

### **ECDC Advisory Forum**

Minutes of the Forty-ninth meeting of the Advisory Forum Stockholm, 23-24 May 2017

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# Opening and adoption of the programme (noting the Declarations of Interest and Specific Declarations of Interest, if any) (Document AF49/01)

- 1. The meeting was opened by Andrea Ammon, Acting Director, ECDC, who welcomed the participants and expressed her sympathy for the victims of the terrorist attack which took place in Manchester, United Kingdom, on Sunday 21 May 2017.
- 2. Paul Cosford, AF Member, UK, congratulated Andrea Ammon on her appointment as the new Director of ECDC. He also explained that Public Health England had been able to play a role in two areas in the aftermath of the Manchester terrorist attack: by providing guidance on blood-borne virus prophylaxis for those exposed, and by establishing a register of those affected in order to enable follow-up from the point of view of mental health and post-traumatic stress disorder.
- 3. Mike Catchpole, Chief Scientist, ECDC, welcomed the AF members and other participants, in particular the new AF Member for Ireland, Kevin Kelleher, Albrecht Werner from the Directorate-General for Health and Food Safety (DG SANTE), European Commission, and Masoud Dara, representative from WHO's Regional Office for Europe. Apologies had been received from Cyprus, Iceland, Latvia, Malta, Poland, Slovak Republic, Slovenia, and the Coalition for Health. He also pointed out that a European Antibiotics Awareness Day toolkit addressing health care professionals had been made available to take home for those interested.
- 4. No declarations of conflict of interest were made.
- 5. The draft programme was approved with one additional item under any other business proposed by Andreas Gilsdorf, AF Alternate for Germany, who offered to provide a brief update on the G20 Health Ministers' summit, which had recently taken place in Germany.

# Adoption of the draft minutes of the 48<sup>th</sup> meeting of the Advisory Forum (21-22 February 2017) (Document AF49/02)

- 6. Changes requested in writing by France (correcting the number of influenza excess deaths in paragraph 58), the Commission (amendments to paragraphs 27 and 137), and the Netherlands (clarification that comments on paragraph 3 concerned the ECDC project on burden of AMR specifically and not the generic ECDC work on burden of disease estimates) had been duly noted.
- 7. Kåre Mølbak, AF Member, Denmark, requested the word 'immunologists' to be changed to 'epidemiologists' in paragraph 117.
- 8. The draft minutes of the meeting were adopted, taking into account the proposed amendments.

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

- 9. Andrea Ammon, Acting Director, ECDC, gave a short presentation to update on ECDC's main activities since the last AF meeting.<sup>1</sup>
- 10. Masoud Dara, WHO Regional Office for Europe, pointed out some additional events: on 11 May 2017 there had been a high-level event on TB in Brussels attended by Commissioner Andriukaitis, on March 2017, there had been a series of events arranged for World TB Day, including the release of the joint ECDC/WHO TB surveillance report, and on 27 March 2017, the Executive Director of UN AIDS had visited ECDC.

<sup>&</sup>lt;sup>1</sup> Update on ECDC activities (A Ammon)

### Update on actions arising from the second External Evaluation of the Centre

- 11. Mike Catchpole, Chief Scientist, ECDC, gave a short update on progress in implementing the Joint Action Plan.<sup>2</sup>
- 12. Karl Ekdahl, Head of Unit, Public Health Capacity and Communication, provided further details on the Continuous Professional Development Programme (CPDP), which would be launched later in 2017. This was not an individual programme but an umbrella for all ECDC training activities designed for senior colleagues. ECDC was currently developing a core workshop which would be given at the end of the year, and further courses were being co-developed by ECDC's Training Unit and the Disease Programmes to meet the specific needs of senior colleagues in the networks.
- 13. Andreas Gilsdorf, AF Alternate, Germany, gave a brief update on G20 Health Ministers' summit, which had taken place in Berlin on 19-20 May 2017. This was the first time that the G20 Health Ministers had met and there were two main topics for discussion: antimicrobial resistance and health crises. A health crisis simulation exercise was carried out with all ministers, WHO and World Bank, including EU ministers participating from France, Italy, Norway, Spain, The Netherlands and UK along with the EU Commissioner. The outbreak scenario involved a respiratory virus. The meeting ended with the publication of a Berlin Declaration, and material would eventually be made available for use at national level.
- 14. Albrecht Werner, DG SANTE, thanked the AF Alternate for Germany for helping to arrange the meeting. He had attended the event and found it very useful for briefing those higher up in ministries, and therefore encouraged everyone to make use of the material when it became available.

### **ECDC Surveillance and Response – Epidemic intelligence**

#### Outbreak of Ebola in Democratic Republic of Congo.

- 15. Thomas Mollet, Senior Expert, Epidemic Intelligence, Surveillance and Response Support Unit, ECDC, gave a short update on the recent Ebola outbreak in the Democratic Republic of Congo after which the floor was opened for comments.<sup>3</sup>
- 16. Paul Cosford, AF Member, UK, asked whether it was possible to confirm the rumours that there had been a separate outbreak of a bloody diarrhoeal disease in a different area of the country.
- 17. Fernando Simón Soria, AF Member, Spain asked if any additional information was available on whether a vaccination programme was being set up or measures put in place to control the movement of population in the area.
- 18. Kåre Mølbak, AF Member, Denmark, inquired whether there were any general guidelines being applied with regard to the use of the vaccine and its use in outbreak situations.
- 19. Aura Timen, EUPHA, asked if there had been any response from the newly established African CDC in helping with the outbreak.
- 20. Andreas Gilsdorf, AF Alternate, Germany, asked whether the WHO assessment of the location as remote had had any effect on the ECDC risk assessment in relation to the outbreak.
- 21. Albrecht Werner, DG SANTE, asked whether a mobile laboratory had been sent or was being set up and, if so, through which mechanism, and whether it would be possible to have access to the strains.
- 22. Thomas Mollet confirmed that there had been a separate outbreak, possibly shigellosis, which began on 21 April 2017, and was currently being investigated by WHO. As yet, there was no confirmation as to whether this was a regional or wider outbreak. With regard to the Ebola vaccine, he explained that there was no cold chain in place as yet, and this was required for the vaccine;

