ECDC Advisory Forum

Minutes of the Fifty-third meeting of the Advisory Forum

Stockholm, 15-16 May 2018

Contents

Day 1

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

1. The meeting was opened by ECDC Director, Andrea Ammon, who welcomed the participants.

2. Mike Catchpole, Chief Scientist, ECDC, welcomed the AF members and other participants, in particular Masoud Dara, WHO Regional Office for Europe, Frank van Loock, European Commission, Ágnes Hajdu, the new AF Alternate from Hungary, Gamze Aktuna, the newly appointed Observer from Turkey, John Watson, Invited Expert from the UK. Apologies had been received from Cyprus, France, Greece, Iceland, Latvia, Lithuania, Malta, and Slovenia.

3. No declarations of conflict of interest were made.

4. The draft programme was adopted without changes.

Adoption of the draft minutes of the 52nd Meeting of the Advisory Forum (20-21 February 2018)

5. Amendments had been received on the draft minutes of the fifty-second meeting from Denmark (points 18 and 47), Slovenia (point 71), and Spain (point 107). These had been taken account of, and the draft minutes revised accordingly. Some amendments were also made by ECDC in the section on hepatitis (points 67-85). There were no further amendments and the minutes were adopted.

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

6. Andrea Ammon, ECDC Director, gave a brief update of the main activities since the last Advisory Forum meeting.[1]

7. Kevin Kelleher, AF Member, Ireland, asked what progress had been made at the Management Board meeting with respect to the next joint strategy meeting and what was the MB decision taken on the external evaluation of ECDC.

8. Anders Tegnell, AF Member, Sweden, referred to the transparency register, which his institute had interpreted as being mainly for private enterprise and therefore decided not to join. He asked how the discussions had gone, and how ECDC and other EU agencies had acted in this area.

9. Kåre Mølbak, AF Member, Denmark, asked whether the AF had seen the Chief Scientist's Annual Report on the work of the Advisory Forum which had been presented to the Management Board as it could be of interest to the AF too.

10. Jan Kynčl, AF Member, Czech Republic, asked for a progress update on the issue of strengthening cooperation between the MB and AF, for example through the sharing of meeting programmes.

11. Frode Forland, Observer, Norway, asked for a definition of the Western Balkan countries. He was pleased to hear that ECDC had begun to define its stakeholders which would be useful for policy advisers and informing policy issues and asked what the next steps would be.

12. Andrea Ammon responded that there would be an update on ECDC's joint strategy meeting during Day 2 of the meeting. With regard to the transparency register, she clarified that it was more for commercial institutions but the decision was taken that ECDC would only use companies represented on the list. With regard to a progress update on cooperation between the MB and AF, she promised that ECDC would investigate and feedback, in particular with regard to the shared work areas. With regard to the definition of the Western Balkan countries, she clarified that these were the six enlargement countries (Serbia, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Montenegro, Albania and Kosovo) and not Turkey. With regard to the next steps in the discussions with

[1] Update on ECDC activities (A Ammon)

the CCBs, ECDC was currently analysing their input and looking at how to arrive at a definition of criteria for ECDC's stakeholders.

13. Mike Catchpole, Chief Scientist, ECDC, pointed out that the move to ECDC's new building had caused a backlog with some issues related to the complementarity between the MB and the AF and it was hoped to be back on track soon.

Epidemic intelligence update

14. Vicky Lefevre, Deputy Head of Unit, Surveillance and Response Support, ECDC, gave a short update[2] on the latest evidence with regard to three specific issues, each followed by a short discussion.

Part 1 - Multi-country outbreak of hepatitis A virus genotype IA infection

15. Mike Catchpole asked for the Advisory Forum's opinion on the potential EU added value of conducting an international outbreak investigation to find the source.

16. Kåre Mølbak, AF Member, Denmark, said that evidence strongly suggested a foodborne source and that a case control had confirmed their suspicion of fresh strawberries. He added that one case had demonstrated an association with consumption of fresh strawberries. He added that one case had an exposure history of both travelling to Morocco and eating fresh strawberries. However, the provenance of the strawberries could also have been Morocco. If this was true the whole picture would fit, however it could not be confirmed as yet. The cases were among men and women so there was no specific association with MSM.

17. Osamah Hamouda, AF Member, Germany, said that Germany had looked at travellers returning from Morocco and there did seem to be an increased number of cases so Germany was in favour of a larger study.

18. John Watson, Invited Expert, UK, said that there had been 23 cases in the UK which was a large number and he was therefore confident that his colleagues would be keen to investigate further.

19. Mike Catchpole concluded that there were 2-3 expressions of interest for a coordinated investigation.

Part 2 – Candida auris in healthcare settings - Europe

20. Mike Catchpole noted that *Candida auris* was clearly a problem that had emerged a few years earlier and was still around. He asked whether the AF felt this was an area in which ECDC should be working more closely with Member States on guidance or to increase in-country monitoring.

21. Frank van Loock, European Commission, pointed out that there was insufficient microbiological knowledge for dealing with this issue, and he would welcome ECDC being on the look-out for rising trends in this area.

22. Jaap van Dissel, AF Member, Netherlands, pointed out with regard to *Candida auris* and also aspergillus in influenza patients that the main concern in the Netherlands was that not every microbiology laboratory identified these strains.

23. Kevin Kelleher, AF Member, Ireland, believed that national reference laboratories in smaller countries might not be equipped to deal with this issue, and suggested it would be more beneficial to work together in strategic terms.

24. Anders Tegnell, AF Member, Sweden, asked to what extent this was a public health issue and to what extent a clinical management issue. Further activity to address this issue could end up being quite a costly exercise for a very rare phenomenon, and as such, he felt that it was a difficult question to answer on whether ECDC should use its resources for further investigation and assessment of the issue. He pointed out that so far at it had mainly been a clinical problem and that little was known about preventive activity and prevention of spread.

[2] Epidemic Intelligence update (V Lefevre)

25. Ágnes Hajdu, AF Alternate, Hungary, said that she wished to know more about the cases and wards affected, even if it was a rare issue. This was an area offering EU added value where it was possible to pool knowledge from Member States to learn more.

26. Isabel Noguer, AF Alternate, Spain, said that in her country surveillance systems were detecting increasing amounts of *Candida auris* from hospital systems. The problem was how to be more coordinated in dealing with the issue which was not just a Spanish problem but an EU-wide one.

27. Kåre Mølbak, AF Member, Denmark suggested looking at the issue from a broader perspective. In the future, it is likely that cancer patients and others would contract this type of infection increasingly and it would perhaps be useful to have a think tank to decide what types of surveillance would be relevant at EU level and develop a strategy. He was certain that the issue would only get worse as time went on, and it was therefore important to do something about it at EU level in the future.

28. John Watson, Invited Expert, UK, pointed out that gathering an expert group to look into the issue in greater depth would inevitably result in them concluding that more work was needed in this area. It would therefore be useful to include people with a broader public health perspective as well.

29. Franz Allerberger, AF Alternate, Austria, was not convinced that this was an issue for ECDC but more for national health systems. He also believed that it would be a mistake to single out one specific species of *Candida* in particular.

30. Andrea Ammon, ECDC Director, thanked the participants for their input. With regard to the comment from Sweden regarding ECDC's work being on the borderline with clinical management, she noted that in essence much of ECDC's work was relevant to clinical management. She agreed that the amount of *Candida auris* would continue to increase in future, albeit possibly due to improved capacity to detect it. However, at a strategic level it was important to know how to react, what to do and when to do it. Although there were only a few cases, it would be better to react sooner rather than later when there would be more. It would be necessary to decide at what point in time action should be taken. She was aware that it was very cost-intensive for countries to set up laboratory services, therefore the suggestion of a think tank was a good idea, but taking account of the UK comment that the experts involved should have a broader public health perspective.

