ECDC Advisory Forum

Minutes of the 38th meeting of the Advisory Forum

Stockholm, 13-14 May 2014

Contents

Item 1 – Opening and adoption of the agenda (and noting the Declarations of Interest and Specific Declarations of Interest, if any).

1. The meeting was opened by the Chair, Johan Giesecke, Chief Scientist, ECDC, and a special welcome was given to Osamah Hamouda, newly appointed Member for Germany, Isabel Noguer Zambrano, newly appointed Alternate for Spain and Frank van Loock from the European Commission. Apologies were received from Austria, Croatia, Greece, Italy, Latvia, Malta and Poland and from Liechtenstein, Montenegro, Serbia, the Former Yugoslav Republic of Macedonia, Turkey and the Standing Committee of European Doctors (CPME) as Observers. The Chair noted that there were two annual Declarations of Interest which had still not been submitted for 2014. There were no new oral declarations of interest made at the meeting.

2. The Chair noted that Item 7b on new case definitions for chikungunya and dengue had been removed from the agenda. He also pointed out that there would be no session of working groups at the meeting due to time restraints and the combined meeting of AF Members and Microbiology Focal Points on the second day (Wednesday 14 May 2014).

3. Herman van Oyen, Member, Belgium, asked if he could canvas the opinions of AF members concerning Lyme disease under Item 11 Any Other Business. The draft agenda was adopted with this addition.

Item 2 – Adoption of the draft minutes of the 37th meeting of the Advisory Forum, 26-27 February 2014

4. The Chair asked for comments on the draft minutes of the 37th AF meeting held in Stockholm on 26-27 February 2014.

5. Referring to paragraph 37, which stated that a second paper on future work with the disease networks would be submitted to the Advisory Forum in May 2014, Mike Catchpole, Member, United Kingdom, asked whether this paper had been submitted. The Chair clarified that the paper was not yet ready but that it will be presented at the next AF meeting.

6. Jean-Claude Desenclos, Member, France, asked that the wording of paragraph 19 be amended and confirmed that he would pass his corrections to the secretariat.

7. Darina O'Flanagan, Member, Ireland, noted that in paragraph 125 she had referred to a high incidence of TB in marginalised groups in certain countries.

8. The draft minutes of the 37th meeting were adopted, pending these revisions.

Item 3 – Update from ECDC on main activities since the last Advisory Forum meeting

9. Marc Sprenger, ECDC Director, gave a presentation on the main activities since the last meeting.

10. Mika Salminen, Member, Finland, reporting on the Global Health Security Agenda Commitment Development meeting in Helsinki on 5-6 May 2014, explained that it was a US initiative aimed at creating multilateral activities to advance the global health security agenda through bilateral work between CDC and other agencies involved. The idea was to use the (global health security) platform and funding to advance implementation of the WHO International Health Regulations (IHR) in third countries with the emphasis on cross-sectoral work (health, security, agricultural and veterinary). At a US launch event in February 2014, the Finnish government had offered to host a forum for preparing the political agenda in Helsinki, and this first meeting discussed the content of the action packages developed. The outcome of the first preparatory meeting was incomplete and there was still work to be done on how to take the initiative forward and how to make the action packages more compatible with countries' interests. Meetings on the next steps would take place

during the next World Health Assembly and the preliminary plan was for a follow-up meeting to be scheduled in the autumn although there had been no official announcement as yet. The US was very keen on taking the initiative forward and it should be seen as a good opportunity for multilateral/bilateral cooperation.

11. Marc Sprenger pointed out that The European Public Health Association (EUPHA) has a very active migrant health section which will be meeting again during the 7th Public health conference in Glasgow from 19-22 November 2014.

12. Frank van Loock, European Commission, referring to AF38/Info Note 1 on ECDC activities since the last Advisory Forum meeting, pointed out that the DG SANCO publications on antimicrobial resistance – 2nd report on the implementation of the Council Recommendation on patient safety, including the prevention and control of healthcare associated infections (2009/C 151/01) and Progress report on the Action plan against the rising threat from Antimicrobial Resistance (COM (2011) 748) – with publication dates quoted as 31 May would be released in July.

Item 11 – Any other business

13. Herman Van Oyen, Member, Belgium, asked if other countries had experience of aggressive activist lobbying in relation to Lyme disease and, if so, how they had dealt with the political impact. The lobbyists claimed that there was an increase in Lyme disease and the size of the tick population but that Member States were ignoring the issue. He wondered whether more concerted action was required through the Advisory Forum to deal with the issue.

14. Darina O'Flanagan, Member, Ireland said that Ireland had a very similar and active lobby group called 'Tick Talk'. There had been similar problems in USA. Ireland had asked experts from the Infectious Diseases Society and the Health Protection Surveillance Centre to issue a joint statement agreeing with the US guidelines for treatment of Lyme disease. This unified approach of all key players had proved helpful. Moreover, at the beginning of each new tick season a great deal of publicity was issued concerning Lyme disease.

15. Anders Tegnell, Member, Sweden, reported similar problems and noted that this issue required a great deal of resources. Professionals in Sweden had been very supportive and all agreed on the treatment necessary. However, individuals were still known to go to Germany and Norway to seek more extensive treatment. The Public Health Agency of Sweden (Folkhälsomyndigheten) had published a paper stating that the diagnostics available in Sweden were sufficient, however, they were less clear on the usefulness of extended treatments, noting that extended treatment could improve outcomes. In Sweden there was no surveillance although it was now becoming necessary in order to be able to give the public better information on risk.

16. Mike Catchpole, Member, United Kingdom, said that lobbying was also very effective in United Kingdom and encouraged concerted action at EU level to in order to better support countries experiencing difficulties with strong lobbies.

17. Hanne Nøkleby, Member, Norway agreed with the others' comments and pointed out that although most medical professionals followed the same guidelines as in United Kingdom, Germany and USA, some private clinics in Germany and Norway were offering private treatment and extended care. In Norway, one of the doctors involved had now been struck off; however, lobby groups were campaigning to have him reinstated. Ticks were spreading much further north than before so there was a need to review diagnostics and surveillance.

18. Darina O'Flanagan, Member, Ireland said that neuroborreliosis had been made a reportable disease in Ireland to answer concerns about lack of surveillance.

19. Kåre Mølbak, Member, Denmark, noted that in Denmark there was a consensus among general practitioners and public health experts on describing the problem and that neuroborreliosis was also reportable. A comparison of reported figures and non-verified data indicated that there was a serious under-estimation of the problem (around 280 cases out of around 10 000 patients tested each year).

20. Marianne van der Sande, Alternate, the Netherlands, suggested that there was a problem with diagnosis that was driving the lobbyists' campaign. Lyme disease was similar to Q fever and

Legionella in that patients reported problems during the post-infection/recovery period although doctors could find nothing wrong. The challenge was how to tackle this problem.

21. Robert Hemmer, Member, Luxembourg, quoting his own experience as clinician, said that he received a number of referrals from GPs to check for borreliosis and that the initial symptoms were very varied and not necessarily symptoms of borreliosis. It was important to explain to patients that there were no good diagnostics for Lyme disease and that there were many false negatives and false positives. He agreed with the US and Swiss guidelines.

22. Ágnes Csohán, Member, Hungary said that her country was also affected and had been dealing with the problem since the late 1990s. Lyme disease had been made notifiable in 1999 and guidelines were on procedures and treatment closely followed US recommendations. The issue was very sensitive among the population and it was the third most reported disease after salmonella and Campylobacteriosis. This year with World Health Day on 7 April 2014 being related to vector-borne diseases, Hungary had taken the opportunity to organise a large press conference on the issue of primary prevention for the general population. Notification was no longer enough and vector surveillance was now required in all European countries. WHO was committed to introducing vector surveillance to follow the spread of ticks and changes in the tick population; however, there was a problem with lack of resources.

