ECDC Advisory Forum

Minutes of the 28th Meeting of the Advisory Forum

Stockholm, 7-8 December 2011

Contents

Item 1 – Opening and adoption of the agenda *(Documents AF28/2 Rev.2; AF28/3 Rev.1)*

1. The Director of ECDC, Marc Sprenger, and the Chair, Johan Giesecke, Chief Scientist, ECDC, welcomed the participants to the Twenty-eighth meeting of the Advisory Forum. The Chair also welcomed Petra Apfalter, newly-appointed member for Austria, Frank Van Loock from the European Commission and Nedret Emiroglu from World Health Organization's Regional Office for Europe.

2. It was stated that from now on, Candidate Countries will be invited to participate in the Advisory Forum (AF) Meetings as observers. The representative from Croatia, Ira Gjenero-Margan, and the representative from the Former Yugoslav Republic of Macedonia, Vladimir Kendrovski, were warmly welcomed.

3. Apologies were received from Liechtenstein, Lithuania, Malta, Slovak Republic, the Standing Committee of European Doctors, the European Public Health Association and the European Patients' Forum. It was noted that the member from Germany would attend only the first day of the meeting and join the second day via audio conference and that the member from Sweden would attend only the second day.

4. The agenda was adopted without any changes.

5. The following declarations of interest were noted: Kåre Mølbak declared, with reference to items 5 (Feedback on inclusion of the Advisory Forum priorities on Scientific Advice in the 2012 Work Programme) and 10 (Facilitation of application for calls for tender or proposals for National Public Health Institutes), that his institute has framework contracts and other agreements with ECDC and thus might be affected by the Work Programme. In reference to item 6, the threat of multidrug resistant gonorrhoea – conclusions on a report from the Euro-GASP project, Mike Catchpole noted that HPA coordinates the laboratory aspects of Euro-GASP. He also noted that HPA hosts both EPIET and EUPHEM fellows (item 13 - EPIET/EUPHEM fellows – from individual to institutional grants). With regards to the item 13, Silvia Declich noted that ISS is a training site for EPIET, Kåre Mølbak stated that the SSI hosts EPIET and EUPHEM and has a contract for the coordination, and Jean-Claude Desenclos noted that InVS is funded for a position of EPIET coordinator. Irena Klavs declared, under item 9 (Update on The European Surveillance System [TESSy]), that she is the principal investigator for the Slovenian national prevalence survey of HAI. In reference to item 10 on Facilitation of application for calls for tender or proposals for National Public Health Institutes, Preben Aavitsland stated that his institute has submitted proposals for several calls.

Item 2 – Adoption of the draft minutes from 27th meeting of the Advisory Forum (28-29 September 2011) *(Document AF28/4)*

6. Comments from France and Germany had been included and highlighted in the text. The members for Germany and France agreed on the text.

7. Preben Aavitsland noted that he would like to see more articles by ECDC experts published in scientific journals, including *Eurosurveillance*.

8. Petri Ruutu mentioned that he would send written comments on the draft minutes to Johan Giesecke.

9. Sophie Quoilin asked if it was necessary to always state in the Declaration of Interest form that an AF member was also representative of the Competent Bodies (CB) under the new system. Johan Giesecke confirmed that this was not necessary.

10. In referring to paragraph 108, Silvia Declich corrected that it is the salary of the EU-track that will be reimbursed by ECDC and not the non MS-track, which is paid by the MS country.

11. Following the above noted comments, the draft minutes were adopted.

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

12. The Director updated the AF on the Centre's recent activities.[1] Highlights included conferences such as Eurovaccine and ESCAIDE and the VAESCO and National Contact Points for Surveillance meetings. He mentioned that ECDC had been extremely busy in recent months finalising the 2012 Work Programme and organising a number of EU-level events on measles, HIV and influenza.

13. The Director informed the AF that there would be a 1% cut in ECDC's budget for 2012. He also mentioned that next year an administrative Memorandum of Understanding would be signed with WHO/EURO to enhance further collaboration and communication.

14. The Director shared his experience of European Antibiotic Awareness Day (EAAD), when he had been invited to participate in the Commission's press briefing with Commissioner Dalli and Commissioner Geoghegan-Quinn. The Director emphasised the importance of the work ECDC has been carrying out in the field of antimicrobial resistance.

15. Johan Giesecke, Chief Scientist, ECDC, updated participants on the outcomes of ESCAIDE and the activities of the various disease programmes.

16. Karl Ekdahl, Head of Public Health Capacity and Communication Unit, gave an update on progress in the Public Health Development, External Communication and ICT sections of his Unit.

17. Denis Coulombier, Head of Surveillance and Response Support Unit, gave an update on epidemic intelligence and emergency operations, response support, epidemiological methods and surveillance.

18. Andrea Ammon, Head of Resource Management and Coordination Unit and Deputy to the Director, gave an update on microbiological coordination, internal communication and *Eurosurveillance*.

19. Participants were informed that on the occasion of World Aids Day *Eurosurveillance* had published a special issue on HIV and that a special issue on Q fever would be published in January 2012.

Item 4 – Update from the EU Presidencies

4a – Polish EU Presidency

20. Andrzej Zielinski updated participants on the activities undertaken during the Polish EU Presidency in relation to infectious diseases. Several events had been held at the Ministry of Health premises on 18 November 2011 associated with EAAD and the annual meeting on antimicrobial resistance and healthcare-associated infections, coordinated by ECDC, had been held in Warsaw on 23 November 2011. Adam Fronczak, Secretary of State at the Polish Ministry of Health, had participated in a debate on the EU global response to HIV/AIDS.