31. Mike Catchpole, Chief Scientist, ECDC, said that although it was important to recognise the role of primary prevention, treatment as prevention was also a crucial part of the public health response and therefore he could not rule out ECDC having a role in at least supporting the development of clinical guidelines, particular with regard to hospital infections. He therefore did not believe that clinical guidance would necessarily be beyond ECDC's remit. He agreed with the idea of a think tank, which could perhaps initially take the form of an AF working group.

32. Frank Van Loock, European Commission, said that it was perhaps too early yet for a discussion on what kind of reference laboratories were needed for the EU as this was a longer term issue. It was more expedient to think globally about the threats coming from the field. EFSA was doing some work in this area, and there were also research networks that had been set up across Europe. It would be necessary to investigate what else was already being done before taking a decision on the type of think tank required.

33. Mike Catchpole concluded that the AF appeared to be in agreement that there was no strong mandate to start work on clinical guidance, however it might be useful to set up a working group to look at the issue of mycology and also ways of working with Member States on emerging but as yet small-scale problems of this nature.

Part 3 – Dengue in Réunion

34. Silivia Declich, AF Member, Italy said that Italy had well organised surveillance systems for West Nile, chikungunya and dengue that had existed for a number of years and were quite well prepared for outbreaks.

35. Carlos Matias Dias, AF Member, Portugal, said that in the autonomous region of Madeira a continuous surveillance system has been put in place to detect outbreaks of dengue. He had no information about preparatory surveillance activities on the mainland of Portugal beside the national vector surveillance network REVIVE.

36. Vicky Lefevre thanked the participants for their input to the discussions.

Conclusions and Actions

There was consensus among those countries with cases considered likely to be linked to the recently observed increase in hepatitis A virus genotype 1A that there would be EU added value in conducting a coordinated cross-border outbreak investigation

There was general support for establishing a suitably constituted Working Group (or 'Think Tank') to consider the issue of current and future needs for EU-level activities in respect of mycology. There was also support for the Advisory Forum considering ways of working with Member States on emerging but as yet small-scale problems, such as that of the recent increase in detections of *Candida auris*.

Prioritisation tool IRIS 2.0

37. Barbara Albiger, Senior Expert Scientific Quality, Office of the Chief Scientist, ECDC, presented the updated IRIS indicators and process[3] and opened the floor for AF views on the revised indicators.

38. Frode Forland, Observer, Norway, was very enthusiastic about the updated proposals and thought that the indicators were fine. Norway was considering using the tool at the national level and it was therefore good that it was so generic. He suggested that *Candida auris* topic presented earlier would be a good candidate for testing and reviewing the tool.

39. Kevin Kelleher, Ireland, said that the revision was excellent. His only concern was the amount of work needed on the documents to enable decisions to be taken. He enquired about how much effort and investment are needed to draft proposals, and asked whether ECDC would filter which proposals it put forward. He also enquired about how ECDC will quantify the Member States resources needed.

40. Jaap van Dissel, AF Member, Netherlands, was pleased with the tool and endorsed the criteria. However he wondered, if it were used for eliciting personal views on priority, whether aspects would be weighed in the same way and the values scored in the same way.

41. Anders Tegnell, AF Member, Sweden, said that the tool was great and the revision good. He shared the same concerns as the AF Member from the Netherlands with regard to weighing the issues. He also asked for the EU-level added value to be made clearer and also what the output would be.

42. Sophie Quoilin, AF Alternate, Belgium, was also enthusiastic about the tool but wondered whether it would be applied transversally or topic by topic.

43. John Watson, Invited Expert, UK, complimented the team on the tool and pointed out that it would become clear how practical it was when moving forward. He noted that it appeared that proposals from single Member States could not be put forward anymore and that this could be frustrating. Member States would probably wish for others to know what they had proposed as topics of concern and how/why these were not being taken forward.

44. Barbara Albiger thanked the AF members for their positive feedback. With regard to concerns as to the amount of work involved for ECDC to draft the proposals and the AF members to read and assess, she was aware of this issue. With regard to concerns on the quantification of the needed Member States resources, she answered that ECDC being in close contact with the disease networks should help to clarify and quantify the resources required. With regard to weighting, she explained that there would not be any as the scoring process would determine whether an issue was taken further. For example, if an issue was not thought to be worthwhile, it would not score highly and the proposal would not be evaluated further. She agreed that having proposals drafted by ECDC could indeed introduce a bias from ECDC, with regards to filtering of proposals, but this could be of benefit if it enabled ECDC to avoid asking AF members to review proposals that were either outside ECDC's mandate or not likely to be feasible to implement. Regarding the issue of a Member State not being able to make proposals in the future, she pointed out that there are other mechanisms available for making country specific proposals or requests, such as the country support mechanism through the CCBs, and the possibility to make formal requests to the ECDC Director at any time as stated in the ECDC founding regulation.

[3] Prioritisation tool IRIS 2.0

45. Mike Catchpole, Chief Scientist, ECDC, said that in previous years the IRIS process tool had been used on limited, specific pieces of work. It was hoped that ECDC was moving towards focusing on the potential broad areas of impact of its work in aiming to achieve a particular outcome. Therefore the proposals would have a broader focus generally, including a 'bundle' of activities that together aim to achieve a particular impact or outcome. Participants would be asked to assess the likelihood of the outcome being achieved with a good return on investment.

46. Ágnes Hajdu, AF Alternate, Hungary, asked whether the potential cross-sectoral impact would also be considered.

47. Mike Catchpole confirmed that potential cross-sectoral impact would be considered.

48. Barbara Albiger continued the presentation focussing on the proposal form.

49. Silvia Declich, AF Member, Italy, said that the format of the proposal itself was very helpful, short and concise. However, it was not clear who the target audience was or what form the activities would take.

50. Anders Tegnell, AF Member, Sweden, asked about feasibility and how likely it was that this new activity/output would actually make a difference.

51. Osamah Hamouda, AF Member, Germany, said that the 'indicator 'realistic' should also take into account the aspect of 'feasibility'. It was necessary to try and evaluate how feasible it was to achieve the goal. It looked very promising on paper, the test would come in use. He thought that the documentation for the proposal looked manageable.

52. Frode Forland, Observer, Norway, said that the format could work in practice. It was necessary to look at the process, how it should be done, how much could be done in a year and/or how many for each meeting. Countries would also need to have their experts at home to review and then they would have to pass judgement as a country but in the AF forum everyone would be judging together. ECDC would be able to provide evidence to help with this. He felt that the documentation needed to specify what type of work would be involved e.g. one, two or three year work packages.

53. Carlos Matias Dias, AF Member, Portugal, thanked ECDC for the work so far but had one concern relating to the indicators and what would happen if there was no clear scientific background for some of them (e.g. return on investment). How would the missing information be handled?

54. Mika Salminen, AF Member, Finland, said that the paper was well developed and the process was sound. He did not quite see how it fitted into the ECDC annual planning cycle but nevertheless thought that it was very useful. He asked for a better idea of the timeline on an annual basis and of the workload. He had a strong recommendation to use the IRIS prioritisation for the entire ECDC Work Plan.

55. Kåre Mølbak, AF Member, Denmark, was eager to see work get underway with the new tool, especially since the number of proposals would be lower than had originally been thought and therefore less problematic.

56. Isabel Noguer, AF Alternate, Spain, said that she appreciated the content and the modifications. She believed that the most important indicators were those relating to resources and impact. It was now important to transform the proposal into action as a way of managing priorities in infectious diseases.

57. Kevin Kelleher, AF Member, Ireland, asked how soon before the meeting the AF would receive the documents, and whether it was expected that AF Members would consult with subject-matter expert in their home countries and if this can impact the AF members' independence.