<sup>&</sup>lt;sup>2</sup> Joint Action Plan to address recommendations arising from the second External Evaluation: Progress Report (M Catchpole)

<sup>&</sup>lt;sup>3</sup> Ebola – Democratic Republic of Congo (T Mollet)

consequently, it would take at least two weeks before it would be possible to begin vaccinating. Distribution would be a challenge as everything would have to be transported by plane/helicopter. The African CDC had been activated but he did not know if it had deployed people in the field. With regard to the assessment of risk, WHO's evaluation at national level was high, although spread was not anticipated due to the remoteness of the area. However, the nearest large city, Kisingani, had a population of over two million people, and Bota, 100 km further south, had a population of over 100 000 which were at risk. The main concern was that the disease might be spread via the pygmies who could travel very long distances very quickly in the bush.

- 23. Masoud Dara, WHO Regional Office for Europe, said that WHO had set the risk at national level as high because it wanted to err on the side of caution after lessons learnt with the most recent Ebola outbreak in West Africa. Secondly, this assessment was based on the fact that there was little access to health in the region and sub-optimal surveillance.
- 24. Thomas Mollet, responding to a question on NGOs active in the region, explained that there are none in the direct vicinity but there were some at a distance of around 100 km (MSF Switzerland and MSF Belgium). There were a number of NGOs based in the Congo area, and they had contingency and emergency plans in place.
- 25. Denis Coulombier, Head of Surveillance and Response Unit, ECDC, said that critical evidence which would change the approach or the level of risk would be a scenario where a case was identified in an urban setting or exported (e.g. to the Central African Republic which has quite a porous border with DRC, or to Europe). However, so far this had not happened and DRC was well prepared and had supplies of PPE ready.

#### Imported cholera cases in Czech Republic

- 26. **Jan Kynčl**, AF Member, Czech Republic, gave a brief update on the cholera cases in the Czech Republic.<sup>4</sup>
- 27. Franz Allerberger, AF Alternate, Austria, opinioned that there was only one case of cholera in the Czech Republic as the second one did not qualify according to the current case definition.
- 28. Denis Coulombier, Head of Surveillance and Response Unit, ECDC, asked whether the first case had been symptomatic and then decided to return to Europe or whether the patient had been planning to return home anyway. He also wished to know if contact tracing had been carried out for passengers on the affected flight.
- 29. Jan Kynčl responded that the case had not gone directly to the health authorities upon return to the Czech Republic. He confirmed that regional public health authorities had been liaising with the Emirates airline and passengers in the immediate vicinity of the case on the affected flights had been contacted.
- 30. Paul Cosford, AF Member, UK, noted that the UK's new rapid international support team had recently returned from its first deployment in Ethiopia involving an outbreak of bloody diarrhoea. He would provide more feedback once the team had been debriefed.
- 31. Sylvia Declich, AF Member, Italy, noted that there had been two other cases of cholera this year in Zanzibar, and wondered whether clearer recommendations were needed in European countries, given that so many Europeans were travelling to East Africa.
- 32. Jan Kynčl added that, although the origin was still unclear, the local sushi eaten by the patient was probably the most suspicious source.
- 33. Aleksandar Šimunović, AF Alternate, Croatia, wondered whether the oral cholera vaccine should be recommended to travellers to countries in the Horn of Africa.
- 34. Kåre Mølbak, AF Member, Denmark, said that in Denmark the oral cholera vaccination was only recommended to people who would be working in situations where they would be exposed to contaminated water (e.g. personnel in refugee camps or sanitary engineers). He noted that imported cases of cholera were possibly underestimated as they were often not picked up by routine PCR tests;

<sup>&</sup>lt;sup>4</sup> Czech Republic imported cholera cases (J Kyncl)

however, the risk for Europe was still very low and would only be of concern if cholera got into the water supply.

- 35. Fernando Simón Soria, AF Member, Spain, commented that also in Spain the oral vaccine was recommended only to people travelling to particular areas for specific purposes, and he agreed that the risk was still extremely low for European citizens.
- 36. Denis Coulombier wondered if there should be special recommendations for travellers to Yemen, Ethiopia, and other countries around the Horn of Africa visiting family and friends and staying in remote areas as in the past there had been outbreaks among travellers in this category upon their return to Europe.

#### Multi-country outbreak of hepatitis A associated with MSM

- 37. Ettore Severi, Expert Outbreak Response, Food- and Waterborne Diseases, Surveillance and Response, ECDC, gave a short update on the outbreak of hepatitis A mostly associated with MSM.<sup>5</sup>
- 38. Franz Allerberger, AF Alternate, Austria, pointed out that work done by ECDC on hepatitis A since the foodborne outbreak associated with berries had helped to improve the quality of surveillance systems for this disease, which had sometimes proved difficult to identify in Europe in the past.
- 39. Isabel de la Fuente Garcia, AF Member, Luxembourg, noted that due to the shortage of paediatric vaccines, Luxembourg had been using adult vaccines for children.
- 40. Fernando Simón Soria, AF Member, Spain, agreed that there was an underestimation of the number of cases, with common strains emerging, and a general increase throughout Europe. He suggested that before the World Pride event in Spain at the end of June it might be useful to ask countries via EWRS to inform their gay communities of the importance of getting vaccinated against hepatitis A. Unfortunately the outbreaks seen among MSM were uncontrolled and would therefore not remain within this group. Recent surveillance data in Spain had shown a slight stabilisation in the number of cases, however, it was clear that there had been an increase overall and that this would be likely to continue.
- 41. Paul Cosford, AF Member, UK, said that although in the UK they were still managing to vaccinate, vaccine supply remained a concern. There had been a couple of recent outbreaks, and although these had mainly been confined to the London area and MSM, there was concern that they might spread to other groups and therefore any information sharing on this issue was really helpful.
- 42. Carlos Matias Diaz, AF Member, Portugal, said that there had recently been a vaccination campaign in Portugal for hepatitis. There were also concerns about national surveillance for blood donors and the residual infectious risk associated with blood donors was now being researched. Consultations were also ongoing with MSM organisations, partly triggered by a recent change in legislation which meant that it was no longer possible to ask people about their sexual behaviour.
- 43. Kevin Kelleher, AF Member, Ireland, said that although he was an advocate of vaccination, offering it meant that people did not change their behaviour. Consequently, the important messages of the last two decades about prevention were beginning to lose their impact. It was therefore necessary to look more at behavioural aspects or other measures to ensure that the availability of treatments and vaccines did not have a detrimental effect on the incidence of certain diseases. He also pointed out the existence of a hard-to-reach group of men who did not perceive themselves as gay although they had sex with men and for whom outreach was therefore not successful.
- 44. Fernando Simón Soria pointed out that while for many STI it was possible to use preventive measures such as condoms, etc., vaccination was necessary against hepatitis. He reiterated that this was a local problem in many European countries where people were already affected within their home communities and therefore it was not necessarily associated with visiting Spain for World Pride.
- 45. Ettore Severi, responding to the comments by the AF Member for UK, noted that there had been reports in the UK of hepatitis A among food handlers, and that ECDC was inviting Member States to enhance their hepatitis A surveillance to monitor foodborne transmission, as well as other events of

