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SHARP

Strengthened International HeAlth
Regulations & Preparedness in the EU

D4.2 Sustainability report Final

Ministry of Health (France)

July 2023

This document is part of the Joint Action 848096 / SHARP JA, which has received funding from the European Union's Health Programme (2014-2020).

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List of abbreviations

AAR	After Action Review
AC	Associated Countries
AMR	Antimicrobial Resistance
CBRN	Chemical, Biological, Radiological and Nuclear
CDC	Centres for Disease Control and Prevention
COVID 19 CMSS	COVID 19 Council of Medical Specialty Societies
CPMS	The Clinical Patient Management System
DCC	Digital Covid Certificate
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
ECHO	European Civil Protection and Humanitarian Aid Operations
EEA	European Environment Agency
EFSA	European Food Safety Authority
EMA	European Medical Agency
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
ENRS	European Network Remembrance and Solidarity
EPW	European Programme of Work
EQA	External Quality Assessments
EU	European Union
EUMS	European Union Member States
GDPR	General Data Protection Regulation
GHSI	Global Health Security Initiative
GNI	Gross National Income
HCAI	Health care-associated infection
HCID	High Consequence infectious disease
HEPR	Health Emergency Preparedness and Response
HERA	Health Emergency Response Authority
HLIUs	High-level isolation unit
HPAI	Highly Pathogenic Infectious Agents
IAR	One-day in-action review
IEM	Inter Epidemic Mode
IFC	Informal Focused Consultations
IHR	International Health Regulation
IHRMEF	IHR Monitoring and Evaluation Framework
INB	Intergovernmental Negotiating Body
IPC	Infectious Prevention and Control
JA	Joint Action
JEE	Joint External Evaluations
MEF	Monitoring and Evaluation Framework
MS	Member State
NAP	National Action Plan
NAPHS	National Action Plans for Health Security
PANSS	Plan d'action national pour la sécurité sanitaire
PPE	Personal Protective Equipment

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PPR	Prevention Preparedness and Response
PRP	Preparedness and response plan
RKI	Robert Koch Institute
SCBTH	Serious Cross-Border Threats to Health
SCHEER	Scientific Committee on Health, Environmental and Emerging Risks
SGT	Sustainability Guidance Tool
SHARP	Strengthened international Health Regulations & Preparedness in the EU
SimEX	Simulation Exercises
SOPs	Standard Operating Procedures
SPAR	State Party Self-Assessment Annual Reporting
TTX	Table Top
WGIHR	Working Group on the Amendments to the International Health Regulation
WGPR	Working Group on strengthening WHO preparedness and response to health emergencies
WHA	World Health Assembly
WHO	World Health Organisation
WP	Work Package

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Executive summary

Implementation of SHARP JA was affected by the Covid-19 pandemic. However, as a JA aiming to strengthen preparedness in the EU against serious cross-border threats to health and support the implementation of the IHR, it is uniquely positioned to contribute to the evolving health security architecture emerging from the pandemic. This represents an opportunity to sustain SHARP outcomes.

To this end, ten key outcomes from SHARP JA have been identified (priority outcomes), each with relevance to national, regional and global priorities in terms on prevention, preparedness and response:

1. Work Package 5: Methodology ,tools and recommendations for improving IHR implementation and evaluation;
2. Work Package 5: Template agreement of intention for cross-border multisectoral collaboration between neighbouring countries;
3. Work Package 6: Consensus to determine core elements of a multisectoral preparedness and response plan and related tools;
4. Work Package 7: the EMERGE laboratory network on highly pathogenic bacteria and viruses;
5. Work Package 8: Methodology to assess the cross-sectoral training needs for IHR strengthening across countries;
6. Work Package 8: Training tools for IHR strengthening, including training material, curricula and on-line platform;
7. Work Package 9: Recommendations to set-up a European chemical laboratory network to respond to serious chemical health threats;
8. Work Package 9: Chemical safety and chemical threats: SOPs on chemical health threats;
9. Work Package 10: Mapping existing High Level Isolation Units likely to be dealing with rare or new high consequence infectious diseases and for an expert clinical support service for high-consequence infectious diseases;
10. Work Package 10: Recommendations on the implementation of a syndrome based clinical protocol.

Sustaining SHARP priority outcomes is envisaged as specifically contributing to the priorities in terms of PPR at all levels:

- At the national level: Contribute to strengthening national prevention, preparedness and response plans and capacities.
- At the EU level:
    - Contribute to the implementation of the new **EU Health Security framework**, in particular aspects relating to reporting and evaluation, preparedness and response planning at national and EU level (with a focus on cross-border and cross-sectoral collaboration), EU level reference laboratories, and training;
    - Contribute to implementation of EU priorities in terms of AMR (through **JAMRAI II**) and all-hazard approach (linking with **BICTRA-TERROR JA** for chemical threats);
    - Contribute to leverage EU efforts at the global level- with neighbourhood countries, and with a pan-European approach with the EU as a driving

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force-to address health security as an issue of common concern and aligning with the **EU Global Health Strategy**.

- At the regional level: Contribute to **cross-border collaborations, and preparedness efforts at the pan-European level**.
- At the global level:
    - Provide the EU with concrete elements towards strengthening the global health security framework, related to the **pandemic agreement, the revision of the IHR**, and the global architecture for health emergencies prevention, preparedness and response;
    - Contribute to global priorities identified related to training (linking with the **WHO Academy**);
    - Contribute to global priorities identified related to IHR strengthening, in particular for laboratory capacities (linking with the **WHO Lyon office**).

This Sustainability report aims to provide a guide for Member States and, where relevant EU and WHO EURO, to integrate the JA-SHARP priority outcomes into national policies, EU or regional policies and plans through operational measures (named “Action Items”) and to ensure the long-term sustainability of priority outcomes, through relevant national, EU, pan-European or international bodies.

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I. Introduction

The SHARP Joint Action (JA) contributes to the implementation of Decision 1082/2013/EU- since repealed and replaced by Regulation (EU) 2022/2371 of the European Parliament and of the council of 23 November 2022 on serious cross-border threats to health. SHARP aims to strengthen the EU level preparedness and responses to health threats and the implementation of the International Health Regulations (2005).

From the outset, SHARP JA set out to produce innovative tools and recommendations on strategic issues regarding IHR implementation, strengthening and evaluation. The SHARP JA overarching objectives are recalled below**:**

1. Strengthening the scientific evidence base on effective actions to prevent and respond to cross-border health threats of biological, chemical, environmental and unknown origin;
2. Exchanging of information and sharing of best practices within and among Member States; Strengthening preparedness and the implementation of IHR core capacities, supporting Member States in developing standard operating procedures, business continuity plans, and promoting the interoperability of national preparedness planning;
3. Improving methods, tools and criteria for monitoring, assessment and reporting under Decision1082/2013/EU (since repealed and replaced by Regulation (EU) 2022/2371;
4. Improving EU Member State coordination as regards different global initiatives, particularly the WHO's IHR Monitoring and Evaluation Framework under the Health Emergencies Programme;
5. Improving the core functions of public health laboratories, including biosafety and biosecurity to ensure systems for the safe referral of clinical specimens for early detection and monitoring of outbreaks, transport in-country and international shipment, which key capacities required under the IHR;
6. The coordination, in collaboration with the European Centre for Disease Prevention and Control (ECDC), of a reference network of European microbiology laboratories specialized in highly pathogenic or newly emerging pathogens to improve laboratory capacity.

These objectives are the basis of technical **work packages (WP)** that structure the Joint Action:

- **WP5**: IHR core capacity strengthening and assessment.
- **WP6**: Preparedness and response planning.
- **WP7**: Laboratory preparedness.
- **WP8**: Training and local exercises, exchange of working practices.
- **WP9**: Chemical safety and chemical threats.
- **WP10**: Case management and infection prevention and control.

The critical challenge of the JA is to sustain the outcomes of the work-packages by integrating them into relevant policies (at national, European level or indeed regional or global levels), and to ensure the continuity of communication and cooperation

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among EU Member States after the SHARP JA project ends, through adequate technical structures and partnerships but also at a political level.

Therefore, the aim of the SHARP Joint Action work package 4 was to develop a sustainability plan, to ensure the Joint Action's priority outcomes are implemented and preserved beyond the timeframe and scope of the programme. To achieve this aim, it was necessary to select priority outcomes, for which efforts should be made to integrate them in the developed sustainability plan.

In this context, sustainability is defined as, "the long-term uptake and implementation capacity of the Joint Action's outcomes".

In this report, we will elaborate on the methodology used to identify priority outcomes, report on the identified priority outcomes and detail where (at what level: national, EU or regional/global) and how (what actions are necessary) to sustain these priority outcomes.

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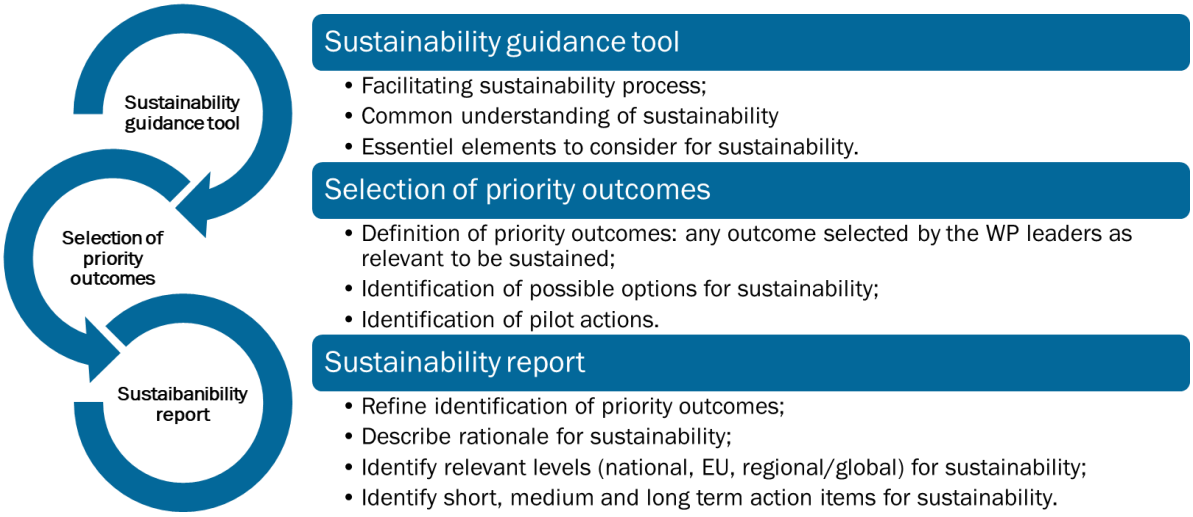
II. Methodology

2.1 Overview of the path towards sustainability



2.2 Sustainability guidance tool

WP 4 elaborated a Sustainability Guidance Tool (SGT) whose purpose was to ensure that all WPs (5 to 10) consider the sustainability of their outcomes within their work and reports. The SGT was a very innovative tool at the time of its development and first in kind. It has been used throughout the JA, but also widely disseminated to other joint actions across the health program. The SGT ensured a common understanding across JA members of sustainability as relating to the uptake and implementation capacity of priority outcomes to 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.

The SGT ensured a stepwise approach to sustainability and that WP leaders considered important aspects to anticipate sustainability during the implementation of the JA, namely:

- Policy and institutional support;
- Existing organizational and regulatory framework and ;
- Contextual factors.

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2.3 Selection of priority outcomes

The identification of the priority outcomes was a collective endeavour of WP4 and WP5 to 10, so that key outputs and deliverables could potentially qualify for implementation in the sustainability plan.

It is important to note that priority outcomes are not only defined **as specific outputs or deliverables but can be more widely understood as comprising outputs/deliverables, working methods developed to achieve those deliverables or higher-level outcomes**.

Work package	Priority outcomes
WP 5: IHR core capacity strengthening	Methodology, tools and recommendations for improving IHR implementation and evaluation.
	Building on lessons learned from Covid-19: Template agreement of intention for cross-border multisectoral collaboration between neighbouring countries.
WP6: Preparedness and Response planning	Building on lessons learned on multisectoral collaboration during the COVID pandemic: Consensus to determine core elements of a multisectoral preparedness and response plan (including which sectors should be involved during pandemic preparedness, response and recovery) and related tools (table-top exercise and e-learning course).
WP 7: Laboratory preparedness and responsiveness	Recommendation to maintain the EMERGE Laboratory Network on highly pathogenic bacteria and viruses.
WP 8: Training and local exercises, exchange of working practices.	Methodology to assess the cross-sectoral training needs for IHR strengthening across countries.
	Training tools for IHR strengthening, including training material, curricula and on-line platform.
WP 9: Chemical safety and chemical threats	Recommendations to set-up a European chemical laboratory network to respond to serious chemical health threats.
	SOPs on chemical health threats (based on findings from the workshops and the best practices, gaps and bottlenecks).
WP 10: Case management and infection prevention and control preparedness	Mapping of existing High Level Isolation Units likely to be dealing with rare or new high consequence infectious diseases and for an expert clinical support service for high-consequence infectious diseases.

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	Recommendations on the implementation of a syndrome based clinical protocol.

2.4 Sustainability report (methodology and objectives)

The Sustainability report is developed to attain the objective of Joint Action Work Package 4 to ensure the Joint Action's priority outcomes are identified, implemented and preserved beyond the timeframe and scope of the Joint Action.

It aims to provide a guide for Member States and, where relevant EU and WHO EURO, to integrate the JA-SHARP priority outcomes into national policies, EU or regional policies and plans through operational measures (named "Action Items") and to ensure the long-term sustainability of priority outcomes, through relevant national, EU, pan-European or international bodies.

