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SHARP Joint Action: Strengthening preparedness in the EU against serious cross-border threats to health, and supporting the implementation of International Health Regulations (2005)

HaDEA Grant number 848096

D2.3 Layman's report

November 2023

As the successful collaboration of public health experts across 30 countries ends, SHARP Joint Action has identified key actions that should be considered in national, regional and EU cross-border health threat preparedness planning and response.

The ten priority outcomes in this document are distilled from four years of practical work, dissemination activities, capacity building, and research focused on strengthening preparedness and response in meeting International Health Regulations amongst European countries. The proposals within the recommendations are reinforced by the lessons learned from the pandemic response and are aligned with the EU serious cross-border threats to health regulation in force since 2022 (EU) 2022/2371.

The actions suggested are seen as a priority to ongoing preparedness efforts in order to better protect the health of all European citizens and promote health security.

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About SHARP Joint Action

Participants in the SHARP Final Conference in Helsinki on 19th and 20th June 2023.

SHARP Joint Action, funded by the Health Programme of the European Union (80%) and by partners' own contributions (20%), was an EU Joint Action whose mission was to strengthen preparedness in the EU against serious cross-border threats to health, and to support the implementation of International Health Regulations (2005). "SHARP" stands for Strengthened International HeAlth Regulations and Preparedness in the EU.

SHARP JA partners worked collaboratively to identify and address gaps in the capacity to prevent, detect and respond to biological, chemical and environmental threats to human health. By working together, the partners and the European Commission aimed to strengthen member's existing capacities and support improvements primarily in those countries and in those areas where IHR capability gaps were widest. The work of this Joint Action contributed to a safer environment for all EU citizens.

The Advisory Board of SHARP JA included HaDEA; DG SANTE; European Centre for Disease Prevention and Control (ECDC); the World Health Organization European Office (WHO Europe); the Scientific Committee for Health, Environment and Emerging Risks (SCHEER) Rapid Risk Assessment Working Group for Chemical Threats; and HEALTHY GATEWAYS Joint Action.

SHARP was supervised by DG SANTE and managed by the EU Health and Digital Executive Agency – HaDEA (the latter replaced CHAFEA from April 2021).

SHARP started its actions in June 2019, and the Joint Action was coordinated by the Finnish Institute for Health and Welfare, Finland; and co-coordinated by Robert Koch Institute, Germany; and National Institute of Infectious Diseases Lazzaro Spallanzani, Italy.

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SHARP Joint Action had an extensive geographical reach. The 26 partner countries and the four collaborating countries of the Joint Action represented ca 95% of the EU population. The 71 partners of the Joint Action represented highly experienced government and national public health institutions, responsible for infectious diseases, epidemiology, preparedness and response, and public health protection.
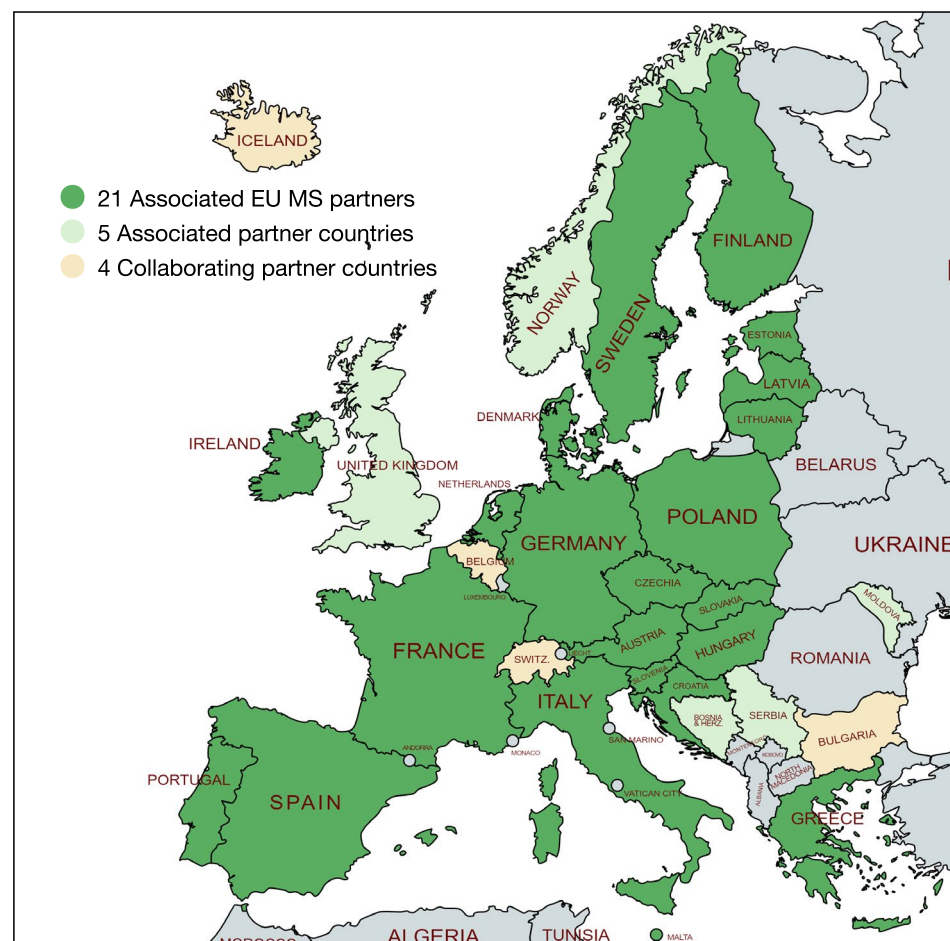
Over the course of the Joint Action, 32 deliverables were produced. The insight generated by this project can inform effective actions to prevent and respond to threats of biological, chemical, environmental, and unknown origin.