<sup>&</sup>lt;sup>5</sup> Multi-country outbreak of hepatitis A mainly associated with MSM, EU/EEA 2016-2017 (E Severi)

concerns like the spread of the disease into schools, or the detection of the outbreak strains in people who inject drugs or in ethnic minorities (for instance the Roma population).

### ECDC Surveillance and Response – Potential options for respiratory syncytial virus surveillance

- 46. Eeva Broberg, Expert Virology/Influenza, Surveillance and Response Support Unit, ECDC, presented the options paper on respiratory syncytial virus (RSV) surveillance.<sup>6</sup>
- 47. Mike Catchpole, Chief Scientist, ECDC, explained that the driver for this work had been the potential availability of a vaccine in the near future, and to therefore develop an expert view on options for national surveillance. The proposal was therefore primarily for surveillance at national level, although the future possibility of EU level surveillance was also considered.
- 48. Paul Cosford, AF Member, UK, said that his agency would prefer Option 2 (to enhance existing ARI surveillance system) or Option 5 (new enhanced sentinel paediatric hospital surveillance network), and it would be important not to disrupt the current flu surveillance system.
- 49. Frode Forland, AF Observer, Norway, said that the proposals were very timely and beneficial. The vaccine had been eagerly awaited for many years. It would be better to build on existing systems, and Norway already had a sentinel system in place. Therefore Options 2 and 5 were also the best choices for Norway.
- 50. Isabel De La Fuente Garcia, AF Member, Luxembourg, agreed that Option 5 was important. In Luxembourg there was no paediatric surveillance or data of this type available so it was difficult to see the impact of the disease. RSV had even been treated in ordinary hospital wards. It would also be very interesting to see the rate of other acute respiratory symptoms after the influenza season because children who had had RSV tended to have an increased tendency to contract other respiratory viruses later. She agreed that much more coordination was needed in this area.
- 51. Kåre Mølbak, AF Member, Denmark, said that better data needed to be available on the burden of severe disease in order to guide decisions on vaccines (e.g. a sentinel paediatric hospital surveillance network). However, it was not a good idea to build too many tailor-made systems for specific diseases. In the short term, there should be better data on the severe end of the spectrum, and he therefore suggested initially trying to focus on hospital data (Option 6) before trying to integrate with the other respiratory surveillance systems in the long term.
- 52. Bruno Coignard, AF Alternate, France, felt that it was premature to implement RSV surveillance, and found it preferable to simply liaise with Member States and continue to explore various options. Option 5 (national registry-based retrieval and reporting of laboratory confirmations) would be a possibility for France, although it should be modified to include adult patients.
- 53. Andreas Gilsdorf, AF Alternate, Germany, agreed with the AF Member for Denmark that too many different parallel information exchanges were being built rather than coordinating the existing systems more efficiently. This created extra work and took away resources from other diseases. He suggested it might be important to explore if the needed information could not be collected through surveys than through an additional surveillance system.
- 54. Jaap van Dissel, AF Member, Netherlands, agreed with the comments made by the AF Alternate for Germany. For the Netherlands Option 1 (RSV reporting through existing ILI/ARI surveillance systems) was the best solution and they were already working on Option 3 (use of existing hospital surveillance systems for influenza). Option 6 would not work for the Netherlands.
- 55. Sophie Quoilin, AF Alternate, Belgium, supported ECDC's approach, noting that although in Belgium many of the options were in place, very few RSV cases were identified.
- 56. Jan Kynčl, AF Member, Czech Republic, said that he was also in favour of Options 2 and 5, but suggested that, with regards to the possibility of formal EU-level surveillance, there should be some flexibility, with ECDC using the different sources available from countries. It would also be useful and productive to combine the data available at European level from available options to save on costs. He

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<sup>&</sup>lt;sup>6</sup> Potential options for Respiratory syncytial virus surveillance (E Broberg)

noted that vaccination should not feature as the main reason for RSV surveillance because it was industry-led.