4b – Danish EU Presidency

21. Kåre Mølbak informed the AF that the general areas of importance for the Danish EU Presidency would be announced in January 2012.[2] One of the tasks within health was to formalise the Health Security Committee. The thematic areas would be innovation in health, antimicrobial drug resistance and chronic disease and ageing. He stated that AMR would be a main priority during the Danish EU Presidency and that both human and veterinary medicine would be taken into consideration. On 14 and 15 March 2012, a conference entitled *Combating Antimicrobial Resistance – Time for Joint Action* will be held in Copenhagen, with a strong focus on the rational use of antibiotics, critically important antibiotics and data collection and surveillance.

[1] Item 3 - Update from ECDC
[2] Item 4b - EU 2012 Danish Presidency (K Mølbak)

22. ECDC's Director inquired whether the conference would be sponsored by the private sector. Kåre Mølbak replied that this would not be the case.

23. Andrzej Zielinski questioned how the Danish EU Presidency intended to enforce legislative regulation. Kåre Mølbak responded that it was a difficult issue which would be straightforward in the veterinary sector but not in the public health sector.

24. Preben Aavitsland congratulated the Danish EU Presidency on having this topic as a priority and wondered how ECDC would be working with the Danish Presidency to ensure that enough attention was given to the conference. Karl Ekdahl replied that ECDC would be collaborating closely with the Presidency on this issue.

25. Robert Hemmer stated that there should be more interaction between microbiologists and clinicians to promote diagnostics before use of antibiotics.

26. Mike Catchpole lauded the initiative and enquired whether the conference conclusions would lead to Council conclusions. Kåre Mølbak responded that some proposed action was already on the agenda for the Council meeting in June, where some decisions would be taken.

27. Petra Apfalter pointed out that it was important to encourage more countries to join EUCAST. Andrea Ammon replied that work on this issue was being undertaken by the ARHAI programme.

28. Kåre Mølbak explained that the content to be discussed by the working groups at the conference was currently being planned. He requested suggestions and feedback from the AF and reminded AF members to fill in the survey he had given them.

Item 5 – Feedback on inclusion of the Advisory Forum priorities on Scientific Advice in the 2012 Work Programme

29. Andreas Jansen, Head of Section, Scientific Advice Coordination, Office of Chief Scientist, ECDC, gave a presentation of the revised priorities.[3]

30. Johan Giesecke, Chief Scientist, ECDC, inviting comments from participants, pointed out that planning for the 2013 Work Programme would have to be finalised much earlier (March 2012) with a view to adopting in June 2012, and that the process will necessarily be done via written procedure next year.

31. Andrzej Zielinski said he would have liked to see a less rigid format to the priorities, given that issues always arise causing reprioritisation to be required.

32. Ágnes Csohán said that without concrete data on measles seroepidemiology, it would be impossible to work out a strategy for measles under the 2012 Work Programme.

33. Johan Giesecke responded that this issue had been discussed at the Eurovaccine Conference, hosted by ECDC two days prior to the Advisory Forum meeting, with the conclusion that if measles was to be eliminated in Europe by 2015, there was no time for sero-epidemiological studies. He also pointed out that there was little need – with so many cases of measles the age and risk groups were already known.

34. Jean-Claude Desenclos noted that there appeared to be a reduction in the number of requests for scientific advice and more for surveillance guidelines, etc., and he wondered how ECDC would accommodate this in terms of management within the units. He pointed out the superficial nature of presenting the Work Programme vertically by programme and encouraged clarification on cross-cutting issues.

35. Sophie Quoilin wished to know if all topics proposed had been included in the list and the criteria used to decide what was included. She suggested that there should be rules/criteria for the number of topics included from each of the partners, e.g. ECDC, Member States, stakeholders.

36. Kåre Mølbak suggested that fewer but more cross-cutting topics be included in the Work Programme in the future to allow more time for each issue to be digested.

[3] Item 5 - Feedback on inclusion of AF priorities on SA in 2012 WP (A Jansen)

37. Robert Hemmer noted that the issue of pneumococcal vaccines for adults had not been included in the Work Programme.

38. Andreas Jansen thanked the participants for their comments and reassured them that a new system would be introduced over the next few years at ECDC which would give more priority to cross-cutting issues. In response to the question on the selection process, all topics were initially included on the basis of stakeholder input and nothing was excluded. The results of the scoring exercise were based on financial, business continuity and other factors, but it was clear that more emphasis need to be given to certain issues.

39. ECDC's Director pointed out that ECDC received wish lists for the Work Programme from many sources, making it difficult to organise the process. Since there must be an accelerated process for the 2013 WP, the new prioritising scheme will probably only be used one year from now, but it should also influence the next multiannual programme 2014–2020.

40. Jean-Claude Desenclos said that the Work Programme prioritisation decisions need to be based on transparency and he encouraged more use of this perspective in the future.

41. Johan Giesecke pointed out that 90% of the proposals made by the Advisory Forum had been included in the WP, and therefore the members should be pleased with the impact they had had on the work of ECDC.