As a result of SHARP Joint Action, ten key priority outcomes from the core technical work packages have been identified to be sustained after the end of the project. These core results were selected based on their significance to national, regional, EU and global priorities. Integrating them into national and EU policies would enhance health protection across Europe.

21 Associated EU MS partners

5 Associated partner countries

4 Collaborating partner countries

Budget
9,875 million EUR Co-funded by the Health Programme of the European Union (80%) and by partners' contributions (20%)
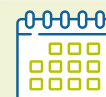
Duration
April 2019 – September 2023

Coordination
Finnish Institute for Health and Welfare

Partners
60 partners from **26** countries

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Aims of the project

SHARP Joint Action aimed to strengthen:

- The implementation of Decision 1082/2013/EU on serious cross-border threats to health, which was revised and replaced by new Regulation on serious cross-border health threats (EU) 2022/2371.
- The implementation of International Health Regulations (2005) in EU Member States
  - ◆ The purpose was to achieve strengthened ability to prevent, detect and respond to biological outbreaks, chemical contamination and environmental and unknown threats to human health among SHARP partners, Member States and the EU.

To achieve these objectives, the Joint Action was organised into 10 work packages. Seven of these were technical work packages, each with a specific aim, that were supported by coordination, communications and dissemination and evaluation.

Work packages

Work package (WP)	Organisation lead; and co-lead
WP1 Coordination	The Finnish Institute for Health and Welfare; Robert Koch Institute, Germany & National Institute for Infectious Diseases, Italy
WP2 Communication and dissemination	Public Health Wales, UK; The Finnish Institute for Health and Welfare
WP3 Evaluation of the action	National Public Health Organization, Greece
WP4 Integration in national policies and sustainability	Ministry of Solidarities and Health, France; National Institute for Public Health and the Environment, Netherlands
WP5 IHR core capacity strengthening and assessment	Public Health Agency of Sweden; Norwegian Directorate of Health
WP6 Preparedness and response planning	National Institute for Public Health and the Environment, Netherlands; Instituto de Salud Carlos III (ISCIII), Spain & ErasmusMC, Netherlands
WP7 Laboratory preparedness and responsiveness	Robert Koch Institute, Germany; National Institute for Infectious Diseases, Italy
WP8 Training and local exercises, exchange of working practices	Institute of Public Health of Serbia; Robert Koch Institute, Germany
WP9 Chemical safety and chemical threats	UK Health Security Agency; National Institute of Public Health, Slovenia
WP10 Case management and infection prevention and control preparedness	National Institute for Infectious Diseases, Italy

