ECDC Advisory Forum

Minutes of the Extraordinary Audio Conference Stockholm, 4 February 2016

Draft Minutes

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Opening and welcome (noting declarations of interest, if any)

1. Andrea Ammon, Acting Director, ECDC opened the session and welcomed all participants.
2. Mike Catchpole, Chair and Chief Scientist, ECDC, noted that the meeting was being recorded, and that apologies had been received from Croatia, Estonia, Norway, and the representative of the Standing Committee of European Doctors. There were no declarations of interest made in response to a request from Mike Catchpole.

Item 1. Update on situation with regard to Zika virus transmission and related ECDC activities

3. Denis Coulombier, Head of Unit, Surveillance and Response Support, ECDC, explained that in light of the rapid spread of Zika epidemic and the postulated association with congenital malformation and neurological complications, ECDC had raised its PHE to Level 1. There had been a number of requests for information and guidance from the Commission which would be discussed at the Health Security Committee meeting next week. Today's teleconference had been arranged to discuss knowns/unknowns and find out how ECDC could support the Member States in the preparation of guidance.

4. Niklas Danielsson, Senior Expert, Communicable Diseases, Surveillance and Response Support, ECDC, gave a brief update on the situation with regard to the Zika epidemic and the current state of play. The epidemic had spread very rapidly since arriving in the Americas in 2014–2015, but it was difficult to measure the speed of the spread because the disease was underreported and there was a lack of diagnostic capacity and misclassification with dengue. The first signal of a possible link between Zika virus infection in pregnancy and congenital malformations came in October 2015 from Brazil.1 Since then, evidence for a causal relationship had increased through case reports but was not yet definite. It was also clear that with the current surveillance definitions in Brazil and other South American countries that the number of cases of microcephaly was likely to be a significant overestimate. The first signal of a link between Zika virus and Guillain–Barré syndrome (GBS) came from French Polynesia and was repeated in several South American countries, although the frequency of GBS after Zika virus infections was unknown. All indications were that the epidemic in South America was currently in its early stages and that it would continue to spread. So far spread in the southern hemisphere had been supported by the abundance of mosquitoes during the summer season. In recent weeks there had been a confirmed case of sexual transmission in the US and confirmed transmission via blood transfusion.2 ECDC was responding to a request from the Commission for an updated risk assessment on Zika; an update on information for EU citizens travelling to affected areas; information for healthcare professionals managing cases of Zika virus infection; ideas on how to monitor the risk of the epidemic spreading to the EU and overseas EU territories and a continued assessment of the risk for pregnant women and of the risk for transmission through substances of human origin. This information would be communicated to the Member States and the NFPs on Friday 5 February. Work was also ongoing to ascertain the capacity for diagnosis of Zika virus in the EU – the deadline for this is 12 February pending the results of a questionnaire, but some information would be provided at the Health Security Committee meeting on 9 February.

5. Denis Coulombier, Head of Unit, Surveillance and Response Support, ECDC, explained that there were three specific areas in which ECDC was looking for feedback from the Advisory Forum: travel advice issues, prevention of sexual transmission and prevention of infection/disinfection of aircrafts, which would be discussed with WHO in a teleconference that day.
6. Mike Catchpole, Chair and Chief Scientist, ECDC, asked AF members to indicate their priorities with regard to Zika and opened the floor for comments.
7. Paul Cosford, AF Member, UK, thanked ECDC for the helpful risk assessment on Zika that had already been published. To underpin further risk assessment work, it would be helpful to determine the strength of the link between Zika and microcephaly. His agency was currently using the wording 'there is now sufficient evidence to warrant public action'. He wondered what would be considered as criteria for disproving the link at a later date, particularly since cases of microcephaly were not yet being seen in other countries.
8. Anders Tegnell, AF Member, Sweden stated that the most problematic area in Sweden was in relation to sexual transmission. They wanted to give advice but were unsure what to say since the evidence was so scant. He wondered whether the aim of the advice should be to protect pregnant women and those intending to become pregnant or to stop further transmission. He did not believe that sexual transmission would represent a significant problem in northern Europe but asked for ECDC's views.

[1] See http://2009.campinas.sp.gov.br/saude/noticias/2016/not_02_16/not_02_0216b.htm

[2] http://www.dallascounty.org/department/hhs/press/documents/PR2-2-16DCHHSReportsFirstCaseofZikaVirusThroughSexualTransmission.pdf

9. Jean-Claude Desenclos, AF Member, France pointed out that the issue of diagnostic capacity for Zika virus in Europe was very important since capacity was very limited. ECDC should prioritise the need for cases to be confirmed and Member States needed guidance and information on antibody testing capacity. At present, evidence appeared to indicate that Zika could affect reproductive outcomes but this still had to be confirmed. In the meantime, there was not much more that could be written in guidance, apart from taking measures for protection, deferring travel, etc. With regard to sexual transmission of Zika virus, he agreed with Sweden that this did not appear to be a significant problem.