The plan comprises:

- The priority outcome undertaken through JA-SHARP, and identified by the Work Packages as relevant to be sustained;
- The rationale for sustaining the selected priority outcomes, taking into account the EU, regional and global contexts;
- Options for relevant levels (national, EU, regional or global) to sustain the priority outcomes;
- The potential ways though which Member States and, where relevant EU and WHO EURO, could integrate JA-SHARP priority outcomes within policies, be they operational tools or recommendations and/or plans.

The draft sustainability report was disseminated for comments to members of the Steering Committee on 2 June 2023. The draft report was presented and discussed (during a panel discussion on sustainability) at the SHARP final conference on 20 June 2023. Comments were received and integrated in the final report.

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III. Sustainability report

3.1 Context

3.1.1 EU level

EU Health Union

The COVID-19 crisis has highlighted the strategic importance of actions foreseen by the SHARP JA, two years before the COVID-19 virus emergence. Gaps related to many topics identified in the work plan to be improved such as variation in IHR implementation within MS, surveillance, laboratory activities, etc were all put at the forefront during the pandemic. **The evolutions led by the response to the pandemic present opportunities to use the SHARP JA outcomes to strengthen EU preparedness and responses to health threats.**

The pandemic has highlighted gaps in the European preparedness and response capacities to health crises, which have been summarised by the European Commission in ten lessons of COVID-19 for public health policy[1]. In particular, we can mention:

- The need for stronger global surveillance and more comparable and complete data (Lesson 1);
- The reinforcement of public-private partnerships, sufficient knowledge on supplies and demand of medical countermeasures with new HERA's mandate (Lesson 6);
- To ensure cooperation and funding for clinical research (Lesson 7);
- The necessity to increase investment in health system to be able to supported the overall strengthening (Lesson 10).

Those gaps have led the EU to act swiftly and undertake major reforms to reinforce its competencies and preparedness regarding health security. The legislative package proposed by the European Commission in November 2022, in the context of the Covid-19 crisis, included four key elements:

- Reinforcement of the mandate of the EMA, adopted by the Council on January 25, 2022. This mandate will allow the EMA to mitigate and closely monitor shortages of medicines and medical devices during major events or public health emergencies and to facilitate faster approval of drugs that may treat or prevent a disease causing a public health crisis;

- The creation of a new European Health Emergency Preparedness and Response Authority (HERA) set up by a Commission decision in September 2020 for non-crisis mode and by a regulation for crisis mode (adopted in

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021DC0380&from=EN

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December 2021). HERA will anticipate potential health threats and crises, through the collection of intelligence and the strengthening of the necessary response capacities. In the event of an emergency, HERA will ensure the development, production and distribution of countermeasures;

- Reinforcement of ECDC's mandate (adopted by the Council on 6 December 2021). Key elements of the strengthened ECDC mandate include:
    - Strengthen its collaboration with Member States;
    - Strengthen the rapid digitization of integrated surveillance systems;
    - Strengthen its capacity for anticipation and forecasting;
    - Develop EU prevention and response plans against future epidemics and capacities for an integrated rapid response to epidemics and outbreaks;
    - Provide non-binding recommendations for risk management;
    - Implement, mobilize and deploy a European Task Force for rapid intervention to support the response in Member States and third countries;
    - Strengthen the monitoring and evaluation of the capacities of national health systems to diagnose, prevent and treat communicable diseases;
    - Strengthen epidemiological surveillance via integrated systems allowing real-time surveillance;
    - Strengthen its cooperation with third countries and its collaboration with the WHO.

- The regulation on serious cross-border threats – SCBTH (political agreement reached on June 23, 2022) which is the final pillar of the foundations of a stronger European Health Union and strengthen preparedness and response planning, and sets out the rules for an improved, flexible and integrated surveillance system. It also increases the capacity of the Union and its Member States to do accurate risk assessments and take targeted response actions, including joint procurement of medical countermeasures, such as vaccines and therapeutics. Key elements of this regulation include:
    - The establishment of a "public health alert at Union level", which, once declared by the Commission, will allow the implementation of emergency measures (including the activation of "emergency mode" of HERA);
    - The establishment of rules for a reinforcement and integration of the epidemiological surveillance system at Union level, supported by improved data collection tools and artificial intelligence;
    - The establishment of common rules regarding the surveillance of new pathogens and the transmission of health systems data and other data relevant to the management of cross-border threats;
    - Strengthening the role and coordination of the Health Security Committee;
    - The development of a Union preparedness and response plan (which will be drawn up by the Commission) and requirements for correspondence to national plans, together with a framework for preparation of reports and audits of national plans;

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- Periodic evaluation of national preparedness and response plans by ECDC (and the formulation of recommendations by ECDC based on its evaluations). ECDC will develop procedures and standards for these assessments and conduct them;
- The implementation by the Commission of capacity building activities for health personnel in crisis preparedness and response;
- Arrangements for the designation and funding of EU reference laboratories in the field of public health (under the aegis of ECDC);

The clear alignment between the gaps identified and the objectives of the SHARP-JA underline the relevance of the strategic focus of this Joint Action. The reforms undertaken represent opportunities for the SHARP-JA to participate in strengthening the EU's preparedness and response.

An analysis was conducted identifying how the implementation of SHARP-JA outcomes could fit with the EU health security framework. The results of this analysis identifies clear links between the new EU health security framework and SHARP-JA outcomes.

Field	Aspect of legislative package for an EU health union	Alignment/ contribution from SHARP JA
Strengthening IHR core capacities	SCBTH calls for strengthened national Preparedness and Response capacities	SHARP JA worked towards strengthening national Preparedness and Response capacities, with a focus on low GNI countries. **> WP 5 – IHR strengthening** **> WP 7 – Laboratory capacities**
Improve external evaluation process	SCBTH calls for Periodic evaluation of national preparedness and response plans by ECDC (and the formulation of recommendations by ECDC based on its evaluations	SHARP JA works towards increasing knowledge about the practicalities and added value of external evaluation processes (JEE, AAR, SPAR). Valuable lessons learned could contribute to ECDC development of procedures and standards for these evaluations. **> WP 5 – IHR strengthening; WP 6 P&R planning**

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Cross-border cooperation	EU health union call for strengthened cross-border cooperation	SHARP JA works towards strengthening cross-border cooperation, notably in terms of patient and health personnel transfer. Valuable lessons learned could contribute to better cross-border preparedness and response planning. **> WP 5 IHR strengthening; WP 6 P&R planning; WP 10 Case management, hospital preparedness**
Preparedness and Response Planning	SCBTH calls for the development of a Union preparedness and response plan (PRP) to be drawn up by the Commission. Plus, requirements for correspondence to national plans via a framework for preparation of reports and audits of national plans	SHARP JA has developed tools to identify core elements of an integrated multi-sectoral preparedness and response plan (PRP). These insights could usefully contribute to Union and national PRPs. **> WP 6 P&R planning**
Training and capacity building	SCBTH calls for the implementation by the Commission of capacity building activities	SHARP JA has developed cross-sectoral basic and advanced training materials (based on ECDC and WHO material), to improve capacity in IHR implementation for serious cross-border health threats in the JA partner countries. These materials could contribute to the EC mandate in this regard. **> WP 8 Training**

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Chemical safety and chemical threats	HERA aims to address a range of threats including Chemical, Biological, Radiological or Nuclear (CBRN) threats.	SHARP JA aims to strengthen preparedness and response to cross-border chemical health threats within MSs and across the EU and can contribute to HERA's action in this regard. **> WP 9 Chemical threats**
Case management capacities	Union prevention, preparedness and response plans will include cross-border and interregional preparedness elements to support aligned multi-sectoral, cross-border public health measures, including capacities for specialised treatment	SHARP JA aims to improve clinical and bio risk management, hospital preparedness and response to high-consequence infectious diseases. A mapping of existing facilities was undertaken. This could usefully contribute to the Union PRPs. **> WP 10 Case management**

Anti-Microbial Resistance

AMR is a policy priority at the EU and global levels. At the global level, **AMR is a core capacity within the IHR MEF and proposals are being discussed (support by the EU) to integrate AMR as a priority of the new pandemic agreement.**

At the EU level, in June 2017, the European Commission (EC) adopted a One Health action Plan against AMR to make Europe a best practice region. From 2017 to 2021, EU-JAMRAI Joint Action supported Member States (MS) in the implementation of concrete measures to fight AMR and resulted in seven policy briefs, and concrete outcomes, such as the AMR symbol or the European AMR Surveillance network in Veterinary medicine, EARS-Vet. Today, AMR remains high on the political agenda.

Key policy initiatives underway to strengthen EU action against AMR are a Commission proposal for a Council Recommendation on AMR and work towards AMR integration in the new World Health Organization (WHO) international pandemic agreement. With its 2022 EU4Health work programme, the EC committed to dedicate €50.3 million to AMR and to launch a new JA on AMR and HCAI.

This new JA, entitled EU-JAMRAI 2, builds on the first EU-JAMRAI experience and results. It will supports MS/AC (Member States / Associated Countries) in their efforts to develop and update their NAP on AMR. It will contribute to several EU4Health

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policy priorities: Strengthening MS/AC coordination against AMR, a serious cross-border threat to health; Strengthening the responsiveness of health systems against AMR; Ensuring the access to important medicinal products and medical devices to fight AMR; Protecting people from AMR.

In line with the 2017 EU AMR One Health action plan, it also promotes capacity building between MS/AC and aims at making Europe a best practice region in the fight against AMR.

European Union Global Health Strategy

The European Commission presented the new European Union Global Health Strategy on November 30th, 2022. The strategy takes stock of the EU and its MS collective endeavours during the pandemic and expresses a renewed and impactful determination to contribute to shaping the future of global health, a geopolitically critical sector that is essential to guarantee the stability of society. The EU Global Health strategy provides twenty guiding principles and proposes subsequent lines of action that tackle global challenges by working in meaningful strategic partnerships as part of the Global Gateway strategy.

The EU Global Health Strategy presents an opportunity to develop mechanisms to ensure that issues of common European and global relevance (such as health security) can be addressed at the global level by leveraging the Union's assets that are developed though EU mechanism such as Joint Actions and institutions with a global reach (such as HERA, ECHO, or ECDC).

As we saw with the EU DCC (Digital Covid Certificate), the EU can successfully leverage its work to set the standards at the global level. SHARP is uniquely placed in this regard, as it addressed strengthening of the IHR, which is a global instrument. To this end, SHARP JA outcomes, and future actions in the field of health security, could be leveraged at the global level.

EU mandate to negotiate a pandemic agreement and revision of the IHR

Ongoing negotiations towards a new international agreement on pandemic prevention, preparedness and response and towards revising the IHR (2005) are two key aspects of the reforms to the international global health architecture (see section 3.1.3).

For these negotiations, the EU has decided to adopt a coordinated approach, with Council Decision of the 3rd March 2022 authorising the Commission, for matters falling within Union competence, to negotiate an international agreement on pandemic prevention, preparedness and response and to negotiate towards revision of the IHR.

Through its concrete contributions to practical implementation of key aspects of the pandemic agreement and IHR revision (such as strengthening IHR core capacities, AMR and multisectoral collaboration), SHARP JA provides the EU with concrete elements towards strengthening the global health security framework.

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3.1.2 Pan-European level

Based on the recommendations of the Pan-European Commission on Health and Sustainable Development, the WHO Regional Office for Europe (WHO EURO) is in the process of developing a new framework for strengthening health security in the EURO region: Preparedness 2.0. Preparedness 2.0 will align with the processes ongoing at the global level (next section) and with the new EU health security framework (previous section).

Preparedness 2.0 is a strategy towards regionalization with a clear focus on closing country capacity gaps. The overall aim of Preparedness 2.0 is to strengthen health emergency preparedness, response and resilience across the WHO Region through and all-hazard and One-Health approach and to support countries to develop fit-for-purpose national health emergency preparedness and response plans and systems. As such, Preparedness 2.0 can build on the outcomes of SHARP JA regarding strengthening IHR core capacities.

Some of the identified priorities of Preparedness 2.0 can build on the work of SHARP JA, namely:

- Strengthening country preparedness and readiness based on lessons learnt and closing gaps (this can build on the outcomes SHARP WP5, WP6, WP7 and WP8);
- Building a flexible and agile health emergency work-force (this can build on the outcomes of WP5);
- Tackle infodemics and build trust (this can build on outcome of WP8)
- Institutionalise a gender perspective in all activities;
- Establish a Pan-European network for disease control.

Regarding the timeline: consultations are ongoing. An intermediate report will be presented at the Regional Committee in October 2023. The Preparedness 2.0 strategy and action plan will be adopted at the 2024 Regional Committee. WHO EURO is also planning to support Member States of the EURO region towards undertaking or updating Joint External Evaluations (JEE).

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3.1.3 Global level

International Health Regulations:

Disease outbreaks and others acute public health risks represent some of the greatest risks that threaten people's health and the global economy and security. To prevent global spread of the disease and minimize its impact with international trade and traffic, the international health regulation was created in 1969[2]. Initially covering only few diseases, with the emergence, re-emergence and international spread of diseases and other threats, it was decided to cover the majority of public health risk that impact human health[3]. In this regard, the revised IHR was adopted in 2005 by the WHA 58 and was implemented on 15 June 2007. States Parties are required to notify WHO a potentially wide range of events. Key actions required of States Parties included assessing their surveillance and response capacities and developing and implementing action plans to ensure the functioning of these core capacities by 2012[4].

