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Strengthened International HeAlth
Regulations & Preparedness in the EU

Assessing public health preparedness and response in the EU
A review of EU-level Simulation Exercises and After Action Reviews

Submitted as part of JA SHARP WP 5: Monitoring and evaluation of IHR (2005) core capacities and implementation of Decision 1082/2013/EU at the European level.

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Table of contents

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List of abbreviations and acronyms

AAR	After Action Reviews
CHAFEA	Consumers, Health, Agriculture and Food Executive Agency (executive EU agency)
DG ECHO	Directorate-General for European Civil Protection and Humanitarian Aid Operations
DG HOME	Directorate-General for Migration and Home Affairs
DG SANTE	Directorate-General for Health and Food Safety
ECDC	European Centre for Disease Prevention and Control (Decentralised EU agency)
EEA	European Economic Area
EFSA	European Food Safety Authority (Decentralised EU agency)
EMA	European Medicines Agency (EMEA) (Decentralised EU agency)
HERA	European Health Emergency preparedness and Response Authority
IAR	Intra action review
IHR	International Health Regulations
IPCEI	Important Project of Common European Interest
JEE	Joint External Evaluation
JRC	Joint Research Centre (European Commission's science and knowledge service)
M&E	Monitoring and Evaluation
MEF	Monitoring and evaluation framework
MS	EU Member State
SimEx	Simulation Exercises
JA-SHARP	Joint Action on Strengthened International HeAlth Regulations and Preparedness in the EU
SOP	Standard Operating Procedure
SPAR	State Party self-assessment annual reporting

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Summary

Background:

The International Health Regulation Monitoring and Evaluation framework aims to deliver a comprehensive overview of the implementation of requirements under the IHR. It includes quantitative tools such as State Parties Annual Report (SPAR) and, Joint External Evaluation (JEE). After Action Reviews and Simulation Exercises were included in the IHR Monitoring and Evaluation framework to expose weaknesses in the functionality of preparedness capacities as well as to identify good practise. As part of a work package to strengthen and assess IHR core capacities in the EU, this report presents an analysis of the feasibility of using these qualitative tools as part of the monitoring for IHR (2005) core capacities and implementation of Decision 1082/2013/EU at the European level. It aims to identify the added value of After-Action Reviews, including Intra Action Reviews, and Simulation Exercises by comparing them to other monitoring tools (i.e., SPAR & JEE); as well as lessons learned from COVID-19; and determine ways to improve their impact on public health preparedness and response in the EU.

Methods:

17 Simulation Exercises and 2 Intra-Action Reviews organized by the European Commission between 2005 and 2018 were included in the dataset. A total of 357 recommendations were categorized according to the IHR core capacities and target audience and analysed using language analysis software. Further analysis was done according to target audience; recommendations to member states were compared to the quantitative tools SPAR and JEE; recommendations to EU agencies were compared to current day mandates of EU agencies, and to lessons learnt during COVID-19.

Findings:

The most frequently addressed issues were within the areas of information sharing, standardisation of procedures across sectors and countries, and clarity and awareness of the roles of the different EU agencies. Recommendations do not focus particularly on low scoring areas in SPAR/JEE. Recommendations to Member States complement SPAR indicators by identifying gaps in functionality. Two thirds of recommendations target EU agencies. Improving information exchange tools, clearer mandates for emergency coordination, procurement and stockpiling of medical countermeasures, and streamlined public communication are frequently addressed issues in the recommendations. Eight out of the ten early lessons learnt during the COVID-19 pandemic had already been raised earlier as recommendations in these exercises. Reports assessed do not include or result in action plans for implementation, but COVID-19 has accelerated implementation of some recommendations.

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Recommendations:

1) SimEx should be carried out at EU level according to a clearly defined programme, as an opportunity both to evaluate functionality and to practise response mechanisms. AAR should be carried out routinely after public health events.

2) It should be considered to include the main lessons/recommendations/ from exercises and after-action reviews in the report on state of preparedness in the EU, which summarize the status in the member states based on their reporting under decision 1082/2013 (and now under the new regulation).

3) Regional SimEx should be designed to target key gaps and challenges for regional preparedness, based on previously identified issues both from monitoring tools, risk analyses and previous evaluations.