10. Darina O'Flanagan, AF Member, Ireland, said that the issue of most concern in her country was sexual transmission and advice relating to this. The evidence base was limited as yet and further evidence would probably only come from returning travellers. She believed that the UK approach, based on the precautionary principle pending further evidence, was the best option. WHO was constrained in terms of what advice it could give, in view of its global remit, and therefore its advice would differ from the advice given in Europe. She suggested that EU advice could focus more on protecting European citizens and on possible transmission in EU areas where the *Aedes albopictus* mosquito was present. France had action plans for its overseas territories but it would be useful if the EU could draw up similar plans for all the areas where the mosquito was present.

11. Denis Coulombier, Head of Unit, Surveillance and Response Support, ECDC thanked the AF Members for their contributions. Responding to the issue of causality and the link between Zika, GBS and microcephaly, he explained that ECDC had been examining the information available and to date all evidence suggested that there was indeed a link. A response would not be available very rapidly, as studies on this issue would take time. During a press conference, WHO Director Margaret Chan had talked about a strong link whereas the WHO Emergency Committee had been more cautious in its press statement. He agreed that it would be necessary to think about what the criteria would be for changing current views on causality. In response to Sweden's question regarding advice on sexual transmission he confirmed that in French Polynesia there had been evidence that the virus could survive in sperm, but to date there was no evidence of sustained transmission, only sporadic cases. Therefore there was no evidence that there would be a risk of extended transmission in the EU and focusing on the protection of pregnant women was more important at present. With regard to France's comments on diagnosis capacity, he explained that ECDC had commissioned a survey that was currently ongoing and should have a better idea of capacity within the next ten days. ECDC would work on algorithms for testing (as had been done for MERS-CoV and Ebola) so as to ensure that resources were not wasted. With regard to establishing the magnitude of the outcome for pregnant women exposed to Zika virus, he explained that the data from Brazil had not been very helpful to date. Whatever was recommended in Europe would have to be proportionate in terms of risk. The retrospective review currently being undertaken in Brazil with the support of the US CDC could be useful for this. The first results indicated that there was indeed a risk but it would still be necessary to agree on the level. He confirmed that more work on preparedness was in the pipeline at ECDC although one of the major unknown factors was the capacity of the vector to transmit the disease in the EU. ECDC was in contact with the French authorities in relation to their overseas territories and capacity was currently assessed as very high in the Caribbean, higher than in Portugal for dengue. This fact would have to be taken into consideration in the planning. When considering stratification of risk and whether the risk applied to all infected areas or just those with high transmission, he pointed out that it would also be necessary to consider how to lift or repeal the recommendations later as the epidemic subsided and transmission rates fell.

12. Mike Catchpole, Chair and Chief Scientist, ECDC asked for further comments and suggestions from the floor.

13. Aura Timen, European Public Health Association, said that her concerns related more to clinical/gynaecological monitoring for symptomatic and possibly exposed women. She pointed out that guidance differed greatly among European countries. Although this was not really a public health issue, she wondered if ECDC would be able to facilitate on the issue of general guidance among European gynaecologists. With regard to Denis' comments on risk stratification and targeting specific areas, she expressed some concerns on the figures being reported for Zika from certain countries in South America. The Netherlands had been continuously seeing imported cases coming from a specific country, however these were not reflected in the figures that the country itself reported to WHO.

14. Paul Cosford, AF Member, UK, said that it would be interesting to keep a close eye on Cape Verde and Colombia over the next couple of months as he believed these countries should be showing an increase in the number of microcephaly cases and/or early terminations of pregnancy with Zika as a likely cause. The UK had been considering levels of risk in countries affected by Zika and trying to determine the areas where there was significantly active Zika transmission. The UK had formulated its advice thus: 'If you travel to an area where there is a significant outbreak of Zika then the risk of being infected is quite significant. If you are not pregnant then the risk of serious consequences from a Zika infection is low but if you are pregnant then the risk of your child being infected is substantially increased.' At present unofficially the figures for babies born in Brazil with microcephaly were 0.5–2.0% which was why they were recommending to pregnant women that they defer travel. He confided that UK laboratories were currently testing the sperm of travellers returning with Zika (very few cases) and finding virus positivity one month after infection. This fact, along with the confirmed case of sexual transmission in the US, provided the basis for UK sex advice: male partners of women who were pregnant or considering pregnancy should use condoms for 28 days after returning from Zika infected areas. If returning male travellers had clinical symptoms compatible with infection they should consider prolonging condom use for up to

six months. The aim was to give travellers the information currently available to enable them to make choices. He asked ECDC to continuously update the list of affected countries as this was really helpful for Member States. UK was currently referring to ECDC's list to determine its travel advice.

