



ECDC Advisory Forum

**Minutes of the Seventy-second meeting of the ECDC Advisory Forum  
Stockholm, 21-22 February 2023**

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## Opening and adoption of the programme

1. Andrea Ammon, Director, ECDC, welcomed the participants to the 72nd meeting of the Advisory Forum which was taking place both in person and via teleconference.
2. Mike Catchpole, Chief Scientist, ECDC, welcomed the participants to the meeting, and in particular the newly-appointed members Greg Martin (Ireland), Trygve Ottersen (Norway), Anneli Carlander (Sweden). He also welcomed Laura Gillini and Thomas van Cangh, joining the meeting online from DG Santé.
3. The draft programme was adopted with no changes and there were no conflicts of interest.

## Adoption of the draft minutes from the 71<sup>st</sup> meeting of the Advisory Forum, 14 December 2022

4. An amendment, requested to the draft minutes of the AF meeting from December 2022 (Norway) had already been incorporated. A further change was requested (Sweden) to Point 17 to remove Sweden from the list of countries from which deaths had been reported for *Streptococcus*. No deaths had been reported, only an increase in the number of cases. The minutes were duly adopted, with the change noted.

## Long-term surveillance framework 2021-2027

5. Vicky Lefevre, Head of Unit, Public Health Functions, ECDC, gave a short presentation and the floor was opened for discussion.
6. Mike Catchpole, Chief Scientist, ECDC, said that this was a major strand of work for ECDC that was relevant to its amended mandate. Although it represented an exciting opportunity, it clearly also had implications for ECDC and for those providing data.
7. Natalia Kerbo, AF Alternate, Estonia, referring to the project to improve classification of national surveillance systems through grants, which was to be discussed during the meeting of NFPs for Surveillance in May, asked whether she was correct in understanding that ECDC intended to collect suggestions from the Member States and organise a consortium.
8. Aura Timen, European Public Health Association, asked about vulnerable groups and whether there were any separate goals to improve surveillance in Europe for these groups. She also asked whether ECDC was planning to use citizen science to achieve its goals in surveillance.
9. Greg Martin, AF Member, Ireland, said that in Ireland they were planning to create a biostats and modelling unit and were thinking about AI and machine learning, all of which was new to them. He therefore wondered if it might be possible to work together with others who were facing the same challenges.
10. Koen Blot, AF Alternate, Belgium, said that in Belgium they were currently looking at pandemic preparedness planning and there were common issues. One of the issues was the number of sentinel hospitals, with plans to increase the number from six to 10 as part of capacity building. However, during a crisis, 10 would possibly be insufficient, depending on the requirements of the stakeholders (health authorities). Therefore, as an undercurrent there was an element of upscaling of systems within pandemic preparedness and he wondered if this would come into play in the framework for long-term surveillance.
11. Bruno Coignard, AF Member, France, pointed out that pandemic preparedness was linked to zoonotic diseases, and he therefore wondered how ECDC would interact with other sectors and EFSA in a 'One-Health' approach to detect outbreaks earlier.
12. Anneli Carlander, AF Member, Sweden, referred to a comment on page 11 of the document relating to SARI surveillance and asked what was meant by 'explore the feasibility and added value of using public health records.'

13. Marko Korenjak, European Liver Patients' Association congratulated ECDC on its amended mandate. Referring to Whole Genome Sequencing (WGS) he wondered whether ECDC had a special group of legal experts who could advise on this issue.

14. Jaap van Dissel, AF Member, The Netherlands, said that he wished to see a paragraph added on governance and privacy issues connected to enhanced surveillance as this was a major issue in the Netherlands and it would be helpful if ECDC could be more explicit on this subject.

15. Jan Kynčl, AF Member, Czechia, pointed out that in smaller countries with limited capacity someone would need to perform the relevant activities at national level. It was therefore important that ECDC emphasised the fact that new duties required new capacity since legislative requirements usually had to be implemented with existing capacity and no additional funding.

16. Mike Catchpole, Chief Scientist, ECDC confirmed that this was a very important point.

17. Vicky Lefevre, Head of Unit, Public Health Functions, ECDC, responding to the comment about the project to improve the capacity of national surveillance systems through grants, said that this issue had already been discussed with NFPs for Surveillance and for Microbiology at the annual meeting and that work was ongoing. The European Commission had set aside EUR 97 million in their 2022 work plan which needed to be allocated by the end of 2024 and this would be done by means of a grant mechanism, with direct grants to countries. The next step would be for ECDC to discuss this with countries and identify their needs. The idea was to focus on digitalisation and this was why it would be preferable to have people on site for the upcoming NFP meeting in May in order to have a better content discussion. Vulnerable groups had not been included because this was a generic, high-level document, and this issue was better addressed within specific disease areas. On the subject of machine learning and AI, she noted that ECDC had mainly been applying AI in epidemic intelligence, not for indicator-based surveillance data. ECDC has developed the epitweetr tool to screen social media (Twitter), so ECDC was certainly able to provide some support in this area. With regard to SARI support, ECDC was working in two different areas: setting up SARI hospital-based surveillance under a VEBIS project and also through the e-health programme for SARI surveillance which was supporting the countries in setting this up on the basis of e-health records. In terms of scaling up for pandemic preparedness, she saw this as part of the setting up of systems, however, there were currently no plans to obtain funding to scale this up. Nevertheless, under Article 8 of the Cross-Border Health Regulations, ECDC had a mandate to assess countries' preparedness plans and health systems and based on such assessments, gaps would be identified and Commission funding could be made available to address these gaps. Therefore, in the longer term this represented a form of support for pandemic preparedness. Responding to the question on zoonotic diseases and 'One Health' integration, she confirmed that this was seen as part of the integration and was currently ongoing for food and water-borne diseases, where molecular surveillance was being set up with EFSA to integrate data from food and humans. Other areas were zoonotic flu and antimicrobial resistance (AMR).

18. Karl Ekdahl, Head of Unit, Disease Programmes, ECDC, confirmed that this was being integrated on a disease-specific basis. Work had now started on having a 'One-Health' framework and although it was not included in the new mandate, the importance of looking at everything from a 'One-Health' perspective was stated in the preambles. Work had already been going on in the areas of AMR and foodborne diseases for some years and this was now being expanded to vector borne diseases, in particular West Nile virus, which was also linked to surveillance and ECDC was now going to look at the impact of climate change on both surveillance and scientific advice.