58. Mike Catchpole, responding to Ireland's question, said that AF members generally had a broad portfolio of interests so they would be expected to pass their own judgement. They could consult with relevant experts but ultimately ECDC was seeking their views as AF Members and experts with a broad overview in their own right. With regard to the planning process, ECDC was looking at how to streamline this. Proposals could be fairly broad but with a view to achieving the same goal. He was also in favour of the suggestion of using the tool to look at the *Candida auris* problem.

59. Barbara Albiger, responded to the issue of whether AF members should ask experts in their country on the feasibility of the approach suggested by ECDC in the proposals, and pointed out that AF Members would ultimately be responsible for their advice to ECDC. She confirmed that ECDC would try

to take into account the feasibility aspect. In answer to the question on how many proposals there would be, it was as yet unsure but unlikely to be more than 15. With regard to the target audience responding to the AF member of Italy, the term target was not about audiences, but about what was to be achieved.

60. Andrea Ammon, ECDC Director, thanked all the AF Members for their comments. The next step would be to try out the proposal and she therefore agreed with Kåre Mølbak that it was just necessary to get going with a trial and then refine it later.

61. Mika Salminen, AF Member, Finland, agreed with this proposal. He pointed out a lack of clarity in Summary point 5b of the document as to which proposals would go through which process and how decisions would be taken.

62. Barbara Albiger gave the last part of the presentation on the scoring and polling process.

63. Jaap van Dissel, AF Member, Netherlands, asked whether it would be possible to accept that none of the proposals went through. Alternatively, what would happen if all of the proposals scored 3.5.

64. Frode Forland, AF Observer, Norway, said that it might be necessary to test 3.5 as the cut-off level for the scoring. He liked the idea of coming back to a discussion before voting if an issue was controversial.

65. Kevin Kelleher, AF Member, Ireland, noted that people approached problems in different ways and therefore there might be very wide variations in the scoring. He agreed that it might be better to have the discussion before the voting rather than afterwards.

66. Barbara Albiger agreed with the observer of Norway about trying out the current proposed scoring and cut-off point.

67. Ágnes Hajdu, AF Alternate, Hungary, referring to the evaluation process, pointed out that the sub points could be kept in the proposal for resources as this would help make the approach more systematic.

68. Mike Catchpole, answering a question on what would happen if no proposals were scored above the pre-determined threshold value, explained that it would also be possible to rank the scores. ECDC would now be preparing some proposals ready for the next AF meeting.

69. Barbara Albiger pointed out that it would take a full day of the Advisory Forum's meeting time to do the scoring if there were 15 proposals, less if some were left out. Members therefore needed to be aware of this fact for the purposes of the September meeting.

Conclusions and Actions

There was a unanimous support of the revised IRIS process, and for proceeding to apply the process to a set of proposals in the next Advisory Forum meeting (AF54, September 2018). It was noted that the value of the process would be dependent on the quality of the proposals put forward for scoring and ranking, and that ECDC would need to ensure that sufficient resource was available to develop high quality proposals. It was also noted that ECDC should make it clearer how the outcome of the IRIS process would impact on its planning cycle.

Brexit Brief

70. Mike Catchpole, Chief Scientist, ECDC, introduced the topic, noting that it had been added to the agenda in response to repeated requests from Advisory Forum members. He emphasised that the background paper consisted only of extracts from the publicly available Draft Agreement document (TF50 (2018) 35 – Commission to EU27), and pointed out that certain areas (i.e. political aspects) would not be discussed. He opened the floor for comments.

71. Frank van Loock, European Commission, said that the Commission was not in favour of the discussion being tabled, and pointed out that future preparedness issues in terms of future relations with UK were not suitable for discussion. He suggested focus should be on advice to ECDC to help it prepare for the departure of UK.

72. John Watson, Invited Expert, UK, agreed with Commission view that this was not the forum for discussing the political negotiations. He pointed out that it should be noted that the paper that had been circulated was balanced by a UK paper on its starting position which was publically available online. He also pointed out that the UK would continue to be a European country, there would still be threats and there would still need to be arrangements in place, in light of mutual interests in the protection and security of public health in Europe. It was also important to be aware of the potential scientific and public health issues that would continue to arise after Brexit.

73. Kevin Kelleher, AF Member, Ireland, said that he had asked for this issue to be discussed because he believed it was necessary to be more prepared. The situation would be particularly difficult for Ireland as there were a number of border issues involved. Losing the UK would also be a significant blow for ECDC, in terms of training, expertise, etc.

74. Frode Forland, Observer, Norway, said that there was a need to be informed about processes because these were relevant for public health. Public health and politics were closely connected. However, it was also important to look at the scientific issues.

75. Sophie Quoilin, AF Alternate, Belgium, pointed out that Brexit was a painful issue on which the AF could have no impact whatsoever. Euroscepticism was growing throughout Europe and it was time to look at how to make the EU stronger. She pointed out that the positive aspects of EU were not adequately communicated and that the needs of European citizens were not sufficiently taken into account. This angle should be examined in order to develop and improve European aspects of public health.

76. Kåre Mølbak, AF Member, Denmark, said that it was difficult to understand the ramifications of the document circulated, particularly since it was impossible to know the outcome of the formal negotiations. However, if the UK would cease to have access to information and databases set up under EU law, it would be a serious problem as it was necessary for European countries to share data. His advice to ECDC would be to follow up very carefully as it was vital to be able to protect the health of European citizens. He agreed with the AF Alternate for Belgium regarding Euroscepticism which was very unfortunate for everyone.

77. Mika Salminen, AF Member, Finland, said that it would be impossible and unacceptable to have a situation in the future whereby there would be no exchange of information. Therefore it was necessary to look at how to make arrangements with the Commission to review all the activities that the UK had been involved in to date in order to get a better idea of what they had contributed to and where the gaps would be.

78. Andrea Ammon, ECDC Director, pointed out that with no transition agreement from March next year the UK would be a third country. ECDC has cooperation with other third countries and there were methods available for working with them so it was not impossible to anticipate some level of continued working with the UK and/or its institutions. However, ECDC as an institution would have to be abide by the decision taken on the political level and until the decision was taken, there was little that could be done. ECDC had looked at how many contracts it had with the UK at present. It has also examined the number of project applications that had only received bids from the UK as this was perhaps a more pertinent indicator. With regard to training, ECDC had made a decision for the cohort starting in September 2018 that EPIET, it would not be offered to UK hosting sites to host a fellow as the situation would be unclear after six months. However, potential UK EPIET candidates could still apply to be hosted elsewhere in the EU (a disclaimer had been added) since the UK would be a part of the EU until March 2019.

79. Andrea Iber, Head of Section, Legal Services, referring to the legal situation with regard to contracting of services from the UK, explained that there was no restriction to prevent third parties and therefore it was possible to sub-contract where specific expertise is required. ECDC currently only had two contracts where the UK was the sole contractor so this was not such an issue.

80. Mike Catchpole commented that having the opportunity to air the topic of Brexit, as requested, had merely highlighted the difficulties surrounding the issue.

Conclusions and Actions

While the Advisory Forum considered that there were potential implications of Brexit for the scientific and other public health activities of the Centre, there was consensus that until the outcome of ongoing negotiations was clear it would not be possible to define what these implications might be.

Virtual country visit – Romania – Public health interventions in Romania for West Nile infections

81. Florin Popovici, AF Member, Romania, gave a presentation[4] and the floor was opened for questions.

82. Mike Catchpole asked whether mild winters had favoured the overwintering of mosquitoes as a reason for the two heavy West Nile seasons in a row. He also wondered if there had been any changes in the specificity of diagnostic tests, which might explain the larger number of cases identified.

83. Masoud Dara, WHO Regional Office for Europe, asked how they could be sure that they were detecting all the cases. What about missed cases and asymptomatic ones.

84. Isabel de la Fuente Garcia, AF Member, Luxembourg, asked if there were any specific risk factors for bad outcome and death.

