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SHARP
Strengthened International HeAlth
Regulations & Preparedness in the EU

Feasibility study for an expert clinical support service for high consequence infectious diseases

Work Package 10 – Deliverable 2

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Summary

A case or an outbreak of a high consequence infectious disease in Europe demands a public health response that includes adequate isolation and clinical management of the patient.

Experience from providers of health care for patients with Ebola virus disease in Europe and the United States in 2014-2015 demonstrated the utility of clinical consultations across borders among experts involved in their management. This need has been reinforced during subsequent infectious disease outbreaks of international concern. In the past, telephone conferences were mostly used for clinical consultations, but the COVID-19 pandemic has accelerated the use of digital video conferences.

The aim of this study was to address the feasibility of an expert consultation service for high consequence infectious diseases (HCIDs) in Europe using a digital platform meeting the legal requirements in the EU. We searched for published literature and consulted SHARP Joint Action partners and external experts.

We conclude that there is a need for a formal network of European clinicians with expertise in HCIDs, a need for a digital platform meeting defined technical and legal criteria, and a need for long-term funding.

We recommend that:

1. a formal network of European clinicians with expertise in high consequence infectious diseases be established
2. a digital platform meeting defined technical and legal criteria be made available to the network
3. this network be funded by the EU.

The formation of a new European Reference Network for high consequence infectious diseases would create a formal network of clinicians, provide a source of funding and, and enable access to an existing IT platform, the Clinical Patient Management System (CPMS).

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Background

SHARP Joint Action is an EU-funded project that aims to strengthen International Health Regulations and Preparedness in Europe.

The International Health Regulations[1] provide an overarching legal framework that defines the countries' rights and obligations in handling public health events and emergencies that have the potential to cross borders. Even a single case of a high consequence infectious disease in Europe could constitute an event that requires a public health response.

In the UK, a high consequence infectious disease[2] (HCID) is defined according to the following criteria:

- Acute infectious disease
- Typically has a high case-fatality rate
- May not have effective prophylaxis or treatment
- Often difficult to recognise and detect rapidly
- Ability to spread in the community and within healthcare settings
- Requires an enhanced individual, population, and system response to ensure it is managed effectively, efficiently, and safely

Capacity for appropriate isolation and treatment of affected persons are important both from public health, medical, and infection prevention and control (IPC) perspectives. In this context, high-level isolation units (HLIUs) have an important role to play.

The European Network for Highly Infectious Diseases (EuroNHID)[3] was a European Union-funded project (July 2007–December 2010). The aims of EuroNHID were to develop evidence-based checklists to assess hospital capabilities on infection control and healthcare workers safety in a network of centres involved in the management of patients affected by highly infectious diseases (HIDs). Also, EuroNHID aimed to support isolation facilities and provide appropriate infection control advice for isolation centres responsible for managing cases of emerging, re-emerging, or deliberately released HID agents. Later, the ECDC has issued checklists for Health emergency preparedness for imported cases of high-consequence infectious diseases[4] that include designated treatment facilities for HCID case(s), i.e., HLIUs.

During 2014–2016, there were multiple importations of patients with Ebola virus disease (EVD) from the outbreak in West Africa to Europe and the USA. Some patients were medically evacuated, whereas others developed symptoms and sought healthcare only after arrival at their destinations. Management of these patients proved challenging both for clinicians and IPC personnel, as few health care workers in the receiving hospitals had prior experience with this disease.

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Even in Europe and the US, there were cases of nosocomial infection among health care personnel involved in the care of Ebola patients. Improved preparedness, infection prevention and control, and capacity for management of these patients were addressed in several international meeting. In November 2014, the European commission also organised a meeting for European health professionals.[5]

However, clinicians involved in the direct care of patients suffering from a deadly disease they had no previous experience with, also saw a need for consultation and sharing of experience among peers. This prompted the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) to organise a network for clinical consultation for clinicians managing EVD patients in both Europe and the United States

From September 2014, conference calls were arranged for physicians in the United States and Europe who were caring for patients with EVD. The aims were to share detailed patient information and experiences, and to discuss the most appropriate clinical management. These conference calls proved extremely valuable, but had several limitations, including:

- Lack of participant verification
- Lack of functionality for visual sharing of patient histories, laboratory results, and imaging
- Difficulties in facilitating discussions among many participants
- Unresolved legal issues related to patient confidentiality.
- Lack of formal network structure and funding

Later, an informal European network of clinicians with experience in management of HCIDs in Europe has proved valuable during subsequent outbreaks. Both EU projects and professional societies have contributed to continued contact between HCID clinical experts in later years. Examples of this include

- the Nordic High-Level Isolation Working Group[6] under the Nordic Society of Clinical Microbiology and Infectious Diseases
- the German Permanent Working Group of Competence and Treatment Centres for high consequence infectious diseases (STAKOB)[7] supported by the Robert Koch Institute
- the French Coordination opérationnelle - Risque épidémique et biologique (COREB)[8] in France, supported by both health authorities and professional societies
- the two NHS England networks of treatment centres: the Contact HCID Network and the Airborne HCID Network.[9]

The recent COVID-19 pandemic has demonstrated the utility of digital platforms for meetings and information sharing, as exemplified by the WHO clinical network meetings. However, these meetings and platforms are generally not suited for

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clinical consultation requiring exchange of sensitive and confidential health information, such as patient histories, laboratory test results, and images.

According to the IHR core capacity requirement for surveillance and response[1], the State Parties are obliged to "establish, operate and maintain a national public health emergency response plan, including the creation of multidisciplinary/multi-sectoral teams to respond to events that may constitute a public health emergency of international concern". Clinical networks of experts in the management of HCIDs could have an important part to play in these national plans — that could be enhanced by contact with peers in an international clinical network.

SHARP Joint Action WP 10[10] addresses case management and infection prevention and control preparedness for high consequence infectious diseases. The objective of this WP is to improve clinical and biorisk management, hospital preparedness and response to high-consequence infectious diseases (HCIDs). It aims to strengthen IHR, through the enhancement of preparedness and response within Europe to possible cross-border health threats due to the HCIDs, and to assure co-operation, communication, and exchange of information among clinicians and public health officers.

WP 10 has four tasks:

1. Mapping of existing facilities for HCIDs
2. Assessment of country hospital preparedness and capacity for HCIDs, including high-level isolation centres
3. Feasibility study for an expert clinical support service for HCIDs
4. Application of a "syndrome based" approach for prompt and early clinical management of HCIDs

We here present SHARP Joint Action WP 10 task 2 – "Feasibility study for an expert clinical support service for high consequence infectious diseases".

The main target groups for this document are European:

1. Public health professionals
2. Infectious disease experts
3. Decision makers at the EU and national level

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Aims of WP 10 task 3

The aims of WP 10 task 3 and its connection to WP 5 task 2 are shown in the table below.

This task (WP 10 task 3) aims to define the characteristics of an expert clinical consultation and support service.

This will result in a set of **technical recommendations** that will be part of the evaluation in WP5 where identification of key challenges in national and international collaboration between governments and national authorities will be discussed in a dedicated workshop (workshop 5.2.2), details in the text boxes below.

5.2.2 Workshop on cooperation between public health and civil protection and on clinical consultation

Objectives	**Topics**
• To identify key challenges in national and international collaboration between governments and national authorities, and • To elaborate on measures for the operationalization of obligations related to response from health systems, cross-sectoral efforts and effective assistance between member states when needed. • Legal issues are highlighted in the workshop.	1) The legal framework in EU to assist neighboring countries during crisis. 2) Clinical management of difficult cases of possible epidemic-prone disease. Is there a need for a European reference network for high consequence infectious disease? 3) Improving National health preparedness plans including measures against serious cross border threats to health 4) Cross-border agreements, protocols, or memorandum of understanding (MoUs) with regards to public health emergencies between neighboring countries

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In addition to WP 5, WP 10 task 3 is also linked to WP 10 task 1 where a map of existing high-level isolation units in Europe will be used to create a referral network between the different countries. The network will identify national centres as clinical referral units and as providers of remote clinical consultations. A template for bilateral/ multilateral memorandum of understanding will be developed and will ensure a safe medical evacuation of patients with HCIDs to the closest health facility with adequate biosecurity level.