23. Andreas Gilsdorf, Alternate, Germany said that Germany had no national surveillance system in place for borreliosis and that they also experienced pressure from similar lobby groups. Historically, in the eastern Federal States of Germany reporting had been mandatory since reunification but Federal States in the west of the country were also now introducing it. To date, nine out of 16 Länder had regional reporting requirements, but they were all different. Diagnosis and treatment were also organised locally which is why people came to Germany for treatment however such practices were highly questionable.

24. Jan Kynčl, Member, Czech Republic said that in his country tick-borne encephalitis and borreliosis were also endemic but that surveillance and notification for these diseases were quite advanced. Although official guidelines existed, private practices were offering alternative guidance and treatment to patients and also tick testing.

25. Marta Grgič-Vitek, Alternate, Slovenia noted that Slovenia had had surveillance of Lyme disease for nearly 30 years and that there were no lobby groups because no one dared to challenge the recommendations made by the Slovenian Society for Infectious Diseases.

26. Jean-Claude Desenclos, Member, France reported that the situation was similar in France but that it was important to investigate other causes of the syndrome such as environmental exposure, vaccination with aluminium, radiation, etc. in order to obtain a better definition of the disease. There were also psychological and sociological factors to be taken into account. ECDC should take action or a lead where Lyme disease was concerned but a description of the whole syndrome and all its possible associations/causes would be outside the remit of ECDC.

27. Herman Van Oyen, Member, Belgium, agreed with the Member for France that it was important to decide whether to focus on surveillance or treatment and not to investigate the diagnosis of unexplained syndromes.

28. While convinced of a possible problem, Marc Sprenger contended that it was not necessarily entirely associated with ticks, and that there were other reasons for chronic fatigue syndrome. He wondered whether it would be useful for ECDC to give a position on guidelines for diagnosis and treatment of Lyme disease and asked for a show of hands.

29. The show of hands confirmed that an overwhelming majority of Advisory Forum members felt the need for ECDC to have a position on this issue.

30. Marc Sprenger informed that the Agency was currently designing its 2015 Work Programme and one possibility might be to have a seconded national expert who could collect all the necessary data for a proper analysis.

31. Darina O'Flanagan pointed out that most countries were suffering from cutbacks in staff and that it would therefore probably not be possible to send a national expert. She recommended that ECDC should make its staff available to develop the analysis of this important issue.

32. Marc Sprenger, Director, ECDC said that if the Advisory Forum felt that the issue was important and should be included in the work programme, resources could/would have to be reallocated. He therefore asked the Advisory Forum for input as to what should be low priority in the 2015 Work Programme. He proposed that the Advisory Forum could draft a statement to ECDC requesting its inclusion in the Work Programme as a clear message. He suggested that Johan Giesecke draft the Advisory Forum a letter to ECDC and send it to AF Members for approval.

Item 5 – Scientific advice and risk assessments: update on assessments, reviews and guidance

33. Johan Giesecke, Chief Scientist, ECDC began by announcing the dates for the ESCAIDE Conference (5-7 November 2014), which will convene in Stockholm. The call for abstracts has been released and these were to be submitted by 25 May 2014. He asked Advisory Forum members to encourage their colleagues to submit abstracts and reminded them that they could be asked to peer-review abstracts. (If they wished to volunteer they were asked to contact Howard Needham: howard.needham@ecdc.europa.eu)

Item 5a – Update on EU Agencies Network on Scientific Advice (EU ANSA)

34. Johan Giesecke, Chief Scientist, ECDC, gave an oral update on the work done at/with/by EU ANSA. He explained that three working groups had now been created: i) how to report uncertainty; ii) how to peer review and; iii) how to determine key performance indicators. The discussions of common issues and ideas among Agency colleagues had been very useful.

35. Kåre Mølbak, Member, Denmark, inquired whether there had been any discussion on the subject of conflicts of interest.

36. Johan Giesecke confirmed that this had already been discussed.

Item 5b – Progress of the IMI ADVANCE project

37. Piotr Kramarz, Deputy Chief Scientist, ECDC, provided an oral update on ECDC involvement, as part of the ADVANCE project, in the work that had been carried out on benefit risk studies for vaccines. The work had been divided into four areas – safety, effectiveness, coverage and burden of disease. ECDC had organised an external expert review panel to evaluate the first key deliverable of the project – the description of the electronic platform for benefit-risk studies of vaccines, and work had already begun on writing the report from the panel work. Each member of the panel, representing a stakeholder type, had to come up with up to five criteria for evaluating the deliverable, and then perform the evaluation along these criteria. The report is due back to the ADVANCE Steering Committee by mid-July. Work had now begun on the second review panel to evaluate the next key deliverable: the paper on the utilization strategy of outputs from other initiatives, which is due by the end of July 2014.

38. Maarit Kokki, Head of Section, International Relations, ECDC, gave a brief oral update on the EU vision for coordinating all the various projects at EU level. A Management Board Working Group has been exploring possible business models and sustainable financing models to run large EU-level studies related to immunisation, and this group will be reporting back in November. The next Working Group meeting will take place on 4 June 2014, in which representatives from the Commission and the European Medicines Agency (EMA) will also be invited to answer questions.

Item 5c – ECDC Expert Directory

39. Rodrigo Filipe, Database Analyst, Office of the Chief Scientist, ECDC, gave a short presentation on the ECDC Expert Directory and opened the floor for questions and comments.

40. Marianne van der Sande, Alternate, the Netherlands, commented that the procedure for using the expert directory was not transparent. The deadline in the call for tender had been short and the focal points in the countries were not properly involved.

41. Andreas Gilsdorf, Alternate, Germany said that the directory was a great resource; however, it remains unclear whether independent experts are selected on the basis of their expertise and not the views of the respective countries. He sought more information on the expert approval process and pointed out that there were experts within the Competent Body structure for each Member State who were committed to covering the various topics for ECDC. It is therefore necessary to achieve a balance between using the Competent Body structure and calling on the experts in the directory. He pointed out that it would be useful for the Member States to access the directory.

42. Haraldur Briem, Member, Iceland inquired about the age distribution of experts and wondered why there were no experts older than 66 years.

43. Herman van Oyen, Member, Belgium, asked whether experts from health councils had been included in the directory. He also expressed his apprehension over the fact that around 50% of the experts in the directory had not agreed to share their details with the Member States. He pointed out that there was a structure in place at ECDC for identifying experts through the focal points. He wanted to know how the information in the expert database would be used and asked for more detail on the structure and process of selection.

44. Jean-Claude Desenclos, Member, France, stated that the directory is a useful tool for missions, scientific advice and rapid risk assessments. Still, the directory needs to be representative of European-wide expertise and country-independent, while also taking into account the diversity of practices in European countries. He noted that more discussion is needed to refine the criteria and ensure that the Member States approve them before the final product is actually presented.

45. Mike Catchpole, Member, United Kingdom, agreed with the utility of the tool, but pointed out that transparency is vital and that a set of criteria should be established to clarify under what circumstances ECDC should consult the directory, rather than the Advisory Forum and its Competent Bodies. He also questioned how contact details could be removed from the directory.

46. Aura Timen, Member, the Netherlands, asked whether ECDC intended to restrict the expertise to disease and pathogen expertise or if it was considered to extend it to other skills such as health service assessments, risk assessments, and other kind of expertise.

47. Anders Tegnell, Member, Sweden, said that clarification was required on how the experts would be used and why ECDC needed these experts.

48. Johan Giesecke, Chief Scientist, ECDC, explained that the directory offers a means of tapping into a pool of experts outside the public health sector. As the experts were not directly linked to public health institutes, or representing Member States, they would be recruited solely on their scientific merits. ECDC would continue to use the scientific networks within countries, but it was also important to have other options.

