



Report on the meeting of the European Ombudsman's inquiry team with the European Centre for Disease Prevention and Control

Correspondence - 08/09/2021

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INQUIRY: OI/3/2020/TE

Case title: How the European Centre for Disease Prevention and Control gathered, assessed and communicated information during the COVID-19 pandemic

Date: Monday, 05 October 2020

Participants

European Centre for Disease Prevention and Control:

- Public Health Emergency Managers
- Principal Expert Emergency Preparedness and Response - Group Leader Response and Emergency Operations - Public Health Function Unit
- Head of Section Legal Services and Procurement
- Head of the Public Health Functions Unit

European Ombudsman:

- Fergal O' Regan - Chief Legal Expert - Directorate of Inquiries
- Tanja Ehnert - Case handler - Directorate of Inquiries
- Michaela Gehring - Case handler - Directorate of Inquiries
- Dorien Laermans - Case handler - Directorate of Inquiries
- Vieri Biondi - Inquiries officer - Case-handling Unit

Introduction and purpose of the meeting

The purpose of the meeting was to help the Ombudsman's inquiry team better understand the context in which the European Centre for Disease Prevention and Control (ECDC) operates and how it ensures transparency in relation to its work during the COVID-19 pandemic.

Amongst other issues, the Ombudsman's inquiry team sought to clarify how the ECDC gathered, assessed and communicated information on the COVID-19 pandemic.

In that context, the inquiry team asked for clarifications and explanations on the documents the Ombudsman had already obtained from the ECDC.



The Ombudsman's inquiry team informed the ECDC that the applicable rules provide that the Ombudsman will not disclose any information or documents identified by the ECDC as confidential to any person outside the Ombudsman's office without the ECDC's prior agreement.

The meeting took place virtually, respecting all applicable social distancing rules.

Issues discussed **On how the ECDC generally operates**

The Ombudsman's inquiry team asked the ECDC to explain how ECDC collected information from Member States during the COVID-19 pandemic.

The ECDC explained that it has four main means of obtaining information:

1. The European Surveillance System (TESSy)

The ECDC's main source of information is TESSy, a system to which Member States upload, at a predefined frequency (currently weekly for COVID-19), data on diseases under surveillance using standardised formats. In the very early stage of the pandemic, COVID-19 was not yet one of the diseases listed in TESSy. In accordance with Article 9(2) of Decision 1082/2013 [1], where an event may constitute a public health emergency of international concern in accordance with Article 6 of the Decision, Member States report the initially imported cases to the Early Warning and Response System (EWRS). In accordance with past practice, the WHO considered that reporting to EWRS fulfils the Member States obligations towards the WHO [2]. Within a few weeks, the WHO case reporting form was implemented in TESSy.

When COVID-19 was added to TESSy on 27 January 2020, the ECDC started collecting case-based data from Member States directly. The COVID-19 reporting form used in TESSy is the same as the one used at WHO level.

The ECDC explained that national authorities in the Member States have access to TESSy's extranet where they can find guidelines and instructions. They can also contact a helpdesk, which is dedicated to guiding them in the reporting process.

2. Epidemic intelligence screening

The ECDC conducts epidemic intelligence screening by monitoring official websites from public health authorities worldwide on a daily basis to gather information on the number of cases and deaths in real time. This was especially useful in the early stage of the pandemic, when the risk of importation in Europe depended on the epidemiology of COVID-19 elsewhere in the world and there was some delay in the Member States reporting to TESSy. At the moment, the daily epidemic intelligence screening still complements the TESSy data, as by "scraping" Member States' official websites it can enrich and complete the information that Member States report to TESSy.



3. Early Warning and Response System of the European Union (EWRS)

The ECDC explained that the EWRS is a notification system for the European Commission and the National Focal Points for Threat Detection in the EU/EEA Member States. As the EWRS is a notification tool for risk managers in Member States and the Commission (DG SANTE), the ECDC's role is limited to operating and monitoring the system. It does not actively participate in the posting of messages on threats.

Every time a Member State detects a disease which fits the EWRS criteria as stated in Decision 1082/2003, it needs to report relevant information through the EWRS within 24 hours. In the early stage of the pandemic, there were some misunderstandings about how to report COVID-19 related information in the system, as a few Member States used a different thread than the one initially launched by the Commission. However, this had no implications as all messages are in the same tool and can be easily retrieved. The ECDC and the Commission rearranged the available information in order to make it easier to manage.