The feasibility of an expert clinical consultation and support service available on a 24-h /7 basis will be explored, through the organization and validation of such services during a "pilot phase". This clinical support service, based on a digital e-platform, will include infection control, including health care workers (HCWs) safety issues. According to specific risk assessment, also on-the-field expert support could be provided, if needed.

Methods

User requirements and desirable characteristics of a clinical support service were discussed among SHARP Joint Action WP 10 participants in workshops 28–29 October 2019 in Rome, and 24–25 February 2020 in Frankfurt. (These workshops were not part of WP 5 task 2). We searched for publications on existing digital platforms for clinical consultation. We also consulted colleagues and authorities for information about existing digital platforms and experiences in their use.

Legal aspects were assessed in cooperation with SHARP Joint Action WP 5 task 2 at a workshop in Lisbon 27–28 February 2023. We also used experiences from the pandemic at the Norwegian Directorate of Health and at Oslo University Hospital. Information on challenges in Norway regarding the implementation of the European Reference Network's digital platform, the Clinical Patient Management System (CPMS), was obtained from Oslo University Hospital.

In addition, SHARP Joint Action WP 10 partners met and exchanged views and information in several digital meetings and by e-mail.

Results and discussion

We identified the following overarching requirements for an expert clinical consultation and support service for HCIDs. Thus, service should:

- Have a clearly defined aim and scope
- Use a secure digital platform
- Comply with European legislation
- Constitute a formal network of experts that is financially sustainable over time

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Aims and scope of a clinical consultation and support service

WP 10 task 3 aims to define the characteristics of an expert clinical consultation and support service for HCIDs.

We propose that this service should facilitate:

1. Clinical consultation and exchange of information among experts
2. Requests for international referral of patients in cooperation with mechanisms already in existence in Europe, e.g., the Emergency Response Coordination Centre (ERCC)[11]
3. Requests for deployment of equipment (e.g., specialized PPE for use for HCIDs that may not be available through the European Civil Protection and Humanitarian Aid Operations[12] and the Health Emergency Preparedness and Response Authority[13])
4. Requests for therapeutics and vaccines between institutions within Europe in case of national shortage
5. Requests for deployment of staff or consultants if the patient is not transportable to higher level care
6. Development and storage of guidelines/standard operating procedures (SOPs)
7. Scientific exchange among clinicians
8. Interaction with public health agencies when relevant

Digital platform

Assigned public health experts in Europe have access to platforms used for discussions and sharing of epidemic intelligence, surveillance, and microbiological data. This includes the Early Warning and Response System[14] and EpiPulse[15]. At present it is not possible to grant clinicians access to these platforms for clinical discussions, and they are not suitable for detailed sharing of clinical information and laboratory results.

We identified only one existing digital platform meeting both the technical and European legal requirements, i.e., the CPMS[16] which is used by the European Reference Network[17] for Rare and Complex diseases (ERN).

> *"The CPMS is a secure IT platform used to support ERNs in the diagnosis and treatment of rare or low prevalence complex diseases across national borders. Health professionals can upload relevant patient data, images and examination findings as well as discuss the case in the panel of experts.*
>
> *For this purpose, CPMS includes a consultation form with an adapted data structure, integrated DICOM viewer (Digital Imaging and Communications in*

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Medicine) and a video conferencing tool. This enables the description of a patient case in a comprehensive manner".

The CPMS could be adapted for use by a clinical support service for HCIDs.

Access to the CPMS could potentially be obtained either by

a. establishing a new network for HCIDs within the ERN system, or
b. by obtaining rights to use of the CPMS outside of the ERN.

European legislation

A digital platform for clinical consultation must comply with European regulation. Most of the legal obstacles to the use of a digital expert clinical support service are linked to the transfer of personal data and required compliance with the European General Data Protection Regulation (GDPR). Any citizen of an EU or EEA member state is entitled to seek treatment in another member state. However, to obtain access to sensitive data, there must be consent from the patient, and the data must be handled securely on an approved platform like the CPMS.

The Commission Implementing Decision (EU) 2019/1269[18] provides details regarding legal requirements linked to the use of the CPMS.

In addition, legal obstacles may be removed by the recent EU Regulation (EU) 2022/2371[19] on serious cross-border threats to health, and the European Health Data Space[20] (EHDS), which is expected to be operational from 2025.