Item 6 – The threat of multidrug resistant gonorrhoea (Euro-GASP) *(Document AF28/5)*

42. Marita van de Laar, Head of Disease Programme HASH, Office of Chief Scientist, ECDC, gave a presentation on the Euro-GASP project, which was followed by a general discussion.[4]

43. Mike Catchpole commented that this project was a good example of EU-wide surveillance providing an alert on an emerging threat. He asked whether information was being collected on prescriptions for gonorrhoea across Europe and whether ECDC was planning to collect an extended set of demographic or risk factor data.

44. Roel Coutinho lauded the initiative, but also sought more information about what was being prescribed and the best treatment regimens. He hoped that ECDC would be able to help by recommending treatment regimens and taking the initiative with two- or three-antibiotic proposals.

45. Preben Aavitsland suggested that more information should be collected on resistant cases to know whether these were individual importations or infections established in EU countries. He agreed that it was necessary to examine the whole spectrum of drugs for gonorrhoea, including the possibility of a three-drug regimen.

46. Petri Ruutu pointed out that there were few strains available in clinical laboratories, meaning that the representativeness of the results could be problematic. With regard to the monitoring of treatment failure, he pointed out that there might be more problems with compliance than for other diseases, and suggested that this issue be addressed in one of the working groups.

47. Frank Van Loock noted that this late reporting represented a missed opportunity for visibility and implementation. He asked how the information had been shared internally within ECDC and why it had not been presented before in connection with the Commission Communication on AMR strategy. He also wished to know whether increased collaboration was required with regard to a case definition and when this would be established, as was requested during the last Network Committee meeting.

48. Marita van de Laar said that she did not know what treatments were being recommended in individual countries. A response was currently being drafted for the expert group, HPA and other ECDC collaborators, which would help tackle questions on treatment alternatives, cocktails and changing regimens. With regard to collection of information, she pointed out that unfortunately many countries could not provide the appropriate data because microbiology/laboratories and treatment were two different areas which do not collaborate on such issues. Men having sex with men were at

[4] Item 6 - Threat of multidrug resistant gonorrhoea (M van de Laar)

high risk of contracting resistant gonorrhoea and it was likely that it would emerge in this population first. Anal rectal gonorrhoea was also more difficult to treat than other types. In answer to the question on monitoring treatment failure, she confirmed that this was a very challenging issue. The expert group had discussed having treatment failure definitions of probable and confirmed, since in order to have a treatment failure, it would be necessary to have a confirmed pre-test in the first instance. With regard to cooperation in the area of surveillance/monitoring, she confirmed that this would be easier if a system was put in place and applied in each country. ECDC hoped to discuss this issue with the Member States at a meeting on STIs in February 2012. In response to the question of a communication strategy, it was important to increase awareness that multidrug-resistant gonorrhoea was imminent by informing GPs and consulting physicians, for example. However, this was difficult because each country has a different public health system. Although ECDC would draft some factsheets, the strategy would have to be implemented at the national level. Information on the multidrug-resistant strain had been shared through EPIS (Epidemic Intelligence Information System), which was the platform for notifying microbiologists and epidemiologists of strange strains, clusters or decreased susceptibility. If flagged or considered important the information would then be passed to EWRS. In answer to the question on case definition, it was necessary to establish a working case definition for the resistant strain in question, which was being done by WHO and CDC Atlanta.

49. ECDC's Director explained that multidrug–resistant gonorrhoea was intentionally not included in the information for European Antibiotic Awareness Day as it was a complicated and cross-cutting issue and ECDC wants to avoid including too many messages at the same time.

50. Frank Van Loock wondered why EPIS was described in the text as a platform for early warning when other platforms have been attributed to this role. Mislabelling EPIS creates a risk of confusion or duplication or for not distributing the information to the persons and authorities who need to know.

51. Denis Coulombier explained that the generic EPIS approach is to enable information to be verified and validated first. He pointed out that there has always been an ECDC monitor trying to establish whether the information needed further verification or whether it should be escalated to EWRS.

52. Marita van de Laar concluded by asking participants for support for the Euro GASP programme in the form of monitoring and by supplying the information to ECDC as promptly as possible. She thanked the participants for their support.

Item 7 – Epidemic intelligence: Update on recent threats in the European Union – the HIV situation among IDUs in the EU

7a – HIV situation in Greece

53. Sotirios Tsiodras gave a presentation on the HIV situation in Greece among people who inject drugs.[5]

7b – HIV situation in Romania

54. Florin Popovici presented the HIV situation in Romania.[6]

7c – Rapid risk assessment on HIV among people who inject drugs

55. Marita van de Laar presented the results of the ECDC/EMCDDA Joint Rapid Risk Assessment on HIV among IDUs.[7]

56. Denis Coulombier, Head of Surveillance and Response Support Unit, ECDC, invited questions and comments on the three presentations.

[5] Item 7a - HIV situation in Greece (S Tsiodras)
[6] Item 7b - Epidemiology of HIV transmission Romania 2011 (F Popovici)
[7] Item 7c - HIV in IDU in the EU (M van de Laar)

57. Roel Coutinho was surprised to see the high number of vertical transmission infections in Romania in 2011 and the high number of new AIDS cases. He also pointed out that there was a general tendency to see needle exchange programmes as the only solution, whereas in practice they needed to be combined with methadone and social support.