49. In response to the above-noted questions and concerns, Rodrigo Filipe, Database Analyst, Office of the Chief Scientist, ECDC, explained that experts could be engaged in activities as representatives of their countries, or as independent experts, but that they were recruited solely for their expertise. He agreed that the process needs to be more transparent and suggested that a working group be established at the next Advisory Forum meeting in order to help establish criteria. He suggested that the lack of older experts was linked to use of technology, but he was baffled regarding why so many experts do not wish to share their profile with Member States (although it could be due to concerns with their workload). He explained that the directory has been segmented according to disease/expertise and a search could combine several areas of interest.

Item 5d – Predictive markets for risk assessment

50. Jonathan Latham, Consultant, Scientific Advice Coordination Section, Office of the Chief Scientist, gave a short presentation on the results of the latest research into a novel system for assessing risks and making short-term predictions before opening the floor for comments.

51. Kåre Mølbak, Member, Denmark, was concerned about experts having conflicts of commitment, and the process involved would therefore need to be very transparent if ECDC was to apply the system in the future. There was also a danger that predictions could end up being self-fulfilling.

52. Jean-Claude Desenclos, Member, France, noted that state agencies were increasingly being asked to undertake early detection work and had to be careful when doing so. He wished to know in which area the system would be most likely to work and whether on a national or EU scale. While recognising its limits, the area of prediction could also be a useful area to move into.

53. Hanne Nøkleby, Member, Norway had been one the few who participated in the trial and it had been fun at first but then interest waned. The system was probably more useful for guessing spontaneously rather than for predicting longer term trends. The financial aspect had been difficult to grasp and for the prediction of flu trends, as per the exercise, she would prefer to use Google flu trends.

54. Osamah Hamouda, Member, Germany, said that although it looked interesting, experts were increasingly trying to base their decisions in public health on hard evidence. He agreed that there was a danger of self-fulfilling predictions with experts eventually following each other's opinions, and it would be necessary to look at how and where such a system could be used.

55. Mike Catchpole, Member, United Kingdom, noted that the system reflected the way in which decisions were made in the Advisory Forum on scientific priorities. However, where such decision-making had implications for resources, it became a matter of concern, which is why he was interested in lead times and accuracy and whether it offered any benefit over traditional methods. While agreeing with the need for an evidence-based approach, it was not necessarily the only valuable approach/tool.

56. Herman van Oyen, Member, Belgium, also emphasised the need to exercise caution and did not have great faith in biometrics as a science.

57. Mika Salminen, Member, Finland had also participated in the trial and had been unfamiliar with the economic terms, although he found the experiment interesting as one way of seeking consensus of opinion on future events. He would have predicted similar results on the basis of available surveillance data. The idea needed more work before it could actually become useful and there was a danger that the results could be misleading without a large, random population sample participating.

58. Jonathan Latham pointed out that the project was still at a very early theoretical stage. Nevertheless, the results had been promising. Participation had been limited and at present it was still only a consensus building tool. He emphasised that they were not trying to predict random events, but were exploring the ongoing dynamics of a process. He agreed that it was difficult to maintain user interest once the novelty wore off, which called into question the longevity of the project.

Item 4 – Epidemic intelligence: update on recent threats in Europe

59. Denis Coulombier, Head of Surveillance and Response Support Unit (SRS), ECDC, gave an update of some of the most recent threats in Europe.

Bilharziasis in Corsica

60. Bertrand Sudre, Scientific Officer, Environmental Determinants, SRS Unit, ECDC, gave a presentation on recent clinical cases of *Schistosoma haematobium* infection in persons exposed at a site on the River Cavo in the south of Corsica (April 2014).

61. Jean-Claude Desenclos, Member, France, gave a short update on the latest information regarding Bullinus which was followed by questions from the floor.

62. Haraldur Briem, Member, Iceland, noted that they had had similar problems in lakes and mountains with hot springs in Iceland in summer, and suggested that warning signs could be erected to discourage people from bathing.

63. Jean-Claude Desenclos, Member, France, was interested in determining whether bilharziasis constituted a public health threat or just a nuisance in that urinary bilharziasis was a serious disease but non-transmissible.

64. Anders Tegnell, Member, Sweden, suggested that the main challenge was with diagnostics since it was not easily recognisable.

65. Mike Catchpole, Member, United Kingdom, suggested that more information was needed about the frequency of visits to the area by those identified as cases. He urged caution in focusing on the attack rates.

66. Jean-Claude Desenclos, Member, France, agreed that information needed to be collected very carefully and accurately, which was difficult when relying on peoples' memories of up to three years ago.

67. Osamah Hamouda, Member, Germany, wished to know what France's plans were in terms of how to inform the public, particularly since there would be a great many visitors from Europe visiting the area in the immediate future.

68. Jean-Claude Desenclos, Member, France, said that it would be necessary to inform the public quickly before the media got hold of the story. Corsica was also a sensitive area and it was necessary to give realistic advice rather than discouraging people from going on holiday there. If the disease was endemic, it would require further research.

69. Kåre Mølbak, Member, Denmark, recalled that tourists visited many places rampant with tropical diseases; thus it is important not to start changing general travel advice. It is also essential to interview carefully those involved as the disease could be related to one specific area only, and it is therefore incorrect to condemn an entire river basin. He then inquired whether there were any theories as to how the parasite infiltrated the river site, and said that it would be interesting to look for serological evidence of *Schistosoma* antibodies to ascertain if it had been present in Corsica for many years.

70. Jean-Claude Desenclos, Member, France, informed that the source of the parasite was purely speculative at present, and that they would have to work on the genome, which would help in terms of knowledge, but that it would not be useful in terms of action to take.

71. Denis Coulombier, Head of Surveillance and Response Support Unit, ECDC, explained that schistosomiasis could be very localised and shedding could vary greatly depending on environmental conditions.

72. Bertrand Sudre informed that the cases had been very localised and had been found upstream, not in the valley, in a very touristic area with road access and a car park, so other cases would be likely and public health specialists in the Member States should be aware of travellers returning from this specific area in southern Corsica.

73. Denis Coulombier said that the schistosomiasis was not a serious cross border threat, but would be useful to circulate in EWRS.

Update on MERS-CoV

74. Denis Coulombier, Head of Surveillance and Response Support, ECDC, gave a short presentation to update the Advisory Forum on his recent participation in the WHO mission to Saudi Arabia to review the MERS-CoV situation in Jeddah and in preparation for the emergency committee taking place on 14 May 2014.

75. Mike Catchpole, Member, United Kingdom, reported on the two UK MERS-CoV cases. Response measures included contact tracing of flight passengers and media announcements. He pointed out that the cases did not represent a major issue in terms of exposure. Regarding the situation of MERS-CoV in Saudi Arabia, he asked how many of the secondary healthcare acquired cases were actually acquired in the ICU.

76. Denis Coulombier pointed out that no specific information on how and where healthcare transmission occurred has been given by the Saudi authorities. However, he argued that most

healthcare acquired cases have probably occurred in the ICU since several ICU healthcare workers have been infected.

77. Andreas Gilsdorf, Alternate, Germany, asked his colleague from the UK how extensive the contact tracing on the plane had been.

78. Mike Catchpole, Member, United Kingdom, explained that the UK followed ECDC's RAGIDA guidance on contact tracing. Passengers seated two rows in front and two behind, as well as two seats on each the side, were contacted within 12-14 hours of notification. All UK citizens on the plane were notified, even those not concerned by the guidance recommendations, within 48 hours. A two-phase approach was implemented: first the active follow-up of passengers seated next to the case, second a less rapid contacting of all other UK citizens.