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Key terms

Serious cross-border threat to health means a life-threatening or otherwise serious hazard to health of biological, chemical, environmental, or unknown origin which spreads or entails a significant risk of spreading across the borders of at least one member state or may necessitate a coordinated response by national authorities to ensure a high level of human health protection. This definition includes events that may constitute public health emergencies of international concern under the International Health Regulations (2005) (IHR).[1]

Public Health Protection means protecting individuals, groups, and populations from infectious diseases and non-infectious public health threats including radiation, chemical, and environmental hazards.[2]

Global public health security is defined as the activities required, both proactive and reactive, to minimize the danger and impact of acute public health events that endanger people's health across geographical regions and international boundaries.[3]

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1   Modified from the Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R2371

2   Modified from Public Health Protection and Health Security Framework Outline Agreement (UK Government): https://assets.publishing.service.gov.uk/media/617a8575d3bf7f-56059041cc/public-health-protection-and-health-security-framework-outline-agreement-web-accessible.pdf

3   Modified from WHO: https://www.who.int/health-topics/health-security#tab=tab_1

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Background to SHARP Joint Action: The state of play in terms of EU preparedness and response planning and IHR implementation at the start of the project

The World Health Organization International Health Regulations (who. int) provides the overarching legal framework for global health security by defining countries' rights and obligations in handling public health events and emergencies that have the potential to cross borders.

The IHR measures the ability of a Member State to act across 19 core IHR capacities. Capacity levels for Member States are captured in the State Party Self-Assessment Annual Reporting Tool (SPAR).

At the outset of the SHARP Joint Action, a 2019 analysis was carried out of country SPARs and Joint External Evaluations (JEEs) reports, supported by qualitative telephone interviews.

It revealed IHR strengths and weaknesses in lower GNI (Gross National Income) countries participating in the survey - Bosnia and Herzegovina, Croatia, Greece, Latvia, Lithuania, Malta, Moldova, Poland, Portugal, Serbia, Slovenia, and Spain.

Areas for development identified were:
- Risk communication
- Points of Entry
- Chemical events
- Implementation of a laboratory biosafety and biosecurity regime
- National health emergency framework
- Zoonotic events and human-animal interface

This insight into the gaps in IHR capacity crystalised the tasks and activities delivered by the multi-disciplined teams within the seven technical work packages of the SHARP Joint Action to strengthen existing capacities and support improvements in partner countries.

At the conclusion of the Joint Action, 10 key outputs and deliverables were identified as contributing to the EU priorities in terms of prevention, preparedness, and response at all levels. These form the core of the results achieved in this project and will be presented in the following pages.

Participants in the SHARP Kick-off Meeting in Vilnius in 2019.

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Key results and outcomes of the project

Detailed in the Sustainability Report, 2023 authored by the Ministry of Solidarity and Health, France (work package 4), the following 10 key recommendations were identified to be sustained after the end of the project. They comprise strengthening of preparedness and response evaluation, planning and capacities across infectious diseases and chemical threats; facilitating cross-border collaborations; fostering a "One Health" multisectoral approach; training and capacity building; and strengthening of laboratory capacities.

SHARP calls for Member States and, where relevant EU and WHO EURO, to integrate these ten operational measures into their national policies and strategic plans. This would contribute towards achieving the all-important impact of the investment by the Health Programme of the European Union and national public health institutes in the critical area of preparedness.

These priority outcomes were identified with the help of a sustainability guidance tool. The purpose of this tool was to ensure that all the technical work packages consider the sustainability of their outcomes within their work and reports. This tool ensured a common understanding across JA members of sustainability. The priority outcomes should be maintained in the long-term with the available resources, taking into account the national, EU, regional and global contexts in which they are implemented.

Each recommendation is underpinned by a link to an open-access report that details levels of capability; why the capacity is important, and insight on how countries can improve.

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Key priority outcomes

1. Methodology, tools and recommendations for improving IHR implementation and evaluation.

This 2023 Final report D5.2 from work package 5, led by the Public Health Agency of Sweden describes a methodology for a multi-country, peer-to-peer approach for strengthening IHR implementation and evaluation. It includes the baseline and follow-up analysis and refers to an Excel tool with activity and strategic suggestions for IHR strengthening within countries across Risk Communication, Chemicals, Biosafety and Biosecurity, Antimicrobial Resistance (AMR) and One Health surveillance. It further considers the utilisation of simulation exercises and After-Action Reviews (AAR) in the context of biological, chemical, radiological, nuclear, and environmental threats, including an assessment of key findings of EU exercises conducted to date.