As SHARP's general objective is to strengthen implementation of the IHR, sustainability of its outcomes needs **to align with ongoing negotiations towards revision of the IHR.**

In January 2021, the Independent Panel on Pandemic Preparedness and Response (IPPR) concluded that the IHR (2005) needed updating to move from the 'analogue' to the 'digital' era of sharing information, so that WHO and its Member States can respond more quickly to global health risks. Under the current IHR (2005) rules, for example, there is no specific period for countries to report suspected outbreaks to WHO or for WHO, in turn, to report them to Member States. The IPPR recommendation was one of the topics addressed by the working group on strengthening WHO's preparedness and response to health emergencies (WGPR- active from July 2021 to May 2022), set up by WHO Member States following shortcomings identified in the global response to the COVID-19 pandemic.

Subsequently, in May 2022 at the 75th World Health Assembly (WHA), Member States agreed to launch a two-year process to amend the substantive rules of the IHR (2005). The aim is to have a set of reforms in place for the 77th World Health Assembly in May 2024 and for the new approved rules to take effect from May 2025. The task of collecting and evaluating proposals of nations to modify the IHR is managed by a new Working Group of Member States on IHR Revision (WGIHR).

At the same time, the Director-General of WHO, Dr Tedros Adhanom Ghebreyesus, was tasked with convening an expert committee to review the IHR (2005) to provide the WGIHR with more information on the most necessary and useful reforms. The WGIHR will review the report from the IHR review committee and oversee negotiations to achieve a package of IHR amendments to be adopted in 2024.

[2] https://www.emro.who.int/international-health-regulations/about/background.html
[3] https://www.who.int/health-topics/health-security#tab=tab_1
[4] https://www.emro.who.int/international-health-regulations/about/background.html

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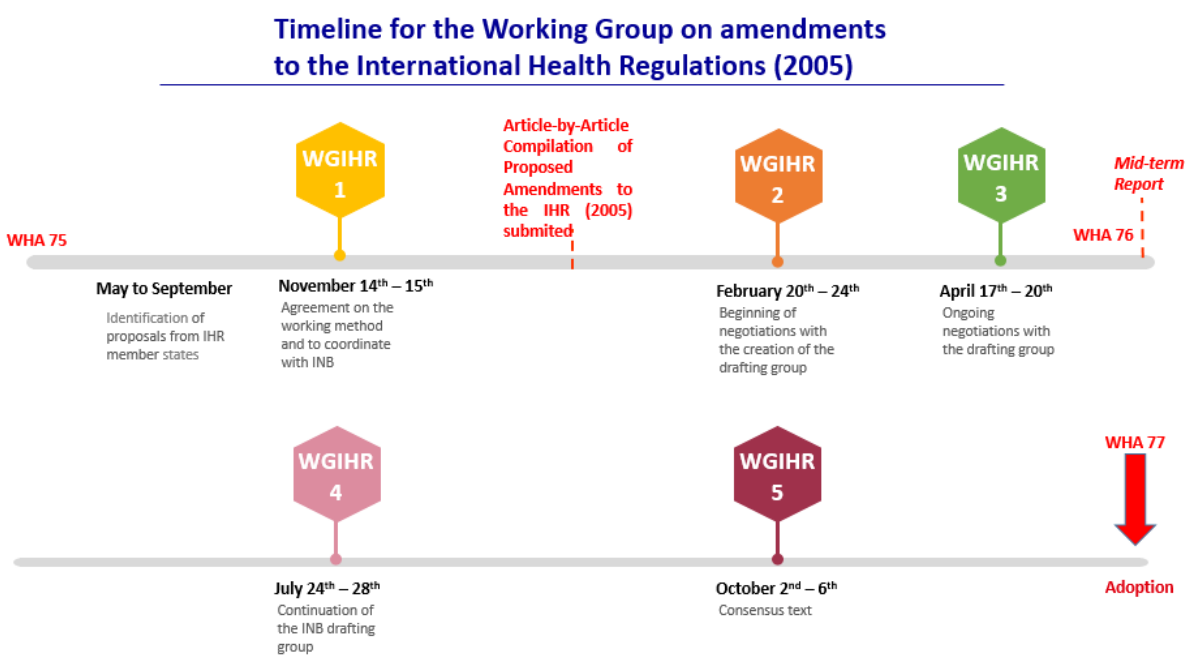

Analysis of the submitted IHR amendments proposals and of ongoing negotiations shows that strengthening the supervision of the implementation of IHR provisions, particularly to strengthen and maintain IHR core capacities, will be a key aspect of the IHR revision process. In this regard, the EU has submitted proposals to strengthen the role of the World Health Assembly in the supervision and oversight of the effective implementation of the IHR. This underlines the increased importance of strengthening IHR core capacities and their assessment through the **IHR monitoring and evaluation framework** (SPAR, JEE, IAR/AAR, SIMEX), linking with SHARP WP5 outcomes.

We can also note the revisions to the IHR Monitoring and Evaluation Framework, with which SHARP aligns. In 2020, the IHR Review Committee and the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme expressed the need to adjust the IHRMEF instruments, including the JEE, based on lessons learned from the COVID-19 pandemic. In 2021, a consultative meeting reviewed lessons from COVID-19 pandemic for IHRMEF instruments and made recommendations for improvement of the JEE. A third edition of the JEE tool was published in 2022, and used for the first time in the EURO region in Azerbaijan in May 2023.

It is also important to highlight the added **emphasis on strengthening the link between evaluations of IHR core capacities and implementation of concrete actions to strengthen preparedness and response capacities**, both at EU level (as per SCBTH, evaluation of national plans will lead to a report with specific recommendations for Members States) and at the global level.

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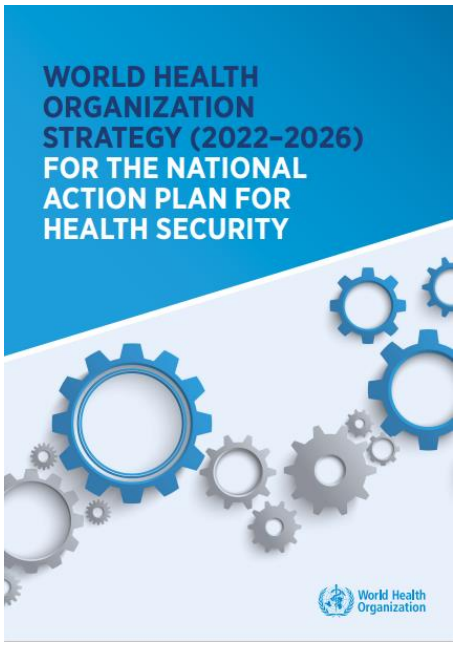
At the global level, WHO has recently developed a five-year strategy (2022-2026)[5] for National Action Plans for Health Security (NAPHS), which is a multi-year planning tool to accelerate the implementation of core capacities of the IHR and is based on the One Health for All Hazards approach. NAPHS aim to capture national priorities for health security, bring sectors together, identify partners and allocate resources for health security capacity development. The PANSS constitutes an important link between the assessment of capacities and the implementation of actions to strengthen them.



The new five-year strategy for the PANSS (2022-2026) is based on the observation that countries have their own planning mechanisms. These may include specific capacity development plans aimed at strengthening IHR, national health security and health risk management. The new strategy encourages Member States to use existing health security capacity development plans and ensure alignment with their national health strategies, planning and budgeting cycles to improve opportunities for investment from national and international budget allocations for health security.

Pandemic agreement:

In parallel, and complementary to the revision of the IHR, a process is underway towards the elaboration and adoption of the new international agreement on pandemic prevention, preparedness and response**.**

Following the outbreak of COVID-19, shortcomings appeared in the application of the International Health Regulations (2005). This gave rise to a number of proposals intended to remedy it, including the idea of creating a new agreement. An extraordinary session of the World Health Assembly in December 2021 saw the creation of an intergovernmental negotiating body (INB), to develop and negotiate a convention, agreement or other international instrument on pandemic prevention, preparedness and response, to be adopted by the WHA in 2024.

[5] https://www.who.int/publications/i/item/9789240061545

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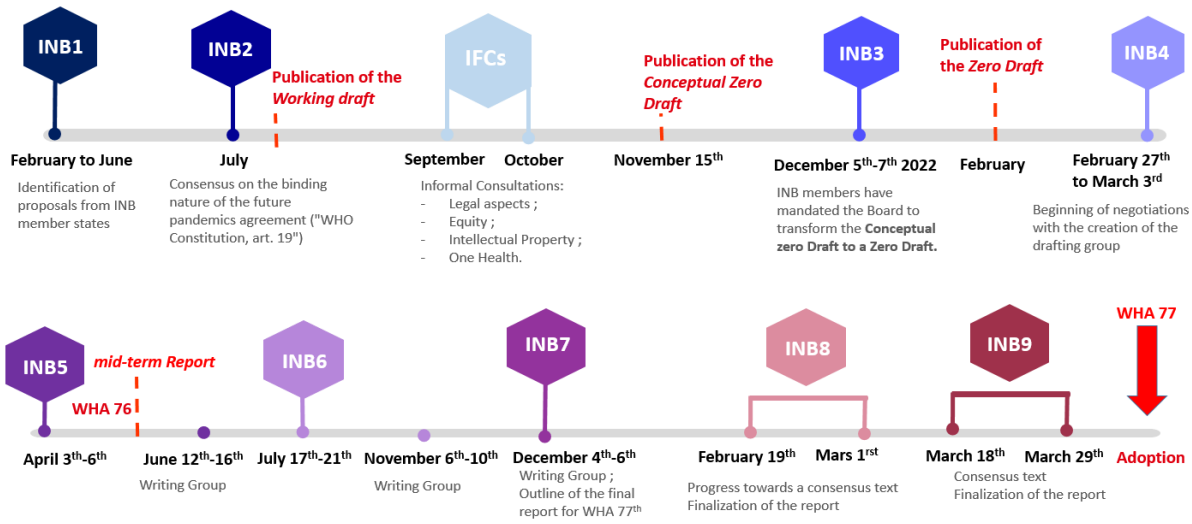
Timeline for the pandemic agreement



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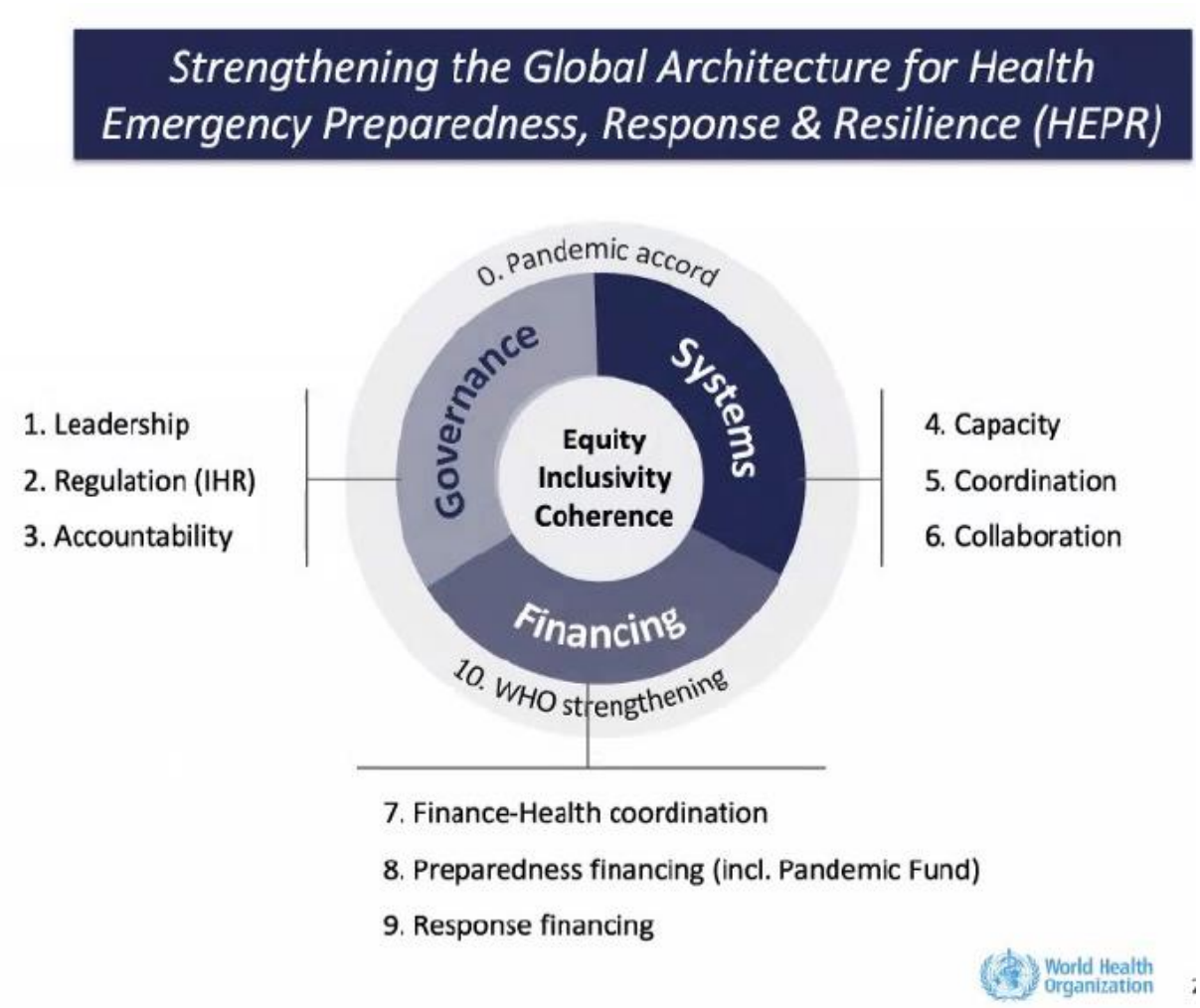
Health emergency preparedness, prevention, response and resilience (HEPR)

WHO has developed a strategic framework for strengthening the Health emergency preparedness, prevention, response and resilience (HEPR). The proposals are grouped in three main pillars of the global HEPR architecture: governance, systems and financing and include the pandemic agreement, leadership, regulation (IHR), accountability, finance-health coordination, preparedness financing, response financing, capacity, coordination, and collaboration.