79. Darina O'Flanagan, Member, Ireland, pointed out that in the documents received by Advisory Forum members prior to the meeting, the RAGIDA guidance was described as not yet approved pending CDC's approval and asked for clarifications on its status.

80. Denis Coulombier, explained that the wording in the document was misleading: since CDC experts participated in the development of the RAGIDA guidance, it needed to go through a clearance process at CDC, not an approval process.

81. Frank Van Loock, European Commission, asked for more light to be shed on WHO's request to send an expert group to Saudi Arabia and why this was done through CDC and not ECDC.

82. Denis Coulombier, explained that the WHO had an office in Saudi Arabia, but no representatives. Only one person worked for WHO in Saudi Arabia and their main task was fundraising. Saudis consider WHO to be a humanitarian agency and not a technical agency that they can ask for help. The WHO IHR investigation is seen as having failed after two years of transmission. The Saudi authorities are taking decisions very rapidly and efficiently. The private company employed by the Saudi authorities to help deal with the MERS-CoV outbreak asked WHO to send a team from CDC.

83. Marc Sprenger, Director, ECDC, pointed out the possibility that the strong media attention given to camels as the suspected source might be overrated since only 10% of primary cases reported contact with camels.

84. Denis Coulombier commented that virological evidence showed that camels were the reservoir but that more studies were required on exposure. The number of primary cases may have been overestimated (because there were secondary community/household contact cases). In the absence of a good description of the cases it was very difficult to obtain correct numbers. As for nosocomial transmission, no data documenting the practice of healthcare workers, the chain of transmission or contacts with patients had been provided.

85. Kåre Mølbak, Member, Denmark, pointed out that if camels were the reservoir, the source of transmission was not likely to disappear, which created a very different situation from the SARS outbreak. He stressed the importance of developing a long-term strategy.

86. Denis Coulombier explained that no long-term roadmap had been prepared yet, since FAO and the veterinary sector had just started looking into the issue.

Item 10 – Spread of polio in 2014

87. Lucia Pastore Celentano, Acting Head of Vaccine-preventable Diseases Programme, ECDC, together with Niklas Danielsson, Deputy Head of Vaccine-preventable Diseases Programme, ECDC, gave a slide presentation of the latest developments of polio spread worldwide and implications for EU Member States. She concluded by putting forward four questions:

i) Have the recent development increased the risk of WPV being imported to the EU?

ii) Should EU and Member States put in place additional measures in support of the Temporary Recommendations? (e.g. environmental surveillance)

iii) What is the burden (in terms of costs and human resources) on EU MS due to the Temporary Recommendations?

iv) Is there a need for an EU preparedness plan (under the new cross-border health threats legislation)?

88. Mike Catchpole, Member, United Kingdom, expressed uncertainty as to whether the risk of sustained transmission in Europe had really increased and argued that it depended on the population in which the imported cases arrived - under-immunised groups or the normal population.

89. Andreas Gilsdorf, Alternate, Germany, pointed out that Germany would not change its recommendations for a temporary WHO measure, and that no exit or entry screening would be performed. He stressed that environmental sampling was difficult and argued that the most important was to focus on good vaccination coverage, both in the EU, and infected countries.

90. Anders Tegnell, Member, Sweden, pointed out that the recommendations were clearly directed towards non-EU countries. He agreed that the focus should be on vaccination coverage. He further explained that all Syrian asylum seekers were offered vaccination in Sweden.

91. Mika Salminen, Member, Finland, explained that Finland was not considering checking vaccination status on exit or entry to the country. Finland may recommend vaccination (booster) on a voluntarily basis for travellers going to the countries concerned by WHO's recommendations, but it would not be centrally monitored, nor enforced, it would be a recommendation.

92. Darina O'Flanagan, Member, Ireland, noted that the risk had increased compared to 2012, but not compared to 2010.

93. Lucia Pastore Celentano, ECDC, pointed out that the number of cases has decreased compared to 2010 but that WHO was very concerned regarding the eradication objective and that was why it was recommending environmental surveillance in order to detect virus circulation instead of more AFP cases.

94. Guénaël Rodier, WHO Regional Office for Europe, explained that the overall risk had decreased compared to five years ago. Recommendations were linked to the eradication itself, not the risk to EU Member States and the discussion should therefore be linked to what the EU could do to help eradication (i.e. advocacy and tools to help exporting and affected countries). He further noted that the international travellers health recommendations had been updated.

95. Kåre Mølbak, Member, Denmark, argued that eradication was achieved by increasing vaccination coverage, not by focussing on international travel.

96. Mike Catchpole, Member, United Kingdom, expressed his country's full support for the eradication objective. He argued that it would be helpful to have a consistent approach among EU Member States, particularly regarding border control.

97. Mira Kojouharova, Member, Bulgaria, underlined Bulgaria's issue with shortage of polio vaccine and explained that it would be difficult to implement recommendations to vaccinate travellers to affected countries.

98. Hanne Nøkleby, Member, Norway, explained that Norway had recommended vaccination before travel to endemic areas for a long time since almost 10% of the population travelled to Pakistan for prolonged periods.

99. Jean Claude Desenclos, Member, France, argued that in many EU countries public health budgets and human resources would decrease and therefore the question of cost-effectiveness and accurate allocation was becoming more and more important.

100. Florin Popovici, Member, Romania, commented that before the PHEIC was declared, Romania was red flagged by WHO as being a country at risk of reintroduction because of immigration from Ukraine. Therefore Romania was currently strengthening environmental surveillance in all districts bordering on Ukraine.

101. Mika Salminen, Member, Finland, noted that the risk that travellers might face difficulties on exit from reported countries had pushed Finland to recommend vaccination before travelling to endemic areas.

102. Agnes Csohán, Member, Hungary, noted that if vaccination was recommended for international travellers, there was the question of charges: IPV vaccines should be made available to

travel clinics. Furthermore, she suggested that the mechanisms of how the vaccines would get to EU countries in case of need should be checked at EU level.

103. Johan Giesecke, Chief Scientist and Chair, ECDC, summarised the answers to the four questions as follows: no to the first question; no country expressed willingness to act regarding the second question; it was a question of priorities for the third question and no to the fourth question.

Item 6 – ECDC Chlamydia guidance evaluation

104. Andrew Amato, Head of HIV-AIDS and Blood-borne infections, Office of the Chief Scientist, ECDC, gave a slide presentation on the evaluation of the ECDC chlamydia guidance.

105. Mike Catchpole, Member, United Kingdom, congratulated ECDC and stressed the importance of evaluating ECDC's products. He argued that this could represent the opportunity to build an evaluation procedure for which ECDC could provide leadership.

106. Anders Tegnell, Member, Sweden, congratulated ECDC and explained that the basic question remained whether the guidance had had any effect on chlamydia. Sweden was seeing an increasing number of cases year after year even though great efforts had been made.

107. Jean Claude Desenclos, Member, France, lauded ECDC for such an evaluation, which represented a clear EU added value. He suggested developing a methodology applicable to all guidance documents and reporting back to the Management Board.

108. Marianne van der Sande, Alternate, the Netherlands, explained how a trial in the Netherlands proved that a systematic screening strategy was not cost-effective and argued that the issue was that it was not clear whether the focus should be on the overall infection level or on enhanced case management.

109. Isabel Noguer Zambrano, Alternate, Spain, congratulated ECDC and commented that the guidelines were being used in Spain, but that due to lack of resources the focus for the time being was on surveillance systems.

110. Andrew Amato thanked the Advisory Forum Members for their encouragement and pointed out that the guidance content would be revised according to the latest data.

111. Otilia Sfetcu, Scientific Officer HIV AIDS and Blood-borne infections, Surveillance and Response Support Unit, ECDC, thanked the Advisory Forum participants and invited them to consult the summary of the most recent data and evidence on chlamydia and related issues.