19. Vicky Lefevre, responding to the question from Sweden on e-health programme activities, explained that ECDC was working with an external contractor who supported the countries individually and directly in setting up surveillance systems based on electronic health records for predefined diseases. With regard to the question on WGS, she explained that genome data were being collected for bacteria and viruses, but not for humans. Referring to the point about smaller countries lacking resources, she confirmed that ECDC was aware of this. In the ongoing review of the diseases under EU/EEA surveillance, the intention is to limit the number of diseases reportable to the EU level to those where coordinated action is required at that level. She also referred to the upcoming surveillance grants to directly support countries in a targeted manner.

20. Andrea Ammon, Director, ECDC, pointed out that it was time for ECDC to change the way it had interacted with the countries for this to become more of a dialogue. With the many changes which were being made it was important not to lose the overview of the whole system, which still had to work in a crisis. She saw this as a good opportunity to look into the development of a community of practice, whereby those with more experience could share with those who were just starting out. It was important to be able to accommodate this and to obtain incentive and support from one another. With regard to vulnerable groups, she pointed out that it would be necessary to find a way to capture data from these groups without increasing the burden on the Member States. With regard to the point made by the AF Member for Czechia regarding lack of resources, she agreed that there was a need for real investment at national level.

21. Henrik Ullum, AF Member, Denmark, congratulated ECDC on its impressive work with the document as this was definitely the way forward. With regard to the points made on WGS and privacy issues, he explained that in Denmark they had been challenged on sharing data on microbiological specimens because these were personally sensitive. He therefore agreed that it would be helpful if ECDC could provide guidance on how it interpreted the possible legal challenges which would arise due to the sharing of data, even though final decisions would lie with the individual countries.

22. Koen Blot, AF Alternate, Belgium, referring to the issues of upscaling and privacy, sharing information on his work with the sentinel hospital system in Belgium, said that they were developing a legal framework whereby, instead of sending clinical and microbiology information, during a crisis this framework could be activated and only basic clinical data would be provided. This could also potentially be implemented at sentinel laboratories. With regard to privacy, he emphasised that this would be very important in the future as all countries had systems with personal health data and innovation meant that data systems were being linked and more detailed epidemic intelligence was becoming available. This called into question the issue of privacy and there was also the moral/ethical element of how much information could be held for public health reasons.

23. Mike Catchpole, Chief Scientist, ECDC, referring to the issue of vulnerable groups, noted that this had been a major area of discussion during the trilogue negotiation meetings between the European Parliament, the Council and the Commission. However, he pointed out that if data on these groups was not captured at national level it could not be captured at EU level. With regard to the issue of privacy and GDPR, he noted that ultimately this was a question of national interpretation. ECDC could provide advice, but he suggested that it might be more powerful if the directors of the Competent Bodies could put out a joint statement on this issue.

24. Andrea Ammon, Director, ECDC, noted that ECDC was also using some of the funding made available for new posts to hire a data protection officer to strengthen its legal team in order to address such issues.

25. Vicky Lefevre, Head of Unit, Public Health Functions, ECDC, thanked the AF members for their feedback. She understood that the difficult issue was that of data protection/GDPR, however it was also important to ensure that ECDC did not overstep its mandate in this area.

## **Implementation Science – implications for future ECDC scientific advice development**

26. Mike Catchpole, Chief Scientist, ECDC, introducing the item and giving the presentation, pointed out that ECDC's revised mandate heralded a new era of dialogue between the Agency and the Member States.

27. Following the presentation the floor was opened for discussion.

28. Jaap van Dissel, AF Member, The Netherlands, said that this was a very relevant, but difficult topic. It was important to try and make a distinction between advice and implementation. Recommendations were made on the basis of epidemiological/medical evidence but then had to be 'translated'. In the end there were political choices involved and these were different for each country. In the Netherlands, they tried to find middle ground by presenting different scenarios which enabled politicians to make a choice. Once a decision had been taken it was then necessary to ensure that

communications were streamlined. However, this was not the same as implementation science, which the public health institute in the Netherlands had tried to avoid.

29. Henrik Ullum, AF Member, Denmark said that one of the major challenges was that states had had to implement measures without solid evidence. Now that the crisis was over, it was important to look at what types of evidence might be needed for future outbreaks. In the beginning, the COVID-19 response in Denmark had been completely governed by medical experts, but as the pandemic progressed, it became clear that other expertise – crisis researchers, administrative experts, economic experts – were needed and these other types of expertise also had to be taken into account.

30. Trygve Ottersen, AF Member, Norway, said that there had been quite some discussion in Norway about how implementation issues should be taken into account in policy advice and how much of that should already be integrated into the advice itself, rather than approaching this from a purely biomedical perspective. Issues of compliance is very much part of this, as is communication. Communication is obviously a key area when talking about implementation of measures, as public behaviour for most of the measures are part of the causal chain. In Norway they had tried to include more behavioural scientists as the pandemic progressed. One area where more could have been done is coproduction and understanding of public preferences, for example with regard to how different measures negatively impacts different population groups in different ways. This is an area to consider before the next crisis.

31. Natalia Kerbo, AF Alternate, Estonia, pointed out that guidance could relate to diseases other than COVID-19.

32. Marta Grgič Vitek, AF Alternate, Slovenia, said that it was important to include the appropriate stakeholders, depending on the issue in question and whether it was during a crisis/outbreak or not. When planning for preparedness, the question was at what stage during an outbreak would coproduction be most valuable.

33. Rebecca Moore, European Institute of Women's Health, was delighted to read the document which made explicit the need for broader consultations and inclusion of stakeholder groups. She suggested that patient groups could also be included as this gave a certain legitimacy (the European Medicines Agency were offering training for patient groups).

34. Aura Timen, European Public Health Association, gave a brief summary of the work done by EUPHA for the Joint Action SHARP to strengthen preparedness in the EU against serious cross-border threats to health. They had examined the situation in four EU countries, looking at citizens' needs on how they wished to be engaged (16 focus groups). They had found that some groups felt the need to be seen by advisory committees and government bodies deciding on measures. At the same time, they did not express an overwhelming desire to move from being informed to being consulted, so it seemed that people simply wanted to have channels to be able to share their opinions and engage in the process.