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WHO Lyon Office:

While WHO is taking steps forward to further develop structures that build systems and capacities required for effective HEPR, the WHO Lyon Office has developed a plan to serve as a **Center of Excellence for public health laboratories and diagnostics** which are critical components of emergency preparedness, readiness and response, building on 20 years of experience of the Office in this area. The Lyon Office will join WHO's newly established BioHUB in Switzerland, which oversees the sharing of biological materials with epidemic or pandemic potential, and the new WHO Hub for Pandemic and Epidemic Intelligence in Berlin.

The WHO Lyon Office will support Member States to increase access and use of diagnostics and laboratories in a safe, secure, timely and reliable manner, to strengthen the capacity for detecting diseases and to maximize the effectiveness of emergency response. Laboratories are at the front line of surveillance and response efforts and among the most critical components of public health and health care systems during disease outbreaks.

The WHO Lyon Office will lead WHO's activities in strengthening laboratory services and diagnostics for health emergencies, leveraging investments made by countries during previous epidemics and pandemics, and through a **close coordination with the WHO Regional Offices- including WHO EURO,** for a stronger country impact.

WHO Lyon office is also the centre for **strengthening IHR core capacities related to mass-gatherings and points-of-entry.** WHO Lyon office is also a key **actor in terms of training to strengthen IHR capacities r**elated to laboratories, mass-gatherings and points-of entry.

WHO Academy:

At the global level, the **WHO Academy in Lyon is been developed as a key tool of the WHO for training its health staff.** The WHO will provide high-level, recognized training to health personnel, with training in health security recognized as a priority. Trainings will include an online training platform. The WHO Academy's mission is to set global standards in health education and mobilize partners in health globally to provide innovative and accessible learning to healthcare professionals around the world. WHO Academy can be a key lever to leverage training material at the global level.

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3.2 Sustainability and integration into national and EU policies of EU-SHARP priority outcomes

3.2.1 Work Package 5: IHR core capacity strengthening and assessment: Methodology, tools and recommendations for improving IHR implementation and evaluation

Description:

WP5 aimed to improve IHR implementation in twelve focus (low GNI) countries by strengthening of selected IHR core capacities during annual workshops and corresponding work between workshops. WP5 developed a **methodology for a multi-country, peer-to-peer approach** for strengthening IHR implementation and evaluation, which included a baseline analysis on core capacities according to common tool and **multi-country peer-led workshops to assess strengthening of IHR core capacities.** A tool with activity and strategic suggestions for IHR strengthening was developed to be implemented in individual country contexts and a progress report template was created. This tool aimed to document progress made in the selected core capacities and was informed by the WHO Benchmarking Tool and interviews. **The tool listed activities to strategically work to level up for upcoming SPAR reports.** IHR core capacities, which were priorities and assessed were: **Risk Communication, Chemicals, Biosafety and Biosecurity and AMR-One Health surveillance.**

Benchmarking_SPAR_JEE_indicators_4th

The methodology (detailed in D5.2: A report on knowledge and practices and added value of external evaluation processes and facilitating strengthening of selected core capacities in the EU and neighbouring countries) **involved a multi-country approach (12 selected countries) with voluntary contributions from all countries by way of presenting examples, moderating sessions, facilitating discussions and sharing perspectives for IHR strengthening.**

WP5 also developed recommendations to improve use of Simex and After/Intra Action Reviews (which are part of the IHR MEF) to strengthen IHR evaluation.

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Rationale:

Evaluating and strengthening of IHR core capacities is a common priority at EU, regional and global levels.

At the EU level, SCBTH Article 7 provides for Member States to report on their national preparedness and response plans, while Article 8 provides for the European Commission and ECDC to evaluate national plans. While the reporting and evaluation templates are to be finalized, they could usefully be based on the IHR MEF as noted by ECDC: "the type of measurement approach and format used in the JEE tool might be useful for the EU's preparedness assessment efforts". Further, Article 5 provides for the implementation of Simex and AAR in order to ensure the implementation of the Union prevention, preparedness and response plan.

Therefore, tools and recommendations developed to improve IHR implementation and evaluation will be useful towards EU assessment efforts.

WP5 work towards strengthening and evaluating "Surveillance" and "AMR" (as two of the prioritised IHR core capacities) align with EU and global priorities regarding Surveillance and AMR. In this regard, at the EU level, JAMRAI II, which aims to strengthen national AMR surveillance systems can leverage work undertaken though SHARP with 15 participating countries to increase and share knowledge of the JEE specific indicators –specifically for AMR, and to identify challenges for improvement. Also at the EU level, the United4Surveillance Joint Action can build on work done towards strengthening surveillance in the EU.

At the Pan-European level, Preparedness 2.0 strategy and action plan will prioritize strengthening country preparedness and readiness based on lessons learnt and closing gaps identified through JEE.

At the global level, evaluating IHR core capacities and strengthening core capacities through the revised NAPHS strategy are priorities. Within the IHR revision process, proposals are under discussion to strengthen mechanisms for IHR implementation. These include proposals from the EUMS that would make the Health Assembly responsible for overseeing and promoting the effective implementation of the Regulations and giving it the authority to take decisions and make recommendations as necessary. The Health Assembly would also regularly assess the implementation of the Regulations by States Parties and establish a review mechanism to that effect. A dedicated meeting would be held every two years during the Health Assembly and a special expert committee would be established to support the Health Assembly in its implementation of the new provisions set out in the proposed amendment. Assessing these proposals, the IHR Review Committee agreed that it would be valuable to have enhanced provisions in the IHR regarding to compliance and implementation.

Options for integration at National level

- The methodology and tool for improving IHR implementation and evaluation could be adapted to local country context and disseminated to other EUMS to support identification of activities to strategically work on.

Options for sustainability at EU level

- The methodology and tool for improving IHR implementation and evaluation could be integrated into EU assessment efforts (Articles 7 and 8 of SCBTH) and EU efforts to strengthen MS preparedness and response capacities;

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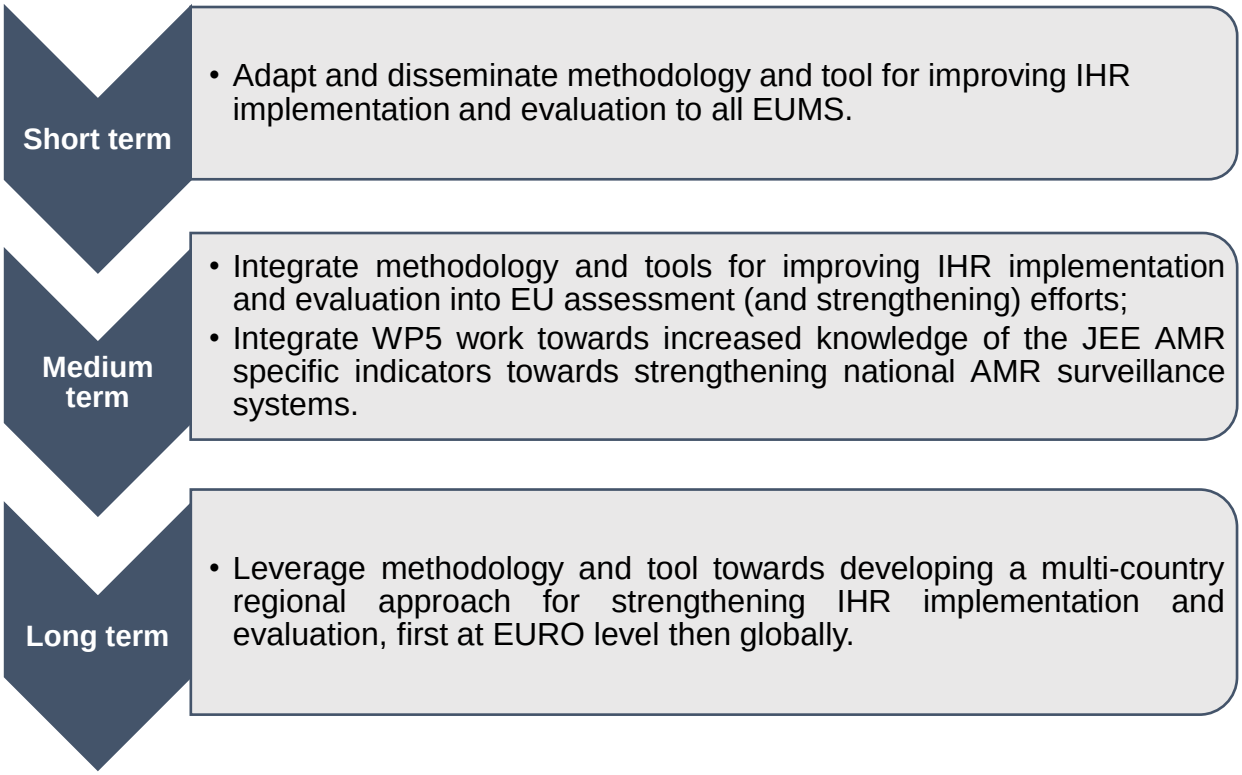
- The recommendations for strengthening use of Simex and AAR can be implemented at EU level to ensure the implementation of the Union prevention, preparedness and response plan;
- JAMRAI II can integrate WP5 work towards increased knowledge of the JEE AMR specific indicators towards strengthening national AMR surveillance systems;
- United4Surveillance can integrate WP5 work towards increased knowledge of the JEE Surveillance indicators.

Options for sustainability at Pan-European and global levels

- The methodology and tool for improving IHR implementation and evaluation inform the development of the Preparedness 2.0 strategy and action plan, towards developing a multi-country regional approach to IHR implementation and evaluation.

Action items:



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3.2.2 Work Package 5: IHR core capacity strengthening and assessment: Template agreement of intention for cross-border multisectoral collaboration between neighbouring countries

Description:
WP5 worked 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. Based on the information collected from MS survey and discussions with MS, it was identified that an agreement of intention, similar to the Nordic Public Health Preparedness Agreement may be helpful in the process of fulfilling the expectations for preparedness and response plans by EU at the regional level. WP5 elaborated a template agreement of intention for cross-border multisectoral collaboration between neighbouring countries or countries who can assist bilaterally based on the Nordic Public Health Preparedness Agreement (detailed in D5.3 : report on international collaboration between authorities during crises).

SHARP template cross-border collabc

Rationale:

Strengthening cross-border collaboration is common priority at EU, regional and global levels.

At the EU level, Article 5 of the Regulation on serious cross-border threats to health describes the requirements for establishing a Union prevention, preparedness and response plan. The plan serves to promote an effective and coordinated response to cross-border threats to health at Union level. The plan will include a Chapter (III) on “Cross-border interregional preparedness elements”. This chapter will start with highlighting areas that Member States should consider in terms of cross-border interregional cooperation, such as capacities for surveillance, testing, laboratories, contact tracing, **healthcare staff and specialised treatment or intensive care across neighbouring regions**. Following this, it will outline areas where the Commission, the Council and Union agencies and bodies can support Member States in terms of cross-border interregional preparedness elements, including on cross border health care, risk communication and community engagement and health security related trainings and simulation exercises.

At the Pan-European level, the Preparedness 2.0 aims to strengthen regional cross-border collaboration, including through building a flexible and agile health emergency workforce.

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At the global level, the COVID-19 pandemic exposed crucial gaps in national, regional, and global response mechanisms to tackle health threats effectively. The intricate nature of these crises strains health systems worldwide, further emphasizing the need for a comprehensive global response. The World Health Organization (WHO) and partners have highlighted the importance of strengthening health emergency workforce capacities in all countries as a central part of the global architecture for health emergency preparedness, response and resilience. As outlined in the G7 Pact for Pandemic Readiness, launched in Berlin 2022, it is essential to rapidly activate professional public health emergency workforce that works with cross-sector partners at all levels.

Strengthening cross-border multisectoral collaboration between neighbouring countries is key to achieving these goals.

Options for integration at National level

- Neighbouring countries could adapt and use the template agreement of intention for cross-border multisectoral collaboration.

Options for sustainability at EU level

- Chapter III of the Union Plan could include a provision for neighbouring countries to strengthen or develop, where relevant, cross-border collaboration, based on the proposed template.

Options for sustainability at Pan-European and global levels

- WHO EURO countries could strengthen or develop, where relevant, cross-border collaboration, based on the proposed template.

Action items:

Short term

- Set-up a cooperative body (composed of authorities party to cross-border agreement) to further develop and update the template;
- Develop detailed operative plans for cross-border collaboration.

Medium term

- Adapt and use the template agreement of intention for cross-border multisectoral collaboration between neighbouring countries, including at the regional level;
- Integrate template agreement within Union prevention, preparedness and response plan.

Long term

- Further develop, update and evaluate template agreement for cross-border multisectoral collaboration both at EU and regional levels.