Item 7 – Surveillance dashboard

112. Bruno Ciancio, Head of Section, Epidemiological Methods, Surveillance and Response Support Unit, ECDC, gave a presentation to introduce the surveillance dashboard, a new ECDC tool to visualise epidemiological surveillance in Europe, and showed some of its functionalities to the AF members. He pointed out that ECDC would welcome comments from the Advisory Forum members over the next two weeks using the email: surveillance@ecdc.europa.eu.

113. Darina O'Flanagan, Member, Ireland, stressed the importance of having a precise case definition for *Haemophilus influenzae.*

114. Marianne van der Sande, Alternate, the Netherlands, congratulated ECDC and explained that in the Netherlands they were currently exploring the possibility of having a similar tool.

115. Mika Salminen, Member, Finland, congratulated ECDC and argued that if all EU Member States could get access to part of the code and use the same tool at national level, it would have a very significant added value.

116. Andreas Gilsdorf, Alternate, Germany, congratulated ECDC. He noted that the difficulties in comparing data still remained but that the dashboard provided a better tool for showing this data. He agreed with his colleague from Finland that it would be very useful to provide the tool to Member States, even at a regional level, so that national data could be inserted directly at regional level. He

suggested contacting European experts at national level who were continuously developing this type of surveillance dashboards and could advise ECDC.

117. Ágnes Ćsohan, Member, Hungary, congratulated ECDC and suggested prioritising vaccine-preventable diseases.

118. Frank van Loock, European Commission, argued that potential issues with the use of the tool could arise, and stressed the importance of carefully analysing each pathogen/disease before adding it to the dashboard. He underlined that this tool should not be used for comparison purposes, but as a quality control. He also warned of the risk of misinterpreting maps and of their politically sensitive nature.

119. Marta Grgič-Vitek, Alternate, Slovenia, agreed with the above comment.

120. Mika Salminen, Member, Finland, supported the dashboard and explained that such a tool would put pressure at the national level to present better data which was why the issue of quality should not stop the deployment of such a tool.

121. Osamah Hamouda, Member, Germany, explained that a similar tool was in place in Germany and there was an ongoing discussion about whether to put surveillance data online for the public. Germany had opted for the transparent solution and until now the experience had generally been very positive. He was very much in favour of data availability which would improve the quality of the data in the long run.

122. Darina O'Flanagan, Member, Ireland, explained that Ireland did not allow deductive disclosure in the case of a very limited number of cases and wondered how ECDC would tackle this issue.

123. Marianne van der Sande, Alternate, the Netherlands, argued that surveillance data should serve action and should therefore be publicly available.

124. Isabel Noguer Zambrano, Alternate, Spain, expressed strong support for the initiative.

125. Jean Claude Desenclos, Member, France welcomed the development and argued in favour of data availability.

126. Bruno Ciancio, ECDC, agreed with the Advisory Forum members that interpretation of data was a challenge, and assured them that ECDC would provide a better description of the different surveillance systems in order to facilitate comparisons. He explained that any category showing five or less cases would not be public. He further explained that ECDC was currently investigating how the tool could be provided to Member States. Regarding the prioritisation of diseases, he explained that the overall timeline was relatively short and most diseases would be presented on the dashboard by 2015. He further noted that the dashboard would partially replace the Annual Epidemiological Report, but it would not have any implication for specific surveillance reports.

Item 9 – Update from the Commission

127. Frank Van Loock, European Commission, gave a brief slideshow presentation of the implementation status of the decision on serious cross-border threats to health.

128. Andreas Gilsdorf, Alternate, Germany, requested more information on the decision's direct implications for ECDC and particularly for the work of the Advisory Forum.

129. Frank Van Loock commented that the European Commission did not foresee any content change in the work delivered by ECDC. The new legislation might entail a consultation procedure with the Health Security Committee on preparedness and risk communication.

130. Andreas Gilsdorf, Alternate, Germany, expressed concern that the new procedures between the EWRS and the Health Security Committee might create confusion at the national level, particularly if the communications to the health security committee bypassed communication to the risk assessors at national level. He also expressed concern that the ECDC's independence might be compromised because of these new procedures.

131. Johan Giesecke, Chief Scientist and Chair of the Advisory Forum, ECDC, pointed out that ECDC did not participate in the Health Security Committee as a regular member but could be called in

as an expert and that the EWRS would continue to function as the communications tool between the European Commission, ECDC and the Health Security Committee.

132. Frank Van Loock commented that the Health Security Committee should be notified of any communications issues. He further mentioned that the information shared with the Health Security Committee was available through EWRS and that ECDC had been present in the Committee's meetings as an expert party. He argued that information exchange between EWRS and the Committee should not cause any problems since EWRS was the tool for sharing information among members of the Committee. However, he agreed that some issues might have been encountered because the system was still in its development phase.

133. Denis Coulombier, Head of Surveillance and Response Support, ECDC, requested some information on the status of the implementation of the act on surveillance.

134. Darina O'Flanagan, Member, Ireland, explained that in Ireland ministries did not have access to EWRS but were members of the Health Security Committee.

135. Frank Van Loock, European Commission, pointed out that a number of nominees for EWRS and the Committee were still pending. Regarding the surveillance act, there was no specific timeline yet.

136. Kåre Mølbak, Member, Denmark, expressed concern regarding the way access was granted to EWRS.

137. Frank Van Loock noted that all questions linked to EWRS access and information exchange should be raised at the Health Security Committee.

138. Darina O'Flanagan, Member, Ireland, stressed that all changes to EWRS should be communicated to all Member States since they could have important implications for work at national level.

139. Frank Van Loock noted that one important future challenge would be to coherently mobilise different alert systems and ensure that those responsible had access to alerts in a timely manner.

Item 8 – Update on MediPIET

140. Karl Ekdahl, Head of Public Health Capacity and Communication, ECDC, gave a presentation to update on ECDC's programme MediPIET.

141. Frank Van Loock thanked ECDC for collaborating on MediPIET and stressed the importance of the regional dimension of the project which enabled collaboration between countries with no previous experience of working together.

142. Isabel Noguer Zambrano, Alternate, Spain, expressed her institute's pride in hosting MediPIET and said that thanks to MediPIET the institute had received the financial and political support needed to continue to offer the Spanish epidemiology training. She invited AF members to participate in the MediPIET kick-off meeting in Madrid.

143. Andreas Gilsdorf, Alternate, Germany, thanked the Chair and expressed his appreciation for the specific questions which were raised to the AF members.

144. Kåre Mølbak, Member, Denmark, suggested discussing the Global Research Collaboration for Infectious Disease Preparedness (an EU initiative aiming to create a global network of funding organisations) during the next Advisory Forum meeting to reflect on how ECDC could be involved in the creation of this network.

145. Johan Giesecke, Chief Scientist and Chair of the Advisory Forum, ECDC, suggested that a representative of the network could be invited to give a presentation.

146. Herman Van Oyen, Member, Belgium, suggested discussing the Cochrane review of antiviral therapy at the next meeting.

147. Johan Giesecke, Chief Scientist and Chair of the Advisory Forum, ECDC, thanked all AF members for the discussions and closed the first day of meeting.

Joint session of the Advisory Forum and the National Microbiology Focal Points on Public Health Microbiology Strategic Developments

Plenary session A - EU molecular surveillance pilot project – context, objectives and evaluation *(Document AF38-NMFP1a)*

148. Johan Giesecke warmly welcomed the participants, introduced the co-chair, Marc Struelens, and stressed the importance of the joint meeting, especially considering the profound influence microbiology developments have on infectious disease surveillance and control.

