Meeting minutes

MedTech Europe and ECDC

24 June 2025

Participants

MedTech Europe (MTE)

- Marcia Cardoso (MC) – Terumo BCT
- Jeffrey Linnen (JL) – Grifols
- Carlos Pérez (CP) – MTE
- Cesar Rubio (CR) – Grifols

European Centre for Disease Prevention and Control (ECDC)

- Marieke van der Werf (MvdW), Head of Section Sexually Transmitted Infections, Blood-borne Viruses, and TB
- Jenny Mohseni Skoglund (JMS), Principal Expert Microbial Safety of Substances of Human Origin
- Francois-Xavier Lamy (FXL), Expert Microbial Safety of Substances of Human Origin

Date and time	24 June 2025, 15:00 – 16:00 CET
Agenda	1. Description of the ECDC SoHO Framework, including the role of ECDC in implementing the SoHO Regulation and coordination with EDQM 2. Discussion and questions on the ECDC technical guidelines as described in the SoHO regulation ○ Exchange on comments provided by MedTech on the "Preventing Donor-Derived HIV Transmission through SoHO" guidelines ○ Exchange on upcoming Guidelines (HIV, HBV, HCV, *T. pallidum*, HTLV): Timelines for development and stakeholder involvement ○ Exchange on possible timeframe for guidelines on breast milk and impact on current practices ○ Questions from MedTech on possible HEV guidelines and the role of HEV RNA testing ○ Questions from MedTech on possible malaria guidelines and the role of NAT testing ○ Questions from MedTech on Arbovirus guidelines and the role of NAT testing for dengue and chikungunya 3. ECDC Question on Post-Mortem Samples: Available evidence in donor screening

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Meeting notes

MvdW introduced the meeting and reminded participants the meeting was recorded for the purpose of minute taking.

The meeting started with a round table presentation.

1. Description of the ECDC SoHO Framework, including the role of ECDC in implementing the SoHO Regulation and coordination with EDQM

MvdW presented the ECDC SoHO framework and its three building blocks: coordination of the SoHO network, providing guidance on microbial safety, and threat detection, assessment, and response.

- CR asked how ECDC interacts with the SoHO Coordination Board (SCB) and whether ECDC is involved in the development of the SoHO platform.
- MvdW replied that national focal points of the SoHO network can include members of the national competent authorities (NCA) which are also members of the SCB. NFPs that are not members of the NCA are required, by the terms of reference of the network, to liaise with the NCA. In particular for the review of the ECDC technical guidelines.
  ECDC is an observer to SCB and to several of the working groups of the SCB and can be invited to provide updates on its activities during the meetings of the SCB.
  ECDC is partially involved in the development of the SoHO platform, namely on the aspects related to the publication of the technical guidelines referred in the SoHO regulation. This work is led by the European Commission and also involves the European Directorate for the Quality of Medicines & HealthCare (EDQM)

2. Discussion and questions on the ECDC technical guidelines as described in the SoHO regulation

JMS introduced the agenda item regarding the comments from MTE on the ECDC guidelines on the prevention of HIV transmission through SoHO by thanking MTE for the very thorough and helpful comments provided. These comments were taken into consideration by ECDC and replies will be provided to MTE after the HIV guideline is published.

- CP indicated that several members of MTE that provided comments are not present in this meeting and it may not be possible to answer specific questions on the comments provided. CP added that, as a general advocacy point, MTE supports the use of nucleic acid testing (NAT) as a standard for the screening of SoHO donors.
- JMS indicated that several countries appear to perform repeat testing of reactive NAT as a means to confirm initial reactivity and asked if MTE members are aware of this approach in countries.
- JL confirmed that repeat testing of NAT is a known procedure, in particular for purpose of the re-entry of donors. But there is a risk of false negative results if used to confirm initial reactive results in a sample with low viraemia. Ruling out false reactive due to contamination should preferably be done on a separate sample.
  Repeating NAT is generally performed in follow-up samples for the re-entry of donors in countries that do not defer donors permanently on an initial reactive result.
- JMS asked whether the use of a more sensitive NAT could be useful to confirm an initial reactive result.
- JL replied that this may not always be practical as NAT used in screening context already have very high sensitivity (i.e., very low limits of detection). Repeating NAT several times on negative samples would increase the likelihood of the NAT detecting the pathogen.
- MC asked whether there exists a recommended minimum number of tests.
- JL replied that this has not been established but could be calculated considering the limit of detection of the test and the target limit of detection of the screening procedure.