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3.2.3 Work Package 6: Preparedness and Response planning: Consensus to determine core elements of a multisectoral preparedness and response plan (including which sectors should be involved during pandemic preparedness, response and recovery) and related tools (table-top exercise and e-learning course)

Description:
Work Package 6 used a RAND modified consensus procedure to determine which sectors should be involved during pandemic preparedness, response and recovery. This involved an integrated literature review of multisectoral collaboration during public health, an initial questionnaire, a hybrid meeting on lessons learnt regarding multisectoral collaboration to discuss the initial questionnaire's results and a second questionnaire to finalize the results, WP6 identified core elements of a multisectoral preparedness and response plan and sectors which should be included in preparedness, response and recovery.

SHARP consensus core elements PRP.p

Work Package 6 has also developed Table Top Exercise (TTX) to enhance awareness on which sectors are currently involved and which should be involved in the initial period of public health emergency response. It is designed to inspire public health professionals to think about multisectoral collaboration in their existing national, (in)formal preparedness and response plans. WP6 also developed an all hazards e-learning tool.

Rationale:

Although the need for multisectoral collaboration is explicit in the IHR (2005), the documents do not stipulate clear processes for multisectoral collaboration during public health emergencies. It is unclear how preparedness and response professionals at different governance levels should operationalise the concept of multisectoral collaboration in policies as well as preparedness and response plans.

The European, regional and global policy contexts, further underscores the need for a common, understanding of multisectoral collaboration.

At the European level, Article 5 of the Regulation on serious cross-border threats to health describes the requirements for establishing a Union prevention, preparedness and response plan. According to the new Regulation, the plan should include provisions on joint arrangements for governance, capacities and resources, including for **"Health preparedness and response and multi-sectoral collaboration**". Further, as per Article 6 ('National prevention, preparedness and response plans'), Member States are tasked to coordinate with the Commission to seek coherence with the Union plan, providing an opportunity to ensure a common understanding and approach to multi-sectoral collaboration across the EU and its Member States.

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Article 7 (Reporting on prevention, preparedness and response planning) further specifies the need for Member States to report on elements of emergency prevention, preparedness and response planning, in particular "**in terms of multi-sectoral collaboration**". Article 20, further mandates a multi-sectoral approach to public health risks assessment at the EU level, involving multiple EU agencies (ECDC, EMA, EFSA, ECHA, EEA, and EMCDDA).

At the regional level, the Preparedness 2.0 strategy and action will be based on an all-hazards approach, involving multi-sectoral collaboration.

At the global level, In September 2022, the United Nations General Assembly adopted a resolution to organize a high-level meeting on prevention, preparedness and response (in September 2023). It aims to further mobilize political momentum, including through the **integration of a multisectoral approach to pandemic prevention, preparedness and response**, given the multifaceted consequences of pandemics.

A multi-sectoral approach is also likely to be a key aspect of the new pandemic agreement (with **12 mentions of "multi-sectoral" in the Zero draft of the agreement proposed** by the INB at its fourth meeting in March 2023). Multi-sectoral approaches are also key to **strengthening capacities** of staff involved in prevention, preparedness and response.

Options for integration at National level

- Member States can strengthen their national prevention, preparedness and response plans to integrate a multisectoral approach based on the core elements of a multisectoral preparedness and response plan;
- Member States to adapt to national context and implement Table-Top Exercise on multisectoral collaboration;
- Member States to adapt to national context and integrate all-hazards e-learning tool into national capacity-building plans.

Options for sustainability at EU level

- The Union prevention, preparedness and response plan can adopt a multisectoral approach based on the core elements of a multisectoral preparedness and response plan.

Options for sustainability at Pan-European and global levels

- Preparedness 2.0 strategy and action plan can adopt a multisectoral approach based on the core elements of a multisectoral preparedness and response plan;
- WHO Academy could integrate core elements of a multisectoral preparedness and response plan into relevant training courses.

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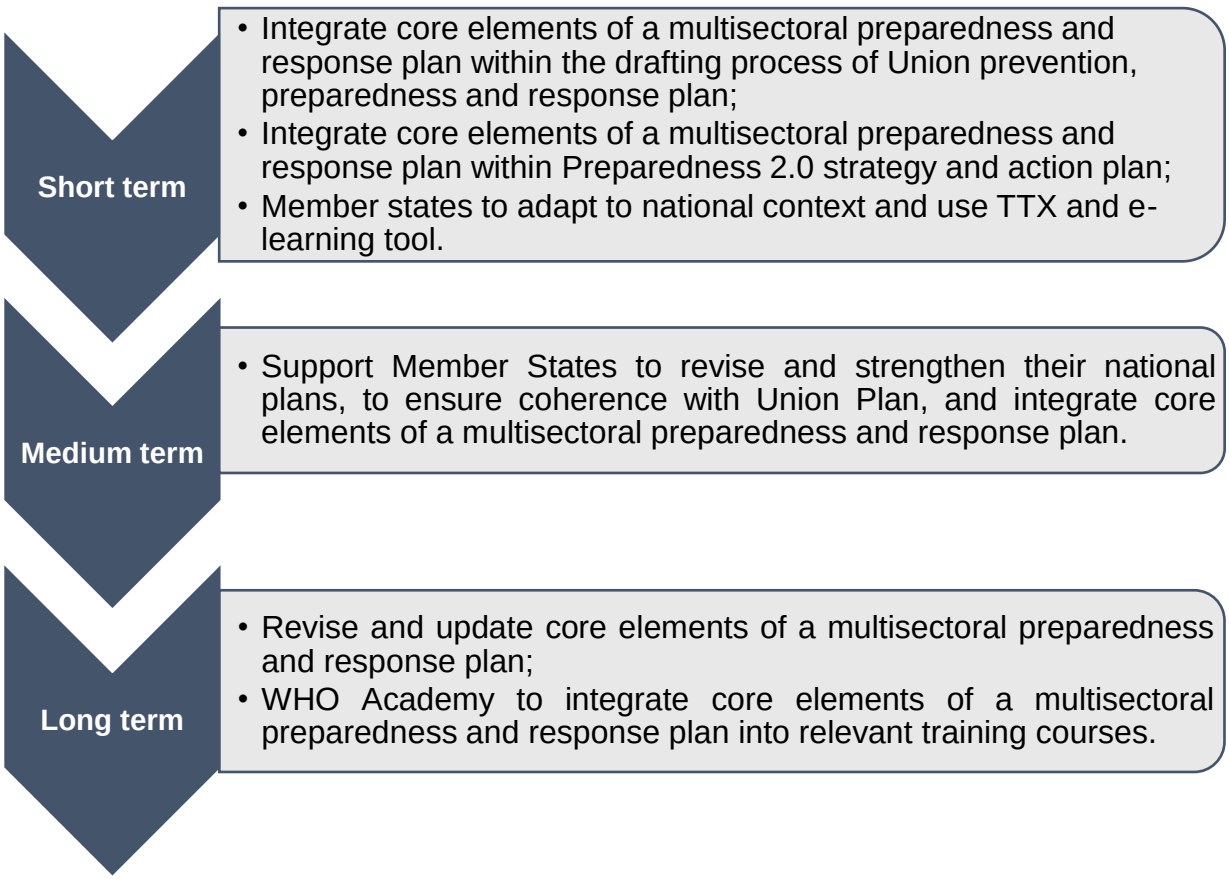
Action items:



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3.2.4 Work Package 7: Laboratory preparedness and responsiveness: the EMERGE laboratory network on highly pathogenic bacteria and viruses

Description:

The EMERGE Laboratory Network was initialized as an EU funded project EQADeBa in 2008 (2008-2011) by the Robert Koch Institute (RKI) and was continued by the Joint Actions QUANDHIP (2011-2015) and EMERGE (2015-2019). It is currently part of the Joint Action SHARP (2019-2023). Forty diagnostic laboratories in about 25 European countries are involved.

The EMERGE Network focuses on risk group 3 bacteria and risk group 4 viruses. It has the potential to be activated by the Health Security Committee and to switch from the Inter-Epidemic Mode (IEM) to the Outbreak Response Mode (ORM). During the ORM all activities are directed to the outbreak management. A number of other laboratory networks, institutions and agencies are contributing to the management of cross-border infectious outbreaks. In close cooperation, the EMERGE Laboratory Network can support the establishment and consolidation of a common, coordinated and effective response to infectious disease outbreaks at EU level and abroad. State of the art and new diagnostic methods for high threat pathogens, including in-house and commercial kits, are evaluated for their applicability and recommended in outbreak situations when suitable.

Yearly organized External Quality Assurance Exercises (EQAEs) ensure best approaches for laboratory responsiveness in outbreak situations. These activities are supported by a training to share best practices of diagnostics and bio-risk management.

The functioning of the EMERGE network is enabled through the **development of key success factors, such as SOPs for exchange of samples and processes for EQA developed throughout the development of the network.**

Rationale:

The consolidation of the laboratory network at EU level would offer a number of non-monetary and monetary benefits depending on the tasks and activities to be carried out (please, also see Study on Cost-Benefit Analysis of Reference Laboratories for Human Pathogens, European Commission, 2016[6]). EMERGE network offers a scope of pathogens (risk group 3 bacteria - and risk group 4 viruses) not covered by any other network (unique feature). It supports the implementation of International Health Regulations (IHR) and offers long-term support for implementation of laboratory elements of core functions of IHR at EU level and as part of the global IHR lead by WHO. EMERGE offers support to low GNI countries by providing access to specialized laboratory diagnostics and bio-risk management, offers support to national networks in Member States (MS) by knowledge transfer through national reference laboratories

[6]https://ec.europa.eu/health/sites/default/files/preparedness_response/docs/2016_laboratorieshumanpathogens_frep_en.pdf

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as multipliers, provides permanent and collated scientific knowledge about relevant pathogens for risk assessments at EU level and offers a European solution to keep the high quality of diagnostics for highly pathogenic and rare infectious diseases, also at national level.

Further, EMERGE provides surge laboratory capacities at EU level in case of national and cross-border outbreaks as the focused diseases are endemic in Europe with various prevalence in different MS. It facilitates self-assessment and accreditation, facilitates implementation of new diagnostics and represents a critical number of participants for External Quality Assurance Exercises at EU level not to be reached in single MS. EMERGE offers support in case of natural and intentional outbreaks, represents an element of public health care and civil disaster management and permits implementation of a common European policy for diagnostic of highly pathogenic infectious agents, setting up a common public laboratory dedicated to these agents offering qualified diagnostics of these rare pathogens not available until now at European level. The network is able to contribute to AMR at European level by contributing to EUCAST with antimicrobial susceptibility testing of highly pathogenic bacteria. First exceptional outcomes of this work have been published by EUCAST, but additional work is required.

At the EU level, Article 15 of the SCBTH regulation the designation of EU reference laboratories, under the aegis of ECDC, with funding provided by the European Commission. The EU reference laboratories will be responsible to coordinate the network of national reference laboratories in the following areas: (a) reference diagnostics, including test protocols; (b) reference material resources; (c) external quality assessments; (d) scientific advice and technical assistance; (e) collaboration and research; (f) monitoring, alert notifications and support in outbreak response, including to emerging communicable diseases and pathogenic bacteria and viruses; and (g) training.

Options for integration at National level

- Network partners (40 diagnostic laboratories in about 25 European countries) could contribute to the funding and operation of the EMERGE network.

Options for sustainability at EU level

- EMERGE network could be designated as an EU Reference Laboratory Network for Highly Pathogenic Infectious Agents- HPAI (not withstanding independent selection and award process).

Options for sustainability at Pan-European/global levels

- EMERGE network could be considered as part of the proposed Pan-European network for disease control;
- At the global level, EMERGE network could contribute to support WHO Member States to increase access and use of diagnostics and laboratories, linking with WHO Lyon office.

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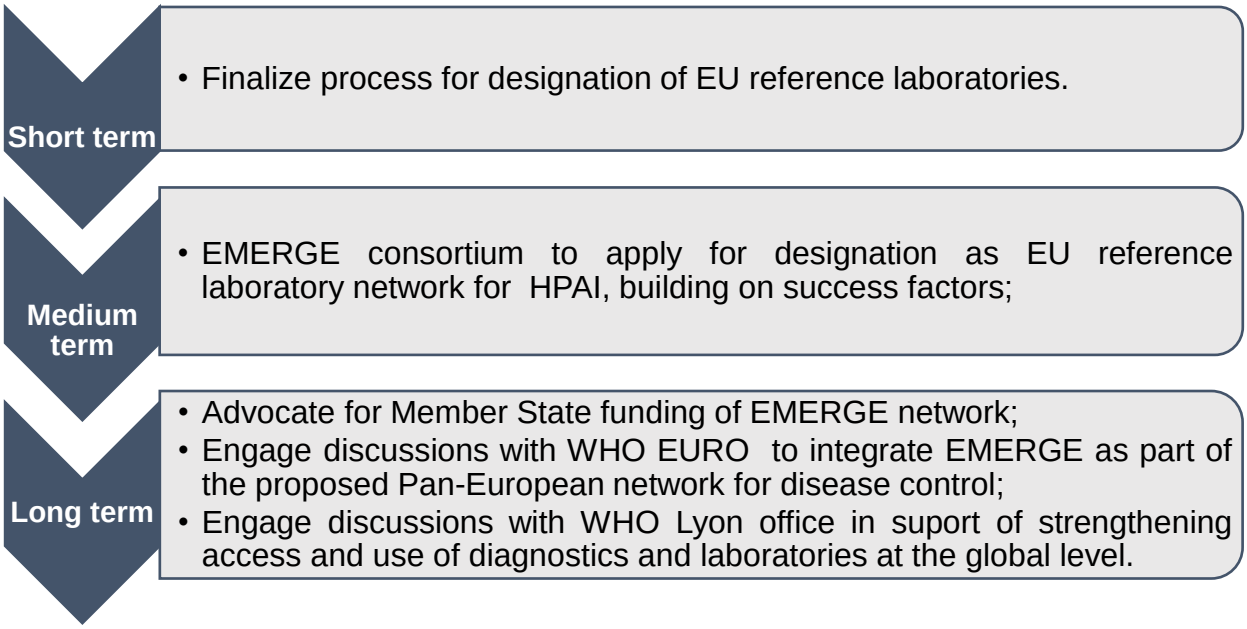
Action Items:



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3.2.5 Work Package 8: Training and local exercises, exchange of working practices: Methodology to assess the cross-sectoral training needs for IHR strengthening across countries

Description:

Work Package 8 developed and implemented a methodology to assess, at a multi-country level, the cross-sectoral training needs for IHR strengthening. The methodology was based on desk-review and involved integration of information from three sources: ECDC training needs assessment survey (which assessed perceived training needs), voluntary JEE (which assessed externally evaluated IHR core capacities) and mandatory SPAR (which assessed self-evaluated IHR core capacities).