85. Kåre Mølbak, AF Member, Denmark, asked whether the issue was being picked up by the media in Romania or whether it was of interest to them.

86. Florin Popovici explained that the only link between the two outbreaks was the existence of both lineages. The tests were the same in 2016 and 2017 and there had been no difference in sensitivity. The emphasis was currently on trying to conduct active case surveillance. With regard to risk factors, these were mainly the existence of mosquitoes around the house. Bucharest had many apartments and previously flooding in basements had offered breeding sites although this was no longer the case. Vector control measures had to be applied regularly to prevent infections. West Nile virus was very complicated in that it was sylvatic, yet also involved the routes of migratory birds, lineages, etc. Austria and Hungary were now detecting the same genetic lineage as in Greece so it was possible to see that there was movement of the virus. In response to the question on media interest, this was usually only local.

87. Osamah Hamouda, AF Member, Germany asked whether it was a problem with the vector control measures being the responsibility of the local authorities, since they had a similar situation in Germany.

88. Florin Popovici responded that the main problem was understanding the area at risk, determining who should do the procurement and the quality of the vector control activities undertaken.

89. Sophie Quoilin, AF Alternate, Belgium, asked about the use of biocide. In Belgium, it was not possible to have access to certain pesticides that were considered to be better for the environment/more effective as they were not approved by the local authorities. She wished to see a mechanism for joint procurement of biocides similar to that for vaccines, pointing out this was a huge problem in many European countries.

Conclusions and Actions

The Advisory Forum noted the challenges that the presentation highlighted with regards to the emergence of vector-borne disease.

[4] Virtual country visit Romania 2018 (F Popovici)

Guidance on the programmatic management of latent TB infection

90. Senia Rosales-Klintz, Expert Tuberculosis, Surveillance and Response Support Unit, ECDC gave a presentation[5] and asked for comments on the document from the floor.

91. John Watson, Invited Expert, UK, commended ECDC on the work done. He said that in the UK there was a major programme underway for latent TB detection and prevention and that the main focus had been on migrants as one of the very high risk groups. The most recent assessment of the UK programme was that its adoption had considerably contributed to the reduction of latent TB. A paper had recently published on this by Public Health England. He noted that, with respect to the delivery of the programme, the biggest barrier had been getting adequately high uptake rates to make the programme effective.

92. Kevin Kelleher, AF Member, Ireland, said that the document was very timely as Ireland was currently implementing public health programmes to tackle this issue. In Ireland, TB was still considered to be one of the 'dirty' diseases that people did not want to be associated with so it was important to have documents of this nature with the scientific background to support measures being taken.

93. Kåre Mølbak, AF Member, Denmark, said that it was also very timely for Denmark as the national health authority was currently revising the whole programme for TB control. In Denmark, TB was declining at a lower rate than in Finland, Sweden or Norway so further efforts were necessary and the document was helpful. He suggested expanding on the social and ethical aspects in Section 5 and for many of the aspects he felt that the evidence was rather weak. However, one item where there was strong evidence was in relation to the importance of nurse case management among the homeless. It was also necessary to emphasise the work of TB 'ambassadors' in the various risk environments and the need to avoid stigma when going out into the community to measure TB. He suggested that a section on bottlenecks and limitations could also be useful to increase awareness of these. A recent report from WHO's reorganised Global Task Force on Latent TB Infection had focused on the key barriers and suggested solutions. This had highlighted the whole issue of financing TB healthcare, contact tracing, costs of diagnostics, interpretation of results, staff reluctance, absence of coherent national guidelines, scientific advocacy, etc. He suggested that some elements of the document could be incorporated into the ECDC conclusions. For example, the fact that efficient contact tracing reduced the need to focus such extensive resources on latent TB, meaning that there was the possibility for a natural progression in the improvement of the programme.

94. Isabel De La Fuente Garcia, AF Member, Luxembourg, said that the guidance had been very useful for them as they were dealing with increasing rates of latent TB. However, it was disappointing that there was so little evidence for most aspects. With regard to content she felt it was important to emphasise more on children as a risk factor group, aspects of neurological disease and pneumonia, and the age for latent TB treatment. It was known that in patients over 35 years the treatment was less effective. She would also have liked to see more information in the guidance on treatment monitoring (e.g. direct observed therapy).

95. Isabel Noguer, AF Member, Spain, had also found the guidance clear and useful particularly since the TB strategy was currently being revised. Spain had a complicated system with autonomous regions, and would like to have included a note identifying the type of institution/group, instance or NGO that should be in charge in each case as there were a number of different high-risk populations.

96. Sophie Quoilin, AF Alternate, Belgium, had asked her colleagues working in the field with TB in Belgium about the guidance. They identified gaps; in particular information was lacking on migrants and the percentage of those with LTBI that ultimately developed TB. Similarly, it would have been useful to know the approximate number of years in a country of residence before this occurred and how many of those with LTBI developed active TB after treatment. She would also have liked to see information on the number of people under treatment in the various risk groups and advice on how to provide faster treatment.

[5] Draft public health guidance on programmatic management of latent tuberculosis control in the European Union (S Rosales-Klintz)

97. Osamah Hamouda, AF Member, Germany said that in general the guidance was very good, particularly the relevance of the organisational, social and ethnic aspects. One element that was missing was monitoring and evaluation of this type of programme, in particular with regard to standardisation of processes and inter-country comparability. With regard to the high risk groups, in Germany these were similar the groups in the UK, and LTBI was mainly increasing among migrants. He would have liked to see children under five years from TB endemic countries included as a risk group. He pointed out that one potential obstacle to therapeutic treatment in Germany was that this was organised by a patient's health insurance while screening was the responsibility of the local health authorities. This was a difficult issue which was particular to Germany's healthcare system.

98. Jaap van Dissel, AF Member, Netherlands, said that the situation was similar in the Netherlands whereby the financial context made the implementation of the policy difficult. The patient had to pay the initial part of the healthcare bill themselves, amounting to EUR 360, also screening and part of the treatment. It was therefore difficult to convince people to participate, given that if they waited and then developed the disease later the healthcare system would take over and cover the costs.

99. Kevin Kelleher, AF Member, Ireland, suggested that more research should be done in areas where evidence was not strong. Although research interventions could be difficult in the specific population groups in question, they were still necessary in order to justify policy measures in the future.

100. Masoud Dara, WHO Regional Office for Europe, commended ECDC for their work and underlined the importance of preventive treatment in moving towards ending/eliminating TB. He added short preventive treatment regimen with Rifapentine and Isoniazid has proven to be very effective, however Rifapentine is not registered in many countries of EU, nor other countries of the WHO European Region.

101. Anders Tegnell, AF Member, Sweden, was happy with the guidance but unsure about the programmatic approach to a disease that was so uncommon. In the past TB treatment had been centralised because there was so much of it but nowadays this was no longer the case.

102. Senia Rosales-Klintz thanked the participants for their input and undertook to address the proposals and comments prior to publication of the guidance.

Conclusions and Actions

There was strong endorsement from the Advisory Forum for the ECDC 'Guidance on the programmatic management of latent TB infection'. Several members of the Forum noted that the guidance was particularly timely as TB intervention strategies and services were currently being reviewed in their countries. It was noted that it was disappointing that the level of evidence that was currently available for many of the interventions covered in the guidance was relatively low. A number of proposals were made with respect to ways in which the document could be further strengthened. ECDC agreed to take action to update the guidance in the light of the comments made by the Advisory Forum, and to then proceed with its publication.

Proposal to establish a system for EU/EEA NITAG collaboration for the sharing and generation of scientific evidence on EU vaccines and immunisation practices

103. Kari Johansen, Expert, Vaccine Preventable Diseases, Surveillance and Response Support Unit, ECDC, gave a short presentation[6] and asked for comments from the floor.

104. Kevin Kelleher, AF Member, Ireland, fully supported the initiative but was concerned about duplication with WHO activities.

