ECDC Advisory Forum

Minutes of the 26th Meeting of the Advisory Forum
Stockholm, 5-6 May 2011

Contents

Item 1: Opening and adoption of the agenda (and noting the Declarations of Interest, if any) *(Documents AF26/2 Rev.1, AF26/3 Rev.1)*

1. The Director, Marc Sprenger, and the Chair, Johan Giesecke, welcomed the participants to the twenty-sixth meeting of the Advisory Forum Meeting. The Chair also welcomed Frank Van Loock from the European Commission and Nedret Emiroglu from World Health Organization, Regional Office for Europe.

2. The agenda was adopted without any changes.

3. The following declarations of interest were noted: Preben Aavitsland noted, under item 9 (Report back from the Fineberg Committee) that he is a member of this Committee. Derval Igoe declared that her organisation, HPSC, is involved in VENICE II and I-MOVE projects and Kåre Mølbak noted that SSI participates in the VENUE and I-MOVE networks (EVER), as well as the SSI has tenders regarding subtyping and is active in PulseNet Europe (item 5 – Update from Office of the Chief Scientist). Silvia Declich declared, under the same item, that she is involved in VENICE and I-MOVE projects for Italy and noted that her unit includes the EPIET training site (item 8). Gérard Krause pointed out that he is the head of EPIET Training site (item 8 – Update from Public Health Capacity and Communication: EPIET Training Strategy). Ágnes Csohán is the representative of Hungary (item 4 – Update on the Hungarian EU Presidency).

4. Apologies were received from Austria, Bulgaria, Cyprus, Czech Republic, France, Latvia, Liechtenstein, Poland, Portugal and the European Patients' Forum (NGO). It was also noted that the member from Belgium will arrive around noon on 5 May.

Item 2: Adoption of the draft minutes of the 25th meeting of the Advisory Forum held in Stockholm (16-17 February 2011) *(Document AF26/4)*

5. The draft minutes were adopted without change.

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

6. The Director updated the Advisory Forum (AF) on the Centre's recent activities.[1] He expressed his concerns about a lack of MMR vaccination uptake and commended Hungary's efforts in connection with the Hungarian EU presidency to develop a common EU approach to vaccination issues.

7. The Chair continued with a review of recent activities that included updates on disease-specific work, country visits, public health development and external communication.

8. Haraldur Briem inquired whether ECDC had been asked for an opinion on the eradication or preservation of the smallpox virus. ECDC responded that there had been no such request from the Commission. Preben Aavitsland added that it was unlikely that the World Health Assembly would take a decision before 2019.

Item 4 : Update on the Hungarian EU Presidency

9. The Hungarian representative, Ágnes Csohán, updated the AF on Hungary's activities in connection with the Hungarian EU presidency.[2] She pointed out Hungary's efforts on childhood vaccination (a Council conclusion on childhood immunisation is pending) and provided additional information on past and future events on health topics in Hungary.

[1] Item 3 - Update from ECDC
[2] Item 4 - Update on Hungarian EU Presidency (A Csohán)

Item 5: Update from Office of the Chief Scientist (OCS)

Item 5a: Feedback on inclusion of the AF priorities for Scientific Advice in the 2012 Work Programme

10. Piotr Kramarz, Deputy Chief Scientist, ECDC, explained the scoring procedure for scientific advice in the 2012 Work Programme and named the top-scoring topics for every disease programme.[3] The Scientific Advice Coordination Section is scheduled to discuss proposals for expanding/enhancing the priority setting process with the AF in September.

11. Gérard Krause inquired about the details of the tallying process and how they will be used in work planning and also pointed out that Web-based voting might complicate matters for some users. He preferred working with an Excel spreadsheet, as this facilitated delegation to co-workers. He also suggested expanding the "general scientific advice" category. Piotr Kramarz emphasised that the AF priority scores are an important factor taken into account when planning work for the following year, but the other issues include resources and continuity of projects started in previous years.