35. Mika Salminen, AF Member, Finland, agreed with the comments made on engagement and stakeholders. In particular, he recognised the comments made about the type of recommendation proposed during a crisis being different to that proposed during peace time. It was also important to understand what was meant by stakeholders. When ECDC or national institutes recommended measures, there were those targeted by the measures, those implementing, those funding and even those indirectly affected despite not being targeted. National institutes were only a small part of the system and it was impossible to estimate all the effects, good and bad, of the measures taken during a pandemic. He believed it would be expedient for the AF to be informed at the start of any process on the drafting of recommendations, instead of during the later stages. It was also important to look at how such recommendations were distributed, since interpretation of ECDC guidance was also a problem. There were often many different interpretations, sometimes diametrically opposed, so a clarification as to who should be the national interpreter might be useful. He also believed that national institutes alone should not issue measures as they were unable to see all the consequences. He therefore suggested that ECDC could consult other institutions (national, social science, economic, healthcare providers, WHO Health Observatory, OECD, etc.) when developing recommendations.



36. Carlos Matias Dias, AF Member, Portugal said that he shared some of the views expressed by the other AF members and felt that this was one of the main challenges facing ECDC. He saw this document could be seen as a way of looking at the potential for changing the status quo at national and European level. If working in a small municipality, an expert might be experienced at dealing with pandemic measures at the local level but not at national or EU level. In Portugal, during the pandemic implementation of measures at national level was carried out by national health authorities. The stakeholders were only involved at the very end of the process, just before the measures were announced. The media were important stakeholders in that they communicated the measures to the public. In Portugal, scientific meetings were held once a month during the crisis, with a public part including scientific experts and a closed part, where scientists and politicians would discuss the element of uncertainty in the available options. He fully endorsed this topic as an area for further development and felt that the involvement of stakeholders should also be discussed, including the media and politicians.

37. Anneli Carlander, AF Member, Sweden, commented that recommendations needed to be based on best evidence but that they also needed to recognise that legislation and feasibility varied in different countries. It was also important that not just infection prevention and legal aspects were taken into account, but also aspects such as proportionality, ethics, and long-term social consequences. She agreed with Finland's comment regarding stakeholders. In Sweden, most measures were implemented both at local and regional level and therefore allowance was made for different interpretations of these measures.

38. Isabel De La Fuente Garcia, AF Member, Luxembourg, said that there was a need to involve people on the ground, frontline and clinical workforce representatives who could be consulted at the review stage as they would have a more realistic view of the resources available and could help to ensure that nothing was omitted from the field and they could also give neutral feedback. In larger countries this was probably already incorporated into well-structured contingency plans, but this was not the case in smaller countries.

39. Trygve Ottesen, AF Member, Norway agreed with the comment by the AF Alternate for Estonia, that too much focus was placed on COVID-19 in examples and planning. He offered two recent non-COVID-19 examples with great potential in Norway – one related to monkeypox vaccination, where it would have been good to have a ready-made framework in place, and the other related to research preparedness. The public was not prepared for operational research in the midst of a crisis, especially not when it involved randomisation, so they needed to be involved and prepped over a longer period of time. One example might be their involvement in the coproduction of guidelines for use during the next crisis.

40. Mike Catchpole, Chief Scientist, ECDC, thanked the AF members for their feedback. COVID-19 had highlighted some of the issues, however, some of the proposals might not be feasible for smaller countries in terms of capacity. ECDC was therefore interested in understanding the scope of feasibility for smaller countries from the outset. Current discussions had revealed the importance of involving the public, which had also been discussed at ECDC and with the Management Board and, as further steps were taken, this issue would also have to be discussed again in more detail.

41. Andrea Ammon, Director, ECDC, noted that it had always been the view of the Management Board that ECDC should not communicate with the public (i.e. non-scientific audiences). However, during the pandemic it had become obvious that the public were accessing ECDC's website, reading its recommendations and contacting the Agency to ask questions. The concern had been more that ECDC was not addressing the specific public in a country and therefore, any campaigns would be run by the national institutes where ECDC would provide the necessary material, as for European Antibiotics Awareness Day, and the countries could use and adapt it as they saw fit.

42. Mika Salminen, AF Member, Finland, responding to the discussion about communicating to the public, noted that such communication could be problematic and that the ideal solution would be for ECDC to produce materials that could then be interpreted and translated in the Member States. This would avoid i) sub standard translations in a complex area and ii) legal challenges in connection with recommendations. He advocated finding a sustainable solution whereby ECDC could provide products which could then have national context added.

## **Proposal for a survey on post COVID-19 pandemic workforce/human resource shortages for surveillance, prevention and control of communicable diseases in EU/EEA countries**

43. Mike Catchpole, Chief Scientist, ECDC, introduced the paper which had been prepared by the AF Alternate Member for Hungary.
44. Koen Blot, AF Alternate, Belgium suggested that the issue of duration of financing should be added, since half of the epidemiological personnel working during outbreaks were on short term contracts, which strongly affected the sustainability of the workforce.
45. Jan Kynčl, AF Member, Czech Republic thanked the AF Alternate for Hungary for preparing the paper and raising the issue. He suggested that national coordinators could be potential partners/stakeholders as their role had a significant impact.
46. Marta Grgič Vitek, AF Alternate, Slovenia, thanked the AF Alternate for Hungary and supported this initiative. She pointed out that although the paper discussed shortages that occurred after COVID-19, some countries had been very under-resourced before COVID-19. In Slovenia, there was a great deal of funding going to new clinics but not to the Institute of Public Health and it was difficult to recruit people to work on surveillance of infectious diseases. She wished to see minimum standards in order to be able to advocate for institutional capacity at national level.
47. Natalia Kerbo, AF Alternate, Estonia, pointed out that recruiting an educated/trained workforce was a problem in that so many educated professionals had left the public authorities during the pandemic due to burn-out and younger generation colleagues were now supporting the surveillance work. All countries were very different and it was difficult to find a gold standard but she felt that it was important to define the difference between 'professional' and 'supporting' workforce.
48. Trygve Ottersen, AF Member, Norway, agreed that it is important to consider the time period for the survey as the situation differ over time. He gave the example of his situation where he was losing around many people each month and had been doing so for around a year, and where the workforce was decreasing more quickly than the workload. He suggested that information should also be captured with respect to some other, less "classical" competencies, such as behavioural science and economics, etc. It would also be useful to know what countries were doing to keep experienced professionals now that the pandemic was over.
49. Henrik Ullum, AF Member, Denmark, agreed with the point made by the AF Member for Belgium regarding sustainability of the workforce. In Denmark there were many specialists who were interested in working in infectious diseases but they needed to be able to provide them with longer-term contracts and better working conditions.
50. Bruno Coignard, AF Member, France, agreed with comments by the AF Members for Belgium and Denmark. In France they were having difficulties in retaining those who had been recruited because of the long working hours, so workload was a very important parameter. With regard to outsourcing, when the workforce was insufficient it was necessary to outsource supporting activities. Therefore, he suggested trying to find a way to document how national public health institutes outsource activities, as with the existing proposal it was not possible to document that.
51. Mika Salminen, AF Member, Finland, said that they had the same retention issues and although they were now scaling down, they were making strategic decisions on permanent positions where possible, even if they were uncertain of funding, to cover future activities. He also pointed out that it was important to think about some of the new professions they would need and include these in the survey. He strongly supported the work on this survey and thought it would be very useful to have a comparison among Member States.
52. Anneli Carlander, AF Member, Sweden, thought the survey was a good idea but she wondered about the intended outcome. She asked how this matter could be taken forward at EU level.