- 57. Kevin Kelleher, AF Member, Ireland, agreed with other colleagues about trying to integrate the surveillance as part of routine systems and look at how to use existing surveillance. The real benefit of the vaccine would not be reducing hospital admissions but the social benefits, in reducing the amount of time parents needed to take off work to care for sick children.
- 58. Denis Coulombier, Head of Surveillance and Response Unit, ECDC, asked if anyone had any concerns with ECDC coordinating the distribution of an RSV surveillance capacity survey as part of RESCEU.
- 59. Franz Allerberger, AF Alternate, Austria said that it would be prudent to avoid direct cooperation with the pharmaceutical industry, if possible.
- 60. Sophie Quoilin, said that if a survey was proportionate to needs, and if it helped in defining the type of RSV surveillance required in Europe then, in principle, she was in agreement.
- 61. Fernando Simón Soria, AF Member, Spain, pointed out that ECDC had already carried out a survey by discussing with those responsible for influenza in the networks, and he therefore wondered if it was necessary to do another one.
- Andreas Gilsdorf suggested discussing the need for extra information and the means to collect it with the respiratory network group.
- 63. Mike Catchpole, Chief Scientist, ECDC, understood that if ECDC were to do a survey it would need to be proportionate, and it would have to be specified how it would fit into ECDC thinking on surveillance.
- 64. Eeva Broberg thanked the participants for their comments, which would be presented to the influenza network meeting in one month's time. She noted that the burden of disease aspect would be studied in detail by RESCEU. With regard to existing systems and issues with current influenza surveillance, it would be difficult to include RSV directly because the existing definitions did not capture the RSV cases and adjustments would therefore be needed. With regard to the survey, RIVM (Netherlands) was leading on the work package within the EU and SSI (Denmark) would be drafting. Although ECDC did not want to duplicate the survey, it would need to obtain some details from Member States as they were not available from earlier surveys, which is why the AF had been asked if it could consider this type of cooperation with RESCEU.

### Consultation on External Evaluation of ECDC's Disease Programmes

- 65. Goritsa Zlatanova, Quality Management Officer, Resource Management and Coordination Unit, ECDC, gave a short presentation on the proposed methodology for evaluation of ECDC's Disease Programmes including two questions for AF Members.<sup>7</sup>
- 66. Bruno Coignard, AF Alternate, France, inquired how this work was related to the planned review of surveillance systems.
- 67. Goritsa Zlatanova explained that she had been liaising with the ECDC project manager responsible for the surveillance system review EPHESUS (Philippe Zucs) to ensure against duplication.
- 68. Frode Forlund, AF Observer, Norway, appreciated that this was a very challenging task. He believed that it was important to consult the AF as part of the process of developing new strategies for ECDC, however, it would be difficult from a methodological point of view. He therefore inquired about the planned approach.
- 69. Goritsa Zlatanova responded that it was envisaged to ensure triangulation of data using available data and triangulating this with scientific literature, additionally collected perception data, etc., as suggested by the Commission's guideline on Evaluation. With regard to the timetable for AF input

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<sup>&</sup>lt;sup>7</sup> Consultation on External Evaluation of ECDC's Disease Programmes (G Zlatanova)

on the final version, one possible option was for an AF working group to review the results over a threeor four-week period, and provide feedback within the next 4-6 weeks.

- 70. Kevin Kelleher, AF Member, Ireland, inquired about the added value of the proposed evaluation.
- 71. Kåre Mølbak, AF Member, Denmark, noted that it might be difficult for some of the disease programmes to provide evidence of effectiveness, relevance and coherence. He suggested using case studies/war stories to document ECDC achievements, and the effect in Member States. For example, this could be done for the antimicrobial resistance and food- and water-borne programmes, although it could not be done for all programmes.
- 72. Sophie Quoilin, AF Alternate, Belgium, said that it might have been interesting to participate in work to draw up the terms of reference, and suggested that in future, it would be useful to discuss the content of this type of project at an earlier stage.
- 73. Goritsa Zlatanova noted that it was still possible to provide comments on the terms of reference as the procurement procedure would not be launched until after the summer. She agreed that the main focus should be the added value, and mentioned that case studies/war stories would be a good way to illustrate ECDC's contributions and enhance its reputation.
- 74. Bruno Coignard believed that the Advisory Forum should be consulted as one of the stakeholders of the project.
- 75. Aura Timen, EUPHA, said that there would be at least two different types of stakeholders those who contributed to the various programmes, and those for whom the programmes would have an impact (patients, health services, institutions, patient groups).
- 76. In referring to the previous session on epidemic intelligence, Sophie Quoilin pointed out that one of ECDC's success stories were the rapid risk assessments. However, she thought that currently the risk assessments were too many. She added that Belgium had started a work to distinguish between the incoming signals as some of them are only signals while others are risks. She felt that a similar approach at EU level could be useful.
- 77. Mike Catchpole, Chief Scientist, ECDC, proposed that a virtual task force should be set up to help look at indicators and terms of references for the evaluation. He noted that AF representatives for Ireland, France, Belgium, and Denmark were willing to participate.

### Virtual country visit: Greece

- 78. Agoritsa Baka, AF Alternate, Greece, gave a presentation on the public health challenges in Greece, with particular reference to vector-borne diseases and migrant health.<sup>8</sup> The floor was then opened for questions.
- 79. Mike Catchpole, Chief Scientist, ECDC, asked how many extra staff had been needed to set up and run the systems.
- 80. Agoritsa Baka responded that around 800 people had been recruited for the whole of Greece and it had taken a great deal of time and resources to do so.
- 81. Andrea Ammon, Acting Director, ECDC, asked what the main challenges were for the local public health authorities when it came to tackling malaria.
- 82. Agoritsa Baka replied that the local authorities were both understaffed and lacking appropriate skills. Many staff had retired and not been replaced and there was not much training available. Regional staff were invited to centralised training, but this was difficult for them as there had to be a presence in the field.
- 83. Frode Forland, AF Observer, Norway, thanked Greece's representative for the presentation and the work being done on migrant health where Greece was on the frontline. He wondered if Greece was receiving the support it needed from the rest of Europe, and how Europe could work together to help. He asked how Greece was dealing with the traumatised individuals and how it was managing the extra burden on the health system.