12. In response to the question why migrant health was only mentioned in conjunction with one disease programme, Piotr Kramarz responded that it was mentioned under several programmes and with the current stream of migrants and refugees, it was quite possible that this topic would become one of the priorities overall.

Item 5b: Update on the process of delivery of scientific advice at ECDC

13. Piotr Kramarz outlined the comprehensive scientific advice process, which has been built in ECDC with the great help of the AF over several years, beginning with the selection of priority topics through the procedures of work on scientific advice and guidance documents to measuring the impact of scientific advice produced by ECDC.[4]

14. Preben Aavitsland supported the idea that ECDC initiates and maintains an online list of current scientific advice, guidance and risk assessment projects. This list should include a timeline and release dates in order that Member States can synchronise their projects with the ones currently in progress at ECDC.

15. The representative from the Commission commended ECDC's intent to evaluate the impact of its guidance and risk assessment documents.

16. John Watson commented on the issues related to the rapid risk assessments, stating that time-critical issues should be addressed by interim preliminary advice.

Item 5c: EVER - European Vaccine Epidemiology Resource: setting up a resource base for collecting, analysing and communicating data and information on immunisation programmes in the EU (Document AF26/5)

17. Pier Luigi Lopalco, Head of Vaccine-preventable Diseases Programme, ECDC, introduced a new umbrella project entitled EVER that would unify current projects such as VENICE, VAESCO, I-MOVE, and others.[5]

18. Petri Ruutu, although welcoming the integration of related projects, questioned the wisdom of outsourcing such a substantial amount of work and recommended that major projects should remain closely controlled by ECDC. This view was shared by Preben Aavitsland, who pointed out that EVER was too essential of an ECDC activity to be outsourced, a view seconded by Gérard Krause who

[3] Item 5a - Priorities for Scientific Advice (P Kramarz, A Janssen)
[4] Item 5b - Update on process delivering SA at ECDC (P Kramarz)
[5] Item 5c - EVER (P L Lopalco)

opined that quality control of outsourced projects was particularly difficult. Kåre Mølbak expressed similar management concerns. Preben Aavitsland added that he was missing plans for a survey among health professionals and the general public to track attitudes on vaccination.

19. Silvia Declich pointed out that a set of clear objectives was essential for all vaccination strategies (short-, mid- and long-term goals). She expressed doubts that short-term outsourced projects could lead to sustainable results and recommended a minimum project run of two years.

20. Frank Van Loock, European Commission, emphasised the need to have a more detailed output description of this project, in particular, showing how it fits the ECDC mandate and how output would be measured. Ágnes Csohán shared similar concerns, as vaccination is the responsibility of the individual Member States, while disease surveillance, data analysis and supporting laboratories to share best practices falls within the remit of ECDC.

21. ECDC's Director pointed out that the new EVER programme would alleviate budget problems, as, for example, ECDC funding for I-MOVE could not continue in its old form.

22. Pier Luigi Lopalco assured the AF that ECDC would not relinquish ECDC core capacities by outsourcing them. The EVER programme itself would not be outsourced; instead, it would be controlled by an ECDC steering committee that would oversee a framework contract (typically lasting between two and three years) with a consortium of institutions and only specific activities (like epidemiological studies or EU-wide surveys) will be outsourced to an external consortium.

Item 5d: Criteria to be used for collecting typing data in TESSy: rationale (info for action) and criteria required to use when deciding on typing strategy, based on no experience in regular typing (by MLVA) of food borne pathogens in national reference laboratories

23. Preben Aavitsland informed the AF on criteria for typing pathogens.[6] He pointed out that genotyping was mostly performed by MLVA (multiple loci variable number of tandem repeats analysis), by merit of its high discriminating power. He ended his presentation with a 'possible way forward for ECDC'.

Item 5e: Framework for enhanced surveillance for hepatitis B and C (Document AF26/7 Rev.1)

24. Marita Van de Laar, Head of Disease Programme HASH, ECDC, reported on efforts to implement enhanced surveillance for hepatitis B and C in 2012. The coordination group has met three times to develop the framework for enhanced surveillance of hepatitis B and C. Case definitions had been reviewed and revised, but the revised case definitions were still awaiting official ratification, a process which potentially could delay the project by another year. A first hepatitis surveillance report is planned for autumn 2012 (2006–2011 data).