💡 **Aligning with EU directives regarding the reporting and assessment of national preparedness and response plans and the WHO IHR monitoring and evaluation framework**, the methodology and tool can be adapted to the local country context and used by Member States to help develop the strategic activities to work on. Taking this initiative supports evaluating and bolstering essential IHR capacities at the EU, regional, and global levels.

2. A framework for collaboration between health authorities during crises

The International Collaboration between authorities during crises report led by the Norwegian Directorate of Health (work package 5) proposes a template agreement for collaboration between health authorities during crises. This timely publication can be used by countries to meet the ongoing requirements of the EU cross-border threats to health legislation. Coherent with the EU-level 'prevention, preparedness and response plan,' the regulation demands member states liaise with each other when drawing up their national plans. A key element of such inter-state liaison is the operationalisation of obligations related to responses from health systems, cross-sectoral efforts, and effective assistance between member states when needed.

💡 **This initiative aligns with EU, Pan-European, and global priorities for strengthening regional and international cooperation in response to health threats.** Neighboring countries can adapt and use this template.

It is hoped that under Chapter III of the Union Plan, a provision is made for neighbouring countries to strengthen or develop, where relevant, cross-border collaboration, based on the proposed template. Furthermore, the EU will set up a cooperative body (composed of authorities' party to cross-border agreements) to further develop and update the template.

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3.   Guidance on identifying the multiple sectors involved in pandemic preparedness

The Multisectoral collaboration during public health emergencies: an integrative review provides insight and guidance from the National Institute of Public Health and the Environment (RIVM, work package 6), Netherlands and other work package 6 partners. A RAND Delphi panel method was adopted to systematically and quantitatively combine expert opinion and evidence to arrive at a consensus on the sectors involved in pandemic preparedness. This is a useful reference to any country working to improve its capacity in multi-sectoral, all-hazards preparedness and planning. The report highlights the need for clearer guidelines on multisectoral cooperation at national and global levels, aligning with EU regulations and global initiatives that recognise this crucial element.

Work package 6 workshop participants in Riga, Latvia in 2023.

A multi-sectoral approach is **not only necessary for IHR implementation in countries but also fundamental for legal requirements** in the Regulation (EU) 2022/2371 on serious cross-border threats to health[4]. The ambition is for member states to integrate this multi-sectoral approach into their national strategies/plans and training programmes.

A tabletop exercise that can be adapted by countries to evaluate and improve multisectoral preparedness and response plans relating to a zoonotic disease is available by creating an account at the SHARP JA Training Platform (batut.org.rs).

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4   Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022R2371

4. Recommendation to maintain the EMERGE Laboratory Network on highly pathogenic bacteria and viruses

The EMERGE Laboratory Network, comprising 40 diagnostic laboratories across 25 European countries, focuses on high-risk pathogens. Led by the Robert Koch Institute (RKI), Germany, the network provides surge capacity and expertise during outbreaks and conducts annual External Quality Assurance Exercises (EQAEs) to ensure readiness and best practices, since 2008.

Sustained by the SHARP Joint Action to September 2023 the network of high containment laboratories is currently making the case for its consolidation at the EU level and offers benefits such as alignment with International Health Regulations (IHR), support for low-income countries, improved risk assessments, and contributions to antimicrobial resistance efforts.