53. Carlos Matias Dias, AF Member, Portugal, was in favour of conducting the survey as it would help ECDC to determine the minimum level of workforce in public health surveillance necessary at national level for future purposes. It would provide a clear description of reasons for people leaving public health surveillance and might also be able to identify some of the solutions being used by countries to tackle this issue. He also supported the comments made by the AF Member for Finland.

54. Bruno Coignard, AF Member, France, pointed out that in his country the laboratories were entirely outsourced and therefore it would be difficult to evaluate their work. It might therefore be necessary to define what was meant by supporting surveillance and to distinguish between primary laboratories, reference laboratories, etc.

55. Mike Catchpole, Chief Scientist, ECDC, noted that there seemed to be broad support for the proposal and that it would be important to highlight the potential variations and shortfalls. He suggested that it might be useful to arrange a Working Group discussion to look at this issue in more detail. He thanked the AF Members for their feedback and the AF Alternate for Hungary for preparing the paper.

## **Update on ECDC Scientific Outputs – review of 2022, forward look 2023**

56. Barbara Albiger, Principal Expert, Scientific Quality, Scientific Methods and Standards Unit, ECDC, gave a short presentation and the floor was opened for discussions.

57. Greg Martin, AF Member, Ireland, was delighted to see that ECDC was producing podcasts and asked if there were any plans to expand on what was already available – for example by turning rapid risk assessments into podcasts.

58. Jaap van Dissel, AF Member, Netherlands, noting that transparency had been mentioned as an important goal, asked whether there was an overview of the data made available online – e.g. underlying data from studies.

59. Anneli Carlander, AF Member, Sweden, noted that there were a huge amount of publications planned for 2023 and suggested that it might be useful for Member States to know which areas the publications covered in order to be ready for any surveys being planned.

60. Carlos Matias Dias, AF Member, Portugal, said that the number of requests for information was impressive and he wondered whether it was possible to analyse these requests in terms of questions asked or link them to operational research topics.

61. Barbara Albiger, responding to questions, said that there was a list of the planned publications at the end of the document and that a list of the planned surveys would also be provided. With regard to the content of information requests, there had been many questions regarding monkeypox, hepatitis and COVID-19. ECDC was working on further centralising requests for information and improving sorting/filtering so data mining and text mining would be useful. With regard to data access, she explained that most people were able to access the data if they requested it and contractors were also asked to make data available.

62. Bruno Coignard, AF Member, France, suggested that the daily and weekly Communicable Disease Threat Reports should also be included as these were very useful.

## Update on matters related to the amended ECDC mandate

### *EU Health Task Force*

63. Thomas Hofmann, Head of Section, Emergency Preparedness and Response, Public Health Functions Unit, ECDC, gave a short presentation and the floor was opened for discussion.

64. Natalia Kerbo, AF Alternate, Estonia, asked about the size of the groups. She wondered whether the NFPs for Preparedness would be involved in the training and she suggested that it might be better to have a broader training programme, especially if it was being organised as e-learning modules.

65. Anneli Carlander, AF Member, Sweden, asked for clarification of ECDC's mandate in relation to the enhanced emergency capacity of the EU Health Task Force and the role of the Member States. In the Regulation outlining ECDC's new mandate, it stated under Article 11a that procedures concerning the mobilisation of the enhanced emergency capacity of the EU Health Task Force were to be adopted under the implementing acts. According to the meeting documents, the framework and practical mechanism for activating the Task Force, its mobilisation and deployment would be undertaken by the ECDC coordination team and the ad hoc working groups. She asked how this interaction would work with the implementing acts and the involvement of the Member States under Article 11.

66. Bruno Coignard, AF Member, France, asked whether ECDC had already begun selecting experts from the Member States, given that the first deployment could be summer 2023.

67. Isabel De La Fuente Garcia, AF Member, Luxembourg, queried the short-term membership of one year, given that it would take time for training.

68. Thomas Head of Section, Emergency Preparedness and Response, Public Health Functions Unit, ECDC, explained that the ad hoc working group would consist of 11 people, voted for by the NFPs in the Member States, and these people would not undergo training. The training would be for everyone who was in the pool. Although some of the people in the ad hoc working group might continue, there would be a new process for the steering group from 2024 because its role would be different to that of the advisory group. The groups would not be part of the pool. With regard to the Implementing Act, he hoped that Laura Gillini from DG SANTE would be able to provide more information when she arrived in Stockholm the next day. With regard to the establishment of a support team, this would also be discussed with the ad hoc working group.

69. Andrea Ammon, ECDC Director, said that the EU Health Task Force represented a fundamental change to ECDC's mandate involving enhanced interaction and the process was dynamic. Over time, the group would probably grow and require people with different languages and disease expertise/public health functions. It was possible that people would receive training in specific outbreak functions, which would also be advantageous for the Member States, facilitating improvement of workforce skills.

### *Substances of human origin (SoHO)*

70. Marieke van der Werf, Head of Section, STI, Blood-borne viruses and TB, and Vanja Nikolac Markic, Principal Expert, Microbial safety of substances of human origin, Disease Programmes Unit, ECDC, gave a short presentation which was followed by a discussion.