25. Preben Aavitsland lauded the effort, but cautioned that the likelihood of obtaining reliable data was rather low. He also noted that the pharmaceutical industry strongly markets expensive treatments for hepatitis C in spite of limited evidence for beneficial long-term outcomes.

26. Marita Van de Laar tried to dispel the AF's concerns and assured the participants that data would not be abused. In the report, data quality would be rated and explained, and double reporting would become a thing of the past. She acknowledged that the project was ambitious, but still manageable. In response to Robert Hemmer's question, she pointed out that distinguishing between acute and chronic hepatitis (with 'unknown' as a fallback category) would enhance the informational value.

[6] Item 5d - Criteria for typing (P Aavitsland)

Item 7: Update: Safety and benefits of vaccines

Item 7a: Update from Sweden including plans for future research

27. Tomas Salmonson, Director, Scientific and Regulatory Strategies, Medical Products Agency, Sweden, informed the AF on the Swedish approach to vaccine safety and outlined the various steps taken after an alleged link between Pandemrix and narcolepsy.[7] Sweden is conducting a registry study to ascertain reported cases using two neurologists. More than 100 cases following immunisation have been reported in Sweden. Further, Sweden is participating in the VAESCO project association case-control study (through a research group at the Karolinska Institute) but has concerns about the VAESCO/CHMP timelines. Sweden will have some case-control sets ready in June 2011, but will continue to recruit new case-control sets throughout the rest of the year. In addition, several proposals were presented concerning possible studies on e.g. genetic and environmental contributing factors to the development of narcolepsy in affected individuals. Currently, there is no funding for such studies.

Item 7b: Update on the Association of Pandemrix Vaccination and Narcolepsy in Finland

28. Petri Ruutu reported again on research in Finland on increased numbers of narcolepsy in children and adolescents in Finland. The signal arose from spontaneous reports that have led to a cohort study conducted by THL in collaboration with Finnish narcolepsy experts. The cohort study has been finalised and sent off for scientific publication. The association observed is stronger in the final study, compared to the preliminary data presented to the AF in February 2011. Questions about confounders remain, since they cannot be addressed in the cohort study. Finland is participating in the VAESCO case-control study, where at least some confounders can be addressed. In addition, Finland is looking into how biological mechanistic studies can be performed and a research meeting is planned.

29. Gérard Krause inquired whether a dose-response analysis had been undertaken, e.g. if more cases occurred in individuals that received two rather than one dose of vaccine. Finland only provided one dose of vaccine, so no dose response was observed.

30. The Finnish and Swedish data also supported the assumption that an ascertainment bias (e.g. diagnostic bias) could be ruled out, as diagnosis of narcolepsy could be firmly established for each case.

31. Kåre Mølbak suggested that transmission patterns might be more relevant than age patterns.

Item 7c: The role of EMA in pharmacovigilance

32. EMA staff members gave a short overview of EMA's role in this context. EMA had earlier published a press release which stated that EMA's Committee for Medicinal Products for Human Use (CHMP) had recommended that the product information for Pandemrix should be amended to advise prescribers to take into account preliminary results from epidemiological studies on Pandemrix and narcolepsy, and to perform an individual benefit-risk assessment when considering the use of Pandemrix in children and adolescents. According to EMA, this was an interim measure pending the outcome of the European review, expected to conclude in July 2011.

[7] Item 7a - Update from Sweden including plans for future research (T Salmonson)

Item 7d: Methodological issues in relation to the ongoing investigations of narcolepsy

33. Pier Luigi Lopalco gave a concise review of major methodological factors that are relevant in the context of narcolepsy.[8]

Item 6: Update from Surveillance and Response Support (SRS)

Item 6a: Mid-term review of long-term surveillance strategy 2008-2013 (Document AF26/8)

34. Andrea Ammon, Deputy to the Director/Head of Resource Management and Co-ordination Unit, ECDC, informed the AF on ECDC's long-term surveillance strategy document.[9]

35. During the discussion, Kåre Mølbak suggested some editorial changes (addition of a time line), which Andrea Ammon accepted. Further modifications were requested by Derval Igoe (addition of emergency departments) and Silvia Declich.