For information email EMERGE-coordination
emerge-coordination@rki.de

💡 Options to sustain the network include national-level contributions from network partners and potential EU designation as a Reference Laboratory Network for Highly Pathogenic Infectious Agents (HPAI) via the EU Reference Laboratories (EURLs) programme.
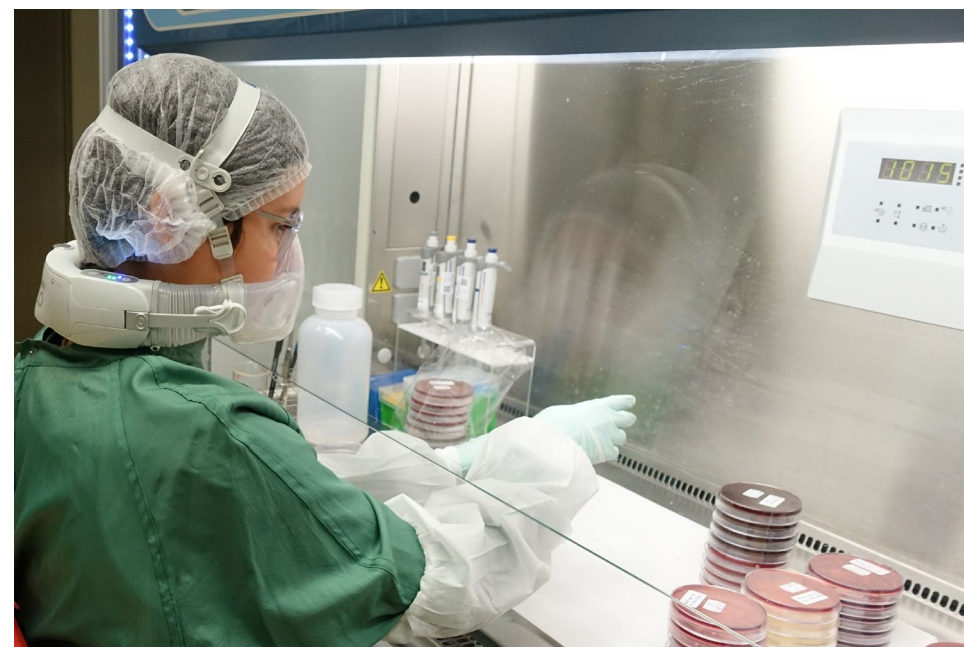
Collaboration with WHO can further strengthen global health security efforts. A detailed Pilot Plan makes the case to decision-makers to support the efforts to obtain permanent funding and to set the network on stable pillars.

Enhancing Biorisk Management in European Laboratories

The Guidance Tool for Enhancing Biorisk Management in European Laboratories (EBRM-Guidance Tool) D7.3. is available for immediate adoption.

The tool is developed by the Unit for Biopreparedness, Department of Microbiology, Public Health Agency of Sweden to support the laboratories that handle highly infectious agents in risk groups 3 and 4 including transport, transfer, and storage of materials that may contain infectious agents.

The tool can be accessed here.

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5. Methodology to assess the cross-sectoral training needs for IHR strengthening across countries

The Report on training needs for IHR strengthening from work package 8, led by the Institute of Public Health of Serbia (IPHS) assessed the cross-sectoral training needs for IHR strengthening at a multi-country level. The methodology used integrates information from the European Centre for Disease Prevention and Control (ECDC) training needs assessment survey, WHO voluntary Joint External Evaluations, and mandatory SPAR sources.

The assessment and methodology can be adopted by Member States to train the staff to develop the national preparedness and response plans and implement activities in crisis preparedness and surveillance.

A selection of training materials to strengthen IHR core capacities are freely available at the SHARP JA Training Platform (batut.org.rs) for Member States to translate and adapt to country context and integrate into national training plans.

6. Training tools for IHR strengthening, including training material, curricula and on-line platform

Work package 8, led by the Institute of Public Health of Serbia (IPHS), together with the other work packages within SHARP and relevant stakeholders including ECDC and WHO EURO, has adapted and developed several training materials and curricula to strengthen IHR core capacities including:

- Training and advanced workshop material on In(tra)-Action Review;
- Material for a risk communication tabletop exercise with a focus on vaccination;
- Material for introduction to simulation exercises;
- Material for online training on laboratory capacities;
- Material for basic online training on IHR;
- Material for advanced chemical training and exercise prepared in collaboration with WP9 Chemical safety and chemical threats;
- Material for a table-top exercise aimed to improve planning and implementing practices using a scenario for control of the spread of transboundary diseases;
- Training on recovery;
- Training on outbreak investigation.

WP8 also developed curricula for basic and advanced face-to-face and online training. Training materials were translated into most EU languages and are available on a dedicated training platform

(SHARP JA Training Platform (batut.org.rs): EduSHARP: All courses (batut.org.rs))

In total, **21 workshops and trainings, 3 national and one international exercise**, and **2 study visits** were organised on-line and on-site with a total number of **943 participants** from **31 countries**.