According to the EHDS regulation proposal, all European citizens should have easy access to their health data in an electronic format, enabling individuals to share their personal data with health professionals both nationally and across borders without compromising on the required safety measures to protect natural person rights under GDPR.

As in existing ERNs, clinicians in a potential future HCID network would be able, with the consent of the patient, to share data and discuss diagnosis and management of patients using the CPMS. The treating hospital will remain in charge and be responsible for the clinical management of the patient in accordance with national legislation.

Clinicians working in ERN Full Member and Associated Partner hospitals can use the CPMS. Other clinicians working in EU/EEA hospitals that are not members of an ERN can refer the patient to an ERN member hospital to access ERN expertise or request a CPMS guest access. In a potential future network for HCIDs, it may also be warranted to invite public health experts to take part in discussions relevant to the public health response to an outbreak of a HCID.

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A digital platform as described may also provide a channel for other requests, e.g., international referral, and deployment of equipment, staff, and therapeutics. It can also provide a platform for guidelines/SOPs, scientific exchange, and interaction with public health agencies.

HCID network of clinical experts

To secure continuity of operation of an expert clinical consultation service for HCIDs, we propose the formation of a formal network of clinical experts that is funded by the EU funding, and that has access to a digital platform. Ownership and responsibility for operation of the digital platform and administration of the clinical network remains to be decided. One model could be to establish a new network for HCIDs within the existing European Reference Network (ERN) umbrella.

In 2020, DG SANTE published a feasibility study on a European Expert Network for rare communicable diseases and other rare pathologies[21] in the context of mobility and globalization. This concluded that a potential new ERN could benefit the quality of care of rare communicable diseases. It is the opinion of SHARP Joint Action WP 10 partners that a clinical network, dedicated to HCIDs and allowing the use of the CPMS, would fill a gap in current preparedness.

Alternatively, a network for clinical support could be established outside the ERNs. However, it is our opinion that linking up to an existing structure in the EU is a more effective use of resources.

In SHARP Joint Action WP 10 task 1, the aim is to map existing high-level Isolation units likely to be involved in the care of patients with rare or new HCIDs. Clinicians from these institutions would have a natural role to play as members of a potential future clinical consultation network for HCIDs. Nomination of experts may come directly from the involved HLIUs, from national societies of infectious diseases, or from the health authorities.

Conclusion and recommendations

Based on previous experience with Ebola virus disease and other public health events of international concern, there is a need for a formal network of European clinicians with expertise in HCIDs, a need for a digital platform meeting defined technical and legal criteria, and a need for long-term funding.

We conclude that this is feasible and propose that the best solution today is to establish a new ERN for HCIDs. This would formalize the network, give access to the CPMS, and provide a source of funding.

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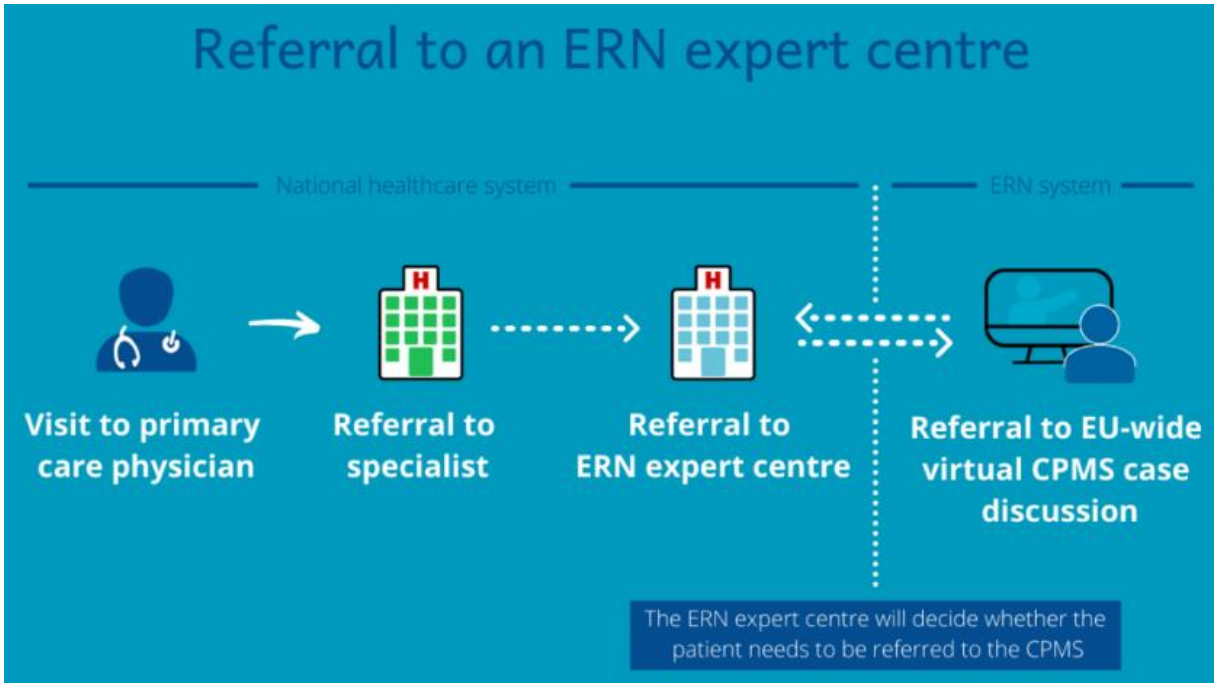
Attachments