36. Andrea Ammon bemoaned the fact that, despite ECDC's efforts to improve timeliness, data upload schedules still varied widely in the EU, with some countries providing daily data uploads while others only supply disease data once a year – a fact that severely limits ECDC's ability to detect outbreaks. She understood the underlying factors (staff and IT restrictions, financial restraints): "We always ask ourselves: how much would a Member State have to invest if they wanted to add a new disease to their surveillance system?" She also defended the decision to have only one Competent Body for surveillance, as this was both a cost factor and a technical matter that required a clear focus on the one person in charge.

Item 6b: Improving data comparability for surveillance of communicable diseases in the EU/EEA Member States (Document AF26/9)

37. Isabelle Devaux and Sergio Brusin, Epidemiological Methods Section, Surveillance and Response Support Unit, ECDC, presented a new project: a self-assessment tool to measure data quality in surveillance systems.[10]

38. Frank Van Loock, European Commission, applauded the project and added that its results could potentially be used as a performance indicator. Preben Aavitsland suggested that the project title should contain a phrase along the lines of 'helping Member States to improve their surveillance systems'.

39. Ágnes Csohán pointed out that meeting ECDC's unrelenting requests for surveillance data resulted in a double workload for her country. Her department had not received any budget increases since 2004 nor had any new staff members been hired during this period. Direct financial support from European sources would be much appreciated; at the same time, a lot of European funds went to the wrong address.

40. Isabelle Devaux agreed that comparability and quality should be the main focus. Denis Coulombier, Head of Surveillance and Response Support Unit, ECDC, added that the new project would not add a new burden to any of the Member States.

41. ECDC's Director encouraged Member States to apply for one or several of the 5000 € grants earmarked for national surveillance systems.

[8] Item 7d - Narcolepsy (P L Lopalco)
[9] Item 6a - Long-term surveillance strategy (A Ammon)
[10] Item 6b - Improving data comparability (I Devaux, S Brusin)

42. A suggestion by Herman Van Oyen to directly tap Commission funds was discouraged by the representative from the European Commission who stated that surveillance issues for communicable diseases are a MS responsibility and that support to this comes through ECDC.

Item 6c: MRSA typing project: review and discussion before the second phase of the project (Document AF26/10)

43. Marc Struelens, Head of Microbiology Coordination Section, Resource Management and Coordination Unit, ECDC, gave a recap of the MRSA typing project.[11]

44. The AF expressed their interest in the project, but also had significant concerns about the additional benefit of typing MRSA strains on EU level, especially given the large number of cases. To address these concerns, several AF members suggested that, in moving the project ahead, ECDC should be asking the project consortium to more clearly demonstrate the public health added value of molecular typing of MRSA for surveillance of staphylococcal infections and outbreak control, both at national and EU levels, and to assess the practical requirements for integration of clinical and epidemiological data with molecular typing data.

Item 6d: Impact of environmental use of azole derivatives on the development and increase of resistance to medical triazoles in human pathogenic Aspergillus spp.: short report from expert consultation

45. Niels Kleinkauf's (Risk Analysis Group, Response Section, Surveillance and Response Support Unit, ECDC) presentation was a response to a request by an AF member to elaborate on the relevance and magnitude of the *Aspergillus spp.* problem.[12]

46. Frank Van Loock, European Commission, expressed his regret over the fact that no prior consultation with DG SANCO services had occurred before the expert meeting was convened by ECDC on 26 April 2011. Nedret Emiroglu, World Health Organization, added that the WHO Regional Office for Europe would also like to get involved.