<sup>&</sup>lt;sup>8</sup> Virtual Country Visit Greece – Public Health Challenges (A Baka)

- 84. Agoritsa Baka said that access to more guidance or reference material on vaccinations or organisation of the camps would have been beneficial. Although guidelines on screening were currently being written, they had not been available when needed. There were also still many unanswered questions for example, as to whether screening for TB or other diseases should be carried out.
- 85. Masoud Dara, WHO Regional Office for Europe, responding to a question as to what would happen after August when the current funding came to an end, suggested that WHO might be able to help at programme level, for example with an external evaluation of the migrant health system. He also appealed to all Member States to share evidence and data with ECDC and WHO so that more information would be available to everyone, particularly if producing guidance of any kind.
- 86. Birgitta Lesko, AF Alternate, Sweden, said that Sweden has a recommendation for vaccination of migrants, and she therefore wondered whether the issue of a migrant registry had been tackled in Greece, and if so, how. If migrants moved on it was important to know which vaccinations they had been given.
- 87. Agoritsa Baka agreed that this was a worrying issue. Funding had been made available from the Philos programme to create a register but this had not been done to date. In Greece the yellow WHO vaccination booklet was completed and given to the migrants, who did seem to keep it and bring it with them when it was time for a second dose.
- 88. Sophie Quoilin, AF Alternate, Belgium, congratulated the representative for Greece on the work they were doing. Belgium had mobilised personnel to go to West Africa during the last Ebola crisis, and she therefore wondered if something similar would be possible to help the authorities in Greece once needs had been assessed.
- 89. Agoritsa Baka thanked the AF Alternate for Belgium, and noted that representatives from Denmark, Norway, Czech Republic and UK had been received, along with many representatives from NGOs.
- 90. Mike Catchpole, Chief Scientist, ECDC, suggested that this issue could be discussed at the next meeting of the Health Security Committee, given that the current resources would run out in August.

### Expert opinion on use of Neuraminidase inhibitors for influenza: revised version following public consultation

- 91. Pasi Penttinen, Head of Disease Programme, Influenza and other Respiratory Viruses, Office of the Chief Scientist, ECDC, gave a short presentation and the floor was then opened for discussion. 9
- 92. Frode Forland, AF Observer, Norway, congratulated ECDC on its expert opinion which was a wide and thorough consultation. He suggested that it might be useful to find another way of communicating this to the general public. He also noted that in Norway some of the drugs had already been withdrawn from the market as they were not being prescribed.
- 93. Paul Cosford, AF Member, UK, agreed that the opinion should now be published as soon as possible. He wished to flag up a common issue in reporting on the publication of scientific findings which was the difference between the actual findings of the study and the findings as communicated in press reports. It was important to take into consideration that the press reports often gave a slightly warped view.
- 94. Jaap van Dissel, AF Member, Netherlands, complimented ECDC on its work; however, he wondered why it had been necessary to repeat work already done by the Cochrane group. He also asked whether pregnant women were not still included as a potential target group. He added that there had been limited use of the drugs in the Netherlands.
- 95. Kevin Kelleher, AF Member, Ireland, said that this was a difficult area in that no matter what was done, the Cochrane group would never be convinced. Ireland was also on the verge of getting rid of its stockpile.

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<sup>&</sup>lt;sup>9</sup> ECDC Expert Opinion on the efficacy, effectiveness and safety of influenza neuraminidase inhibitors (P Penttinen)

- 96. Paul Cosford agreed with the AF Member for Ireland. It was therefore very important that ECDC gave a clear opinion on this issue and that the document was published.
- 97. Bruno Coignard, AF Alternate, France, suggested that a meeting should be convened between ECDC and Cochrane before publication as the issue threatened to limit the impact of the document.
- 98. Mike Catchpole, Chief Scientist, ECDC, asked that any AF members uncomfortable with supporting publication of the document should express their opinion. No concerns were expressed in response.
- 99. Pasi Penttinen explained that the document was an "ECDC expert opinion" because a full systematic literature review had not been done, and the evidence had not been graded. The document was also based partly on observational studies. The results of the 2014 Cochrane review were actually very similar to some of the industry-funded MUGAS analysis, and he agreed that there was a communication issue in the public perception of the Cochrane results. There had been a change in Table 2 after the public consultation for zanamivir because it was still off-label for pregnant women. However, a recent large study of foetal outcomes and Osetalmivir use had been carried out in Denmark, which did not reveal any counter indications.
- 100. Mike Catchpole, responding to the question as why the opinion had been produced, explained that there had been a broad consensus that it would be useful to counterbalance some of the media reporting, and there had also been direct requests from the AF and the Health Security Committee.
- 101. Jaap van Dissel, said that, similar to antimicrobials, these drugs were registered with the European Medicines Agency with the specific advice to always check in-country guidance for usage. In other words, the principle of subsidiarity applied.
- 102. Mike Catchpole concluded that with such a controversial issue, it was important and useful for ECDC to makes its position clear based on its interpretation of the evidence base.

# Second Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) Report

- 103. Ole Heuer, Senior Expert, Surveillance, Group Leader Surveillance Group A, Surveillance and Response Support Unit, ECDC, informed the AF of the results of the report and opened the floor for discussion.<sup>10</sup>
- 104. Kåre Mølbak, AF Member, Denmark, asked whether travel-associated infections had been excluded from the analysis.
- 105. Ole Heuer explained that where possible they had been excluded, noting that specific studies were needed to look more closely at this issue.
- 106. Jaap van Dissel, AF Member, Netherlands, asked what the message should be from the report, whether the study had looked at the size of a country as a measure of environmental contamination with antibiotic residues, and whether a correlation had been found between closeness to animals and increased resistance.
- 107. Ole Heuer agreed that direct transfer may not be the main culprit for increased resistance, and that the best approach might be to do further research into resistant genes rather than the spread of the disease itself as there was still a lot of uncertainty about how resistant determinants could spread.
- 108. Bruno Coignard, AF Alternate, France, asked if there were any discrepancies in the correlation between resistance and different animal farming practices in European countries, for example, when looking at specific countries specialising in pork or other animals. He also inquired whether biomass-corrected antimicrobial consumption was the appropriate indicator for antimicrobial consumption in humans.
- 109. Ole Heuer responded that the differences between animal production in the countries was not described in the report, but that large production of pigs would have effect on the occurrence of resistance and would be reflected in the results. There was a very good correlation between the defined

 $^{10}$  2<sup>nd</sup> Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) report: Results, conclusions and recommendations (O Heuer)

daily doses (DDD) and the milligram per kilo measurement, so information was not lost when transferring to milligram per kilo.