71. Henrik Ullum, AF Member, Denmark, noted that this was a difficult area to move into which had been run for a long time using the precautionary principle. He therefore suggested that it might be useful to work on the principle of risk calculation, as in other areas.

72. Jaap van Dissel, AF Member, the Netherlands, asked about the definition blood cells and organs related to reproduction and also about faecal transplants (used for *C diff* treatment and metabolic syndrome).

73. Marko Korenjak, European Liver Patients' Association, understood that the Council of Europe was responsible for the monitoring of blood safety, and wondered whether ECDC would be taking over responsibility for this monitoring as well.

74. Marieke van der Werf said that she understood the point about SoHO being a complicated area in which many different organisations are working. They had included a number of observers in the SoHO network, to incorporate their ideas. She confirmed that they planned to listen to the experts, by setting up scientific panels for the development of guidelines. ECDC was dependent on the Member States nominating the appropriate experts for the network. ECDC had set out a list of criteria but some countries had managed to adhere more closely to the criteria than others. With regard to the precautionary principle or risk calculation, when ECDC develops the guidelines for testing and ensuring the microbiological safety of SoHO, they intend to have a good expert panel to advise in this area. They are also discussing these issues with the Chief Scientist. Responding to the question as to what was included in SoHO, the proposed regulation had a wider scope than the previous one and it is proposed to also include e.g. faecal transplants and breast milk. ECDC would be responsible for any guidelines on the microbial safety of SoHO and is currently discussing with the Commission and European Directorate for Quality of Medicine (EDQM) what the borders are between laboratory safety and microbial safety in order to ensure that there are no overlaps.

75. Vanja Nikolac Markic, Principal Expert, Microbial safety of substances of human origin, Disease Programmes Unit, ECDC, explained that the Council of Europe set up the European Directorate for Quality of Medicine (EDQM) some years ago and this body had published technical guides for blood, tissues, cells and organs and they would continue to do so. However, this body did not really monitor communicable diseases in the world of SoHO. It was impossible to separate other SoHO issues from microbial safety. The Commission had contracted EDQM some years previously just to analyse data in this area. One of ECDC's new tasks would also be monitoring of potential transmissions in this field in real time, and obviously this involved more than just collecting data on an annual basis.

76. Andrea Ammon, ECDC Director, pointed out that when the recommendations came into force they would be binding, which meant everyone would have to become more involved in SoHO in the future.

77. Henrik Ullum, AF Member, ECDC, said that to date donor protection had always focussed on infectious threats to the recipient. These days with good regulations in effect, occurrences were rare. However, protein depletion in plasma donors etc., was still a frequent occurrence and he wondered if ECDC's mandate would cover this.

78. Marieke van der Werf explained that it was not connected to communicable diseases and therefore did not come under ECDC's mandate. It fell within the domain of EDQM and would continue to do so in the future.

### ***EU Reference labs (EURLs)***

79. Yoline Kuipers, Policy Officer, Unit B2, Health Security, DG for Health and Food Safety, European Commission and Karin Johansson, Principal Expert, Molecular Surveillance for Communicable Diseases, Microbiology and Molecular Surveillance, Public Health Functions Unit, ECDC gave a short presentation which was followed by a discussion.

80. Greg Martin, AF Member, Ireland, asked whether one function of the EURLs could be to audit national reference laboratories and if so, this could be important under Option 3.

81. Natalia Kerbo, AF Alternate, Estonia, said that this type of reference centre would be very useful, however she wondered whether there was any overlap with WHO's reference centres.

82. Jan Kynčl, AF Member, Czech Republic, answering the questions set out in the paper under the section 'Scope of the consultation', said that 1) with regard to gaps in the diseases covered by the current disease networks, it was desirable to support the activities of the existing network as it was not yet known exactly which agents would be covered by the EURLs; 2) the future EURLs should cover all the activities set out in the list (a-g), and 3) those activities/support functions that should be given particular attention in order to further improve quality were the regulation of external QA for reference laboratories and increasing the capacity of molecular and WGS typing laboratories.

83. Anneli Carlander, AF Member, Sweden, suggested that COVID-19, RSV and influenza could be placed in the same network. A network for highly pathogenic agents was also needed. She asked how

the cooperation with the WHO reference laboratories would be designed and whether this would be coordinated or duplicated for the same diseases. She would provide further comments from colleagues in writing.

84. Bruno Coignard, AF Member, France, was pleased to see this topic finally advancing. With regard to the list in Annex 1, he suggested starting with the list of disease pathogens instead of the disease surveillance networks in order to include some rare pathogens that could benefit from a surveillance network – e.g. rabies. He asked how ECDC intended to coordinate the EURLs with HERA's European reference laboratories for diagnostic devices to avoid overlaps. He also asked for clarification on the designation of EURLs in the first quarter of 2024 and wondered whether this was referring to specification of needs or selection of candidates.

85. Aura Timen, AF Member, European Public Health Association, asked about the interface between human and animal microbiology. She wondered whether the EURLs had to be Member State reference laboratories.

86. Koen Blot, AF Alternate, Belgium, pointed out that the EU reference laboratories had a role in cross border outbreak investigation through genomic sequencing and coordinating of samples and also that there were some pathogens for which there were very few samples available (e.g. those associated with bioterrorism).

87. Jaap van Dissel, AF Member, Netherlands, reiterated the importance of a 'One-Health' approach and also pointed out the consequences in terms of laboratory findings. For example, one Member State might produce much more poultry and many of the pathogens have severe economic consequences. He asked how this issue would be tackled, suggesting that there would have to be interaction with EFSA or other agencies to deal with these consequences.

88. Karin Johansson, Principal Expert, Molecular Surveillance for Communicable Diseases, Microbiology and Molecular Surveillance, Public Health Functions Unit, ECDC, responding to the question on the audit function of EURL, said that she was aware that many of the current EQAs organised by contractors were used for accreditation at national level and the expectation was that this would continue, if not increase. ECDC could not mandate the use of EQAs but they should be available, should the national system deem that they were appropriate for accreditation. In response to questions about coordinating with WHO, she pointed out that the legislation was very new but that they were discussing the role of their coordinating centres with WHO and how the EURLs could be aligned with this. The reason for starting with the laboratory networks rather than the list of disease pathogens was that ECDC wished to try and build on existing functional collaborations rather than destroying existing networks. She agreed that there was some streamlining to be done to the current networks, such as combining COVID-19 and flu, as suggested by the AF Member for Sweden. With regard to sequencing capacity/EQAs, this was the reason for modifying activities because so much had changed since 2016 when the initial report was drafted. With regard to 'One Health', the networks working on FWD, AMR and emerging vector borne diseases were already collaborating with their colleagues on the food/animal side and where there were EURLs on food and animal health, the intention was that this would continue. In terms of the funding, this would come from a variety of elements, even though there were currently no plans to fund/establish EURLs with a specific 'One Health' mandate. The general surveillance, monitoring and coordination of outbreaks would continue through TESSy and EpiPulse, with additional support from ECDC.