149. Marc Struelens set the scene for the morning's discussion by reflecting briefly on progress achieved since the first surveillance strategy was put in place in 2007, and on how integration of molecular typing information has evolved from a concept to practical surveillance. He then introduced the ECDC discussion panel members[1].

Marc Struelens continued by presenting "EU molecular surveillance pilot project – context, objectives and evaluation" and summarising the evaluation's main findings and conclusions.

To open the discussion, he put forward two questions for the pilot pathogens Salmonella, Listeria, STEC/VTEC and MDR TB:

1) Do the results obtained to date meet in a satisfactory manner the expected disease surveillance outputs according to the project objectives?

2) In your opinion, do you consider the value and potential public health benefits of molecular surveillance at the EU level for these pathogens in equilibrium with the (extra) efforts?

150. Mike Catchpole, Member, United Kingdom, commended the evaluation report and noted that, overall, the results of the pilot were encouraging. He noted the lack of comparison between the data obtained via the traditional reporting for these pathogens and the data obtained via the molecular surveillance pilot project. He added that such a comparison in terms of completeness and timeliness would serve as a benchmark for the performance of the pilot. Marc Struelens agreed with the suggestion to include such a comparison in the next developments. Bruno Ciancio supported the suggestion as well and added that there was no comparison between regular TESSy data quality and the quality of data generated by the pilot. However, he noted that in case the frequency of reporting would be compared, the pilot would demonstrate better results.

151. Karl Kristinsson, NMFP, Iceland, commented on the high rate of PFGE data rejection for Listeria. He questioned whether we should invest in WGS instead of training to improve PFGE outputs. Marc Struelens clarified that the high rejection rate was due to submitted historical data, i.e. with gel images that were less well standardised compared to today. He agreed that WGS would be the way to go, but stressed the need for further validation work. Ivo Van Walle supported that idea by noting that the use of WGS would indeed solve many of the current technical issues.

152. Maria Zambon, NMFP United Kingdom, shared feedback of her UK colleagues who had been involved in the work described. Namely, the importance of recognising the need for finding a sensible strategy to deal with differences between the Member States in relation to molecular surveillance capabilities. She highlighted that the direction for the roadmap towards adopting genomic surveillance in the coming years was more critical than whether the pilot had fulfilled its narrow objectives. Secondly, the pilot system was seen as insufficiently connected to food safety monitoring practice and therefore raised a risk about possible divergence.

153. Marc Struelens expressed his appreciation of the feedback shared by the UK and encouraged the experts present at the meeting to discuss and progress further towards molecular surveillance.

[1] Ivo Van Walle, Expert Data Management, Surveillance and Response Support Unit; Csaba Ködmön, Expert Respiratory Diseases, Surveillance and Response Support Unit; Karin Johansson, Expert Molecular Surveillance for Communicable Diseases, Surveillance and Response Support Unit; Marc Struelens, Chief Microbiologist, Office of the Chief Scientist; Bruno Ciancio, Head of Section, Epidemiological Methods, Surveillance and Response Support Unit.

Regarding the link to microbiological analysis of food and feed isolates, he informed of ECDC's attempts to ensure the data would be comparable, e.g. via liaison with the Commission and EFSA.

154. Ivo Van Walle, ECDC, added that with regards to molecular typing data, ECDC and EFSA are planning a joint database that will allow for the detection of similar isolates across food and human.

155. Osamah Hamouda, Member, Germany, supported ECDC's efforts and agreed with the previous comments from the UK. He added that the major challenge in going forward and a key weakness in the pilot was the necessary linkage between microbiological and epidemiological data. More joint work to find solutions would be desirable.

156. Mika Salminen, Member, Finland, agreed with the previous comments and added that a vision is needed in which the efforts at EU level in the field of molecular surveillance can be consolidated to align research to public health needs. Marc Struelens shared the view that the rapidly developing research and development work on typing may not necessarily fulfil the needs of public health. He cited an example of ECDC's contribution to steer such research work (by participation in advisory boards to DG RTD funded translational projects, e.g. Patho-NGen-Trace) and hoped that ECDC will be an active advocate and effective broker for public health in Horizon 2020 research projects on genome-based infectious disease surveillance.

157. Marianne Van der Sande, Alternate, the Netherlands, shared positive feedback on the pilot from both microbiology and epidemiology Dutch experts, noting this work should continue. She stated that the decline in laboratory diagnostics at clinical level was a concern and would likely introduce a bias in the data collected and its use. She further stressed the need to consider the added value of molecular surveillance for public health and the need to link microbiological and epidemiological data.

158. Darina O'Flanagan, Member, Ireland, reported positive feedback on the pilot from the Irish experts involved. She warned about the decrease in routine clinical microbiology use of culture-based diagnostics that will require adapting for data production. Regarding data sharing, she suggested that contractual arrangements are made both with microbiology as well as epidemiology stakeholders. Ivo Van Walle agreed with the suggestion, and confirmed it would be taken on board, albeit cautioned it might take time since the current collaborative agreement discussions took more than a year to conclude.

159. Guido Werner, NMFP, Germany, noted that lengthy reporting delays are impeding the timely recognition of multi-country outbreaks. He inquired whether there is a strategy to deal with such timelines and whether the system has any added value compared to EPIS and EWRS.

160. Marc Struelens clarified that currently it is not easy to report and compare microbiology data in EPIS and EWRS. Consequently, the possibility to compare such data was recognised by the pilot participants as an added value, along with the quality assurance of data and facilitation of outbreak investigation support. Regarding the delay in reporting data, he explained that there were several factors that need to be worked on, namely, the referral of isolates from clinical to national reference level, the typing workflow and linking epidemiological and microbiological data. He noted that the PulseNet USA programme took 10 years to develop to its current system, which offers real-time recognition of foodborne outbreaks.

161. Alkiviadis Vatopoulos, NMFP, Greece, commented on the national practice in some Member States, where currently a message would be posted on EPIS notifying e.g. of an unusual increase in the frequency of a certain Salmonella serotype. The National Reference Laboratory would then need some weeks to retrieve the isolates and analyse them national level; hence the delay. Not all countries are performing continuous typing work on all clinical isolates. He noted the possibility of fewer multi-country outbreaks during the pilot. He further stressed the need to link epidemiological and microbiological data.

Ivo Van Walle noted the unlikeliness of few outbreaks considering that there are around 200 multi-state outbreak investigations in the U.S.S. annually. Hence the under detection of outbreaks in Europe is likely.

162. Isabel Noguer, Alternate, Spain, congratulated everyone on the initiative and stressed that Spain would continue supporting it. She further stated that they were developing a new Centre of Infectious Diseases, aiming at the close link between epidemiological and microbiological work.

163. There was a brief discussion with several participants on the fact that there is no need for molecular typing data for rare serotypes in relation to outbreak detection. Karin Johansson, ECDC, commented that the idea that Member States submit data on these serotypes without molecular typing data has already been proposed by the pilot participants and that more detailed discussions with the FWD network will be initiated by ECDC in the post-pilot phase.

164. Kåre Mølbak, Member, Denmark, stated his interest and participation of his Institute in the pilot project. He noted that the main weaknesses were indeed the epidemiological data linkage and the timeliness of data sharing. He agreed that outbreaks are likely missing due to partial coverage. He proposed that the Roadmap should investigate these hurdles and also define who, how and when to respond to the detected outbreaks. He added that it was in the interest of public health to conduct isolate typing and that each country should be responsible for ensuring that comparable food isolate analysis and data sharing with the food sector is integrated into national legislation

165. Mickael Kalai, NMFP, Belgium, shared that beyond a comparative analysis of human and food isolates, which is routinely done in Belgium, a solid surveillance system that identifies the source of an outbreak is needed.