- 110. Paul Cosford, AF Member, UK, referring to the fluroquinolones and salmonella and campylobacter graphs, noted that animal consumption appeared to drive animal resistance, which drove human resistance, and human consumption did not drive human resistance.
- 111. Ole Heuer confirmed this conclusion, pointing out, however, that there were differences in the way the data was collected on the animal and human side. For example, human samples were taken from patients in hospitals already having been subject to several courses of antimicrobials whereas, on the animal side, samples taken during routine surveillance were from healthy animals.
- 112. Sophie Quoilin, AF Alternate, Belgium, commented that she did not like the idea of placing human and animal use in the same graph when one was for cure and one for prophylaxis. She thought it would be more interesting to explain why there were so many differences in EU countries. For example, why was consumption in humans higher in one country than in another?
- 113. Ole Heuer responded that the relative homogeneity in human consumption seemed to be the result of regulation and prudent use policies for a number of years. Since surveillance had only recently begun for animal consumption, it might take a while before countries with high consumption rates for animals decided to take action to reduce it, resulting in a similar pattern to that for humans. With regard to data presentation, it had been decided to leave in all the outliers and present the data as collected by ECDC and EFSA.
- 114. Mike Catchpole pointed out that humans and animals moved around Europe a great deal, which meant that it was impossible to look at countries in isolation.
- 115. Frode Forland, AF Observer, Norway, asked what countries intended to do, knowing that consumers could have a powerful effect on changing eating/buying habits, based on such data.
- 116. Fernando Simón Soria, AF Member, Spain, asked where the data on use of antibiotics in animals came from.
- 117. Ole Heuer responded that the data for animals came from the ESVAC report published by EMA and was based on the amount sold/imported, although it was difficult to know what proportion of the amount sold/imported ended up in animals, and therefore it was still a rough estimate of consumption.
- 118. Emese Szilágyi, AF Alternate, Hungary, asked whether quality had also been analysed as well as quantity (e.g. critically important antimicrobials that should not be used in animal health).
- 119. Ole Heuer, replied that it had not been analysed, but that the selection of pathogens and antimicrobials included took into account the List of Critically Important Antimicrobials from WHO as the main focus.
- 120. Bruno Coignard asked whether it might be possible to combine the data on antimicrobial consumption in mg/kg from animals and humans to have a true, one-health indicator.
- 121. Ole Heuer responded that the more combined and the more composite you make your indicator, the less sure you can be what caused the change in a measurement afterwards. It would therefore be advisable to keep these two measurements separate. The total antimicrobial consumption in animals and in humans were already in themselves large composite indicators.
- 122. Andrea Ammon, Acting Director, ECDC, explained that although this report could not answer all the questions, it contributed to a rational discussion on where data collection could be improved. Questions and comments by the AF participants had been very helpful in providing a basis for future work. Even though at present it was still difficult due to the way in which data was collected, in the future, she hoped that similar reports would provide examples of how to improve human health through joint analysis. This type of report also helped to make ECDC more visible and to highlight the good work being done. She thanked the ECDC team, EFSA and EMA for their efforts.
- 123. Mike Catchpole thanked the AF participants for their helpful comments and suggestions.

### Advisory Forum Working Group Topic: Principles for publication of Member States' data

#### Working Group B

- 124. Frode Forland, AF Observer, Norway reported on the results of discussions in the Working Group B.<sup>11</sup>
- 125. Mike Catchpole, Chief Scientist, ECDC, referring to an appropriate period of prior notice, asked whether the group had discussed this in more detail.
- 126. Frode Forland explained that the Group agreed it was appropriate to assume acceptance if a deadline was given for responding and no responses were received by that date.

#### Working Group A

- 127. Sophie Quoilin, AF Alternate, Belgium, presented the results of discussions in the Working Group  $A^{12}$
- 128. Masoud Dara, WHO Regional Office for Europe, reiterated the importance of using data to help develop guidelines and produce Member State, ECDC and WHO publications. If the data was not analysed it could not bring about changes in policies and guidelines.
- 129. Mika Salminen, AF Member, Finland, believed that it was important to have a documented process, but not to involve too many partners or to ask for permission as this was implicit in the existing legislation. A written process would probably help to solve 90% of issues and the rest could be handled on a case-by-case basis.

#### Working Group C

- 130. Kåre Mølbak, AF Member, Denmark, presented the results of discussions in the Working Group C. 13
- 131. Bruno Coignard, AF Alternate, France, noted that discussions on this topic often involved ECDC wanting to carry out analysis and asking the Member States for approval for use of data. It would be preferable to consider the data as part of a common European database accessible to all.
- 132. Albrecht Werner, DG SANTE, suggested that with health security issues becoming increasingly topical, it might be useful to look more closely at how to deal with such issues.
- 133. Andrea Ammon, Acting Director, ECDC, suggested that instead of having a memorandum of understanding, a policy on ECDC's website would clarify most issues. She suggested that a draft policy paper be presented at the next AF meeting for discussion.
- 134. Franz Allerberger, AF Alternate, Austria, did not believe that there was a need to seek approval from Member States for each ad-hoc peer review publication. Approval by Member States would mean having to seek approval from a member of the Minister's cabinet in each case, which could be a very difficult and protracted process. The EU had an open data policy, and ECDC had the right to state facts based on this policy.
- 135. Kåre Mølbak said that the word 'approval' was not being used in the strictest sense, and was perhaps not well chosen since, at ministerial level, it would only be an agreement for the joint use of data, taken as accepted if there were no comments within two weeks.
- 136. Fernando Simón Soria, AF Member, Spain, could not see that there was any difference between epidemiological and microbiological data, and thought that it might be dangerous to make a difference between the two.

<sup>&</sup>lt;sup>11</sup> Feedback WG B (F Forland)

<sup>&</sup>lt;sup>12</sup> Feedback Working Group A (S Quoilin)

<sup>&</sup>lt;sup>13</sup> Feedback Working Group C (K Mølbæk)

- 137. Mike Catchpole explained that there was no difference in the data per se but that there could be differences in the origin and funding of the data.
- 138. Kåre Mølbak clarified that if countries spent time and energy on collecting supplementary information and additional variables, it was important to involve them in the process and the use of the data
- 139. Mika Salminen, AF Member, Finland, said that all countries struggled with the issue of a mixed funding base for data used for research and public health purposes. He agreed that no distinction should be made, and that it should be possible to use all types of data. If all data was provided with the same purpose in mind on the same basis there would not be such a problem; ideally there should only be one policy, in order to keep it as simple as possible.
- 140. Mike Catchpole thanked the AF participants for their very helpful feedback, which would be crucial for developing the paper to be presented at the next AF meeting.