Further to the EU level, training is key priority at regional and global levels. At the regional level, training and capacity building are key elements of the WHO EURO European Programme of Work (EPW) 2020-2025, notably for Core priority 2 (Protecting against health emergencies) of the EPW. At the global level, the WHO Academy in Lyon has been developed as a key resource for training of health staff. The purpose of collaborating with the WHO Academy is to integrate the JA training into the WHO health guidance tools. This will extend the desired impact to other countries, and help health workers, policy makers and other public health practitioners to keep up with evidence-based health practice and policy.

Work package 8 kick-off meeting in Belgrade in 2019.

7. Creation of a European chemical laboratory network

Please replace the highlighted sentence with: Recommendations to respond to serious chemical health threats are made in the Feasibility of a Chemical Laboratory Response Network – fact-finding report, May 2021 and scoping report, April 2022.

Led by the United Kingdom Health Security Agency (UKHSA) and co-led by the National institute of Public Health, Slovenia, this paper recommends further exploring the feasibility of setting up a European chemical laboratory network to respond to serious chemical health threats. This assessment involves a gap analysis of chemical capacities in European countries, an examination of existing relevant networks, and outlines the need for further study to assess the network's size, scope, technical requirements, costs, and funding.

Addressing chemical health threats is a priority at both EU and global levels, as evidenced by EU regulations and initiatives like the Joint Action TERROR and the Global Health Security Initiative.

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8. Improving capacity to respond to chemical events

A report detailing Standard Operating Procedures (SOPs), led by the United Kingdom Health Security Agency (UKHSA) and co-led by the National institute of Public Health, Slovenia, focuses on building a baseline competency among EU Member States in dealing with cross-border chemical health threats. The SOPs cover surveillance, risk analysis, multisectoral collaboration, decontamination, sampling and detection, and recovery.

Preparing for and addressing chemical health threats is a requirement in the IHR and a priority at both EU and global levels, making these SOPs crucial for preparedness and response.

Training materials are available at SHARP JA Training Platform (batut.org.rs). Member States can translate and adapt the SOPs and this training to the country context and integrate it into their national preparedness and response planning for chemical events and training plans.

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9. Creating an expert clinical support network for high-consequence infectious diseases

A feasibility study on the Need for an expert clinical support service for high-consequence infectious diseases in Europe was led by the Department of Acute Medicine and Department of Infectious Diseases, Oslo University Hospital, Norway. This study outlines how isolation and clinical management of patients can be strengthened via an expert consultation service for high consequence infectious diseases that typically have a high fatality rate. The background research included mapping existing high-level isolation units (HLIUs) likely to be involved in the care of patients with rare or new high-consequence infectious diseases (HCIDs).

The recommendations comprise:

1. a formal network of European clinicians with expertise in HCIDs be established. The formation of a new European Reference Network for high-consequence infectious diseases would create a formal permanent reference network, provide a source of funding, and enable access to an existing IT platform, the Clinical Patient Management System (CPMS).

2. a digital platform meeting defined technical and legal criteria be made available to the network

3. this network is funded by the EU.

ECDC or WHO EURO could consider adopting, updating, and extending the mapping of existing High-Level Isolation Units at the European level.

- The findings of the feasibility study could form the basis of discussion between the EU and member states for the creation of an expert clinical support service for HCIDs within the EU health programme

- Union preparedness and response plan could integrate provisions for cross-border collaboration for HCIDs

10. Recommendations on the implementation of a syndrome based clinical protocol

Recommendations on the implementation of a syndrome-based clinical protocol, is a multicountry review, leading to a practical framework for patient management at emergency departments.

This review by work package 10 lead National Institute for Infectious Diseases (Italy) is a standardised pathway that includes specific disease lists and provides a diagnostic decision-tree for prompt and appropriate clinical actions focusing on efficient triage, standardised processes, effective isolation, and protection against occupational exposure risks.

The protocol aligns with the European Centre for Disease Prevention and Control (ECDC) operational checklist for enhancing national preparedness for imported high-consequence infectious diseases (HCID) cases.

Medical councils and expert bodies, such as members of the European Reference Networks who facilitate the exchange of best practices among EU countries, can adapt the recommendations to national context and pilot to improve clinical and biorisk management, hospital preparedness and response to (HCIDs).