The results of this analysis, comparison and integration of data obtained from relevant sources identified the areas with the needs for development and/or improvement, which is a key pre-requisite to develop and implement capacity-building programme.

Rationale:

Training is key priority at both EU and global levels.

At the EU level, Article 11 of the SCBTH regulation (Training of healthcare staff and public health staff) confers a mandate to the European Commission to implement training activities. The training will to provide staff with the knowledge and skills necessary, to develop and implement the national prevention, preparedness and response plans, and implement activities to strengthen crisis preparedness and surveillance capacities, especially regarding the gaps identified.

The regulation strengthening the ECDC mandate further provides for a stronger role of ECDC in terms of training. The regulation (Article 3- (l)) provides that ECDC should "*contribute to strengthening preparedness capacities under the IHR, including training, in Member States and in third countries, in particular partner countries, while ensuring that synergies with the work of the WHO are achieved*".

At the global level, training of heath staff is at the core of strengthening IHR capacities for stronger health emergency prevention, preparedness and response. Strengthening capacities is a key component of the WHO framework for strengthening the global architecture for health emergency preparedness, response and resilience.

In this regard WHO Academy and the WHO Lyon office are key actors for capacity-building, in support of Member States and WHO regions, including WHO EURO. Training developed through SHARP could be integrated at the global level through WHO Academy and/or WHO Lyon office. WHO Academy's is a key tool of the WHO for training of health staff, and has identified training in PPR as a priority while WHO Lyon office is responsible for strengthening country's IHR core capacities.

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Options for integration at National level

- Member States could adapt to country context and use the methodology to assess the cross-sectoral training needs for IHR strengthening to strengthen their national training plans.

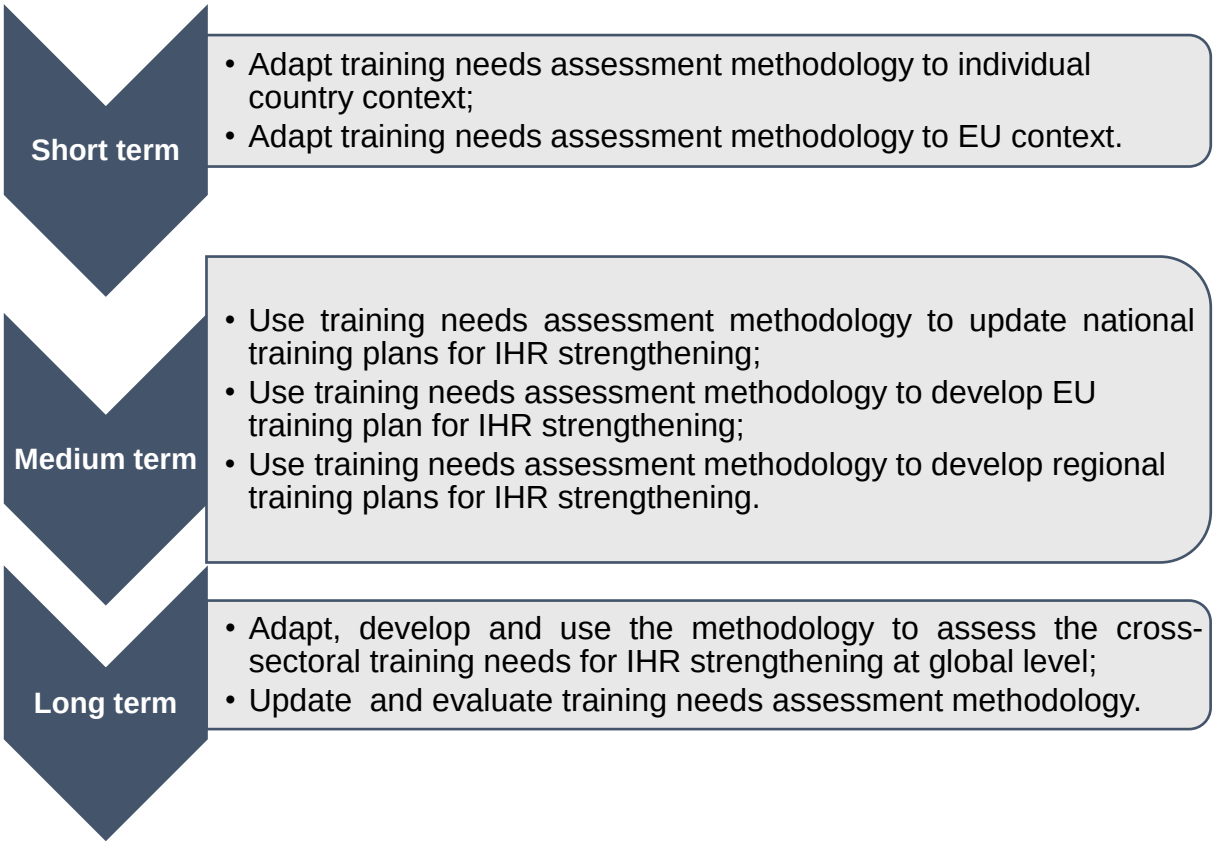
Options for sustainability at EU level

- EU could adapt, develop and use the methodology to assess the cross-sectoral training needs for IHR strengthening to develop and implement a training programme at EU level, in application of Article 9 of SCBTH regulation.

Options for integration at pan-European and global level:

- WHO EURO could adapt, develop and use the methodology to assess the cross-sectoral training needs for IHR strengthening to develop and implement a training programme at pan-European level;
- WHO Lyon office and WHO Academy could adapt, develop and use the methodology to assess the cross-sectoral training needs for IHR strengthening at global level.

Next steps:



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3.2.6 Work Package 8: Training and local exercises, exchange of working practices: Training tools for IHR strengthening, including training material, curricula and on-line platform

Description:

WP8, working with the other Work Packages within SHARP and relevant stakeholders including ECDC and WHO EURO, adapted and developed several training material and curricula to strengthen IHR core capacities including:

- Training and advanced workshop material on In(tra)-Action Review;
- Material for a risk Communication Exercise with a focus on vaccination;
- 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 of for control of the spread of transboundary diseases;
- Training on Recovery;
- Training on outbreak investigation.

WP8 is also developing **curricula for basic and advanced face-to-face and online training.**

Training material were translated into most EU language and are available on a dedicated training platform (SHARP JA Training Platform (batut.org.rs): EduSHARP: All courses (batut.org.rs))

Rationale:

Training is key priority at both EU and global levels.

At the EU level: see above.

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.

Options for integration at National level

Member States could integrate the training material and curricula for IHR strengthening into their national training plans.

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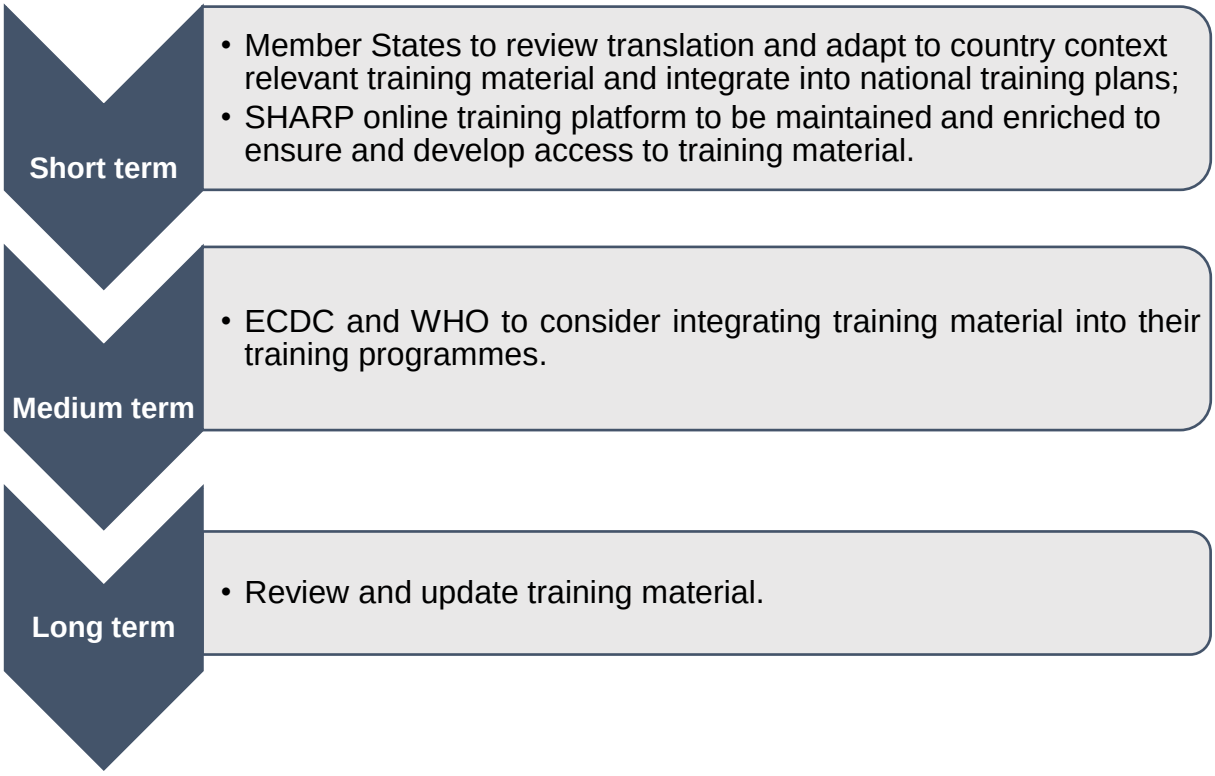
Options for sustainability at EU level

- ECDC could integrate the training material and curricula for IHR strengthening into its training programme.

Options for sustainability at regional level/global

- WHO EURO and WHO Academy could integrate the training material and curricula for IHR strengthening into their training programmes.

Action Items:



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3.2.7 Work Package 9: Chemical safety and chemical threats: Recommendations to set-up a European chemical laboratory network to respond to serious chemical health threats

Description:

Work Package 9 is developing a report outlining the desirability and the feasibility to set-up a European chemical laboratory network to respond to serious chemical health threats (D9.2) assessed through a questionnaire developed for gap analysis of chemical capacities in European countries and through an **analysis of existing relevant networks at the international, EU and national levels.**

The report outlines a clear desire for a chemical laboratory network and outlines necessary next steps, including the need for further study to assess the size, scope/remit, technical aspects (such as requirements for instrumentation/expertise and accreditation), costs involved and funding of this network.

The report further suggests to link with the EC Scientific Committee for Health, Environment and Emerging Risks (SCHEER) and, if such a network were to be established, to start with establishing a project whose deliverables can form the building blocks for future collaboration and which can maintain momentum for the network after the project has ended.

Rationale:

Addressing chemical health threats is a priority at both EU and global levels.

At the EU level, Article 2 of the SCBTH regulations specifically mentions "**threats of chemical origin**" as within the scope of the serious cross-border health threats addressed by the regulation. Article 20 further specifies the consideration of chemical health threats with regards to public health risk assessments linking with the European Chemicals Agency (ECHA).

Further, In July 2022, the Commission (HERA) established a list of **three priority health threats, which includes chemical health threats** (The list includes pathogens with high pandemic potential, chemical, biological, radiological, and nuclear (CBRN) threats originating from accidental or deliberate release and anti-microbial resistance).

In the EU, Joint Action TERROR is currently being implemented with its main objectives to address gaps in health preparedness and to strengthen cross-sectoral work with security, civil protection and health sectors response to biological and chemical terror attacks. JA TERROR works to provide knowledge and information to all relevant sectors to support health preparedness and strengthen cross sectoral response to biological or chemical terror attacks. In this regard, JA-TERROR will map international networks and expert groups of relevance in the EU for biological and chemical attacks. This information will be used to assess to what degree they cover the needs in this area and identify if there are gaps that need to be addressed by strengthening the existing networks and committees, or through the establishment of new collaboration mechanisms. In this regard, the WP10 analysis of existing relevant

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Networks at the international, EU and national levels could be integrated into and inform JA TERROR's mapping.

At the global level, in line with the all-hazard approach of the IHR (2005), the JEE includes "**Chemical Events**" as a dedicated technical area, while the "National Laboratory System" technical area includes an assessment of laboratory capacities to detect and characterize chemical health threats.