105. Frank van Loock, European Commission, said that the Commission supported the proposal and its content but had two concerns: the Commission's Joint Action would have its kick-off in September, and at that point there would be a great deal of political drive to move forward and tackle the issue of the mapping exercise and the survey of the range of evaluations in order to create a structure. ECDC

[6] Proposal to establish a system for EU/EEA NITAG collaboration for the sharing and generation of scientific evidence on EU vaccines and immunisation practices (K Johansen)

needed to take this into account in its planning but possibly the timelines would match so this would be more of an opportunity for reinforcement rather than duplication. Secondly, the proposed Council recommendations would hopefully also have positive repercussions, as the ECDC system could be embedded into the structures that would be proposed under these recommendations.

106. Jan Kynčl, AF Member, Czech Republic, said that although he could perceive the added value, he was concerned about the content and workload that would be involved since he has no NITAG secretariat.

107. Anders Tegnell, AF Member, Sweden, agreed with the comment by the AF member from the Czech Republic and questioned the added value. This was not an area in which there was a lack of initiatives, there was plenty to do and the proposal needed to be developed further. The networks already existed and there were lots of fora in which to meet. It was therefore important for ECDC to think more about what it wished to achieve in terms of outputs and how this related to work in the Member States. He noted that sharing of existing scientific outputs is helpful, and advised a step-wise approach. It would take time and involve significant resources to establish what needed to be done, but it would also be important not to interfere with national decision-making. He also wondered how the proposal would complement rather than interfere with other initiatives. He advised that this collaboration should not be based on creating a new network of experts.

108. Osamah Hamouda, AF Member, Germany, stated that overall the idea was good, but it was necessary to avoid duplication and there would be a need for a secretariat so that ECDC could generate the resources to keep the process moving and that ECDC should ensure these resources. Concerning which experts to involve, the preferred option would be NFPs for VPD.

109. Mika Salminen, AF Member, Finland, agreed with much of what had been said. In the context of producing evidence reviews, the initiative would be beneficial for certain countries with less resources. Although he agreed that there were many platforms where this information was already shared, he could see the added value of having an EU platform, since the EU and WHO were very different organisations with different remits. A platform to look at disease models would be useful but such models would need to be applied separately in each country, to reflect differences in service delivery models and epidemiology. To develop this any further would require a good knowledge of national structures and individual health systems which was why the health economic evaluation aspect should not be included. Finland would not be in favour of anything perceived as a European recommendation or task to be implemented. This also related to the decision on health technology assessment currently being prepared by the Commission which contained elements of centralised decision-making. The Finnish government had been critical of the part of the initiative which related to vaccine issues.

110. Silvia Declich, AF Member, Italy, pointed out that the VENICE network was available to deal with this topic and that work had been going in this network for a number of years. Sharing evidence and information was not just an issue for less well-resourced countries. It helped to avoid duplication and was very useful for everyone and therefore Italy fully supported the proposal. She believed that ECDC activities and the Commission Joint Action would reinforce one another rather than conflicting. She suggested that the collaboration be based on the NFPs for VPD, plus the addition of a NITAG member if the NFP for VPD is not a NITAG member already.

111. Sophie Quoilin, AF Alternate, Belgium was in favour of the project encouraging collaboration among Member States to collect evidence and bringing together scientific evidence with public health evidence from various research projects in the Member States. In Belgium, the authorisation and use of vaccines and policy was spread across a number of different authorities and institutions and she would therefore be pleased to work with the NFP for Vaccine-Preventable Diseases to coordinate vaccine issues at national level. She noted that she was in favour of the step-wise approach.

112. John Watson, Invited Expert, UK, said that he had been on the UK's national NITAG for the last four years and broadly welcomed this paper. Firstly, he pointed out that the sort of information that was considered to be of great value was that obtained from industry confidentially and it was important to think how to benefit from this without betraying confidentiality. Secondly, he noted that the modelling work required was extensive and although it was good to share, it still had to be adapted to the country-specific situation. Thirdly, he advocated cooperation with the network for early implementers of national vaccination programmes (e.g. UK, US, Canada, Australia) as this network would be sure to make their information available for any EU collaboration.

113. Frode Forland, Observer, Norway, echoed the comments made by Belgium and Finland, and suggested that the prioritisation issue could be subject to use of the new IRIS 2 instrument they had been discussed. He highlighted the critical phase of summarizing evidence to content experts and suggested that methodological experts would be required in the reference group to look at the implications of this. He advocated the pooling of efforts wherever possible but leaving national issues to the NITAGs. He welcomed the initiative as a means of preventing the wasting of resources or duplication.

114. Isabel De La Fuente Garcia, AF Member, Luxembourg suggested that a pictogram could be useful in the document to help envisage all the various elements of the project and other efforts. It would also be useful to be more specific about prices in different countries and provide more information in order to give more leverage in the negotiating procedures with industry.

115. Isabel Noguer, AF Member, Spain, said that she found the document very useful and strongly supported it although she did see some duplication. The stakeholders to be consulted were the NFP for VPD and this was absolutely indispensable. She further expressed a particular interest in looking at evaluation of evidence from impact studies

116. Jaap van Dissel, AF Member, Netherlands, said that the experts in his country were broadly supportive but worried about duplication with WHO. It was important to reduce overlap and also to clarify the added value in the document. The context meant that this area would always be a national issue and therefore it should be very clear which area the document was limited to. He also suggested that there should be closer collaboration with the European Medicines Agency who actually register the vaccines.

117. Mike Catchpole noted that written feedback had been received from Jean-Claude Desenclos, AF Member, France, mentioning that France welcomed the document on NITAGs and strongly supported it, believing it should be a priority for action. However, ECDC needed to commit resources to its implementation.

118. Mike Catchpole summarised the discussion saying that he understood there was support for the proposal but that there was also an absolute need for it to be focused, and to ensure that there was no duplication. He also liked the suggestion that there should be a pictogram showing more clearly the interrelationship with other initiatives.

119. Kari Johansen thanked the AF for its input. She pointed out that the WHO regional NITAG network was proposed in October 2017 but had not yet been set up. ECDC had decided to focus on vaccines authorised and used in EU countries as they were slightly different to those used elsewhere (for example there are many UNICEF vaccines used in non-EU countries of the WHO EURO region). She was also convinced that there were lessons to be learned from the early adopters. She hoped that the work done by ECDC would be supportive and complementary to WHO initiatives at global and regional level.

120. Ágnes Hajdu, AF Alternate, Hungary suggested that the pictogram should show which countries were involved in which bodies under which initiatives. Hungary was not involved in any initiatives to date which is why it was keen to participate in the ECDC initiative.

121. Masoud Dara, WHO Regional Office for Europe, stressed that there is already a lot of collaborations between the WHO EURO office and ECDC and that there had been consultation on this project before the AF meeting. WHO has no objection to the establishment of the network and its teams would be happy to work with ECDC and the AF on the initiative, and noted that this new system will not be formulating policy recommendations but rather provide evidence for those recommendations to be done at the country level. He highlighted the need for continuous collaboration and coordination to ensure synergy among various platforms.

122. Mike Catchpole said that there was definitely added value in the proposal and it was important to make this clearer. He thanked the AF for all the helpful comments which would be taken into account developing this project further.

Conclusions and Actions

There was consensus among the Advisory Forum members that the proposal to establish a system for EU/EEA NITAG collaboration for the sharing and generation of scientific evidence on EU vaccines and immunisation practices could deliver EU added value. The need for ECDC to ensure resources to develop and sustain the implementation of the system was voiced by several MS. There were also several members that emphasised the need for the proposal to be focused, for the collaboration to be based on existing ECDC NFPs or national NITAG nominees, and to ensure that there was no duplication either with other existing national or collaborative multi-national initiatives, or with WHO activities. It was noted that a clearer mapping of initiatives and networks with potentially overlapping or synergistic activities would facilitate the latter including a dialogue with key partners as WHO and JAV. ECDC undertook to revise the proposal in the light of the comments received, including the additional mapping of related initiatives, and would then proceed to establishing a forum and agreeing its terms of reference as a first objective.