Item 6e: Epidemic intelligence: update on recent threats in the EU

47. Denis Coulombier hosted the segment on epidemic intelligence.

i. Belgium, investigation of an autochthonous case of malaria

48. Herman Van Oyen informed the AF about a case of malaria and the Belgian public health experts' efforts to identity the case's origin. The investigation remained inconclusive: 'This event remains an isolated case but must be seen in the context of emerging vector-borne diseases.'

ii. Greece, public health issues related to influx of refugees at the Turkish border

49. Sotirios Tsiodras reported on the difficult public health situation in Greek refugee camps.

50. Silvia Declich concurred with Denis Coulombier that a health assessment at the point of entry was essential. Some countries had begun vaccinating refugees according to national guidelines.

51. ECDC's Director pointed out that the EU had to invest in the countries of origin, and that the Commission had asked to add capacity aimed towards the Middle East and Northern Africa.

[11] Item 6c - Molecular typing in surveillance and control of MRSA (O Heuer)
[12] Item 6d - Meeting report_pathogenic Aspergillus spp (N Kleinkauf)

iii. Situation of measles in the EU: review and possible concerted action for the EU?

52. So far this year, measles cases have increased in a number of countries, including Denmark, France, Germany and the Netherlands. Tarik Derrough, Expert VPD, Surveillance and Response Support Unit, ECDC, gave a presentation on measles vaccination in the EU.[13]

53. Given the seriousness of the situation, Ágnes Csohán opined that all countries should report case numbers on a monthly basis. Haraldur Briem called the measles situation a 'public health scandal' and called for drastic measures. Frank Van Loock said that it was an embarrassment for the EU that U.S. public health experts now routinely issued health warnings due to the increased measles infection risk: 'Measles outbreaks are common in many areas, including Europe, making the risk for exposure to measles high for many U.S. travellers' (CDC, 2011 Measles Update).

54. Gérard Krause remarked that, contrary to conventional wisdom, it was not 'easy' to control (or even eradicate) measles and that there was a number of serious obstacles on the road to measles eradication.

55. The ECDC Director recommended concerted action on measles and called for five volunteers from the AF to establish a task force led by ECDC that would launch an all-out effort to promote measles vaccination.

56. Frank Van Loock, European Commission, cautioned that the solution to this problem might be different for every country, both in terms of risk groups and in terms of media response.

Results of the Working Group Sessions

Working Group A: International outbreak response

57. Derval Igoe summarised the results of her working group.[14] Thus far, international outbreak response showed limited success and feedback. Most ECDC missions had been carried out under the auspices of WHO's Global Outbreak Alert and Response Network (GOARN) or the WHO Regional Office for Europe.

58. The working group stated that ECDC participation in international missions had an added value (solidarity, gaining experience, scientific interest, capacity building, and international networking) and demonstrated the EU's competence in international outbreak response. The downside was that sending personnel on an extended outbreak mission created strains back home where jobs had to be 'backfilled'.

59. Gérard Krause said that in order to make an informed decision on this topic, the ECDC Management Board should be given a detailed list of pros and cons. At the level of implementation, he thought that a simple set of SOPs was insufficient and that international outbreak response should be based on a full-fledged strategy.

Working Group B: Criteria for molecular typing: what are the public health and European added values?

60. Kåre Mølbak emphasised that molecular typing at the EU level should be driven by practical surveillance needs, providing information for action. Following this concept, the working group identified seven areas in which typing data would improve surveillance and control of a disease/pathogen.[15]

61. Efforts to improve the situation in Europe are hampered by the heterogeneity between countries. A solution should include sub-regional collaboration, supported site visits and information exchange and best practice examples.

[13] Item 6e - Situation of measles in the EU (T Derrough)
[14] Working Group A
[15] Working Group B

62. Petri Ruutu noted that many countries were struggling with budget cuts and that reduced funding affected many national reference laboratories.

63. Continuing in the same vein, the Director said that it was difficult to find a way to bridge the resource gaps that exist in Europe. "We could make a difference", he said, "if we supported those countries that would benefit the most from our help."

64. Regardless of which typing method was chosen, two factors were essential: cost and portability/comparability, Kåre Mølbak pointed out. This was seconded by Johan Carlson, who thought it was important to find a way through the jungle of available methods by identifying methods that fit a country's needs and context.