58. Andrzej Zielinski was of the opinion that the relationship between IDU and HIV was much better illustrated by data for Hepatitis C infections as a methodological approach to assessing the number of HIV infections because the figures were more reliable. He also recommended a birth cohort approach, as applied in Poland, which provided a much better picture of exposure.

59. Josep Maria Jansà asked whether certain phenomena were changing the drug market in Greece as described in the presentation on HIV in Romania. He also wished to know whether countries had been asked in the questionnaire about safe injection facilities which had proved useful in many countries. He also requested more information on ethno-botanic drugs in Romania.

60. Guðrún Sigmundsdóttir said that in Iceland there had been an outbreak of HIV among IDU users going on since 2007 and the number of cases had doubled, especially for stimulating drugs among younger males. Iceland was planning to repeat a small study done previously to obtain updated figures on this issue.

61. Jurijs Perevoščikovs asked whether there was any data about the denominator for the number of HIV infections in Europe and whether the number of people being tested had increased in recent years since previous surveys.

62. Ágnes Csohán noted that cooperation between EMCDDA and ECDC was very fruitful. The risk assessment represented a warning signal for other countries in a similar economic situation to stay ahead of the game of the increasing risk of an HIV outbreak. Hungary had excellent monitoring centres and good data, but no funds available for screening and prevention. She therefore appealed to the Commission for support with prevention before it was too late.

63. In responding to questions relating to Romania, Florin Popovici stated that most of the vertical transmission cases in Romania were among young females who had become HIV-infected during the HIV paediatric epidemic during the 1990s and were now sexually active. Those that received treatment were monitored but not all of them received treatment. The figures for AIDS cases were taken from HIV infected patients that had gone on to develop AIDs. In response to the request for more information on the ethno-botanic drug, its name was cathinone, an amphetamine-type stimulant.

64. Sotirios Tsiodras, answering questions relating to Greece, said that an ethno botanic type of synthetic drug was being used in Greece but that data was not yet available on whether the pattern of use had changed or if injections were more frequent. He was unaware of any recent major changes on the drug market in Greece. A huge study had been carried out before 2010, but the data now available was different, indicating that the situation had become an epidemic. It was hoped that the transmission source would be pinpointed more accurately in the future.

65. Marita van der Laar said that the guidance recently issued jointly by ECDC and EMCDDA was based on two evidence reports, one on substitution and treatment and one on all other types of intervention. They advocate for combining services and interventions to increase synergy. EMCDDA covers a different area within the field and has different stakeholders, which was a useful combination for this topic. Cooperation would continue next year with a Hepatitis framework strategy. She agreed with Andrzej regarding Hepatitis C which was why it was included in the survey to countries. Based on the figures for Hepatitis C, ECDC had been able to identify a number of countries at risk because Hepatitis C was easily transmissible and could be seen as an early warning of an HIV outbreak. The birth cohort suggestion was interesting, however, ECDC risk assessments have been produced quickly. In the discussion on the difference between a trend and an outbreak, she pointed out that if HIV was introduced into a network, it became an outbreak, with the number of cases increasing very quickly, as seen previously in Estonia, thus in current circumstances it could be described as an outbreak. Hepatitis C was curable, Hepatitis B and HIV were treatable. Referring to the comment by Ágnes Csohán about the reduction of services during an economic turndown, she confirmed that there were a number of indications that this would happen over the next few years. A think tank was currently examining this issue in Brussels and they had sent out a survey on HIV and treatment. Thus far, although only eight countries had replied, six of them had said they would soon be implementing reductions, which was not a good sign.

66. Frank Van Loock, European Commission, thanked all three presenters and noted that the economic crisis seems to be the growing excuse for decreasing actions in public health. It is necessary to support MS to ensure that the appropriate prevention programmes are in place and maintained. Maybe it could help to establish minimum standards and to get the message across about advocacy and to communicate properly about what was needed from a European perspective. The Commission could assist to fully support the Member States to improve this advocacy towards such initiatives and to give the countries the tools they needed for this.

Item 8 – ECDC work with the Competent Bodies

8a – Update on nominations (Document AF28/6)

67. Alena Petrakova, Head of Section, Country Cooperation, Director's Office, ECDC, gave a combined brief presentation on the update of the nominations as well as the key messages from the Annual Meeting of Competent Bodies and National Coordinators, which took place on 25-26 October 2011.[8]

8b – Key messages from the Annual Meeting of Competent Bodies and National Coordinators (25-26 October 2011, Stockholm, Sweden)

68. Please refer to the previous item.

8c – One national Coordinating Competent Body: Structures and terms of reference (Document AF28/7 Rev.1)

69. Denis Coulombier noted that the new document had been changed to reflect discussions at the previous sessions of the Advisory Forum and the Management Board and to incorporate the proposal for one Coordinating Competent Body per Member State. He explained that the new document would be the one discussed in the working groups.

70. Jan Kynčl was pleased to see the possibility of having more than one Competent Body, particularly for countries where competence was shared among a number of institutions. He pointed out that under the new regime, emails from ECDC should not be sent to any email address in blind copy as it is necessary to know to whom the emails were sent as only this approach enables proper management.

71. Mike Catchpole requested clarification as to whether each Member State would select one model or if one model would be selected that all countries would have to agree to.