Update on the Third External Evaluation of ECDC

123. Andrea Iber, Head of Section, Legal Services, Resource Management and Coordination Unit, ECDC, gave a short update on the status of the Third External Evaluation of ECDC.

Day 2

Advisory Forum Working Group topic: IMI ADVANCE project blueprint
Feedback on Working Group discussions

124. Ágnes Hajdu, AF Alternate, Hungary reported on the discussions in Working Group A.[7]

125. Birgitta Lesko, AF Alternate, Sweden, reported on the discussions in Working Group B.[8]

126. Isabel Noguer, AF Member, Spain reported on the discussions in Working Group C[9] and the floor was opened for discussion.

127. Kåre Mølbak, AF Member, Denmark, commenting on the rationale for the project, said that the debate had been going on for many years as to whether it was efficient to do analysis in specific countries followed by meta-analysis, or to look at the bigger picture. His institute was part of ADVANCE and although it had not yet been proven that it was a healthy concept, that it was feasible. Since discussions had come this far, he believed it was important to continue and that there should be a trial period rather than establishing permanent structures.

128. Mike Catchpole, Chief Scientist, ECDC pointed out that when the current ADVANCE project finished there would be no structure left unless funding could be found. Common themes in the group discussions appeared to be the new data protection regulations, the need for flexibility in governance to accommodate different systems at the various public health institutes, and the need for a permanent secretariat with funding.

129. Kevin Kelleher, AF Member, Ireland, said that it was necessary to document the benefits of vaccination. Furthermore, in his working group, the biggest issue was that of industry involvement and the impact on public trust. In Ireland, if there was any hint of industry involvement, public health messages were immediately disregarded. This issue had to be resolved and further consideration given to whether to go forward with industry partnership or not.

130. Jaap van Dissel, AF Member, Netherlands, asked if spending money on a large structure of this kind was an appropriate way to improve vaccination rates and whether it would actually help. Big databases were not always the best means of investigation.

131. Anders Tegnell, AF Member, Sweden, echoed the point made about contact with industry. The Swedish public health institute was often expected to give recommendations and advice which meant that it was very difficult for them to be involved with industry. All the public health institutes had different roles and some were more closely linked to industry than others which meant that this was a sensitive national issue. He agreed with the suggestion by Denmark that smaller studies might be a better option than meta-analysis of data from a large database.

132. John Watson, Invited Expert, UK, said that industry was an essential partner in this kind of work, not just because of the potential for funds but also technical expertise. However, with respect to governance, there had to be a clear mechanism demonstrating that decisions were ultimately taken independently at the top of the tree.

133. Piotr Kramarz, Deputy Chief Scientist, Head of Section, Disease Programmes, Office of the Chief Scientist, ECDC, responding to comments, said that the issue of data protection and the impact of GDPR had been assessed but would be reviewed again to ensure all aspects had been taken into account at the original level. With regard to public health institute and Member State involvement, the problem was how to ensure public health ownership of the results of the analysis. At present there was still no funding but if funding became available it would be for the coordination of a loose network of technicians/experts. Clarifying some points from the discussion, he explained that if there was a safety issue or a need for a vaccination study using databases, this would be done at country level and the meta-analysis would be done at a central level. The project wanted to go beyond meta-analysis but there was no discussion of building a big database in Europe. The model was a distributed data network

[7] ADVANCE project Blueprint: Group A
[8] ADVANCE project Blueprint: Group B
[9] ADVANCE project Blueprint: Group C

with databases owned by data custodians in the respective Member States. The project would be coming to a close in September and a request had been made for a no-cost extension. If funding were granted for an extension, this could possibly be used to retain a group of people who could meet occasionally to keep the project alive.

134. Maarit Kokki, Senior Adviser to the Director, Head of Section, International Relations, ECDC said she had been pleased to see some of the working groups coming to the same conclusion as to what EU-level action could be taken. She thanked the participants for their input and confirmed that they would continue to discuss the issue further with the AF.

135. Mike Catchpole understood that there were still concerns as to whether there was real added value in undertaking cross-border studies based on the collation of data rather than just using national studies. However, he pointed out that the approach could allow for more rapid analysis if there was negotiated agreement for the use of data. He wondered whether the ADVANCE project could have helped with past crises such as narcolepsy, HPV, MMR and autism and whether it might help to more rapidly address concerns in the future.

136. Kåre Mølbak, AF Member, Denmark, said that Denmark and Sweden had combined forces to look at their datasets and assess outcomes with regard to HPV vaccines. By combining the populations of Denmark and Sweden they now had a cohort of 16 million and the structure was similar in both countries. There was a good scientific argument for pooling data and doing analysis in common. However, researchers had to trust one another and be willing to share data. He wondered if a large consortium consisting of university academics, public health institutes, pharmaceutical industry experts and regulatory instances would be able to achieve the same level of trust. He believed that the project should continue but that it would definitely need some funding for a secretariat to support its activities and it required distance from industry.

137. Anders Tegnell, AF Member, Sweden, wondered what the added value of this structure would be if it was possible to find collaborators and work together on projects anyway. However, for narcolepsy he pointed out that it had been difficult to get good data together and that was the most crucial element.

138. Jaap van Dissel, AF Member, Netherlands, agreed with the comments made by others. His main concern was that databases did not necessarily help with the identification of cases. It was only after there was a new awareness of a phenomenon that it was possible to go back 30 years and find cases. If a new study was undertaken based on signals then new cases would immediately be found. So awareness had the greatest impact and he was not convinced that looking at existing databases would be useful.

139. Frode Forland, Observer, Norway, noted that there had been a reluctance from industry to release data for this work, yet industry benefitted greatly from using public health data so the relationship was slightly biased.

140. Kevin Kelleher, AF Member, Ireland, disagreed with comments by Denmark. As a small country Ireland did not have the same amount of data that Denmark and Sweden had available. Therefore taking a metadata analysis approach would enhance their analysis. By way of example, he explained that Ireland was far too small a country to have ever identified the narcolepsy issue on its own. The approach represented an important way to take immunisation forward.

141. Piotr Kramarz said that some AF comments had already been raised by one of the ADVANCE review panels. After every larger deliverable from the project a panel had been assembled to give feedback and lack of input by market authorisation holders was one of the issues raised. He confirmed that they would make a point about this in the blueprint. The narcolepsy experience had actually been one of the stimuli for the ADVANCE project. When ECDC had first been made aware of the narcolepsy signals and countries suggested doing a larger study, a great deal of time had been spent on selecting the data, study type, protocol development and approval, methodology, looking at coding systems for data sources, obtaining ethical approvals, etc. which was why it had taken so long to get results. Meanwhile the national study results became available much more quickly. Through ADVANCE the idea was to be able to give a much better picture of risks versus benefits. It would be good to already have a list of data sources ready, a collection of template protocols, potential collaborators and a network of people to make things happen more quickly. Consequently, if a similar crisis occurred it would be possible to react much more quickly not having to start from scratch with tools and rules. Narcolepsy was not a good example because from a pharmaco-epidemiological point of view, it had been very

difficult to define, and also to disentangle the media impact. However, the process had been useful as a stimulus for the work currently being undertaken.

142. Andrea Ammon also thanked the participants for their useful comments. She pointed out that one of the aims of ADVANCE had been to provide a platform for multi stakeholder cooperation and some members had expressed concerns that the pharmaceutical industry was a part of this. She had the impression that even if all the issues with data protection, data security and databases could be solved there would still be concerns about the role of industry. Therefore she suggested taking a practical approach and asking what was necessary for industry to be a part of the collaboration since this was an issue that should be solved with this blueprint above all else.