In the medium term, ECDC and/or WHO EURO could adapt and issue recommendations for a "syndrome-based" approach for prompt and early clinical management of HCID.

Longer term, ECDC and/or WHO EURO could update the recommendation for a "syndrome-based" approach for prompt and early clinical management of HCID.

11. From paper to practice - Further practical information you can use

Other tools for EU-member states and associated countries to adapt to the multi-faceted crises that face European citizen and health systems are available until March 2024 at https://sharpja.eu/. Externally available deliverables, as well as other important documents can also be accessed on the website of the Finnish Institute for Health and Welfare.

These include qualitative insights and quantitative statistics, evidence reviews, and training to inform systems/processes improvement for health security.

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Conclusion: Better preparedness for the cross-border health threats in the EU

SHARP Joint Action has contributed to strengthening IHR implementation among countries over the course of the project. During the implementation of SHARP JA, there have been major upheavals to national, regional and global health security frameworks due to the covid-19 pandemic. The lessons learned, After Action Reviews and evaluation processes are still on-going in many countries, and to be adopted in national preparedness plans and legislation.

Effects and consequences of the pandemic has led to revising not only national, but EU and global level frameworks, such as the ongoing revision of International Health Regulations, and to the WHO process to negotiate an agreement, or other international instrument on pandemic prevention, preparedness and response through the intergovernmental negotiating body (INB), besides the EU processes mentioned earlier.

Through its efforts to strengthen preparedness (including laboratory preparedness) in the EU against serious cross-border threats to health and support the implementation of International Health Regulations, the SHARP partnership has also contributed to supporting countries in responding to the pandemic, by adjusting some of the original tasks and aims towards response to the pandemic.

Building on this work, sustaining SHARP priority outcomes will contribute to continued strengthening of national, EU, pan-European and global efforts for preparedness and response, in support of common priorities including: strengthening of preparedness and response evaluation, planning and capacities; supporting cross-border collaborations; fostering a multisectoral approach; training and capacity building and strengthening of laboratory capacities.

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List of partners

SHARP JA partner organisations

These 26 associated partners are supported by 35 affiliated entities.

- **Austria:** Federal Ministry of Social Affairs, Health, Care and Consumer Protection (BMSGPK)

- **Bosnia and Herzegovina:** Ministry of Civil Affairs of Bosnia and Herzegovina (MCA)

- **Croatia:** Croatian Institute of Public Health (CIPH)

- **Czech Republic:** National Institute for Nuclear, Chemical and Biological Protection (SUJCHBO)

- **Denmark:** Statens Serum Institut, Department of Infectious Disease Epidemiology (SSI)

- **Estonia:** Ministry of Social Affairs of Estonia (MSAE)

- **Finland:** The Finnish Institute for Health and Welfare (THL)

- **France:** Ministry of Solidarities and Health (MoH-FR)

- **Germany:** Robert Koch Institute (RKI)

- **Greece:** National Public Health Organization (NPHO)

- **Hungary:** National Public Health Center (NPHC) - Nemzeti Népegészségügyi Központ (NNK)

- **Ireland:** Health Service Executive (HSE)

- **Italy:** The National Institute for Infectious Diseases "L. Spallanzani" (INMI)

- **Latvia:** State Emergency Medical Service (SEMS)

- **Lithuania:** Ministry of Health of the Republic of Lithuania (MOHLT)

- **Malta:** Ministry for Health, Government of Malta Directorate Environmental Health (MFH)

- **The Netherlands:** National Institute for Public Health and the Environment, The Centre for Communicable Disease Control (RIVM)

- **Norway:** Norwegian Directorate of Health (HD)

- **Poland:** National Institute of Public Health - National Institute of Hygiene (NIPH – NIH)

- **Portugal:** Directorate-General of Health, Ministry of Health (DGS/MS)

- **Republic of Moldova:** National Agency for Public Health (NAPH)

- **Serbia:** Institute of Public Health Serbia (IPHS)

- **Slovenia:** National Institute of Public Health (NIJZ)

- **Spain:** Instituto de Salud Carlos III (ISCIII)

- **Sweden:** Public Health Agency of Sweden (FoHM)

- **United Kingdom:** UK Health Security Agency (UKHSA), Public Health Wales (PHW)