166. Frank Van Look, Member, European Commission, noted the possible increase in food trade with the U.S.A. in the light of the transatlantic trade talks and the possibility of the U.S.A. detecting EU outbreaks faster than the EU. Marc Struelens responded that this is already taking place and that it is pertinent that Europe establish a vigilant system for detection of such outbreaks and source identification. This would strengthen the excellent collaboration on epidemic intelligence and molecular surveillance with U.S. CDC.

167. Anders Tegnell, Member, Sweden, supported the pilot and shared positive feedback from Swedish colleagues. However, he stressed that the pilot included very different pathogens and hence the differences in practice and added value. While typing for FWD is well-established, he was more hesitant with MDR-TB. He noted his apprehension of the lengthy reporting timelines and questioned the feasibility to achieve real-time reporting at EU level.

168. Herman Van Oyen, Member, Belgium, noted that the EU-wide molecular surveillance could have other added values than finding the source of an infection, e.g. detection of genetic variants relevant to vaccine escape of vaccine preventable disease. He further emphasised the importance of linking microbiological and epidemiological data and suggested to expand beyond the area of food safety and explore other public health fields.

169. Mike Catchpole, Member, United Kingdom, added that there were two key aspects to consider. First, mainstream, i.e. to prepare for what is going to drive molecular surveillance in the future, that is, whole genome sequencing (WGS) by working on cluster naming, analysis, and other interpretation challenges with whole genome sequence data. Second, add value, i.e. to define it and the way to achieve it (e.g. work on timeliness, linking data but also the right organisations).

170. Ivo Van Walle clarified that with the advent of WGS, it may be well worth to think beyond the current practice of naming, i.e. assigning a subtype label to a group of strains implying that they are the same and all others are different. Rather, WGS data may well be able to provide a satisfactory estimate of evolutionary time passed since the last common ancestry, which is information that can be correlated with available epidemiological data. For example, it could be estimated that there are 10±2 days of evolution between two particular isolates, which may or may not correlate with exposure to a common source around that time. With regards to the link to food data, he added that it was not an obstacle from a technical perspective, but a challenge with respect to getting people and organisations to work together.

171. Marc Struelens encouraged the participants to take part in the upcoming EFSA scientific colloquium on WGS-based surveillance of foodborne pathogens, which would be addressing the question of how to ensure cross-sector collaboration in terms of validating methodology, data sharing, informative sampling, etc.

172. The Co-Chair, Johan Giesecke, put forward the questions posed by Marc Struelens and summarised the replies as follows:

For the pilot pathogens Salmonella, Listeria, STEC/VTEC and MDR TB:

1) Do the results obtained to date meet in a satisfactory manner the expected disease surveillance outputs according to the project objectives?

Answer: Yes

2) In your opinion, do you consider the value and potential public health benefits of molecular surveillance at the EU level for these pathogens at balance with the (extra) efforts?

To the request for the question to be better formulated, namely, to stipulate what the extra efforts are, Marc Struelens clarified that it meant efforts to share the available data at EU level, as measured in the report.

Answer: Based on a show of hands and comments made by participants, there was overall agreement to answer yes to the question of added value and potential benefit for the control of foodborne pathogens. As for MDR-TB, the benefit was considered different; it is useful mostly for monitoring trends.

173. Bruno Coignard, NMFP, France, suggested that answers to the question should be differentiated since they were mainly relevant for the foodborne pathogens. For MDR TB, it was less evident as this was based on person-to-person transmission. His answer would then be yes for foodborne and maybe for MDR TB.

174. Guido Werner, NMFP, Germany, said that the question had to be answered from the perspective of one's own country as standard reporting at national level already exists. In response to whether it was worth the extra effort of reporting, he would say yes, and that this should be the primary goal at EU level through ECDC.

175. Maria Damian, NMFP, Romania, commented that the technology is now in place in her country, but discussions remain pending on how to link molecular and epidemiological data. In the case of such a link, she added, the value of molecular surveillance would be higher.

176. Vera Katalinić-Janković, NMFP, Croatia, highlighted the support of the European tuberculosis laboratory network for the TB molecular surveillance pilot project.

177. Christopher Barbara, NMFP, Malta, clarified that for a small country, the extra efforts were different, i.e. they could be technical (e.g. train and hire highly specialised staff) or logistical (e.g. ship isolates to another country for testing).

178. The Co-Chairs added that if WGS would indeed be the preferred technology in the near future, it would offer a universal solution, which would give the necessary information for any disease agent provided adequate bio-informatics expertise.

179. Mike Catchpole stated that the question could be reformulated as follows: "Does the extra effort justify not going in the molecular typing path?."

180. In supporting the statement above, Mickaël Kalaï, NMFP, Belgium, added that the extra effort is in implementing new methods for some, while others need to keep old and less useful methods. This is due to the fact that there is no clear EU golden standard for cross-border surveillance. He proposed that a new common modern methodology and approach in the EU need to be agreed upon.

181. Mika Salminen, Member, Finland, stressed that the future of public health laboratories is at stake and the fundamental question is who will lead molecular typing? He added that ECDC needs to lead at EU-level and national authorities need to lead at national level to ensure good cooperation between microbiology and epidemiology. He added that if ECDC and national authorities do not take the lead, somebody else will, which might steer the course of the future into another direction (e.g. academic research, not public health).

Discussion - Future ECDC molecular surveillance activities[2]

Question 3: How should EU molecular surveillance proceed for each of these pathogens and are the ECDC future options appropriate as proposed in the evaluation report?

Options per disease: a) continue; b) expand; c) reduce; d) modify; e) discontinue

182. Jaana Vuopio, NMFP, Finland, informed that she had consulted with the involved Finnish experts and they agree with the recommendations as stated in the report; both for the zoonotic pathogens and for tuberculosis. She encouraged the continuation of molecular surveillance for the zoonotic diseases.

183. Guido Werner, NMFP, Germany, followed up on the comment of Maria Zambon, NMFP, United Kingdom, on inequalities in technical capabilities across the Member States. He noted that if we should continue with technologies that are compatible and comparable than we should revisit what we use. For example, MLVA would not comparable with WGS since the information could not be extracted with current technology.

184. Johanna Takkinen, ECDC, agreed with the statement and clarified that MLVA is an interim method between PFGE and WGS. She explained that the methodology was discussed with the Food- and Water-borne diseases and zoonoses network and they support MLVA for Salmonella Enteritidis. Hence, ECDC would be supporting conventional methods for a while and keeping a link to historical data. She added that ECDC would be supporting exchange of expertise and training – both microbiology and epidemiology - so that countries using old techniques would have an opportunity to learn how to develop WGS based methods. She further added that any technique had drawbacks and uncertainties; hence we would still need to understand those in applying next generation sequencing (NGS) to public health and validate their use.

185. Mike Catchpole stressed that it would be valuable for ECDC and EFSA to discuss together what technology to use and the two Agencies should work together to define what a significant signal would be and who should act on it. Karin Johansson clarified that ECDC was just starting to accommodate the need for the system to detect signals rather than clusters and that was currently being discussed with the involved experts.

186. Kåre Mølbak, Member, Denmark, emphasised the need for ECDC to lead in developing a strategy for which methods should be used, along with EFSA. He noted that the success of this had been shown in the U.S.A. He added that for the foodborne pathogens, Campylobacter was indeed important as more common than Salmonella, but less prone to outbreaks. However, he stressed that molecular typing had not been shown to add value to understanding the epidemiology of Campylobacter and therefore, there would likely be no public health benefits from including it now. He advised to focus on the three pathogens in the pilot and make these more successful. Marc Struelens added that in the case of molecular surveillance of Campylobacter, there would be more value in food source attribution for sporadic cases rather than outbreak detection.