72. Josep Maria Jansà sought advice on the Competent Body nomination process and how countries had organised this.

73. Andreas Gilsdorf appreciated the improvements to the document, but said that there was a need for an overview of tasks and functions, especially where experts in the system represented several specialities. With regards to the question of emails, he also had, as national coordinator, experienced receiving around 10 emails a day from ECDC and it was difficult to see if he was just copied in for information or expected to take action. He suggested that the system should allow for more filtering and more visibility in this regard as the problem would only increase by including more communicators in the system.

74. Sylvia Declich noted that some of the recommendations were very important and that it was important to maintain a general structure with some flexibility. This would imply understanding the various problems at the national level. The countries would have to discuss the issues within their different Competent Bodies and this would take some time. She also referred to the sensitivity of issues with regard to different national institutions. Often the same persons were involved in different

[8] Item 8a - CB list and Key Messages from CB meeting (A Petrakova)

forums so she proposed that the role of the Management Board and the Advisory Forum be clarified accordingly.

75. Alena Petrakova, clarifying the situation with regard to the Czech Republic, explained that the terms of reference for the coordinating body and the function of the national coordinator were as approved by the Management Board which was why no specific terms of reference had been specified. With regard to the disease-specific and public health body functions, she confirmed that there would be a description of duties and responsibilities. The new e-tool would hopefully resolve the email issue and comments by the participants would be useful in helping ECDC to structure the tool for the future. With regard to the issue of AF and MB and alternates, she confirmed that this was being investigated and pointed out that only four countries had no link between CCBs and the AF.

76. In responding to a question whether one particular Competent Body model would be imposed, Denis Coulombier confirmed that ECDC would not impose a model and that the countries would be able to choose different models to reflect their systems.

Item 9 – Update on the European Surveillance System (TESSy)

9a – Policy on data submission, access and use of data within TESSy (2011 revision) *(Document AF28/8)*

77. Sergio Brusin, Senior Expert, General Surveillance, Surveillance and Response Support Unit, ECDC, presented the changes in the policy on data submission, access and use of data within TESSy.[9]

78. Irena Klavs highlighted a possible conflict of interest. She stressed that the surveillance datasets submitted by Slovenia to TESSy could be very different in terms of permission to view, download or publish, and therefore one general policy was not appropriate for dealing with that. For example, no potential problems are anticipated for new HIV diagnoses data. However, health-care associated infections (HAI) data are different. Slovenia is only setting up its HAI surveillance system and the process has sensitivities in terms of developing cooperation with hospitals. The national HAI point prevalence survey protocol specified that hospitals participated voluntarily, names would not be disclosed, individual hospitals would receive their own datasets and hospitals would not have access to one another's datasets. Given the specific context of how datasets were obtained, Slovenia would not be able to submit data to TESSy under current ECDC policy on data access and use. She therefore proposed that a generic ECDC procedure should be adapted to take into account such specificities.

79. Mike Catchpole had similar concerns. Access to data could identify hospitals and the country that the data came from. There was also an issue of sequencing and when national authorities placed material in the public domain and whether this was done in advance by submitting to TESSy. He was concerned that if a freedom of information request was received, ECDC or the country concerned would have no control over the outcome.

80. Sophie Quoilin said that Belgium endeavours to retain the right to data sharing. In Belgium, data are requested, among others, from national reference centres/laboratories. These data providers are also often researchers. If they share internally and with ECDC for well known outputs, Belgium endeavours to retain the right to data sharing with third parties if data are currently in use for a similar research project already started by the Belgian researchers.

81. Preben Aavitsland suggested that ECDC should ask those who receive data and plan to publish it to ensure that the word 'TESSy' was used and referred in the abstract. Similarly, he inquired about the procedure for dealing with requests received from two bodies for similar projects. In Norway, the right of receipt would be given to the first applicant for a given period. Requests for data usually requests for aggregate data and in Norway an online query tool had been developed to facilitate access and save time. He suggested that ECDC should consider something similar for aggregate data.

[9] Item 9a - TESSy Data access policy 2011 (S Brusin)

82. Josep Maria Jansà inquired when the peer review group would be consulted, whether ECDC would inform a Member State of requests and whether there was any possibility of a Member State denying access.

83. Jean-Claude Desenclos noted that Member States should be more open to sharing data from TESSy. Countries should be discouraged from preventing use of their data as this would defeat the object of collecting data at EU level.

84. Petri Ruutu was concerned about the ownership of data issue. Much of the data obtained was from laboratories and often had already been in the public domain for a long time, but the issue needed to be considered more carefully in connection with the national institutes. Here, results were novel by nature and often involved public funding. Molecular typing data and surveillance data, once submitted to TESSy, were then automatically available. At the national level, requests could be examined and controlled to a certain extent to decide whether the research questions were appropriate. However, ECDC only had limited experience in dealing with this type of scenario.

85. Andreas Gilsdorf supported the wider use of TESSy as an output and felt that the direction of the paper was positive and better than the previous, more restrictive proposal. Germany also had a query tool which facilitated access to aggregated data. It might be difficult to judge objectively if the outcome was scientifically appropriate and by making data available generally this problem could be avoided. However, when TESSy moved to a real time scenario it would be different. He urged that the policy should only apply to topics already included in TESSy. For new topics, this has to be evaluated individually in order to ensure that there is no conflict for the data providers.