89. Andrea Ammon, ECDC Director, confirmed that there would be no duplicate reporting. Although the role of the EURLs in monitoring was yet to be defined, it would not open a second line of reporting.

90. Karin Johansson, referring to the eligibility of the laboratories, said that the Regulation set out certain criteria for the laboratories (being free of bias, having the required expertise) so this would mean there was a natural tendency towards the national laboratories. However, the competent authorities in each Member State would be the ones to nominate.

91. Yoline Kuipers, Policy Officer, Unit B2, Health Security, DG for Health and Food Safety, European Commission, referring to EURLs for in-vitro diagnostics to illustrate the point about the long nomination process, said that national authorities had to nominate the laboratories they wished to see

become EURLs, then the Commission reviewed the nominations and finally formalised. They were currently trying to look at ways in which to shorten this process.

92. Vicky Lefevre, Head of Unit, Public Health Functions, ECDC, referring to the 'One-Health' component, said that this issue had been raised at the meeting of NFPs for Surveillance and Microbiology. She pointed out that there was no reason why an EURL specialising in *Salmonella* detection in food or animal sources could not become an EURL for public health, however the laboratory would have to comply with all the criteria.

93. Bruno Coignard asked for clarification of the nomination process as this was quite complicated. After selection at Member State level, he wondered what would happen if there were several laboratories selected since there would not be an open call for tenders. He was also concerned about the criteria for selecting laboratories.

94. Karin Johansson said that they had to use the existing system for nominating EURLs since the system already existed for areas other than public health. Member States were asked for nominations. The laboratories were then designated and asked to apply for funding. However, there were still a number of issues to be clarified, such as the case of a consortium of laboratories in different countries. Referring to the collaboration with other EURLs (a project called 'Durable' funded by HERA), she said that ECDC was aware of the project and involved on the Steering Committee and there would be a kick-off meeting in late February after which further information would be made available to the AF members.

96. Koen Blot, AF Alternate, Belgium, pointed out that operations at Member State level and the EU level could be different and that this needed to be taken into consideration.

## **ECDC Chief Scientist's Annual Report on the work of the Advisory Forum in 2022**

97. Mike Catchpole, Chief Scientist, ECDC, gave a broad overview of the report and noted that the link to ECDC downloadable datasets was now online in Webex along with the link to Ireland's study on burden of disease/cost of information requests. With regard to future meetings, he asked whether it was reasonable to stipulate that for some meetings AF Members should attend in person.

98. Maarit Kokki, Head of Executive Office, ECDC, said that this issue had been discussed with other groups, including the Management Board, and the general consensus was that when in-depth discussion was needed, presence in the room was preferred, which was why she would advocate for in-person meetings where possible.

### **Day 2**

## **Feedback from Advisory Forum Working Group Sessions on Generating evidence through coordinated epidemiological investigations and operational research during public health events**

### ***Working Group A***

99. Greg Martin, AF Member, Ireland, gave a short summary of the Working Group's discussions. Early in the COVID-19 pandemic, there was a great deal of confusion about aspects such as incubation period, infectivity period, mode of transmission, etc., yet there was the feeling that information on these very obvious questions was not available even though this was the kind of operational research that could be done very quickly. The group had discussed the idea of using randomised control trials which, in the context of operational research (e.g. clusters, cities) and in the context of a multi country outbreak, could be conceivable and perhaps interesting for ECDC. Funding was also a function of the political role in the countries, and it was important for ECDC to advocate for funding for operational

research. There had also been a discussion about ECDC having some kind of fund available for multi-country operational research. They had also discussed the importance of collaborating cross country in the context of operational research.

100. Henrik Ullum, AF Member, Denmark, referring to randomised control trials, said that during the pandemic, they had realised in Denmark that the evidence was weak, but it was not the appropriate time to discuss the issue, whereas now, in 'peace time', was the right time.

101. Mike Catchpole, Chief Scientist, ECDC, was interested in the comment about the early questions that needed answering. For influenza many countries had a first few 100 investigation protocol yet it sounded as though this had not been used during the COVID-19 pandemic.

102. Henrik Ullum, AF Member, Denmark, pointed out that the infection fatality rate would have really helped to determine how big the impact would be on society, yet that was one of the major questions that was unknown. If countries had collaborated on this earlier in the pandemic, perhaps more answers would have become available.

103. Mike Catchpole asked generally whether AF Members had included influenza in their pandemic preparedness plans.

104. Greg Martin, AF Member, Ireland, said that in Ireland they had had a flu pandemic plan however they did not use it at any point during the crisis. They had tried to look at the literature in the early stages of the pandemic but that was not very helpful.

### **Working Group B**

105. Anneli Carlander, AF Member, Sweden presented the feedback from Working Group B.

106. Henrik Ullum, AF Member, Denmark, referring to the first slide, pointed out that every outbreak was always unexpected. With regard to the point about divergent results, he pointed out that sometimes results were released and then there were local geographical locations where there were anomalies, so there were always challenges with conflicting results.

107. Mike Catchpole, Chief Scientist, ECDC, suggested that perhaps the issue was the interpretation of the results.

### **Working Group C**

108. Aura Timen, European Public Health Association, presented the feedback from Working Group C which was followed by a discussion.

109. Bruno Coignard, AF Member, France, described a solution which had worked for his institute which involved it working with another agency, the National Research Agency for Emerging Infectious Diseases, an agency which was preparing operational research in peace time to be ready for a crisis.

