, said that ECDC also wished to thank Darina for her input and contributions over the years. She had always been impressed by how fiercely she defended public health principles and she had learned a great deal and benefitted personally from her views. She thanked Darina for being such a good role model to her personally and also for having contributed so much to the Advisory Forum. They would miss her very much and wished her all the best for the future.

187. Mike Catchpole, Chief Scientist, ECDC, informed the members that the next meeting would be on 12-13 May 2016 and that ECDC would continue to involve the Advisory Forum in audio discussions in the meantime where appropriate. He thanked the AF members for their energy and input throughout the meeting and wished them a safe journey home.