86. Sergio Brusin, ECDC, responding to the specific issue with Slovenia, explained that a moratorium had been proposed, with a deadline, on disclosure of data for specific countries or particular types of data. A country could also claim its data as 'intellectual property', automatically meaning that any disclosure would have to be subject to its approval. In many instances, molecular surveillance data could be considered intellectual property and this could be one possible solution. Another solution could be to partially amend the policy giving special status to some sub-sets of data. Another proposal could be to involve the peer review group for every request relating to HAI data involving Slovenia per se. Other countries could request this type of approach if they were having similar problems. In response to the UK question on the Freedom of Information Act he acknowledged that this was a problem. ECDC had no control whatsoever over national legislation. Thus if a person in the UK requested access to information via a UK university, for example, there was nothing that could be done. This also applied to the United States. If a person requested access to TESSy data by invoking the US Patriot Act, there was nothing that could be done to prevent it. One solution might be to copyright or place intellectual property limitations on data, and he pointed out that entire surveillance systems had been patented in the past. It was not a good idea for TESSy, but would offer the possibility of more strict regulation. He acknowledged that the idea of citing TESSy as the origin of the data and putting it in abstracts was a good idea that could be considered. With regard to the issue of not disclosing data because of a dislike or mistrust of the scientific protocol, he quoted the decision of the EU ombudsman when this had happened with regard to EUROSTAT data, In all cases, the decision was in favour of the applicant. He clarified that ECDC had refused disaggregated data requests in a couple of cases because the requests did not make any sense.

9b – Paper outlining policy areas related to the enhanced inclusion of molecular typing data in The European Surveillance System (TESSy) (Document AF28/9)

87. Karin Johansson, Expert, Surveillance and Response Support Unit, ECDC, informed the AF that the comments received during the joint Working Group session between the Advisory Forum and NMPF in September had been recorded and that all the participants had received a draft of the document to comment on.[10] The replies received had been taken into consideration.

88. Participants were informed that a new TESSy Data Access Policy had been adopted by the ECDC Management Board in November 2011. The main changes related to disease-specific policies

[10] Item 9b - Policy areas_molecular typing data in TESSy (K Johansson)

for all pathogens, data accessibility and visibility, nomenclature, database functionality and data curation, ownership and allowed use, projected outputs and the roadmap for molecular surveillance implementation.

89. Referring to the roadmap for molecular surveillance implementation, Karin Johansson said that the plan would be presented to the AF in the near future. She welcomed further comments, especially in the section related to the consultation process with Member States on the proposals for inclusion of typing in TESSy.

90. Andreas Gilsdorf considered the developments since the last proposal to be important and mentioned that an official letter had been sent to ECDC expressing Germany's general support for the project; however, many questions related to the curation process and the connection between surveillance and typing data were still open and that ECDC needed to consider them thoroughly. He pointed out that Germany could have problems feeding data systematically into the system over the coming years.

91. Sophie Quoilin sought clarification on what was required from the contributors to the database, taking into consideration that it is probably not necessary to include all the strains. She urged ECDC to establish clear criteria to decide how many and what type of methods were necessary in microbiology surveillance.

92. Jan Kynčl expressed general support for the initiative. He informed participants that in the Czech Republic there was one main database for infectious disease notification, which fed into TESSy, and a different one for microbiology. He mentioned that this would create problems, since ECDC asked Member States to report from a single database. He recommended that the NMFP should be responsible for the provision of molecular typing data and added that since the national identifier was deleted after the submission of data was completed, there was no way of knowing where the information came from, which could lead to a possible duplication of the real figures, as had happened in 2010 with rubella and measles.

93. Referring to data ownership, Petri Ruutu suggested that ECDC should adopt an initial policy whereby molecular typing data would only be available after a year of submission. He requested clarification on the role of the curator as it seemed to be of great importance, yet was ambiguous in the document.

94. Jurijs Perevoščikovs asked if legislation existed at the international level stating that countries should report on molecular typing data. He suggested ECDC should clarify and elaborate further on the reporting procedure for the contributors in the various countries.

95. Jean-Claude Desenclos also requested a clear definition of the term 'curator', given that it was new for many of the participants and suggested ECDC use a term that had already been agreed upon. He mentioned that, while the ownership issue is important, it should not be a reason not to make further progress.

96. Guðrún Sigmundsdóttir considered the plan ambitious and stated that there were many technical issues which needed to be improved, such as data ownership, which could become an obstacle and make data collection more complicated.

97. Preben Aavitsland said that the inclusion of new elements in TESSy would probably encourage Member States to participate, even though it meant an increase in their workload. He suggested ECDC should critically evaluate the added value of molecular typing data and consult the national coordinators before any implementation. He also said that there had been budget cuts all over Europe and it would be difficult for Member States to cope with ECDC's proposals.

98. Roel Coutinho said that he would prefer the laboratories network to be involved since they would be the main providers of data. He stated that there were many issues that were not standardised or covered and suggested that ECDC should do more work on them.

99. Kåre Mølbak agreed, noting that the document underestimated the need to harmonise methods and recommending that the role of the curator should be better developed. He suggested ECDC should start by finding success stories to encourage other parties to contribute as well.

100. Silvia Declich said that she had discussed the document with the Italian NMFP and they had concluded that the document should be seen as a very general framework, that DSPs should be developed and that the networks should be involved in the drafting process from the beginning and

not only at the end. She also said that the curator position should be handled carefully, since it could create conflicts of interest.

101. Johan Giesecke said that all comments would be taken into consideration for the next AF meeting.

102. The Director said that the comments were highly encouraging and that two small pilots would be proposed for the next AF meeting.