FXL presented the current timelines for the development and publication of the guidelines on HIV, HBV, HCV, *T. pallidum*, and HTLV. These guidelines will then be followed by guidelines on arboviruses, with work on these guidelines starting in 2026.

- CR asked whether the SCB is involved in the review of the guidelines.
- MvdW replied that the specific working groups of the SCB will receive future guidelines (starting with *T. pallidum*) for review.

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- JL asked whether the guidelines on arboviruses will include recommendations on the use of SoHO screening data as a possible source to inform public health.
- FXL replied that the topic of using screening data to inform surveillance is discussed at ECDC and that this point will most likely be part of the topics addressed by the scientific expert panel supporting ECDC in the development of the guidelines.
- MC asked whether ECDC was considering developing guidelines for CMV or parvovirus B19.
- MvdW replied that ECDC will eventually need to develop guidelines for all pathogens relevant to SoHO, however these specific pathogens were not prioritised by the SoHO network and the development timelines for these are unknown. MvdW reminded participants that ECDC has published a threat assessment brief regarding parvovirus B19 in 2024.

JMS presented the considerations of ECDC to cover human breast milk in the technical guidelines, either through the adaptation of the published ECDC guidelines or through reference to guidelines published by other stakeholders such as the IMAGINE HMB project.

- CR asked if ECDC has information on the current practices regarding the screening of HMB donors in the EU and if the impact of future recommendations on current practices is known.
- JMS replied that for the moment this information is unknown to ECDC but that the description of current practices is part of the scope of the IMAGINE HMB project.
- FXL added that EDQM is in the process of updating the "Tissues and Cells guide" and the new version (6th edition) will include specific recommendations for the prevention of communicable disease transmission through HMB.

JMS read the questions posed by MTE on the role of NAT for HEV, dengue virus, chikungunya virus, and malaria; and replied that, as the work on the guidelines for these pathogens has not yet started, ECDC cannot provide replies to these questions for the moment.

- JL indicated that recently developed NAT for malaria represent a significant change in the technology using ribosomal RNA, and these recent tests should be considered separately from the previous PCR detecting DNA as they offer much higher accuracy for the detection of the parasite.
  JL also indicated that babesia screening could provide useful information when discussing the role of NAT for malaria as the tests for *Plasmodium* and *Babesia* parasites share similarities and the experience with babesia (and lack of reported transmissions) could provide helpful insights.
- ECDC acknowledged this information and indicated that the evidence base supporting the development of the guidelines will include evidence on available tests for screening of SoHO donors.
- MvdW added that, as ECDC will most likely not be able to publish guidelines on these pathogens before the date of application of the SoHO regulation (August 2027), ECDC will refer to the requirements set in the current EU Directives to avoid a legal gap.

3. ECDC Question on Post-Mortem Samples: Available evidence in donor screening

FXL asked MTE whether members could comment on available evidence on the accuracy of NAT (HIV, HBV, HCV in particular) in post-mortem samples, in particular in the context of dilution and haemodilution.

- JL replied that this evidence exists, at least for tests used to screen deceased donors in the US, as it is needed to obtain FDA approval for the screening of these donors, but is uncertain whether it is publicly available. Regarding dilution, several tests include the recommendation to test samples undiluted and diluted (e.g., 1:5 dilution factor).

AOB

MvdW asked participants whether there were any other business.

- CP asked if any industry representatives were included in ECDC networks and scientific panels and indicated that MTE can support ECDC in identifying experts for these activities.
- MvdW replied that, due to the ECDC policy on scientific independence, the interactions with members of the industry was generally restricted to meetings such as the present one. However, ECDC aims to continue

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collaborating with the stakeholders on the list established by the European Commission, in particular on the review of the technical guidelines and looks forward to feedback from MTE on future documents. If the need is raised by ECDC or MTE, future similar meetings can be organised.

MvdW thanked all participants and closed the meeting at 16:00 CET.

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