4) To ensure national ownership, each regional SimEx should be followed by national ones with a similar, adapted scenario in the native language. The combination of regional and national exercises could contribute to better harmonization of preparedness plans as described in the new regulation.

5) Future exercises and AAR should follow WHO's 2018 Guideline for SimEx and AAR, or similar guidance from ECDC. Based on the recommendations in the reports, the commissioner of the exercise should establish a plan for follow up and implementation, including assigned responsibilities and a plan for accountability. Assessment of whether improvements have been made regarding follow-up of SimEx conducted after 2018 should be done.

6) The EC should, as the organiser of the SimEx at EU level, centralise information about the implementation of recommendations to identify the areas where progress have been done and not.

7) A simulation exercise repository should, in addition to documenting exercises and recommendations, include the possibility to assess progress in implementation of the recommendations, to ensure improvement and accountability in public health preparedness as well as to inform the cost/benefit of carrying out exercises.

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1. Introduction

1.1. Background

As the threat of emerging diseases has increased due to human behaviour, population growth, globalisation, global environmental changes and other factors (Carlson et al., 2022), it is important that efforts are made by all countries to improve global health security (?). The International Health Regulations (2005), or IHR (2005) were ratified in 2007 and are legally binding for all WHO Member States. The IHR (2005) is a framework aiming to "prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade."

The IHR (2005) monitoring and evaluation framework supports countries to assess their IHR (2005) core capacities and has four components (figure 1): State Party self-assessment annual reporting (SPAR), Joint External Evaluation (JEE), after action reviews (AAR), and simulation exercises (SimEx). The SPAR and JEE are quantitative assessment tools with standardized indicators which allow for comparison and tracking capacity level over time. However, these indicators may not accurately reflect the functionality of existing preparedness systems and capacities, and can obscure important gaps (Bartolini, 2021). For instance, both frameworks were criticized for their inability to predict national needs in the response to the COVID-19 pandemic (Haider, 2020, Kandel, 2020). AAR and SimEx were included as qualitative tools in the monitoring and evaluation framework as these types of activities that may better expose weaknesses in the functionality of preparedness capacities. As a sub-type of AAR, Intra-Action Reviews (IAR) have also been carried out in events of longer duration to guide an ongoing response. However, the results from AAR/IAR and SimEx are not easily standardized and may be difficult to link to specific preparedness capacities or indicators.

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Figure 1: The IHR (2005) monitoring and evaluation framework (WHO, 2016).

In 2019, the EU Joint Action SHARP (**S**trengthened International **HeA**lth **R**egulations and **P**reparedness in the EU) was launched in order to strengthen the implementation of the IHR (2005), as well as the implementation of Decision 1082/2013/EU on serious cross-border threats to health, to ultimately support the EU- level preparedness and response to health threats. Work Package (WP) 5 of this Joint Action focused on *IHR core capacity strengthening and assessment*. One of the objectives of this WP was to support ongoing processes lead by ECDC and WHO to compile and use the results of SimEx and AAR/IAR systematically to inform the monitoring and evaluation of IHR (2005) capacities and implementation of Decision 1082/2013/EU at the European level. One of the tasks was to analyse the feasibility of using qualitative tools as part of the monitoring for IHR (2005) core capacities and implementation of Decision 1082/2013/EU at the European level. This report presents the results of that task.

1.2. Aims and research questions

The intended outcome of this WP Task (Task 5.3) was improved use of results from EU-level SimEx and AAR/IAR as part of a comprehensive monitoring and evaluation strategy for IHR (2005) core capacities and implementation of Decision 1082/2013/EU at the European level.

The report will address the following research questions:

- What is currently the added value of IHR MEF qualitative tools (SimEx and AAR/IAR) in the IHR (2005) monitoring and evaluation framework?
- What is the output of these qualitative tools in the EU?

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- How can the use of these tools be improved to maximize their added value in the European context?