143. Osamah Hamouda, AF Member, Germany, said that the solution would be for money to be given to perform studies independent of industry. However, such funding was not available and therefore there was a dependence on industry. Funding provided by industry should therefore be placed into a pool from which it could be drawn independently. No other solution would work. Although he gave credit for all the work done to date, he was still sceptical.

144. Andrea Ammon said that it was important for this issue to be captured now and set down in the blueprint very clearly.

145. Mike Catchpole pointed out that there had been a clear opinion from the AF when IMI Drive had been discussed and that the AF opinion also needed to be set out clearly for the ADVANCE blueprint.

146. Ágnes Hajdu, AF Alternate, Hungary, said it could be beneficial to show the complete potential of the project by using concrete examples. She also suggested that there should be a register of the databases to be used (both those of public health institutes and those in industry) and, of course, the project required full transparency about who could contribute what.

147. Mike Catchpole supported the idea that pharmaceutical company databases should be registered alongside others and open to those wishing to do research. If pharmaceutical companies were not willing to open their databases there was a problem.

148. Sophie Quoilin, AF Alternate, Belgium, said that the funding for vaccination was lacking at the public health level yet public money was financing private enterprise in this area. She therefore suggested that some of this money could be put into an independent fund for the development of the studies needed to maintain and protect vaccine strategies.

149. Carlos Matias Dias, AF Member, Portugal, suggested looking at the issue from a different angle to ascertain what made it so important that industry in Europe should insist on participating in such studies.

150. Silvia Declich, AF Member, Italy, was in favour of the idea of a trustee or a pool for the money which would solve many of the problems. Data for any studies performed had to be made available to the community and proper governance would ensure that any decisions were made independently from the manufacturer. She believed that now was the right time to put these elements into the blueprint otherwise it would be too late.

151. Kevin Kelleher, AF Member, Ireland, suggested that a clear statement was required from ECDC and from the EU on how it worked with industry.

152. Isabel Noguer, AF Member, Spain, agreed with the framework proposed by Germany although she anticipated this being problematic. She wished that there were more public resources available to develop projects of this type.

153. Kåre Mølbak, AF Member, Denmark, noted that industry was clearly reluctant to do any real studies or proof of concept studies that could generate results that damaged their own products. Therefore if there was a real concern regarding the safety of a product, the study could become a bottleneck. One issue which had not been touched upon in the discussions was the vulnerability of public health authorities as a result of perceived closeness to industry. One recent example in Denmark had been the adverse events after HPV vaccination. When the EMA had produced an opinion, this had been rejected in Denmark's parliament because the EMA as regulatory agency, the medical profession and industry were perceived as working so closely together that they could not be trusted. It was therefore important for the Commission to ensure that there was strong public financing of vaccine safety evaluation to prevent this.

154. Mike Catchpole thanked the AF Members for their input.

Conclusions and Actions

The Advisory Forum Working Groups, and the plenary session discussions, highlighted a number of significant issues that the Advisory Forum considered needed to be emphasised in the ADVANCE Blueprint document. These issues included: the concerns and barriers for some national public health authorities regarding working with industry on vaccine-related studies, in particular concerns regarding public perceptions of the scientific independence of the results arising from public-private collaborative studies; the question of whether meta-analysis of several smaller nationally-conducted studies was more likely to yield useful results than analysis of a single collated multi-national dataset; the potential impact of the new data protection regulations; the need for flexibility in governance to accommodate different systems at the various public health institutes; and the need for a permanent secretariat with funding. Several members advocated for the creation of an independent EU fund that could be accessed by public bodies proposing to undertake vaccine studies. ECDC thanked the participants for their input and confirmed that they would take the opinions of the Advisory Forum into account in further revision of the paper, and would continue to keep the Advisory Forum updated on progress with the ADVANCE project.

Update on Third Joint Strategy meeting

155. Mike Catchpole, Chief Scientist, ECDC, gave a brief update, explaining that ECDC had now received endorsement from all bodies to go ahead with the Joint Strategy meeting (JSM). The third JSM would most likely take place during the second half of 2019, or early 2020. The meeting would be an opportunity to look at ECDC's long term strategy (to 2027). It was hoped that there would be a report on the third external evaluation of ECDC available by the time of the third JSM, with some recommendations to address. ECDC had recently asked the representatives of the Competent Bodies what they saw as the main public health issues over the coming five years and they had identified antimicrobial resistance, adapting the skills and competence of the public health workforce in the future, and the determinants of infectious disease. With regard to technology, some of the issues for discussion could be the new diagnostics and statistics around genomics; IT developments and making use of standards; integration of data systems, the skills of the public health workforce required to exploit these new technologies and bridging gaps in standards across Member States. The third JSM meeting is proposed to last for 1.5 days and should be informed by well-developed papers with clear proposals rather than taking the form of a brainstorming session. ECDC wished to set up a programme committee to help finalise the topics and oversee the background documents for the discussions. He asked if there were any volunteers for the committee and explained that there would also be an official call for expressions of interest in participating. The floor was opened for comments.

156. Kevin Kelleher, AF Member, Ireland, asked whether immunisation should feature on the list of topics since it was a prioritisation area for the EU.

157. Frode Forland, Observer, Norway, suggested that combining European and global aspects of public health might also be a topic of interest for the Commission.

158. The AF Members for the Netherlands, Ireland and Germany expressed an interest in participating in the Programme Committee.

Conclusions and Actions

ECDC will issue an official call to Advisory Forum members for expressions of interest in participating in the Programme Committee for the third Joint Strategy Meeting. The Programme Committee, which will also include representatives of the ECDC Management Board and the Coordinating Competent Bodies, will oversee the development of the meeting programme and the development of the background documents.

Update on the ECDC Fellowship Programme

159. Karl Ekdahl, Head of Unit, Public Health Capacity and Communication, ECDC gave a short update on the ECDC Fellowship Programme[10].

160. Franz Allerberger, AF Alternate, Austria, said that the programme should be applauded and that it offered real added value. A recent outbreak affecting two persons in Austria (caused by frozen corn) would probably never have been possible to solve in the past yet the Fellowship Programme had made this a reality.

161. Kevin Kelleher, AF Member, Ireland, said that there was a real need to expand the programme and to recognise the many different scientific methodologies that could be applied in support of interventions against infectious diseases rather than focusing only on microbiology and epidemiology as had historically been the case.

162. Isabel Noguer, AF Member, Spain, said that her country had been collaborating with ECDC on a MediPIET project and was hoping to develop greater collaboration for the next MediPIET extension. She hoped that this would be a success in the European neighbourhood regions of the Black Sea and the Mediterranean countries. She invited other countries to participate alongside Spain, Portugal and Greece.

163. Anders Tegnell, AF Member, Sweden, referring to the competencies that should be included in the EPIET programme of the future, pointed out that different competencies would be required and the programme needed to be broadened to accommodate these. He suggested involving the directors of the Competent Bodies to obtain a better idea of needs.

164. Osamah Hamouda, AF Member, Germany, thanked ECDC for addressing the differences that had evolved in the past between EPIET and EUPHEM and for taking account of this in the organisational structure in order to resolve them in the future. He was pleased to see that both branches would be considered separately in the evaluation.

165. Karl Ekdahl thanked the participants for their comments and added that a recent brainstorming session on future competences had identified health economics, public health informatics and behavioural science in social media as possible candidates for future inclusion in the curriculum. With regard to MediPIET hosting the project team office in Madrid for the next two years, he hoped that this would lead to an excellent exchange of facilitators and that some of the countries involved would be able to provide some excellent training opportunities.

Conclusions and Actions

The Advisory Forum welcomed the update on ECDC Fellowship Programme, and expressed support for the measures that had been taken to address concerns that had been raised previously.