110. Trygve Ottersen, AF Member, Norway, said that it is possible for ECDC to support countries individually to better prepare for fast research, as well as how to better coordinate with other countries, but the latter adds a layer of complexity. In Norway they had had some successes with regards to intervention studies of the effect of public health and social measures, but also a long list of study plans that had to be aborted due to different barriers (including time, alignment with policy cycle, political acceptability, legal, ethical clearance). With regard to topics for research, he emphasised research on the effectiveness of interventions. At his institute this was the area in which they were investing a lot of energy at present.

111. Mike Catchpole, Chief Scientist, ECDC thanked the AF Members for the useful information. He suggested that desktop exercises might be one way of exploring the challenges. Another solution might be something similar to the situation in the UK which involved a collaboration between academic research units and the national public health body which had created a structure that could be mobilised very quickly. However, he pointed out that although this was an area in which improvement was needed, it was important not to take too many parallel paths.



112. Bruno Coignard, AF Member, France, said that in France they wanted to link together different databases on vaccination, as had been done in the UK. As they had not been able to do this as quickly as they wanted in France, they had not been able to produce the same type of information. Behavioural studies were also important in order to assess how the population was adopting prevention measures.

113. Greg Martin, AF Member, Ireland said that when carrying out a trial across multiple countries it was important not to be too prescriptive, since different countries had different approaches and priorities. For example, during the pandemic, Ireland had been concerned about case numbers but other countries with a larger number of ICU beds per capita might have had different priorities, and these factors needed to be taken into account.

114. Henrik Ullum, AF Member, Denmark, said that the databases that were most useful in a crisis were the ones that had been established and maintained during 'peace time'. Although in Denmark they had a national database both for vaccination and one for microbiology covering all microbiological results in Denmark, and although this was boosted by COVID-19 results, the basic infrastructure had to be in place before a crisis occurred. With regard to academic collaboration, he commented that in Denmark they were setting up a similar network to the one described in the UK and hoped that this would help in the next crisis.

115. Jaap van Dissel, AF Member, Netherlands, said that one of the underlying components was that healthcare was national and not European, so all interventions needed to be addressed in context of national priorities and ideas. In the Netherlands, the priority was efficiency, keeping costs down and ensuring that hospitals were competitive, which was the opposite of Denmark or the UK which had national systems. In the Netherlands, hospitals did not share information on admissions because there was an element of competition involved. Therefore, although in the Netherlands they did have all the data, it had been difficult to access and connect it. One of the major challenges had been to link all databases, which had still not been completely achieved so they could not automatically link vaccination numbers to testing. With regard to a pre-ethical clearance, it was possible but it took many months and still involved further research. On the other hand, funding was not an issue.

116. Mike Catchpole wondered if there was some way to fast-track ethical clearing during a crisis, even though he was aware that this might be more difficult in certain countries. He suggested that some countries could be the pioneers for cross border operational research in the form of some proof of concept work in the first instance.

117. Trygve Ottersen, AF Member, Norway, said that in Norway financing or researchers had not been the limiting factors with regard to conducting rigorous effectiveness studies. Rather, one limiting factor was simply time and lack of a prepared set of protocols. Another key barrier for many proposals for randomised control studies of public health and social measures was legal constraints, including with respect to individual consent. He suggested that some support on how countries can review and approach these issues and better prepare could be useful. This includes how to prepare the public with respect to research within and between crises. Experience from Norway suggested that sometimes decision makers were initially in favour of research, including randomisation, but later hesitated due to concerns about public acceptability.

118. Carlos Matias Dias, AF Member, Portugal, said that in Portugal there had been a task force for the vaccination and the actual vaccination roll-out had been handled by the military who were more interested in the operational aspects. The amount of preparedness also depended on the type of research in question – e.g., preparedness for pathogen research, research on the effects of intervention measures, research into behaviour, public opinion, etc. If ECDC wanted to have a centralised system for gathering signals from across Europe, these signals would come from the laboratories and therefore the interface between research led by laboratories and research led by academic institutions or public health institutes was important. During the COVID-19 there had inevitably been divergent research results which had very rapidly been transferred to the public and political arena and discussions about causality could sometimes backfire. Therefore, when preparing research agendas to use in a crisis, it was important to have several studies at different levels. In Portugal they had one centralised agency for IT and information systems which held all registries from the public sector. This was an important factor that allowed them to link records, build electronic cohorts and carry out studies on vaccine effectiveness. He also wondered whether it would be possible to look at mathematical data for the

purposes of operational research as there would be a great deal of retrospective data available on the crisis.

119. Aura Timen, European Public Health Association, said that it was important to take advantage of low hanging fruit in the form of the capacity to be able to undertake operational research should another outbreak emerge, by having a generic protocol ready (on the shelf), and then having the momentum, political or public, to move forward.

120. Vicky Lefevre, Head of Unit, Public Health Functions, ECDC, said that it was a question of how ECDC could drive this forward. It was important to study the design protocols, know the networks and the tools available, and determine where to start – possibly by mapping the tools/partners in Europe.

121. Alexander Šimunović, AF Alternate, Croatia, said that he would support simulation exercises as these could be done in real time and transformed into a real situation very quickly and practically.

122. Henrik Ullum, AF Member, Denmark said that what was needed was a simple output protocol, based on the generic questions to be answered for any outbreak. It would then be necessary to create a data model, carry out meta analysis and then finally find some partners to work with.

123. Jaap van Dissel, AF Member, Netherlands, said that during the pandemic, small groups of countries had begun interacting together and this had been very helpful. Although ECDC was not involved, this was perhaps a model that it could explore for the future, whereby the Agency could initiate contacts and help countries to work together in groups to share information, new findings and ideas on research.

124. Greg Martin, AF Member, Ireland, said that there were two types of questions that needed answering – the first concerned transmission dynamics and the second concerned the effect of NPIs.

125. Andrea Ammon, Director, ECDC, agreed that there was preparation that could be done and that the main issue was the protocols. She suggested that a package could be prepared in advance for a protocol, obtaining as much pre-approval and funding as possible. She agreed with the idea of carrying out work to link databases and computers where possible. Technical issues also needed to be overcome – she quoted the example of ECDC's insufficient capacity to run its models – and noted that the solving of such technical issues could be included in a preparedness plan. With regard to diverging results, the most important aspect was how these results were communicated. It was important to build a consensus within the community first and look at initiatives already taken to see how to harness these and determine whether they could be used as a basis for other projects. ECDC would investigate whether funding could be made available quickly via DG Research and the EU4Health Programme. She noted that the free-range protocols used for hepatitis would perhaps have been useful during the COVID-19 pandemic.