Activity in the EWRS has remained at a very high level with threat notifications and selective exchanges between Member States since the beginning of the pandemic. The incident management module designed to collect information on response measures taken by countries has proven not to be very effective during the pandemic. For this reason, a response measures database has been built by the ECDC in cooperation with the JRC. The EWRS is a less structured system than TESSy and extracting information from it in an automated manner is more difficult as it was also not designed to receive large amounts of information. Therefore, from when the first importations started to occur in the EU/EEA countries and the UK, information on case numbers started to be reported in TESSy (this was about a month before community transmission was detected in North Italy).

4. Surveys conducted by the ECDC

The ECDC distinguished between surveys that it carries out as part of its routine work ("*in peacetime*") and those launched during the pandemic.

Routine surveys are planned two years in advance and are discussed in an *ad hoc* committee, which assesses their relevance and appropriateness. ECDC surveys are normally presented in its work programme, which the Commission reviews annually. In addition, deadlines are usually much longer than the ones given during the COVID-19 pandemic (weeks instead of days).

The ECDC explained that when the subject of a survey relates to the implementation of public health measures, it is the Commission (DG SANTE), as coordinator of national public health measures, which initiates the survey. As the difference between public health measures and scientific assessment might be narrow, the ECDC can be asked to review surveys prepared by the Commission before they are launched. During the pandemic, the ECDC did so in relation to certain surveys that the Commission launched through the EWRS. When, however, a survey is exclusively of a technical nature, the ECDC carries it out independently. The Commission and the ECDC often prepare complementary reports.



The ECDC noted that during the pandemic, most of its surveys were carried out upon request from the Commission. The ECDC used surveys only when the requested data could not be collected through alternative means, such as TESSy, the EWRS or the epidemic intelligence screenings. For example, the ECDC noted that it never asked Member States to submit information about their lockdown measures, as it could obtain this information by consulting their official websites.

As an example of a situation in which it had to carry out a survey, the ECDC mentioned that it was asked to compare the different incidence rates of the virus in all Member States. In order to carry out such an analysis, it needed to know what the different testing strategies were in the Member States and thus launched a survey to collect this information. It then published it as part of its weekly outputs to allow decision makers to understand the meaning and quality of the data published by Member States.

The ECDC further noted that surveys are often the starting point and that, in certain cases, Member States then realise the value of the information requested and start making such information proactively available. The ECDC added that it might also decide to start collecting such information on a regular basis by adding an entry in TESSy or through its epidemic intelligence screenings.

The Ombudsman's inquiry team asked the ECDC to explain the reason why, in its view, the results of the two surveys on laboratory shortages of March 2020 differed from the ones of the EVD-LabNet 2019 n-CoV laboratory preparedness survey of 22 January 2020.

The ECDC explained that these are two very different surveys conducted at different stages of the pandemic. The differences can be explained by different aims, times (January versus March), questions, completeness of response / survey participation and type of respondents.

The first survey used the EVDLabNet and was sent out on 22 January 2020 to the Operational Contact Points for Influenza representing 81 laboratories in, among others, 30 EU/EEA countries. The survey was closed on 29 January 2020. The results were published on 13 February 2020. [3] The survey intended to assess the required expertise and capacity for molecular detection of 2019-nCoV in specialised laboratories in 30 European EU/EEA countries at a very early stage.

The March survey was conducted upon the Commission's request and was intended to assess laboratory shortages during the first wave with the aim of launching a joint procurement for personal protective equipment and laboratory materials.



The Ombudsman's inquiry team asked how Member States cooperated with the ECDC during the pandemic

The ECDC explained that, in the context of the pandemic, the level of Member State response to surveys was lower than normal and noted that, in many cases, the most affected countries were the ones with lower response rates. The ECDC considered that this was understandable in the context of the crisis and that it was probably due to the higher workload experienced by these Member States. The ECDC added that it tries to follow up with individual Member States or to fill the information gaps by using alternative data, if possible.

In reply to the question whether the ECDC would now organise differently how it launches its surveys, the ECDC replied that this question is addressed as part of an internal review of the early stages in the COVID-19 crisis. It added that it has started presenting updates on surveys and upcoming actions in weekly COVID-19 calls with the COVID-19 network (in the framework of national competent bodies) and the WHO. It considers these meetings useful to prepare the launch of surveys and increase response rates.

The Ombudsman's inquiry team asked how the ECDC cooperated with the WHO and the Chinese Centre for Disease Control and Prevention (Chinese CDC) during the pandemic.

The ECDC said that it has regular and intense contacts with the WHO at various organisational levels, including weekly bilaterals on surveillance, and weekly meetings on various microbiological matters.