The work presented in this report started in 2019, before the COVID-19 pandemic. The pandemic introduced an unprecedented level of complexity in responding to a communicable disease outbreak, which has put a lot of the theory on preparedness into action. As there have been many changes and lessons learned during the pandemic, we have added an additional analysis to this report, which is to use the intermediary experiences from the international response to the COVID-19 pandemic as a backdrop for assessing the SimEx and AAR/IAR carried out on the EU level. Another research question was therefore added, which is:

- To what extent do recommendations from SimEx and IAR correspond to lessons learned in the EU response to COVID-19?

1.3. Objectives

In order to determine the added value of the qualitative M&E tools, our objectives were:

- to compile and describe the EU-level SimEx and AAR conducted between 2005 and 2021

- extract recommendations from the SimEx and AAR, and create a structured dataset in order to:

  - compare recommendations to SPAR and JEE scores to determine the concurrence between the SimEx findings and the results of other M&E tools, as well as to determine whether SimEx target low scoring areas of SPAR.

  - compare the recommendations to the mandates of relevant organisations as they are in 2022, to determine concurrence as an indicator of progress of implementation, without assuming a causal link.

  - compare the recommendations in the dataset to the lessons learnt during the COVID-19 response in the EU, to determine concurrence as an indicator of pertinence of recommendations.

- based on the above, propose improvements in the use of exercise results.

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2. Methods

2.1. Sample and time period

We included SimEx/AAR that involved at least one EU agency in addition to states. EU countries were invited to participate in all the SimEx/AAR, EEA countries invited to most SimEx/AAR (16/19), and Switzerland to over half (11/19). Workshops and trainings that did not include an exercise component were not included. As the JADE simulation exercises carried out by WHO EURO with member states in 2018 and 2019 did not include EU agencies, they were not included in this sample. SimEx and AAR conducted on the national level were not included, as they have been thoroughly assessed elsewhere (WHO EURO, 2022) (Copper et al., 2020). An overview of included reports can be seen in Annex 1.

EU member states, EEA countries and Switzerland were also included for calculating total SPAR scores, in addition to UK which was an EU member in the period of the study. For the JEE we included all reports from the European region as there were few countries which has done this, and the use of a different methodology was the most important aspect of the comparison.

The SimEx/AAR we retrieved were from the time period between 2005 and 2018. No EU level SimEx/AAR, including both EU agencies and member states, were conducted from 2018 to 2021 according to the information we have from the EC. The IHR (2005) annual reporting framework was initially adopted in 2008, however the first ever annual report was presented to the World Health Assembly in 2010. For comparability with the exercise results, SPAR and JEE scores were included from the implementation of SPAR scores in 2010 and until 2018.

2.2. Data collection

2.2.1. SimEx and AAR/IAR

We retrieved a list of SimEx, AAR and IAR from the database for the Health Security Committee maintained by DG SANTE in CircaBC. Reports from each exercise were accessed from the database or found by web search and reviewed for additional information. For each exercise included in the data, we extracted the following information:

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Table 1: Information extracted from each exercise

Information type	Variables
Exercise description	- Number of participants - Number of Member States (MS) - Duration of exercise - Type of exercise (e.g., TTX, CPX) - Role of invited participant/target group (e.g., PH expert, communication expert) - EU agencies involved
Exercise scope	- Objective of the exercise - Cause of the hazard event (e.g., deliberate, natural) - Type of hazard/events
Exercise results	- Main gaps and strength identified - Recommendations - Target audience for recommendations (MS, regional EU agencies, both, not specified)

2.2.2. SPAR and JEE

We relied on the WHO e-SPAR platform (WHO, 2022b) to obtain data on SPAR, and on the Strategic Partnership for Health Security and Emergency Preparedness (SPH) Portal (WHO, 2022c) for JEE scores. SPAR scores for the EU, EEA and Switzerland were calculated using the average score for all member states that had responded from the period of 2010-2018 (n=32). JEE scores were calculated using all available JEE reports for EU member states from 2010 to 2018 (n=7).

The SPAR framework went through updates in 2017, 2018 and 2021, whereby some capacities were merged, renamed, or added. In order to be able to compare scores over the years, we adapted and aligned the SPAR core capacity framework from pre-2021 to the current framework and will be referring to the latest version of the indicators in this report, as seen in Table 2. The adaptation can be seen in Annex 2.