#### Joint Strategy Meeting 2018 – Options for planning

- 141. Mike Catchpole, Chief Scientist, ECDC, gave a short introduction setting out a plan for 2018.
- 142. There were no objections raised to the convening of a Joint Strategy meeting in 2018.
- 143. Andrea Ammon, Acting Director, ECDC, noted that in 2018, ECDC would be planning its activities for the period 2019-2021 as well as a longer term strategy, and it would therefore be useful to discuss this with the AF, MB and Coordinating Competent Bodies. Changes in technology were already affecting the way in which ECDC worked (e.g. microbiological techniques, e-health), and it would therefore be useful to have a joint strategy meeting to discuss changes in policy and new approaches during the planning phase.
- 144. Kåre Mølbak, AF Member, Denmark, following up on possible areas for discussion at the meeting, mentioned point-of-care tests which were increasingly being used by staff in hospitals and clinics with no training in laboratory techniques. At present, there was no EU system for approval of these tests so choices were being made by purchasers in hospitals based on information from providers. There were also no standards in Europe defining how the data should be stored, or whether data should be transmitted to surveillance networks and/or subsequently confirmed in a laboratory. He suggested that ECDC could draw up European guidelines for point-of-care testing which was placing the future of clinical microbiology under threat.
- 145. Bruno Coignard, AF Alternate, France, felt that e-health and big data were two of the most challenging topics. ECDC needed to take the lead on providing guidelines in certain areas, such as healthcare-associated infections, which were proving challenging for many, if not all, Member States. Sequencing for microbiology was also a topic which required discussion.
- 146. Sophie Quoilin, AF Alternate, Belgium, said that in order for the Joint Strategy Meeting to be useful, it was important to be able to exchange views properly on topics rather than just having a brief overview of each area. She agreed that the topics of whole genome sequencing and e-health were appropriate for discussion.
- 147. Andreas Gilsdorf, AF Alternate, Germany, suggested that project sustainability might be an issue for discussion. However, he did not think that a large meeting was the best forum in which to discuss issues and come up with plans for solving problems.
- 148. Kevin Kelleher, AF Member, Ireland, wished to see more focus on interventions and surveillance and agreed that small groups would be better than a large meeting which would not generate the same debate.
- 149. Aura Timen, EUPHA, suggested that it might be useful to discuss country support versus country capacity training from a broader EU perspective. It might also be useful to discuss whether there should be a baseline level of country capacity/preparedness within Europe.
- 150. Frode Forland, AF Observer, Norway, felt that the Joint Strategy Meeting should be reduced to an even smaller scale than the previous one in order to achieve the desired outcomes. The list of proposals was good but it would depend on how discussions were prepared. He suggested adding globalisation and the split between infectious and non-infectious diseases as topics. He also suggested

discussing a priority list of guidance documents that could be drawn up at EU level on behalf of European countries to avoid having to do them at the national level.

- 151. Mike Catchpole said that he perceived a general view that future meetings should have focussed discussions and that the background papers and topics should be developed well in advance in consultation with stakeholders.
- 152. Denis Coulombier, Head of Surveillance and Response Support Unit, ECDC, said that ECDC had learnt from the previous joint strategy meeting that it did not totally fulfil expectations. He pointed out that it should not be a one-off event but part of a process. The idea would be to extract two or three common issues from discussions with focal points in the networks and prepare them in advance as a springboard for moving forward.
- 153. Mike Catchpole concluded that there would be further discussion on this issue with the MB and the Coordinating Competent Bodies in order to have a clear framework for the specific topics to prioritise. ECDC would work with the AF to develop papers with clear proposals instead of just having general topics. In this way, he hoped that it would be possible to make the third joint strategy meeting the best to date.

#### 2019 priorities (Single Programming Document 2019-2021)

- 154. Andrea Ammon, Acting Director, ECDC, gave a short presentation on the 2019 priorities. 14
- 155. Sophie Quoilin, AF Alternate, Belgium, suggested that the term vaccine hesitancy should be replaced by the term vaccine accessibility since most of those who were not vaccinated simply did not have the right information.
- 156. Lucia Pastore Celentano, Head of Disease Programme, Vaccine-Preventable Diseases, Office of the Chief Scientist, ECDC, acknowledged the validity of the comment. This issue had been discussed with WHO and among colleagues and that is why for European Immunisation Week, ECDC had decided to change its approach. Internally, and when talking to doctors and healthcare workers, ECDC still used the term 'hesitancy', but in external communications, it talked about strengthening programmes for cooperation and increasing coverage.
- 157. Aura Timen, EUPHA, said that the concept of zoonotic disease appeared to be missing from the one-health approach.

### **Expert Opinion on rotavirus vaccination**

- 158. Kari Johansen, Expert, Vaccine-Preventable Diseases, Surveillance and Response Support Unit, ECDC, gave a short presentation and asked for comments from the AF. 15
- 159. Fernando Simón Soria, AF Member, Spain, suggested referring to the generic name (racecadotril) rather than the commercial names of the treatments. With regard to cost effectiveness, he felt that if there was a dynamic model available then this should be used. The EU joint procurement agreement was not intended for this type of procurement of routine vaccination, but for specific instances in outbreak situations. Regarding the funding of cost effectiveness studies, he believed that it did not matter whether this was private or public, as long as industry was not involved in the study. He suggested that a summary might help in reading such a long document.
- 160. Isabel De La Fuente Garcia, AF Member, Luxembourg, mentioned that data was available on coverage in Luxembourg from a survey carried out in 2012, and at that time coverage had been very high: 89%. She was pleased to see strategies being employed to avoid intussusception as there had been reduced uptake of rotavirus vaccines since France had changed its recommendation and there were now doctors in Luxembourg who were not recommending the vaccination, even though it was free. With regard to effectiveness studies, it was important to have a case definition as there were significant numbers of false positives, with many hospitals and laboratories using ELISA/antigen tests to do the diagnosis.