Item 10 – Facilitation of application for calls for tender or proposals for National Public Health Institutes *(External Document)*

103. Sophie Quoilin gave a presentation and clarified that the external document had been prepared by her institution in Belgium and not by ECDC.[11]

104. Referring to the calls for tender, Sophie Quoilin noted that some of them could be covered by the national objectives of the National Public Health Institutes (NPHI) and could therefore be awarded to the Member States. She mentioned that it was important for NPHI to become actors and not only providers of data. Even after consideration of the limitations imposed by EU regulations, some topics in the calls for tender could still be transformed into disease programme activities or used to create internal calls so the NPHI could benefit directly from the activities and the funds. Some of the advantages would be tight collaboration between the NPHI, increased motivation and strong contributions to national and European objectives.

105. Johan Giesecke presented statistics related to the number of calls for tender that were awarded over the years and the countries they had been given to.[12] He mentioned that the figures showed a clear inequity.

106. Johan Carlson pointed out of the 33 tenders given to Sweden. Only a few were related to public health. He added that it was important to fund public health institutions and use the skills in-house in order to ensure long-term solutions.

107. Mike Catchpole stressed that ECDC should aim for best science and try to sustain and develop the capacity in public health by being flexible and not launching too many calls for tender for external parties.

108. Mira Kojouharova thanked Sophie Quoilin for the presentation and pointed out that changes in the system were necessary in order to be able work in these projects. Some countries were not motivated to contribute as suppliers of data.

109. Andrzej Zielinski stressed that many countries were eager to develop activities and were open to participating in scientific programmes.

110. Petri Ruutu noted that it might be difficult to meet ECDC deadlines, particularly given the decrease in manpower due to the crisis. Likewise, he stated that many of the tenders had been directed to the academic world and had not produced as their outcome the public health value that was the objective of the tender.

111. Ágnes Csohán proposed a discussion on how to improve closer collaboration between ECDC and the NPHI at the next AF meeting. She said that ECDC had limitations that could be covered by the NPHI.

112. Kåre Mølbak outlined the importance of involving the NPHI and suggested ECDC should give more weight to their applications, since their activities may lead to direct action in the policy making process.

113. Frank Van Loock expressed his concerns about this sensitive issue and stressed that there were EU rules and regulations that ECDC needed to follow. He added that, in order to identify better ways on how the ECDC could provide targeted support to the Member States, he would set up a meeting between ECDC and involved Commission services ahead of the next AF meeting.

[11] Item 10 - Facilitation of application for CfT for National PH Institutes (S Quoilin)
[12] Item 10 - Open calls history ECDC (A Ammon)

Item 11 – European Union Standards for Tuberculosis Care

(Document AF28/11)

114. Andreas Sandgren, Expert Tuberculosis, Surveillance and Response Support Unit, ECDC, presented the European Union Standards for Tuberculosis Care.[13]

115. Andrzej Zielinski pointed out that TB was not an isolated problem in the European Union and that many of the neighbouring countries also had problems with MDR-TB.

116. Andreas Sandgren replied that ECDC was in close collaboration with the neighbouring countries and was certain that they would benefit from the standards managed in the EU setting.

117. Kåre Mølbak said that there were two issues needing further clarification. The first referred to the follow up on the treatment to evaluate completeness of the therapy and the second was the emphasis required both on contact tracing procedures and identification of the source for children with TB.

118. Andreas Sandgren mentioned that childhood TB was being addressed in other specific guidance documents and the document under discussion would possibly be updated when those guidelines were finalised.

119. With regard to Standard 3, Ana Maria Correia pointed out that many rapid molecular tests had not yet been validated for the samples stated in the document. She also asked ECDC to include the total number of doses in Standard 8 and stated that she would send comments to Johan Giesecke on the subject of TB outbreak investigation.

120. Mike Catchpole noted that all patients with TB should be offered an HIV test and that Standard 20 should be applied not only for TB but for a number of other infectious diseases.

121. Referring to Standard 20, Andreas Sandgren agreed and said that infection control in healthcare settings was a priority area.

122. Roel Coutinho considered it important to combine surveillance data with advice to health practitioners and encouraged ECDC to do the same with other infectious diseases.

123. Frank Van Loock asked for clarification on how the document had been developed and on the plans for dissemination. He also asked how the standards would be implemented in the Member States, how ECDC planned to monitor progress is and who would be in charge of the evaluation. It would be helpful to have an annex in the document with the answers to the above. He also requested clarification of the reason for selection of ERS to support this project.

124. Andreas Sandgren replied that the document would be distributed among the 10 000 members of ERS and all of ECDC's TB contact points in the Member States through ECDC's external communication channels. He mentioned that although it was the Member States' responsibility to implement the standards, ECDC would monitor the progress and impact of the guidance. He added that ERS was considered to be the only large clinical society capable of spreading ECDC's message as widely as possible in the EU.

125. Jean-Claude Desenclos congratulated ECDC on the document and recommended that it be published. Although there may be differences in practice in the Member States, this was not a reason not to move forward with the standards since guidance could be accepted or rejected.

126. Josep Maria Jansà said that the standards represented a practical tool for guidance, despite the differences in practice in the Member States and irrespective of whether they already had TB programmes in place. They would also provide the motivation to establish such programmes in those countries where they had not yet been implemented.