The ECDC referred to the COVID-19 case definition and noted that, initially, the WHO definition (and also its own) was limited to people who visited the Wuhan wet market area. On the basis of the number of infections and the geographical information available, the ECDC decided to diverge from the WHO definition, as it considered it to be too restrictive, and to include those who had been in any part of China. The ECDC considers that this decision might have helped delay the spread of the virus in Europe, which was important in allowing testing capacity to be built up. However, at the time, it was not known that there was a high number of asymptomatic cases and that, consequently, screening in airports was ineffective.

Regarding the Chinese CDC, the ECDC explained that there was intense cooperation already before the signature of the memorandum of understanding in 2007. It noted that during the pandemic, the Chinese CDC was very collaborative and shared with the ECDC relevant data and information, and even translated it into English.

The ECDC is not in a position to assess whether or not the Chinese CDC shared *all* the information it had and whether or not it did so in a timely manner. However, the ECDC has



no reason to question the cooperation with the Chinese CDC. It noted that it received information from the Chinese CDC that was adding value to what ECDC could detect through epidemic intelligence. Furthermore, the public sharing of the genetic sequence of the virus was done in an extremely timely manner. Also, the information received on the management of cases was considered good. The ECDC added that where it noted that there was a lack of information, it tried to get back to the Chinese CDC with specific questions, such as about the geographical spread of the virus and the probability of human-to-human transmission.

Any issues in relation to the information coming from China might have been due to the structure of the Chinese health system. The ECDC noted that the local public health authorities in China report to the Chinese National Health Commission, which is linked to the Ministry of Health, and not to the Chinese CDC. Therefore, if the Chinese CDC did not communicate certain information, or did not communicate it earlier, the reason could have been that they themselves did not have this information at the respective point in time.

The ECDC further noted that, during the COVID-19 outbreak, the situation was changing rapidly and the information received increased gradually. It noted that the early symptoms of COVID-19 are common to many other diseases and that it is normal that during the outbreak of a new disease early information is uncertain. The ECDC said that if the outbreak had started in the EU, it would have probably faced the same challenges in detecting it before it led to sustained community transmission. The ECDC noted that the Chinese CDC published a first paper on this issue as early as 21 January 2020. [4]

By way of example, the ECDC noted that in Italy, there was already community transmission by the time the virus was detected in an individual without history of travel to the affected countries in Asia.

The Ombudsman's inquiry team asked the ECDC whether it is conducting any internal review of the way in which it acted during the COVID-19 pandemic.

The ECDC said that it has produced a guidance document for future "*in- and after-action reviews*" related to COVID-19. [5] However, it considers this step premature whilst the pandemic is ongoing.

At this stage, the ECDC has commissioned an external contractor to conduct a review of how the public health emergency has been handled. The contractor has interviewed ECDC and Commission staff. The review will take into consideration the actions of the ECDC, the Commission, the WHO, and the JRC. The review covers a strategic and performance analysis of ECDC's response to COVID-19 from the detection of the first cases of COVID-19 in China until October 2020. The evaluation focusses on ECDC's activities, organisation and processes that were in place during this period. The focus of the analysis is to assess ECDC's operations in times of crisis compared to ECDC's organisation and processes in a business-as-usual setting. It will cover ECDC's outputs during this time and the internal organisation and



processes that led to these outcomes. The report is expected to be finalized by mid/end of November.

The Ombudsman's inquiry team asked the ECDC to clarify how Member States normally approach the ECDC with questions.

The ECDC said that COVID-19-related questions normally go to the COVID-19 network, either by email or via the weekly meetings of national competent authorities. It said that it also has functional mailbox (the PHE Manager mailbox), where it receives detailed questions from Member States almost on a daily basis. The ECDC added that questions can also arise in the context of Advisory Forum or Management Board meetings.

Depending on the nature of the question, the ECDC might either reply individually to the relevant Member State or, if the answer is also of interest to other Member States, it may publish its reply in the form of a scientific opinion or report.

On the transparency of the ECDC's work

In relation to the surveys carried out by the ECDC to assess the laboratory preparedness in the EU, the inquiry team asked what the ECDC's view is about making publicly available information about response rates.

The ECDC said that when it makes publicly available information concerning a survey via its website, it provides information related to data completeness for each Member State. It added that, on its website, it is possible to see the (often significant) difference between data reported in TESSy by Member States and that collected by the ECDC through its epidemic intelligence screenings (for example, from Member States' websites).

The ECDC clarified that irrespective of how Member States present data at national level, the ECDC tries to give the best possible standardised analysis of the data.

The inquiry team asked the ECDC whether a well-informed individual would be able to find on the ECDC's website the information related to the evolution of its COVID-19 related scientific assessments over time.