126. Mike Catchpole, Chief Scientist, ECDC, thanked the Working Groups for their feedback and excellent discussions.

## **Update on Epidemic Intelligence and response support activities**

### ***Public health considerations for MPX in the EU/EEA***

127. Vicky Lefevre, Head of Unit, Public Health Functions, ECDC, gave a short presentation.

128. Jaap van Dissel, AF Member, Netherlands, said that the arguments put forward in the Netherlands were to prepare to communicate with high-risk groups and to offer them vaccination. In the Netherlands they had done extensive modelling on the effectiveness of the monkeypox vaccination which had shown that, if the 0.7% of the population who were highly active became infected, a herd immunity threshold was achieved that actually caused the outbreak to wane, as had been observed last summer. Therefore, monkeypox appeared to be less infectious than had been assumed and the highest risk group would have already had the infection. Nevertheless, the outbreak had highlighted the fact that this type of disease could be globally active, if introduced into a certain group, and it was important to communicate this fact. The problem was that even in the Netherlands, where there was little stigma, this group was hard to reach.

129. Henrik Ullum, AF Member, Denmark, said that it was important to prepare for long-term work on this issue because the underlying drivers of the outbreak had not disappeared. There would be new introductions and a new young cohort who were unvaccinated and sexually active so there could be a new outbreak. For this reason, complete elimination might not be feasible either. By continuing to vaccinate, test and advise the high-risk population, it would be possible to keep the outbreak under control and monkeypox would be just another sexually transmitted disease.

130. Mike Catchpole, Chief Scientist, ECDC, noted that the cost benefit argument for elimination did not appear to be compelling.

131. Laura Gillini, DG Santé, wondered whether there was still interest in/demand for the monkeypox vaccination as HERA had just delivered the second batch of vaccination, but there was little demand for it, unlike last July when there had been a shortage. Many countries had had the vaccination donated by HERA and had not procured it themselves. She agreed about not striving for elimination but wondered whether countries were confident that they could procure vaccinations, undertake testing and have a long-term strategy for monkeypox if they did not believe that the argument for elimination was compelling.

132. Kamilla Jósefsdóttir, AF Member, Iceland said that in Iceland high-risk groups had been targeted via PrEP advisers. In Iceland, it was illegal to vaccinate a person without entering a name in the system so it was difficult to vaccinate the groups of sex workers that they had reached out to via a voluntary organisation on an anonymous basis. They were continuing to vaccinate and although there were criteria for being vaccinated, they were not very strict. They had received a second delivery of monkeypox because their stocks of smallpox were unsafe and because the shelf-life of the monkeypox vaccine would enable them to keep it for longer and also to use it against smallpox if necessary. In Iceland, there were quite high rates of sexually transmitted diseases, so they needed to use every opportunity possible to engage with the community in question and to promote health messages in general. Elimination was a double-edged sword and for this disease it was unlikely to be successful because not all the risk groups were known. Using the word 'elimination' could backfire badly if countries campaigned for it and then it did not work.

133. Marta Grgič Vitek, AF Alternate, Slovenia, said that for as long as monkeypox was perceived as a non-serious disease it would be very difficult to eliminate. In Slovenia, the MSM group was very well organised and they had requested the vaccination before it was even available. However, if trying to eliminate it completely, those with very high-risk behaviour would probably not be reached.

134. Vicky Lefevre, Head of Unit, Public Health Functions, ECDC said that ECDC's guidance would cover how to reach out and protect this group, continued monitoring, testing, awareness-raising and offering the vaccination to high-risk groups. She was also glad to hear that everyone appeared to be in agreement on the elimination issue.

## Update from ECDC Director

135. Andrea Ammon, ECDC Director, gave a short presentation on her recent activities.

## IRIS – Principles and process

136. Barbara Albiger, Principal Expert, Scientific Quality, Scientific Methods and Standards Unit, ECDC, gave a short presentation.

137. Mike Catchpole, Chief Scientist, ECDC, said that the idea was to look at broad topics and then identify specific activities. IRIS was a collaboration process between ECDC and AF which had been going on for over a decade and had been refined over the years to become a powerful tool. He explained that the AF members would receive a package of proposals to read before the next AF meeting. He also pointed out that discrepancies in scoring created a background for really useful discussions and therefore it was much better to attend in person if possible.

138. There was no other business.

139. Mike Catchpole, Chief Scientist, ECDC, thanked the AF members for the excellent discussions and contributions, noting that it had been great to see so many of them attending in person and to meet the new members. The next meeting would be on 16-17 May 2023, and he looked forward to seeing everyone then.

**Annex: List of participants**

<b>Member State</b>	<b>Representative</b>	<b>Status</b>	<b>Participation Mode</b>
Belgium	Koen Blot	Alternate	In person
Croatia	Aleksandar Šimunović	Alternate	In person
Czech Republic	Jan Kynčl	Member	In person
Denmark	Henrik Ullum	Member	In person
Estonia	Natalia Kerbo	Alternate	In person
Finland	Mika Salminen	Member	Online
France	Bruno Coignard	Member	In person
Germany	Ute Rexroth	Alternate	Online
Hungary	Zsuzsanna Molnár	Member	In person
Ireland	Greg Martin	Member	In person
Italy	Silvia Declich	Member	Online
Lithuania	Jurgita Pakalniškienė	Member	Online
Luxembourg	Isabel De La Fuente Garcia	Member	In person
Malta	Tanya Melillo	Alternate	Online
The Netherlands	Jaap van Dissel	Member	In person
Portugal	Carlos Matias Dias	Member	In person
Slovenia	Marta Grgič Vitek	Alternate	In person
Sweden	Anneli Carlander	Member	In person
	Birgitta Lesko	Alternate	In person
<b>Observers</b>			
Iceland	Kamilla Jósefsdóttir	Member	In person
Norway	Trygve Ottersen	Member	In person

<b>European Commission Non-Governmental Organisations (NGOs)</b>			
European Public Health Association	Aura Timen	Member	In person
European Institute of Women's Health	Rebecca Moore	Member	In person
European Liver Patients' Association	Marko Korenjak	Alternate	In person
<b>European Commission</b>			
DG SANTÉ	Laura Gillini		Online/In person
DG SANTÉ	Thomas van Cangh		Online
DG SANTÉ	Yoline Kuipers		Online