Supplementary Information about the Clinical Patient Management System (CPMS)

European Reference Networks (ERNs) are virtual networks connecting healthcare professionals around Europe with expertise in rare diseases, which allows them to discuss a patient's diagnosis and care, with their consent, via an online IT platform called the Clinical Patient Management System (CPMS).



The CPMS is a secure IT platform used to support European Reference Networks in the diagnosis and treatment of rare or low prevalence complex diseases across national borders.
Health professionals can upload relevant patient data, images and examination findings as well as discuss the case in the panel of experts.
For this purpose, CPMS includes a consultation form with an adapted data structure, integrated DICOM viewer (Digital Imaging and Communications in Medicine) and a video conferencing tool. This enables the description of a patient case in a comprehensive manner.
By providing a structured and safe environment to exchange opinions, CPMS facilitat es and intensifies the collaboration between expert centres within the European Refe rence Networks.

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HOW TO USE IT / BEST PRACTICE

1.) Create an account (Registration guide)

2.) Obtain training by the CPMS Helpdesk (CPMS Training environment - 1 page document, User Guide)

3.) Obtain patient consents (pdf consents in different languages)

4.) Enroll patient case

5.) Provide the ERN-RND CPMS helpdesk with the following data:

- Type of expertise you would need
e.g. pediatrician, geneticist
- Recommend experts as panel members OR state if the CPMS Helpdesk should choose
- State your focus for the case discussion/outcome? e.g. treatment options
- Propose suitable time slots for a discussion

6.) CPMS Helpdesk organizes a virtual discussion

7.) Panel lead performs the recommended tests/investigations (if any)

Optional: another case discussion to present the new results (with the same or other panel members)

8.) Write an outcome

9.) Sign off and close the panel

10.) For any questions during this process contact the CPMS Helpdesk

WHO CAN USE IT?

You are a clinician working in a hospital member of an ERN:

Clinicians working in ERN Full Member and Associated Partner hospitals can have direct access to the CPMS.

You are a clinician working in an EU/EEA hospital non-member of an ERN:

You can refer your patient to the relevant ERN member hospital so that (s)he can get access to the ERN-RND expertise or request a CPMS guest access.

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Examples of guest users are:

- The 'Point of Care specialist' (treating doctor) of a patient referred to the CPMS.
- Health professionals who need to upload patient data to a panel in agreement with an ERN Member or Affiliated Partner.
- Health professionals who are needed on a case-by-case basis, because of the clinical expertise they can bring to the specific consultation panel to which they are invited.

The CPMS is not directly accessible to individual patients.
Integration of CPMS in national care pathway:
In the near future, rare disease care pathways will be implemented at the regional or national level. These pathways will regulate which patients will be discussed in CPMS (gatekeeping function).
In Germany, for example, the German Academy for Rare Neurological Diseases is implementing CPMS based online case discussions. Further information can be found here.

See video. For more information see also Online case discussion with CPMS – ERN-RND | European Reference Network on Rare Neurological Diseases).

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