187. José Miguel Rubio Muñoz, NMFP, Spain, shared that Span is content to continue participating in the pilot, especially for Salmonella. He inquired whether other countries could be included to make more data available (e.g. as part of the laboratory expertise mentioned).

188. Karl Kristinsson, NMFP, Iceland, sought clarification on what expanding would really mean, considering that we could only type what a laboratory would culture, noting the increased use of culture-independent testing. Karin Johansson explained that ECDC would not be likely to impose a sampling strategy, while noting that the current system is based on routine testing and surveillance.

189. Marc Struelens, ECDC, added that availability of isolates was indeed fundamental and was something that should be agreed with the countries. He further added that there might be solutions to the dependency on culture, namely, NGS technology that can sequence directly from clinical specimens or be performed on selected culture isolates from samples screened positive by molecular tests.

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[2] ECDC panel members: Karin Johansson, Expert Molecular Surveillance for Communicable Diseases, Surveillance and Response Support Unit; Andreas Sandgren, Expert Tuberculosis, Surveillance and Response Support Unit; Marc Struelens, Chief Microbiologist, Office of the Chief Scientist; Johanna Takkinen, Head of Disease Programme Food and Waterborne Diseases.

190. Maria Zambon, NMFP, United Kingdom, stressed that clinical microbiology would indeed be molecular, even in low-income countries due to the economic advantages. She added that the sample/material of choice would depend on the signal it gives with a certain technology; hence the need to define the threshold.

191. Darina O'Flanagan, Member, Ireland, commented that private laboratories play a pivotal role and the way they were to be integrated in the public health system needed a political discussion. She added that the latter should be taken irrespective of what methodology would be chosen. She suggested that there should a Directive at EU level addressing the matter. Otherwise should there be no specimens/isolates, even the best technology would not offer the possibility of reaching our public health objectives.

192. Frank Van Look, Member, European Commission, asked how the Commission could assist to make the system more effective. He explained that on the food safety side, there was the Zoonosis Directive, now 10-years-old. He said that it might be possible to work on getting the Directive updated to ensure that a sufficient number of clinical specimens/isolates are collected and analysed; thus supporting the respective public health objectives. Regarding tuberculosis, he asked how the Commission could contribute to what is already in place. He added that Decision 1082/2013[3] threats could lead to an implementing decision that supports the matter discussed. With support of structural funds, the Commission could assist the countries further with capacity building. He encouraged the participants to reflect upon how the Commission can assist from an EU perspective, and whether more legislation might be beneficial.

193. Andreas Sandgren, ECDC, clarified that the goal of molecular surveillance of tuberculosis is not necessarily to find outbreaks, but to identify transmission routes. He added that moving to WGS should also clarify drug-resistance patterns and drug resistance. He agreed with Frank Van Look and stressed that tuberculosis culture would never be replaced fully by WGS. He underlined the need for priority setting in building capacity for disease control, by addressing first access to TB diagnosis and drug susceptibility testing before advanced typing services.

Conclusions and next steps

194. Co-chair Marc Struelens thanked the AF and NMFP for their helpful comments. He concluded the discussions of the session and summarised the agreed next steps as follows:

How should EU molecular surveillance proceed for each of these pathogens and are the ECDC future options appropriate as proposed in the evaluation report?

Options per disease: a) continue; b) expand; c) reduce; d) modify; e) discontinue

For Salmonella, Listeria monocytogenes and VTEC:

- Continue/improve system
- Expand coverage
- Improve quality and timeliness
- Integrate epidemiological and microbiological data
- Prepare transition to WGS based methods jointly with EFSA

MDR-M.tuberculosis

- Continue/improve system
- Align to annual data reporting
- Integrate epidemiological and microbiological data

Plenary session B - The influenza molecular EU surveillance strategy *(Document AF38/NMFP1b)*

[3] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health

195. Eeva Broberg, Expert, Influenza, Surveillance and Response Support Unit, gave a presentation introducing the rationale and objectives for EU/EEA influenza molecular surveillance, after which the floor was opened for general discussion.

Discussion[4]

196. Anders Tegnell, Member, Sweden, shared positive feedback from the Swedish colleagues involved in such work. He noted, however, that achieving objectives with the current proposal was doubtful. He expanded on this by highlighting the need to discuss sampling to ensure representativeness and data completeness, different from the current sampling based on convenience. Eeva Broberg explained that the European influenza network had been discussing the sampling representativeness and would work an approach to improve it.

197. Jan Kynčl, Member, Czech Republic, agreed in general with the proposal. He questioned the possibility for sustainable funding of such work, considering its current dependence on research grants. He also added that there was a need to focus on single reporting.

198. Kåre Mølbak, Member, Denmark, agreed with the comment of Anders Tegnell on fulfilling the objectives. He stressed that in some countries, patient data (including history) is difficult to obtain, but without such information the data collected would not be of sufficient quality to answer the objectives. He advised to put reflect upon the data workflow (avoiding double reporting) and quality. He shared the concern that this work is moving more towards research rather than public health.

199. Eeva Broberg, ECDC, stated that after the pandemic, there were fewer countries with problems in sharing sequence data globally. Regarding double reporting, she explained that ECDC had proposed a solution where all data would be sent to TESSy and the sequence data with certain associated variables would then be forwarded to GISAID. Unfortunately, that was not acceptable to GISAID as it needed to sign an agreement with individuals, not ECDC. She explained that a number of other technical solutions for reporting were being discussed with GISAID. She added that Member States were mostly reporting to both systems as of now, which was in line with the current proposal.

200. Pasi Penttinen, ECDC, added that the proposal was indeed in the grey zone between research and public health regarding determinants of resistance. He explained that the severe influenza surveillance system would be discussed further with respect to what would be feasible and practical.

201. Isabel Noguer, Alternate, Spain, supported the proposal and the likely added value for the EU, especially with regards to seasonal influenza.

202. Marianne Van der Sande, Alternate, the Netherlands, commented that it was well-taken that ECDC was trying to use existing data, and encouraged everyone to consider how best to link to WHO data. She cautioned the use of GISAID data due to issues with quality and completeness. She said there was a need to evaluate whether the routine data could answer all surveillance objectives listed.

203. Regarding determinants and severe influenza cases, Eeva Broberg explained that, in that particular data set, data are reported from eight countries on hospitalisation, underlying illness and basic demographic information. Hence there was no need to collect more new data, but simply to put together existing data. Thus the countries with functioning severe influenza monitoring programmes should be invited to join the pilot. Regarding data quality and harmonisation, she explained that it is already possible that the peripheral laboratories send isolates to a central laboratory for characterisation and then the central laboratory shares the data directly; or, if needed, via the institute of public health.

204. Pasi Penttinen stated that ECDC will likely see a rapid increase in sequencing data in the next five years; thus surveillance systems need to be up to speed. He added that there are still many questions that need to be addressed on how to analyse and interpret the data.

205. Anders Tegnell reiterated that the objectives might not be achievable and sought clarification in the proposal on what is "surveillance for action".

[4] ECDC panel members: Marc Struelens, Chief Microbiologist, Office of the Chief Scientist; Eeva Broberg, Expert Influenza, Surveillance and Response Support Unit; Daniel Palm, Expert Microbiology, Office of the Chief Scientist; Pasi Penttinen, Acting Head of Disease Programme Influenza and Respiratory Diseases, Office of the Chief Scientist.

Conclusions and next steps

206. Co-chair Marc Struelens thanked the AF and NMFP for their helpful comments. He concluded the discussions with regard to the influenza molecular EU surveillance strategy, stating that ECDC will carefully review and clarify the proposed objectives and data collection processes with the influenza surveillance network to provide the appropriate answers.

207. Johan Giesecke also extended his thanks and farewell to the delegates. The next Advisory Forum meeting will convene on 24-25 September 2014.