At the global level, the importance of preparedness and response to public health emergency in the field of CBRN (Chemical, Biological, Radiological and Nuclear) is increasing in the world where any crisis can become a reality, such as the Ukraine conflict centred in Europe and political and geographical tensions of other countries are recognized by the U.S. and Japan. Launched in 2001, the Global Health Security Initiative (GHSI) (an informal, international partnership among like-minded countries and organizations to strengthen public health preparedness and response globally to threats of chemical, biological, and radio-nuclear terrorism (CBRN), as well as pandemic influenza) aims to address such threats.

Options for sustainability at EU level

- EU could consider further exploring feasibility of setting up a European chemical laboratory network;
- JA TERROR mapping of international networks and expert groups of relevance in the EU for biological and chemical attacks could integrate analysis of existing relevant networks at the international, EU and national levels.

Options for sustainability at EU level

- GHSI could consider exploring feasibility of setting up a global chemical laboratory network.

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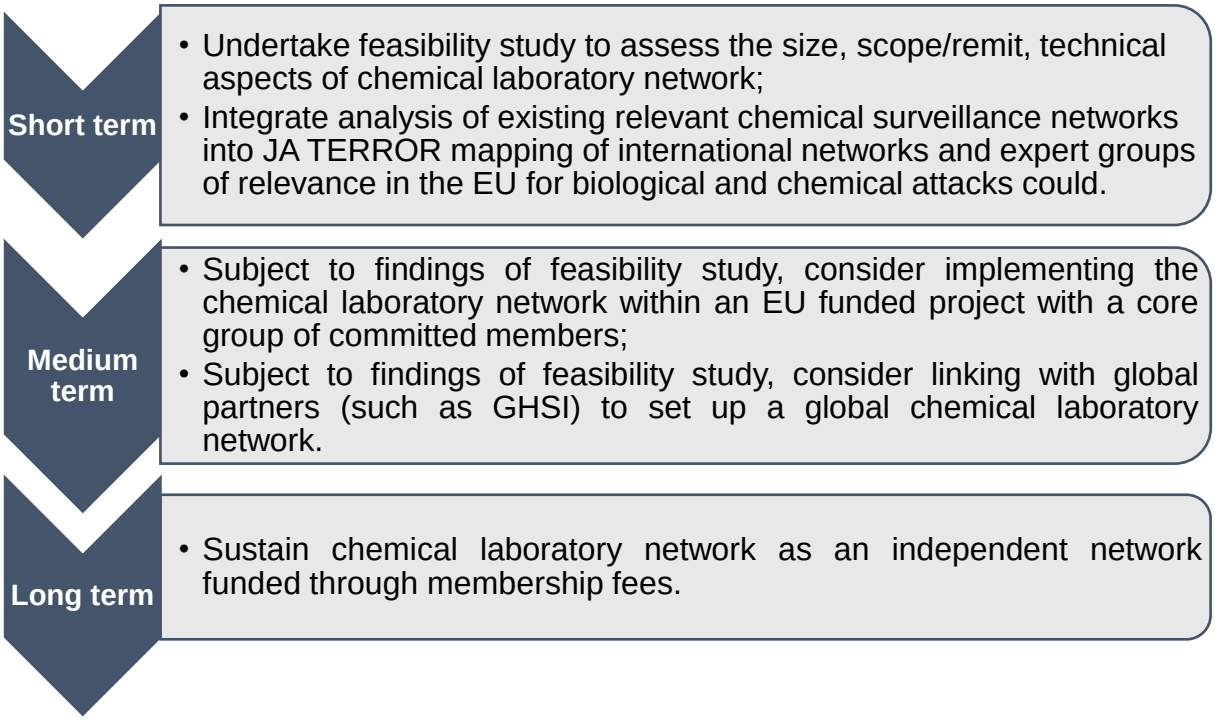
Action items:



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3.2.8 Work Package 9: Chemical safety and chemical threats: SOPs on chemical health threats

Description:
To ensure a baseline competency among EU Member States on their approach to cross-border chemical health threats and promote sustainability of the outputs of this Joint Action, WP9 is developing SOPs on topics related to chemicals and chemical incidents based on findings from the fact-finding report, surveillance activities, chemical workshop feedback and the laboratory network report.

The SOPs include

- Surveillance;
- Risk analysis of chemical health threats;
- Multisectoral collaboration;
- Decontamination;
- Sampling and detection;
- Recovery.

WP9 conducted a literature review focusing on chemical event surveillance in relation to public health preparedness. This review examined examples of good practices and opportunities for implementing surveillance of chemical incidents.

Additionally, WP9 produced a Surveillance Strategy report, which provides definitions, extensive background information on surveillance methods and types related to chemical incidents, and multiple country examples. The report covers various aspects such as governance, funding, ethics, and offers valuable insights into establishing and maintaining surveillance systems for chemicals/chemical incidents.

Rationale:

Addressing chemical health threats is a priority at both EU and global levels: see above.

Options for integration at National level

- Member States could integrate SOPs for cross-border chemical health threats in their national preparedness and response plans.

Options for sustainability at EU level

- Chapter III of the Union Plan could include a provision to strengthen the approach to cross-border chemical health threats, based on the developed SOPs.

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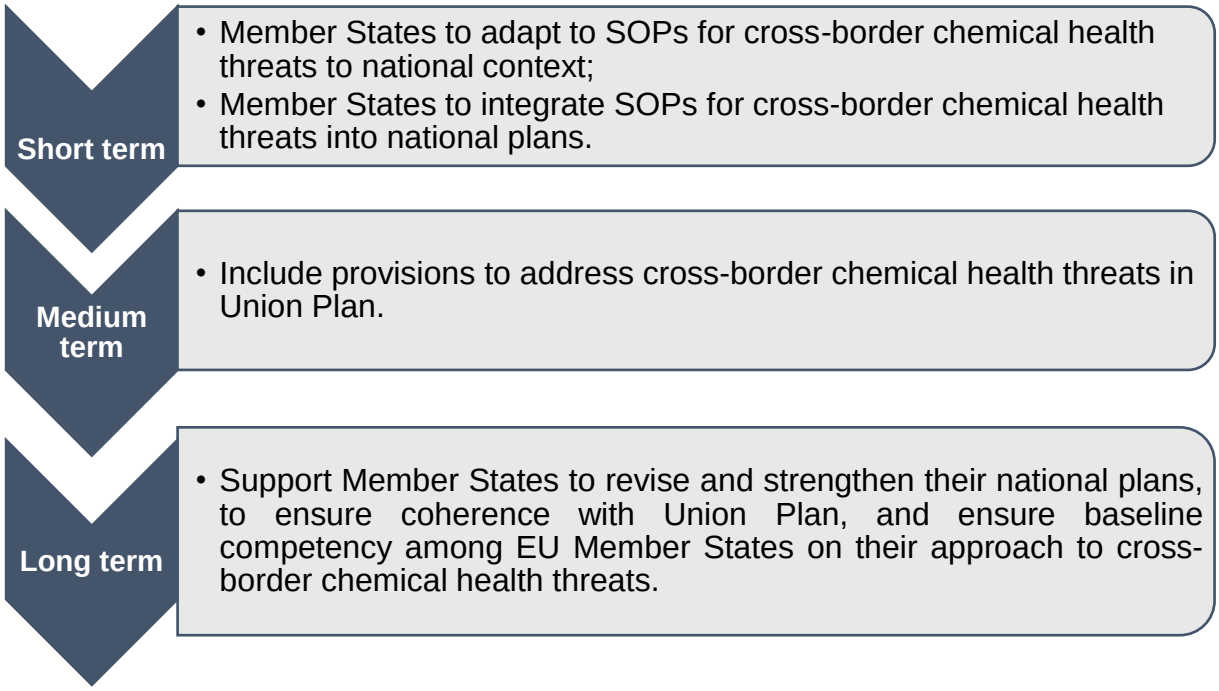
Action Items:



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3.2.9 Work Package 10: Case management and infection prevention and control: Mapping existing High Level Isolation Units likely to be dealing with rare or new high consequence infectious diseases and for an expert clinical support service for high-consequence infectious diseases

Description:

WP 10 mapped existing IPC facilities/High Level Isolation Units likely to be dealing with rare or new high consequence infectious diseases. WP 10 mapped clinical preparedness tools for hospital preparedness and capacity (including IPC) in dealing with high consequence infectious diseases in JA participating countries. Based on this mapping, options for a referral network between countries are proposed. The proposed referral network would identify national centres as clinical referral units and as providers of remote clinical consultations. WP 10, in collaboration with WP5, aimed to define the characteristics of an expert clinical consultation and support service and to elaborate technical recommendations.

Based on literature search, two platforms for clinical consultation and support service were identified within the European Reference Networks (ERNs) (the Clinical Patient Management System (CPMS) or COVID19 clinical management support system (COVID19-CMSS)). Challenges have also been identified.

A feasibility study was conducted which proposes the establishment of a permanent reference network of clinical experts on HCIDs recruited from HLIUs across Europe that would replace present informal networks (detailed in D5.2). The feasibility study (to be completed) will aim to provide indicative costing of this support service for possible future inclusion in EU health programme.

Rationale:

The feasibility for an expert clinical support service for high-consequence infectious diseases recalls the rationale for such a network. Management of Ebola cases in 2014 2015 was challenging, as there was limited experience of this kind of diseases among clinicians and infection prevention and control personnel in the receiving hospitals. This led clinicians in Europe and USA to set up a network for clinical consultation led by CDC in cooperation with the WHO. This network suffered from several limitations: lack of verification of participants, discussions were complicated to organize, no possibility for sharing of laboratory results or images other than verbally difficulties to disseminate and retrieve information about patients often due to unresolved legal issues related to patient confidentiality/GDPR and lack of formal structure and funding for the network.

Mapping of map existing High Level Isolation Units likely to be dealing with rare or new high consequence infectious diseases the setting of an expert clinical support service for high-consequence infectious diseases will also contribute to strengthening cross-border collaboration, which is a shared priority at EU, regional and global levels.
At the EU level, JAMRAI II Joint Action will aim, inter-alia, to improve the Infection Prevention and Control (IPC) actions with a One Health approach. In this regard, JAMARAI II will aim to provide an EU Framework for IPC to support implementation of core

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competencies for the IPC team in human health care. This work could integrate WP10 work in terms of mapping of clinical preparedness tools for hospital preparedness and capacity (including IPC) in dealing with high consequence infectious.

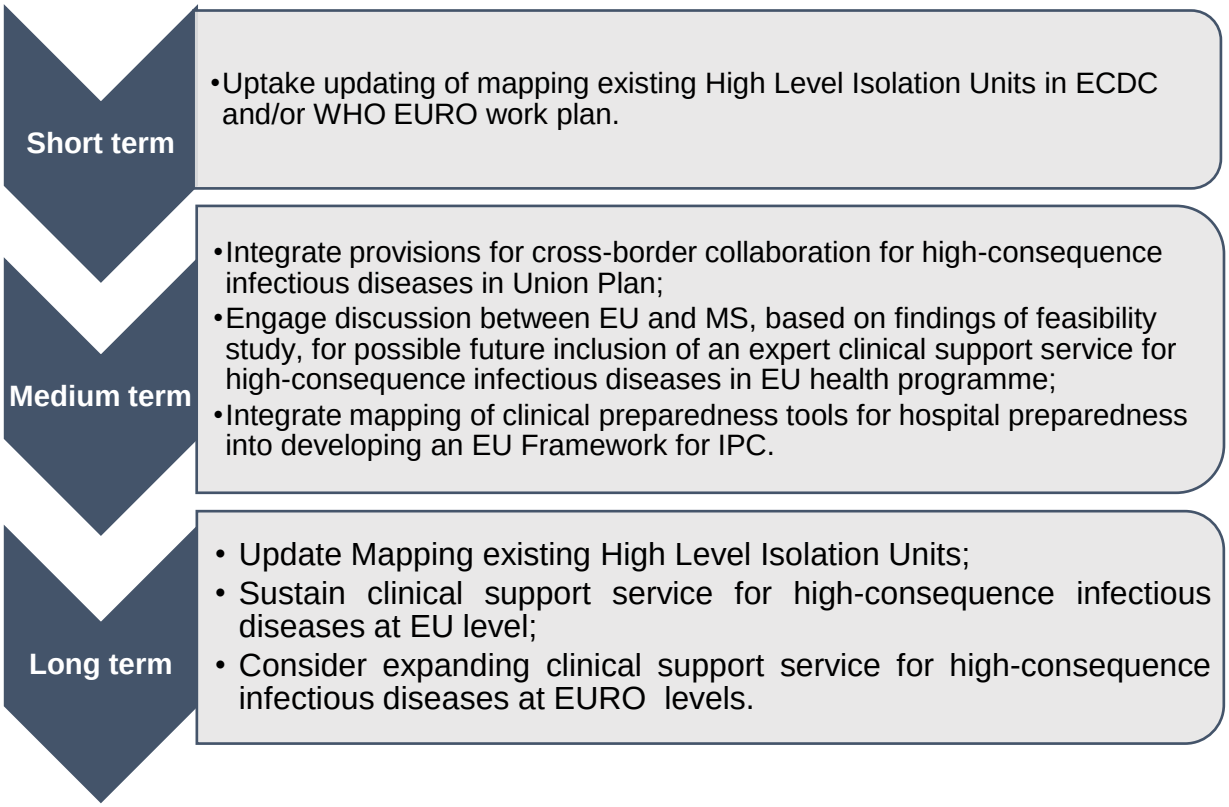
Options for sustainability at EU level

- ECDC could consider adopting and updating of the mapping existing High Level Isolation Units;
- Based on findings of feasibility study, engage discussion between EU and MS for the creation of an expert clinical support service for high-consequence infectious diseases for possible future inclusion in EU health programme;
- Union preparedness and response plan could integrate provisions for cross-border collaboration for high-consequence infectious diseases;
- JAMRAI II could integrate information into developing an EU Framework for IPC.