<sup>&</sup>lt;sup>14</sup> 2019 priorities (Single Programming Document 2019-2021) (A Ammon)

<sup>&</sup>lt;sup>15</sup> Expert Opinion on rotavirus vaccination in infancy (K Johansen)

- 161. Sophie Quoilin, AF Alternate, asked that the Member States be given some time to review the document which was very large and difficult to read. She had found errors in relation to Belgium and therefore needed to look at it in more depth.
- 162. Frode Forland, AF Observer, Norway, felt that private sector studies should be viewed with scepticism, given that the role of industry was to sell their products. He found it very difficult to do a cost effectiveness analysis including all the various aspects for the whole of Europe when systems were so different. He also needed more time to obtain feedback from national experts.
- 163. Aura Timen, EUPHA, noted that cost effectiveness was very different in each country and it was not so much the cost but the parameters as to how the cost had been calculated that were most useful.
- Kari Johansen, responding to the comment from Spain on the names of the treatment against 164. diarrhea, explained that it will be changed to racecadotril. She pointed out that the EU had experienced a shortage of vaccines over the last year, and a VENICE survey conducted in 2016 highlighted the main reasons for the vaccine not having been introduced in some Member States was the price and the increased incidence of intussusception. She was also pleased to hear that Luxembourg had such high coverage and asked for a copy of the survey results. In response to the positive view expressed from Luxembourg on the risk mitigation strategies she shared that STIKO (the Standing Committee on Vaccinations at the Robert Koch Institute) had recently published an article with ECDC and their systematic review confirmed that the strategy of vaccinating all children early at 6-9 weeks of age was the best way of avoiding intussusception following rotavirus vaccination. With regard to giving feedback, she confirmed that she would be happy to extend the time period and asked the AF members to flag up any errors in the text. With regard to studies produced by the private sector, she pointed out that these had been included due to the need to be transparent; however, some bodies (STIKO) did not do this. With regard to cost effectiveness calculations, she said that the relevant chapter attempted to make clear which parameters were being used.
- 165. Mike Catchpole, Chief Scientist, ECDC, said that ECDC would ask AF members to check with their immunisation experts that there were no discrepancies in the description of the vaccination strategy in country. Given that price changed over time, price thresholds would not be included. ECDC would ensure absolute transparency on the origin of any cost effectiveness studies included. Subject to any further feedback over the next 3-4 weeks, the expert opinion would be considered final and would be put into the public domain as soon as possible.

### Update on migrant health task force

- 166. Maarit Kokki, Senior Adviser to the Director/Head of Section, International Relations, ECDC, gave a short presentation. 16
- 167. Sophie Quoilin, AF Alternate, Belgium, said it was important to define the terminology used since migrants, asylum seekers and refugees were all different. She pointed out that for most people fleeing from war, the main problem was not communicable diseases. She stressed the dramatic lack of resources available to receive these people in Belgium. Upon entry into the country, they were checked for TB, received basic vaccinations and were asked if they had any chronic diseases. Doctors had a few minutes with each person at a reception centre when they arrived. They then did not receive access to care under the public health system until they had been granted asylum.
- 168. Sylvia Declich, AF Member, Italy gave a short presentation on migrant health in Europe. 17
- 169. Mike Catchpole, Chief Scientist, ECDC, said that it was necessary to be clear where ECDC and the EU could provide added value. He pointed out that although there was no explicit mention of migrant health in ECDC's work plan, this did not mean that work was not going on.
- 170. Andrea Ammon, Acting Director, ECDC, said that topic of migrant health required an integrated approach, and ECDC was just a small part of this. She suggested that when countries were reviewing the list of priorities for 2019, they could add some comments or make suggestions on this issue in their

<sup>&</sup>lt;sup>16</sup> Update on the ECDC Migrant Health Task Force (M Kokki)

<sup>&</sup>lt;sup>17</sup> Migrant Health in Europe (S Declich, A Baka)

feedback. She also suggested that the topic be raised at the Health Security Committee meeting at the end of June with a proposal for an integrated, Europe-wide approach.

- 171. Mike Catchpole proposed that AF members encourage their representatives to raise the issue at the Health Security Committee.
- 172. Agoritsa Baka, AF Alternate, Greece, asked ECDC to collect and place all documents at one location (both ECDC and any other useful documents produced by Member States) to ensure easy access.
- 173. Maarit Kokki thanked the AF participants for their input and proposals on how to take the issue forward.

### Any other business

174. Mike Catchpole, Chief Scientist, ECDC, thanked all participants for their contributions to the AF meeting. He wished them a pleasant summer and looked forward to seeing them again in the autumn.

### **Annex: List of Participants**

Member State	Representative	Status
Austria	Franz Allerberger	Alternate
Belgium	Sophie Quoilin	Alternate
Croatia	Aleksandar Šimunović	Alternate
Czech Republic	Jan Kynčl	Member
Denmark	Kåre Mølbak	Member
Estonia	Kuulo Kutsar	Member
Finland	Mika Salminen	Member
France	Bruno Coignard	Alternate
Germany	Andreas Gilsdorf	Alternate
Greece	Agoritsa Baka	Alternate
Hungary	Emese Szilágyi	Alternate
Ireland	Kevin Kelleher	Member
Italy	Silvia Declich	Member
Lithuania	Loreta Ašoklienė	Member
Luxembourg	Isabel De La Fuente Garcia	Member
Netherlands	Jaap van Dissel	Member
Portugal	Carlos Matias Dias	Member
Romania	Florin Popovici	Member
Spain	Fernando Simón Soria	Member
Sweden	Birgitta Lesko	Alternate
United Kingdom	Paul Cosford	Member

Observers				
Norway	Frode Forland	Member		
Non-Governmental Organisations (NGOs)				
European Public Health Association (EUPHA)	Aura Timen	Member		
European Commission				
DG Santé	Albrecht Werner			
WHO				
	Masoud Dara			