15. Ágnes Csohán, AF Member, Hungary, referring to diagnostic capacity, pointed out that in many countries there was no capacity for Zika or other similar infections. She asked how countries could obtain support for establishing microbiological diagnostic capacity, particularly given the intense media interest. She also wished to know if a case definition was being planned for reporting and whether data collection at European level was being planned or whether ECDC believed this was unnecessary.

16. Kåre Mølbak, AF Member, Denmark, also wondered whether it would be useful to carry out some kind of surveillance on imported cases for Europe, having first agreed on an appropriate data set. He underlined the need to work on risk variables (e.g. how to define a significant outbreak or whether risk was confined to areas with new introduction of the virus.) In Denmark there had been confusion in relation to travel to Thailand where Zika was endemic at a very low level and not newly introduced. Another aspect which needed to be addressed was how and when to add and remove affected countries from the list. His third point was whether there should be screening or advice on condom use for travellers returning from affected countries having had no Zika-like symptoms at all. This was linked to the point on making use of diagnostic capacity and providing information to the public.

17. Darina O'Flanagan, AF Member, Ireland, asked about Africa in relation to stratification of risk and wondered what evidence was available on whether Zika was endemic in African countries, other than Cape Verde. The ECDC list was very useful but what was the general view on Zika in relation to Africa? It would be very beneficial for Member States to be able to stratify risk in those countries affected by Zika virus. With regard to surveillance of imported cases, she believed that it would be very helpful to collate this at European level and one of the variables would be to establish where the virus had been imported from in each case.

18. Marianne van der Sande, AF Alternate, the Netherlands, noted that within the EU the situation with Zika was complicated since in some countries Zika was likely only to be imported but in other countries (southern Europe and EU overseas territories) the vector could be present. She wondered how to deal with this issue. She recommended caution with regard to communication since surveillance was not yet strong and the risk was as yet unknown. This fact had to be made clear in communications, rather than just working on assumptions – a strategy which had been seen to backfire during the pandemic. Although in countries such as Thailand the risk was thought to be low, she pointed out that surveillance there was not so good. Therefore the risk was still inherent and should not be disregarded.

19. Mike Catchpole, Chair and Chief Scientist, ECDC, noted that the key issues appeared to be the list of affected countries, stratification of risk, surveillance, screening and diagnostic support.

20. Denis Coulombier, Head of Unit, Surveillance and Response Support, ECDC, responding to comments on stratification of risk, explained that in its risk assessment ECDC had included a definition involving two levels: sporadic and widespread transmission. Widespread transmission was defined as where there were more than two areas with autochthonous transmission in an affected country or where there were more than three weeks of cases occurring in one area. It was necessary to be extremely sensitive because many cases were not being reported. In the Americas, stratification was easier because in all the countries affected the populations were naïve and, once autochthonous transmission was established, this tended to develop into widespread transmission. However, in countries with endemic Zika, such as Thailand, it was more difficult to stratify the risk. There were questions such as what constituted a baseline and what would happen after an epidemic wave. This could cause other new countries to be included in the list as the epidemic evolved. The situation in French Polynesia had been very different to that now being seen in Brazil due to differences in scale. In Africa, transmission was ongoing, but at quite a low, sporadic level. One of the factors which might affect Cape Verde was the small population – only 500 000 people – which meant that signals were not so strong, unlike Brazil, with a large population and a high number of cases. With regard to reporting, ECDC was currently in discussion with the Commission because Zika did not figure in EU reporting requirements. ECDC would revert with more information on case definition and variables as soon as possible. With regard to disinfection, WHO's Emergency Committee had recommended following standard procedures, however it was unclear whether this advice applied to all areas or was differentiated. ECDC had information that WHO planned to stratify disinfection advice depending on the country concerned. The second aspect was the type of product being recommended and whether this conformed with EU regulations. ECDC would revert to Member States following a teleconference with WHO later that day.

21. Mike Catchpole, Chair and Chief Scientist, ECDC thanked all the AF Members for helping to identify the key issues requiring focus. With regard to support for diagnostic capacity, he confirmed that ECDC was in contact with various networks about what could be done and had a number of teleconferences scheduled over the next few days. ECDC's list of affected countries would be updated daily. If AF members wished to raise any other issues he suggested that they should send an email to him or get in contact as necessary.