Options for sustainability at regional level

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

Action items:



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3.2.10 Work Package 10: Case management and infection prevention and control: Recommendations on the implementation of a syndrome based clinical protocol.

Description:

Good clinical management of infectious diseases and the prompt application Infection prevention and Control (IPC) are both core elements in implementing IHR. Experience has also shown that frontline clinicians are often the first to recognize and alert their colleagues to the presence of a novel threat. Early detection of HCID can be challenging but remains vital, relying on epidemiological awareness and clinical knowledge.

In this regards, WP 10 developed recommendation for a “syndrome based” approach for prompt and early clinical management of HCID.

WP 10 has identified a specific list of diseases and formulated a syndrome-based approach protocol designed for managing patients with HCID in the Emergency Department. By implementing this framework, the overall objective is to improve the preparedness and response capabilities of healthcare personnel when treating HCID cases. This includes creating a fast triage algorithm within healthcare services, standardizing triage processes, implementing effective isolation measures, and providing the necessary knowledge and resources to protect against occupational exposure risks.

Rationale:

Addressing HCID at the national level is crucial. To support countries in the EU/EEA in reviewing their preparedness system planning, ECDC has launched an operational checklist specifically focused on health emergency preparedness for imported cases of HCID. The ECDC preparedness checklist is a valuable tool for public health planners. It provides guidance based on experiences during the Ebola outbreak and peer-review visits to EU member states. It complements broader checklists from other international organizations. The protocol developed by WP10 can be a valuable addition to ensure that the preparedness planning includes a syndrome-based approach, aligning it with the operational needs for managing imported cases of such diseases. The integration of the recommendations from WP10 creates a more comprehensive framework for enhanced preparedness and response capacities.

At Pan-European level, integrating the syndrome-based approach protocol developed through SHARP into the WHO EURO's Preparedness 2.0 framework would be beneficial. As good clinical management of infectious disease is at the core of strengthening IHR capacities, this integration would enhance the region's preparedness and response capacities for HCID outbreaks.

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Options for sustainability at national level

- Recommendation for a "syndrome based" approach for prompt and early clinical management of HCID could be adapted to national context, piloted and sustained at national level through medical council and expert bodies.

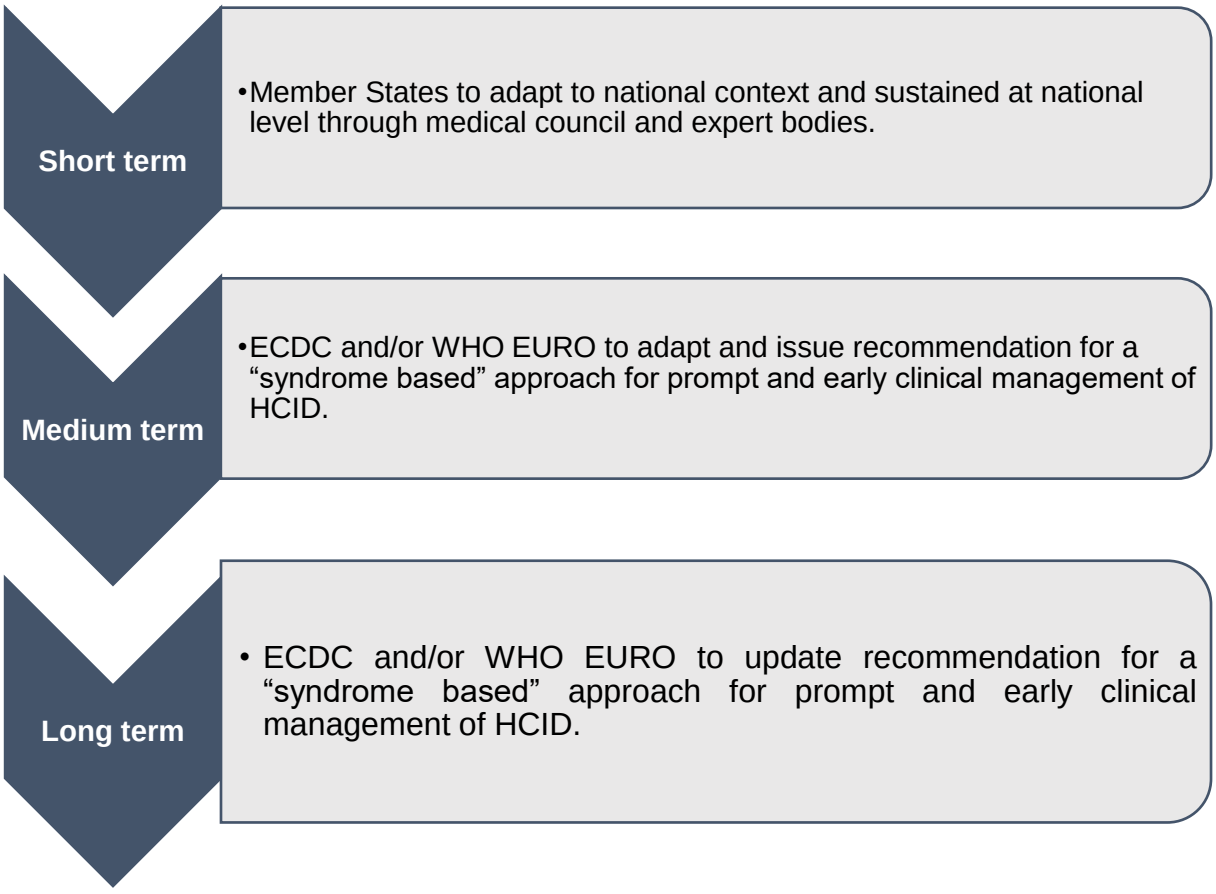
Options for sustainability at EU level

- Recommendation for a "syndrome based" approach for prompt and early clinical management of HCID could be adapted and issued by ECDC.

Options for sustainability at regional level

- Recommendation for a "syndrome based" approach for prompt and early clinical management of HCID could be adapted and issued by WHO EURO.

Action items:



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IV. Sustainability Plan

The sustainability plan summarizes, in a table form, the relevant levels (national, EU, regional/global) and action items (short, medium or long term) detailed in the sustainability report for sustainability of JA-SHARP priority outcomes.

Priority outcomes	National Level			EU Level			Regional/Global Level		
	Short term	Medium term	Long Term	Short term	Medium term	Long term	Short term	Medium term	Long term
WP 5: Methodology, tools and recommendations for improving IHR implementation and evaluation	Adapt and disseminate methodology and tool for improving IHR implementation and evaluation to all EUMS	Integrate WP5 work towards increased knowledge of the Surveillance and AMR specific indicators towards strengthening national surveillance systems	/	/	Integrate methodology and tools for improving IHR implementation and evaluation into EU assessment (and strengthening) efforts; Implement recommendations to strengthen use of Simex and AAR at EU level	/	/	/	Leverage methodology and tool towards developing a multi-country regional approach for strengthening IHR implementation and evaluation, first at EURO level then globally

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Priority outcomes	National Level			EU Level			Regional/Global Level		
	Short term	Medium term	Long Term	Short term	Medium term	Long term	Short term	Medium term	Long term
WP 5: Template agreement of intention for cross-border multisectoral collaboration between neighbouring countries	/	/	/	Set-up a cooperative body (composed of authorities party to cross-border agreement) to further develop and update the template;		/	/	/	Set-up a cooperative body (composed of authorities party to cross-border agreement) to further develop and update the template;
WP 6: Consensus to determine core elements of a multisectoral preparedness and response plan and related tools	Member states to adapt to national context and use TTX and e-learning too	/	/	Integrate core elements of a multisectoral preparedness and response plan within the drafting process of Union	Member states to adapt to national context and use TTX and e-learning too	/	/	Integrate core elements of a multisectoral preparedness and response plan within the drafting process of Union prevention, preparedness and response plan;	Member states to adapt to national context and use TTX and e-learning too

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Priority outcomes	National Level			EU Level			Regional/Global Level		
	Short term	Medium term	Long Term	Short term	Medium term	Long term	Short term	Medium term	Long term
				prevention, preparedness and response plan;					
WP 7: the EMERGE laboratory network on highly pathogenic bacteria and viruses	/	/	/	Finalize process for designation of EU reference laboratories.	EMERGE consortium to apply for designation as EU reference laboratory network for HPAI, building on success factors ;	/	/	/	Finalize process for designation of EU reference laboratories.
WP 8: Methodology to assess the cross-sectoral training needs for IHR strengthening across countries	Adapt training needs assessment methodology to individual country context;	Use training needs assessment methodology to update national training plans for IHR	/	Adapt training needs assessment methodology to EU context;	Use training needs assessment methodology to develop EU training plan for IHR strengthening	/	/	Use training needs assessment methodology to develop pan-European training plan for IHR strengthening	Adapt, develop and use the methodology to assess the cross-sectoral training needs for IHR strengthening at global level; Update and evaluate training needs

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Priority outcomes	National Level			EU Level			Regional/Global Level		
	Short term	Medium term	Long Term	Short term	Medium term	Long term	Short term	Medium term	Long term
		strengthening;							assessment methodology
WP 8: Training tools for IHR strengthening, including training material, curricula and on-line platform	Member States to translate and adapt to country context relevant training material and integrate into national training plans;	Review and update training material.	/	SHARP online training platform to be maintained to ensure access to training material	ECDC to consider integrating training material into their training programmes	Review and update training material.	/	WHO to consider integrating training material into their training programmes	Review and update training material.

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Priority outcomes	National Level			EU Level			Regional/Global Level		
	Short term	Medium term	Long Term	Short term	Medium term	Long term	Short term	Medium term	Long term
WP 9: Recommendations to set-up a European chemical laboratory network to respond to serious chemical health threats	/	/	/	Undertake feasibility study to assess the size, scope/remit, technical aspects of chemical laboratory network. Integrate analysis of existing relevant chemical surveillance networks into JA TERROR mapping of international networks and expert groups of relevance in the EU for	Subject to findings of feasibility study, consider implementing the chemical laboratory network within an EU funded project with a core group of committed members.	Sustain chemical laboratory network as an independent network funded through membership fees.	/	Subject to findings of feasibility study, consider linking with global partners (such as GHSI) to set up a global chemical laboratory network	/

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Priority outcomes	National Level			EU Level			Regional/Global Level		
	Short term	Medium term	Long Term	Short term	Medium term	Long term	Short term	Medium term	Long term
				biological and chemical attacks could					
WP 9: Chemical safety and chemical threats: SOPs on chemical health threats	Member States to adapt to SOPs for cross-border chemical health threats to national context; Member States to integrate SOPs for cross-border chemical health threats into national plans	/	/	/	Include provisions to address cross-border chemical health threats in Union Plan.	Support Member States to revise and strengthen their national plans, to ensure coherence with Union Plan, and ensure baseline competency among EU Member States on their approach to cross-border chemical health threats	/	/	/

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Priority outcomes	National Level			EU Level			Regional/Global Level		
	Short term	Medium term	Long Term	Short term	Medium term	Long term	Short term	Medium term	Long term
WP 10 : Mapping existing High Level Isolation Units likely to be dealing with rare or new high consequence infectious diseases and for an expert clinical support service for high-consequence infectious diseases	/	/	/	Uptake updating of mapping existing High Level Isolation Units in ECDC work plan.	Integrate provisions for cross-border collaboration for high-consequence infectious diseases in Union Plan; Engage discussion between EU and MS, based on findings of feasibility study, for possible future inclusion of an expert clinical support service for high-consequence infectious diseases in	Update Mapping existing High Level Isolation Units; Sustain clinical support service for high-consequence infectious diseases at EU level.	Uptake updating of mapping existing High Level Isolation Units in WHO EURO work plan.	/	Update Mapping existing High Level Isolation Units; Consider expanding clinical support service for high-consequence infectious diseases at EURO level.

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Priority outcomes	National Level			EU Level			Regional/Global Level		
	Short term	Medium term	Long Term	Short term	Medium term	Long term	Short term	Medium term	Long term
					EU health programme; Integrate mapping of clinical preparedness tools for hospital preparedness into developing an EU Framework for IPC				

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Priority outcomes	National Level			EU Level			Regional/Global Level		
	Short term	Medium term	Long Term	Short term	Medium term	Long term	Short term	Medium term	Long term
WP 10: Recommendations on the implementation of a syndrome based clinical protocol	Member States to adapt to national context, pilot and sustained recommendations for a "syndrome based" approach at national level through medical council and expert bodies.	/	/	/	ECDC to adapt and issue recommendation for a "syndrome based" approach for prompt and early clinical management of HCID	ECDC to update recommendation for a "syndrome based" approach for prompt and early clinical management of HCID	/	WHO EURO to adapt and issue recommendation for a "syndrome based" approach for prompt and early clinical management of HCID	WHO EURO to update recommendation for a "syndrome based" approach for prompt and early clinical management of HCID

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V. Conclusion

During the implementation of SHARP JA, there have been major upheavals to national, regional and global prevention, preparedness and response frameworks, drawing the lessons from the Covid-19 pandemic.

Through its efforts to strengthen preparedness (including laboratory capacities) in the EU against serious cross-border threats to health and support the implementation of International Health Regulations, SHARP has contributed, not only to the response to the pandemic, but also to strengthen preparedness and response capacities.

Building on this work, sustaining SHARP priority outcomes will contribute to strengthen national, EU, pan-European and global efforts for preparedness and response, in support of common priorities identified at all levels 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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