127. Petri Ruutu stated that the document would be consulted carefully in Finland as the country was currently revising its national TB programme. With regard to Standard 10, he asked Andreas Sandgren to verify whether, according to the WHO, the sputum smears should be examined after five months and not after three months, as stated in the document. He added that this should be clearly defined and compatible with the current monitoring system.

[13] Item 11 - European Union Standards for TB Care (A Sandgren)

128. Darina O'Flanagan welcomed and endorsed the document. She suggested the authors should verify the treatment stated on Standard 19 and compare it with the one described in the CDC guidelines.

129. Andreas Gilsdorf who was not attending in person but attending by telephone, stated that he would send his comments by e-mail.

130. Johan Giesecke expressed his reservations about working with ERS, given that it was a private sector organisation. He added that it was satisfying to see that the AF supported this action. He thanked the participants for their excellent feedback.

Meetings of the Advisory Forum Working Groups

Working Group A: How to define endemic/affected/transmission areas in the EU for malaria and other arthropod-borne diseases

131. Kåre Mølbak presented the conclusions of Working Group A, which had discussed how to define affected areas in the EU Member States for malaria and other anthropod-borne diseases.[14] Their conclusions included the need for action to simplify the nomenclature and apply the same principles to other issues than blood.

Working Group B: Impact of the financial crisis on public health and communicable disease control

132. Preben Aavitsland presented the conclusions of Working Group B which had discussed the impact of the financial crisis on public health and communicable disease control.[15] He gave examples of the situation in the countries represented in the group and concluded that the crisis should be seen as an opportunity for closer collaboration between national public health institutions and ECDC. Sixteen proposals were presented where ECDC could support Member States.

Working Group C: Parameters for surveillance reports

133. Mike Catchpole presented the conclusions of Working Group C which had discussed parameters for surveillance reports.[16] The group made an analysis of the current situation, strengths and weaknesses, inclusion of statistical and geospatial methods in ECDC outputs, potential increased accessibility to surveillance analysis and integration of an indicator and event-based surveillance in ECDC reports.

134. Andrzej Zielinski requested inclusion of his and Irena Klavs' comments urging ECDC to develop programmes to increase quality of surveillance in order to improve data collection.

Item 12 – Public Health Microbiology

12a – Update on the Position Statement of the Commission and ECDC on human pathogen laboratories: a joint vision and strategy for the future

135. Marc Struelens informed the participants about the updates made to the document after review by the Management Board. The document has been revised and the clarifications requested by the MB have been added. He explained that the changes referred mainly to terminology and further precision of the roles of respective EU bodies as the interface between risk assessment, risk management and mobilisation of laboratories.

[14] Working Group A
[15] Working Group B
[16] Working Group C

12b – Revised ECDC Public Health Microbiology Strategy and Work Plan 2012-2016 *(Document AF28/10)*

136. Marc Struelens also mentioned that the latest version made available to the AF included the input given during the NMFP and AF joint working group in September.

137. With regard to Strategy 1, he said that an element of advocacy had been added to the programme and that ECDC needed to highlight for policy makers and general public the public health added value of the microbiological data from the laboratories. He also explained that there would be further clarification of the need to ensure good coordination of activities involving close consultation with national partners. He stated that training opportunities, beyond the EU public health microbiology training programme (EUPHEM), such as technical courses hosted in partner institutes within the Member States and short-term professional training opportunities in public health microbiology, would be explored. Similarly, he confirmed that aspects of the technical guidance in Strategy 2 regarding development and application of laboratory capability appraisal tools would be developed step by step, with ongoing consultation of the NMFP and AF as well as disease experts from the Member States. Regarding Strategy 3 on the development of roadmap towards integration of molecular typing data into surveillance, further evidence needed to be obtained of the effectiveness and assessment of the usefulness for public health measures. Data ownership and legal issues also needed to be reviewed further before appropriate plans could be produced. Communication among experts would also be improved by means of regular consultation and the circulation of draft documents using extranet exchange platforms. He agreed to add all the useful suggestions from AF participants and after receiving the final feedback from the NMFP, if endorsed, the document would be used for guidance purposes in the coming years.

138. Mike Catchpole welcomed the link in the document between epidemiology and microbiology, but also expressed his concerns about the lack of connection between the ECDC goal of enhancing capacity and reduction in budget allocated to ongoing laboratory based activities in the Member States.

139. Marc Struelens replied that ECDC was fully aware of budget constraints and that the aim was to develop a credible tool to demonstrate that there would be real value for the money. He added that resources were limited and that it would be increasingly necessary to focus on what was most efficient.

140. Sophie Quoilin informed that this year her institution had received two different requests for External Quality Assessment (EQA), one from the EU and another from WHO. She asked for better coordination between ECDC and WHO in order to avoid duplication of work.

141. Marc Struelens agreed with the proposal and said ECDC would strive to improve in this area, particularly with regard to the timing of activities and the avoidance of duplication.

142. Nedret Emiroglu apologised and explained that work was being done to make improvements in this area.

Item 15 – Any other business

143. The Director expressed his frustration at not being able to move forward in the discussion about the molecular typing data. However, he thanked the Advisory Forum for their commitment and useful critical remarks.

144. The Chair and the Director closed the meeting, thanking everyone for the fruitful discussions. The next Advisory Forum meeting will convene in Stockholm on 22-23 February 2012.