



Seventy-second Meeting

Stockholm, 21-22 February 2023

Discussion paper on Generating evidence through coordinated epidemiological investigations and operational research during public health events

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Summary:	Seek the advice from the AF members on how ECDC can best support and coordinate epidemiological investigations and operational research during public health events in the EU/EEA to generate evidence for action.		
Action:	For Advice/Opinion		
Background:	Through 2022, ECDC has worked to identify best practices and challenges encountered during the COVID-19 pandemic and to prioritise needs for strengthened preparedness, response to and recovery from future emergencies. Operational research was identified as a priority by Member States during lessons learned country visits and the 2022 annual meeting of the National Focal Points for Preparedness and Response and Threat Detection, EWRS and IHR. One of the roles of the EUHTF will be to support operational research during the early phases of a disease outbreak.		

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Background

Through 2022, ECDC has worked to identify best practices and challenges encountered during the COVID-19 pandemic and to prioritise needs for strengthened preparedness, response to and recovery from future emergencies. Operational research was identified as a priority by Member States during lessons learned country visits and the 2022 annual meeting of the National Focal Points for Preparedness and Response and Threat Detection, EWRS and IHR. During discussions, countries reported that research programmes related to COVID-19 were established slowly and difficulties were encountered in both defining research agendas and coordinating their implementation. Recent experience at ECDC from the response to the severe acute hepatitis of unknown aetiology in children and monkeypox has further highlighted the need to improve capacities for in-action research to rapidly inform public health decision making.

The newly established EU Health Task Force (EUHTF) will support EU/EEA Member States, partners countries and international organisations for timely emergency response during outbreaks and crises and strengthening emergency preparedness, as outlined in the EUHTF concept note. One of the roles of the EUHTF will be to support operational research during the early phases of a disease outbreak. In later phases, operational research activities can become part of mid- and long-term operational research agenda. Following initial discussions last year with the AF and with Member States during the meeting of National Focal Points for Preparedness and Response & National Focal Points for Threat Detection, EWRS and IHR, ECDC would like to discuss more in detail with the AF the possible role of ECDC and the EUHTF in this area, possible coordination mechanisms at the EU and Member States levels as well as methods for the generation of evidence.

The EUHTF will work in collaboration with WHO and GOARN, as well as with partners in the European Commission, such as Directorate-General (DG) for Research and Innovation (RTD), DG for European Civil Protection and Humanitarian Aid Operations (ECHO), Joint Research Centre (JRC), and Health Emergency Preparedness and Response Authority (HERA), and other EU Agencies such as European Medicines Agency (EMA).

What is operational research?

Operational research is a field which focuses on the planning and quick implementation of appropriate and targeted research during infectious disease outbreaks/emergencies. Operational research supports the rapid generation and collection of evidence that aims to inform timely emergency response, supporting appropriate strategic, tactical, and operational decision making.

Considerations for AF discussion on Operational Research

ECDC would like to seek the advice from AF members on the potential role of the ECDC and the EUHTF in supporting and coordinating operational research, in particular related to multi-country outbreaks and cross-border threats.

AF members are also asked to consider how, and by which approach ECDC could better support timely operational research, in collaboration with Member States, academia and partners, in view of a more coordinated EU-wide approach. The EUHTF aims to be a flexible body able to support different approaches to operational research. The EUHTF could focus on operational research related to

emerging events with a focus on rapidly obtaining key information for risk assessment and disease control, such as:

- Transmissibility, route of infection, severity, risk factors, clinical spectrum of disease.
- Strategies for detection (rapid assessment of surveillance and laboratory capacities, sensitivity, and specificity of new diagnostics).
- Effectiveness of public health measures (impact, feasibility, and acceptability).

The work of the ECDC disease programmes would continue to focus on longer-term public health research focused on studying the impact of preventive and control measures.

To start the discussion on operational research with a practical example, during the **working groups** AF members will be invited on a voluntary basis to briefly report on a specific operational research study that was implemented in their country related to COVID-19, paediatric acute hepatitis of unknown aetiology, Mpox or any other infectious disease outbreak. Alternatively, AF members can report on whether there are examples of operational research, in relation to these public health emergencies, that could have provided impactful evidence but were lacking or not conducted. The following topics will then be included in the working group discussions:

Open discussion **on current capacities for operational research** in Member States that AF members are aware of:

- Plans, teams, and tools available in Member States to implement operational research.
- Templates and protocols for rapid implementation of epidemiological and microbiological studies at the outset of an outbreak.
- How Member States raise funding for operational research.
- How operational research is coordinated at the national level in relation to the regional and local level.
- How is/would timely ethical approval be achieved for operational research?
- Data sharing agreements with stakeholders.
- Are collaborative agreements in place between public health agencies and academic institutions, clinical societies the EC or WHO, with clear roles and responsibilities? What areas are covered by such collaboration agreements (e.g. management of early ethical reviews, production of systematic literature review, data collection to analysis, scientific writing)?

Open discussion on **priorities for operational research** considering the current epidemiological context and capacity gaps in the EU/EEA, including:

- Priority diseases or disease groups.
- Criteria for identifying research areas or questions for multi-country studies.

Open discussion on **how ECDC can best assist Member States in setting up a more coherent framework within the EU/EEA countries for operational research** related to multi-country outbreaks and cross-border health threats from infectious diseases. Areas for consideration during the working group discussions:

- A mechanism for defining knowledge gaps, research questions and priorities for rapid operational research in response to a new/emerging public health threat.
- Supporting established partnerships between public health institutes, academic institutions, and clinical societies at the Member States level during "peace" times.
- What could be the role of the future EURLs in multi-country outbreak investigation and operational research in public health events?

- Promoting the implementation of common protocols by MS to enhance comparability, timeliness, and robustness of results in the various phases of the response to multinational events. For example:
 - o Developing template study protocols using different study designs (e.g., case-control studies).
 - o Providing data collection tools and analysis packages.
 - o Promoting data sharing agreements.
 - o Coordinating operational research initiatives for multi-country studies.
- Supporting analysis of findings, such as with centralised databases hosted at ECDC for pooled analyses of multi-centric/multi-country studies.
- Providing expert advice and convening Member States calls and expert working groups.
- Supporting implementation of operational research in countries upon request (deployment or distance support such as through EUHTF) and ensuring ECDC field teams are effectively collaborating with national counterparts in the design and implementation of studies for national events with the potential to cause cross-border threats.
- Disseminating research findings.
- Support training activities and/or exchange programmes between EU countries.