The ECDC explained that all its rapid risk assessments (and updates thereof) are published on its website. By reading them, it is possible to trace the evolution of the scientific assessment. The data on which the ECDC's risk assessments are based is publicly available



either in the risk assessment itself or elsewhere on the ECDC's website. In general, the data that the ECDC uses is fully available on its website, in a form that can be further processed.

The inquiry team asked the ECDC to explain the reasoning behind the decision not to publish the results of the early March laboratory shortages survey.

This specific survey was conducted at the request of the Commission for its risk management purposes within a very short timeframe. ECDC compiled the answers in a summary report mapping the laboratory shortages. Based on this report, the Commission launched a joint procurement for personal protective equipment and laboratory materials.

ECDC shared this report with the respondents and the Commission but never intended to publish the results as this was not a full technical report by the ECDC. The ECDC explained that, when launching this specific survey, it had informed Member States that the results of the survey would be used to inform the Commission only.

If the ECDC had conducted such a survey with the intention of publishing the results as a technical report, Member States would have been informed of this, given more time to respond and given the opportunity to comment on the draft report. In addition, the report would have gone through the ECDC full clearance and editing.

The ECDC explained that in sensitive cases, the Member States might prefer that certain information is not published, but this was not the case here. However, the ECDC considers that the sharing of the requested information from Member States is not conditional upon the decision not to make it publicly available. The ECDC considers there is a good level of trust with Member States and said that even where Member States raise concerns in relation to the sharing of certain information, then the requested information might still be shared. The ECDC added that if a Member State were to complain about the accuracy of the information published by the ECDC, the ECDC would re-assess the information and only change it/remove it from its website if it agreed that it was inaccurate.

The inquiry team asked the ECDC whether it received requests for public access to documents related to its surveys.

The ECDC explained that it has already received between 50 and 60 public access requests this year, while it received a total of 29 requests in 2019. However, none of these requests concerned specifically the surveys. Most of the requests came from journalists and related to correspondence exchanged between the ECDC and other individuals, minutes of meetings or statistics. The report on the laboratory shortages survey was disclosed as part of an access to documents request by a journalist which requested the correspondence with a specific



Member State (Spain).

In this context, the ECDC pointed out that, even in cases where a Member State asks the ECDC not to disclose a document, it would assess the Member State's position in the light of the provisions in Regulation 1049/2001 [6]. In the context of this assessment, the ECDC would consult the Member State concerned.

The inquiry team asked whether the ECDC would like to add any remarks regarding the transparency of its operation.

The ECDC noted that its relationship with its stakeholders (which it understands to be its counterparts in the Member States) is different from that of EU regulatory agencies such as the European Food Safety Authority, the European Medicines Agency, and the European Chemicals Agency. As the level of trust between the ECDC and its stakeholders is high, it is not questioned as much as other agencies in terms of transparency.

Finally, the ECDC noted that the Council and the Commission are currently evaluating whether to strengthen the EU competence on cross-border health threats from infectious diseases and that any change would inevitably affect the ECDC's work.

Conclusion of the meeting

The inquiry team informed the ECDC that it would draw up a report of the meeting and that the ECDC will be asked to provide its comments on the report. The inquiry team thanked the ECDC representatives for their time and for the explanations provided. The meeting then ended.

Brussels, 11 November 2020

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[1] Decision 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32013D1082>.

[2] See Commission Communication of 2005: https://ec.europa.eu/commission/presscorner/detail/en/IP_06_1276.



[3] Reusken Chantal B.E.M. , Broberg Eeva K. , Haagmans Bart , Meijer Adam , Corman Victor M. , Papa Anna , Charrel Remi , Drosten Christian , Koopmans Marion , Leitmeyer Katrin , on behalf of EVD-LabNet and ERLI-Net . Laboratory readiness and response for novel coronavirus (2019-nCoV) in expert laboratories in 30 EU/EEA countries, January 2020. Euro Surveill. 2020;25(6):pii=2000082. <https://doi.org/10.2807/1560-7917.ES.2020.25.6.2000082>.

[4] Wenjie Tan, Xiang Zhao, Xuejun Ma, Wenling Wang, Peihua Niu, Wenbo Xu, George F. Gao, Guizhen Wu. A Novel Coronavirus Genome Identified in a Cluster of Pneumonia Cases — Wuhan, China 2019–2020[J]. China CDC Weekly, 2020, 2(4): 61-62. doi: 10.46234/ccdcw2020.017.

[5] Conducting in-action and after-action reviews of the public health response to COVID-19. Stockholm: ECDC; 2020, available at: <https://www.ecdc.europa.eu/en/publications-data/conducting-action-and-after-action-reviews-public-health>.

[6] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32001R1049>