Update from European Commission

166. Frank van Loock, European Commission, reported that the Commission was in the process of obtaining nominations for non-voting members of the Advisory Forum from interested parties at European level, such as non-governmental organisations representing patients, professional bodies or academia, and noted that the list would be presented by the end of June. The Commission was also in the final stages of updating the list of diseases and case definitions and the next step would be to publish the translated decision by mid-June. The recently adopted proposal for a Council Recommendation on the strengthened coordination of vaccine-preventable diseases had involved substantial input from ECDC and he expressed his gratitude for all the efforts in bringing this to fruition. The proposal called for EU-level action to strengthen cooperation between countries, with industry and other relevant stakeholders. The proposal would exploit synergies with the other EU actions and policies already in place. The Commission Communication on protecting citizens against health threats was due in the coming weeks, as was the Agenda on Security and the Action Plan on Antimicrobial Resistance. The Communication on digital transformation of healthcare had been adopted on 25 April 2018, and there was also a lot of work being done on preparedness and crisis management. The Commission

[10] Update on the ECDC Fellowship Programme (K Ekdahl)

proposal was developed as an open consultation and targeted stakeholder consultation with meetings of representatives from NGOs, youth organisations, experts from national groups, etc. The consultations had begun at the end of 2017 and during the public consultation there was substantial negative feedback (particularly from the French and Italian public) regarding mandatory vaccination policies, even though the Council Recommendation did not mention mandatory vaccination. The consultations revealed the extent of interest in this issue generally and the extent of concerns and opposition within certain societal groups. The Communication highlighted the need to simplify and broaden the opportunities for vaccination and to target outreach to vulnerable groups. The proposal called on health authorities to strengthen vaccination training in medical educational curricula and to encourage the setting up of electronic registers of vaccination. The Commission also proposed concrete action to establish a European vaccination information sharing system. Under the system, different stakeholders could develop guidelines for a possible EU-wide vaccination schedule. Another issue addressed was vaccine supply and the Commission had suggested having a virtual data warehouse for vaccine needs and stocks and a mechanism for mutual exchange of vaccines where necessary. The Joint Action on vaccination would be coordinated by France and would have its kick off in September, focusing on immunisation systems, supply management, vaccine research and vaccine hesitancy. The Commission proposal was in line with the objectives of the European Parliament Resolution on vaccine hesitancy passed on 19 April 2018. It was now up to the presidencies to take the initiatives forward and finalise them in the coming months.

167. Masoud Dara, WHO Regional Office for Europe, asked if there was an update on the Commission's HIV, Hepatitis and TB Staff Working Document that was due to be launched soon.

168. Frank van Loock responded that the document was almost complete and would be finalised in the coming weeks and presented during the International AIDS Conference in Amsterdam, July 2018.

Update from World Health Organization Regional Office for Europe

169. Masoud Dara, WHO Regional Office for Europe, gave a presentation to update on WHO activities on Communicable Diseases.[11]

170. Frank van Loock, European Commission, said that although the situation was not ideal with regard to measles vaccination in the EU, the figures for the Ukraine appeared to be very serious. He therefore wished to know if it would be possible to address a joint EU/WHO plan, or whether there were any ideas in the pipeline or action being undertaken by WHO.

171. Masoud Dara responded that it was not just a question of resources but also access and behavioural issues that needed to be addressed. Ukraine was a specific case due to reforms and the security situation in the country, so there was no simple answer, but there were WHO staff based in Kyiv carrying out work on vaccination. WHO had ministerial commitment and there were no vaccine shortages, however further work was needed in terms of resource allocation and staffing.

172. Kevin Kelleher, AF Member, Ireland, suggested that by helping middle-income countries, EU Member States would also be protecting themselves. He suggested that a 'buddy' scheme could be set up for partnering middle-income countries to give them support and that perhaps the EU could even consider some way of funding this.

173. Franz Allerberger AF Alternate, Austria, asked which of the EU countries are in the latest list of middle income countries.

174. Masoud Dara responded that he would check and revert on this issue.[12] He pointed out that it was not always a question of level of income, but funding allocation. For example, there was the issue of donor dependency too. He pointed out that the Ministers of Health from EU countries would be

[11] WHO Regional Office for Europe updates (M Dara)

[12] Masoud Dara was asked during the meeting which of the 28 EU countries fitted the classification of Middle Income Countries. His answer in writing: Bulgaria, Croatia and Romania: https://data.worldbank.org/income-level/upper-middle-income

attending the upcoming WHO Regional Committee which would be an excellent forum for discussing this issue.

175. Ágnes Hajdu, AF Alternate, Hungary, reflecting on a recent antimicrobial resistance cooperation between WHO and Hungary, said that the activities in the area of policy briefs and the linking of stakeholders to the AMR programme had been highly successful. In 2016–17 a policy dialogue had been initiated with the Ministry which had been very well received and she highly recommended this approach as a way of engaging stakeholders and high-level actors.

Revised rules of procedure of the Advisory Forum

176. Corinne Skarstedt, Head of Section, Corporate Governance, ECDC, gave a short presentation on the revision of AF Rules of Procedure[13] which was followed by a discussion.

177. Kevin Kelleher, AF Member, Ireland, suggested that for the sake of good governance a review of the rules would be expedient if this had not been done since 2005.

178. Frank van Loock, European Commission, referring to NGOs, said that there was still a problem with the logistics of their participation since they did not represent an organisation. They were also unable to send an alternate to meetings which meant that there should be a separate approach to inviting them. There were also new areas entering into play, such as conflicts of interest and data laws, which made it appropriate to review the rules.

179. Mike Catchpole, Chief Scientist, ECDC suggested that ECDC's legal team could look through the current version of the rules to see if there were areas requiring change before circulating a new version. This could be done as a written procedure if there were not too many changes but, if not, it was also possible to discuss. ECDC would circulate the revised version and invite comments from the AF.

Conclusions and Actions

ECDC will review the existing Rules of Procedure for the Advisory Forum and, if deemed necessary as a consequence of changes in relevant policies or legislation, will propose revisions that will be circulated to the Advisory Forum for comment through Written Procedure.

Any other business

180. Isabel Noguer, AF Member, Spain, proposed that at the next session of the AF there should be a discussion on GDPR which had enormous implications and consequences for work in the field of public health.

181. Kevin Kelleher, AF Member, Ireland, suggested that the September meeting could be extended to two full days to accommodate the very full agenda.

182. Mike Catchpole, Chief Scientist, ECDC thanked the AF Members for participating and for the excellent discussions. He wished them all a safe journey home.

Conclusions and Actions

ECDC will include an item on the new GDPR in the programme for the September Advisory Forum (subject to competing priorities for items for Advisory Forum opinion).

[13] Revision of Rules of Procedure of the Advisory Forum (C E Skarstedt)

Annex: List of Participants

Member State	Representative	Status
Austria	Franz Allerberger	Alternate
Belgium	Sophie Quoilin	Alternate
Croatia	Sanja Kurečić Filipović	Member
Czech Republic	Jan Kynčl	Member
Denmark	Kåre Mølbak	Member
Estonia	Kuulo Kutsar	Member
Finland	Carita Savolainen-Kopra	Alternate
Germany	Osamah Hamouda	Member
Hungary	Ágnes Hajdu	Alternate
Ireland	Kevin Kelleher	Member
Italy	Silvia Declich	Member
Luxembourg	Isabel De La Fuente Garcia	Member
Netherlands	Jaap van Dissel	Member
Portugal	Carlos Matias Dias	Member
Romania	Florin Popovici	Member
Spain	Isabel Noguer	Alternate
Sweden	Anders Tegnell	Member
Sweden	Birgitta Lesko	Alternate
United Kingdom	John Watson	Invited Expert

Observers		
Norway	Frode Forland	
Turkey	Gamze Aktuna	
European Commission		
DG Santé	Frank Van Loock	
WHO		
	Masoud Dara	