65. Kåre Mølbak defined best practice as applying a specific method while taking care that the surveillance loop remains intact.

66. Ruth Gelletlie warned against underestimating the difficulties of adopting a common approach. She also pointed out the difficulties in receiving data from laboratories in order to evaluate the public health impact. At the same time, she encouraged countries to evaluate this technology, if their budgets permitted it. All in all, she concluded, the public health case for molecular typing still needed to be made.

Working Group C: Report back from the Working Group on Evidence-based Medicines for Public Health: Next steps?

67. Gérard Krause outlined the step-by-step approach of evidence-based methods for public health. The working group emphasised the need for better guidelines for conducting/reporting of outbreak studies, and rapid and sensitive search strategies ('intelligent data mining').[16]

68. Ruth Gelletlie added that a good system to capture all outbreak management decisions in a standardised format would be helpful.

69. Kåre Mølbak stressed the importance of a grading system for evidence in public health. In cases where no evidence was available (e.g. new threats), some precautionary principle should be incorporated into the planning.

70. Marianne van der Sande said that the working group's list for future development was highly impressive, but she wondered who would be developing all these tools.

71. Frode Forland, Scientific Advice Coordination Section, Office of the Chief Scientist, ECDC, responded that at this point, ECDC has focussed on assessing needs and feasibility, but there were also some training activities and projects in the pilot phase. Some of the mentioned tools were under development in the Surveillance and Response Support Unit (e.g. rapid risk assessments).

Item 8: Update from Public Health Capacity and Communication (PHC): EPIET Training Strategy

72. Arnold Bosman, Head of Public Health Training Section, Public Health Capacity and Communication Unit, ECDC, informed the AF on the latest changes in EPIET and EUPHEM.

73. Silvia Declich reported that out of 17 Italian EPIET graduates, only one returned to Italy. This was a factor behind Italy applying for the Member State Track, but the process proved to be difficult and more time consuming than expected.

74. Arnold Bosman explained that the EPIET office had to solve several legal issues, which delayed and complicated the implementation of the Member State Track, but that he did not expect any delays for the 2012 cohort. In response to a remark by Gérard Krause, he said that EPIET would eventually become a recognised academic programme, offering a Masters in Applied Epidemiology, but this was a long-term goal. He added that almost all EPIET graduates have secured jobs to date; however, the last cohort of graduates experienced difficulties in finding employment. A

[16] Working Group C

comprehensive alumni programme with a follow-up component would be beneficial to keep track of the career options embarked upon by EPIET graduates.[17]

75. Ruth Gelletlie agreed that EPIET had to address two problems: the brain drain and the inability of training people already in office. She therefore suggested that ECDC should target courses toward upscale public health staff already in office for 10 years or more. Web-based training courses and webinars (web seminars) aimed at senior local staff would be most welcome in the Member States.

76. Arnold Bosman stated that e-learning had been less of a priority as the Programme simply did not have the resources, but e-learning would resurface as a priority in the upcoming work programme.

Item 9: Report back from the Fineberg Committee

77. Preben Aavitsland, who served on the Fineberg Committee, reported on the recently released Fineberg Report and its critical stance towards WHO's handling of the influenza pandemic in 2009.[18] The full report is available from: http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_10-en.pdf

Item 10: Any other business

78. The Chair pointed out that ten delegates did not participate in the meeting and that ECDC endeavours to take measures to increase participation.

79. The ECDC Director thanked all participants for their hard work, focus and valuable input.

80. The next Advisory Forum meeting will convene in Stockholm on 28-29 September 2011.

[17] Following the meeting, Gérard Krause specified his interest in the development of CME credits for ECDC training modules. To this regard, Arnold Bosman noted that as of February 2011, ECDC has established a procedure to allow accreditation of all ECDC organised training modules through CME credits of the European Accreditation Council for Continuing Medical Education (EACCME)

[18] Item 9 - Report back from Fineberg Committee (P Aavitsland)