Table 2: SPAR, Second edition capacities (WHO, 2022)

C1. Policy, legal and normative instruments to implement IHR
C2. IHR coordination and National IHR Focal Point
C3. Financing
C4. Laboratory
C5. Surveillance
C6. Human resources
C7. Health emergency management
C8. Health services provision
C9. Infection prevention and control (IPC)
C10. Risk communication and community engagement (RCCE)
C11. Points of entry (PoEs) and border health

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C12. Zoonotic diseases
C13. Food safety
C14. Chemical events
C15. Radiation emergencies

2.3. Data analysis

2.3.1. Structuring the database

The intended aim of SimEx is usually, among other things, to test functionality of response mechanisms in a specific field such as business continuity or international coordination, using a hypothetical scenario. This may often result in recommendations pertaining to a variety of IHR capacities. We therefore categorized each extracted recommendation from SimEx and AAR by IHR core capacity as seen in Table 2, and by indicator. Some recommendations were relevant for several core capacities – in which case the most relevant one was selected. If a recommendation could not be linked to a capacity and/or indicator, we categorised the recommendation as "Not linked to an IHR capacity". The attribution of a core capacity to a recommendation was done by one person and then reviewed by a second person. Inconsistencies were discussed and a decision reached by consensus.

Recommendations were sorted according to their target audience– Member States, regional agencies, or both. In many recommendations the target audience was not clear. In some cases, it could be deducted from the report, but in others the target audience was left unspecified.

2.3.2. Analysis of recommendations

In order to determine the feasibility of using information from SimEx and AAR/IAR to assess the state of public health preparedness at regional level and inform recommendations on how the findings from exercises can be better used to inform the European state of preparedness, we conducted three different analyses.

First, in the process of categorizing the recommendations, overall recurrent issues were identified. To triangulate findings, SHINY language analysis was performed to find recurrent issues/recommendations throughout the material. SHINY is a software that identifies words and phrases in text and counts them (R, 2022). Searches were done for nouns and adjectives. High frequency terms were identified and used as search terms to identify clusters of topics in the recommendations which were then described.

The next two analyses were carried out based on the target audience categories. Recommendations targeting Member States, or both Member States and regional agencies, were summarized according to IHR capacity and compared with the

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corresponding SPAR indicators for each capacity. SPAR and JEE pertain to member states' IHR capacities and we therefore consider them to be relevant only to the recommendations to Member States. We sought through this analysis to determine the added value of the exercises, and to clarify which capacities are most frequently assessed in qualitative exercises.

Lastly, recommendations to EU agencies were compiled and compared to the current mandates of EU agencies, in a bid to say something about the status of implementation. Without insinuating a causal link from the recommendations to the establishment of new agencies or mandates, we present some recent developments that correspond to come of the most frequent recommendations to EU agencies.

2.3.3. Comparison with lessons learnt from COVID-19

The recommendations in our dataset were compared to lessons learnt from the COVID-19 pandemic. The aim of the analysis was to identify commonalities between the recommendations in our dataset and the lessons learned during the pandemic. This can allow us to say whether the SimEx identified issues that turned out to be relevant in an actual event. It also shows, to some degree, whether they were followed up.

We used the mid-2021 communication "Drawing the early lessons from the COVID-19 pandemic" from the EU commission (European Commission, 2021) as a baseline for this. The document identifies the 10 most important points of improvement in the EU response to the pandemic.

3. Results

3.1. Description of SimEx and IAR data

3.1.1. Overview of SimEx and IAR

In total, there were 17 SimEx and 2 IAR registered in the EC database, for which all reports were available. These 19 reports included a total of 357 recommendations. The two IAR were carried out during the H1N1 outbreak in 2009, and were not called IAR at the time, but fall under this definition today. No AAR had been carried out on the EU level in the last decade and had available reports. From 2005 to 2018, no more than two SimEx/IAR was carried out annually, except for 2011 (four exercises). In 2006, 2007 and 2012 no SimEx/IAR reports were available. One exercise was held over three days, one over one day and the other exercises were held over two days.

Of the SimEx, twelve were discussion-based exercises or tabletop exercises (TTX) while five were command post exercises (CPX). The health events included in the

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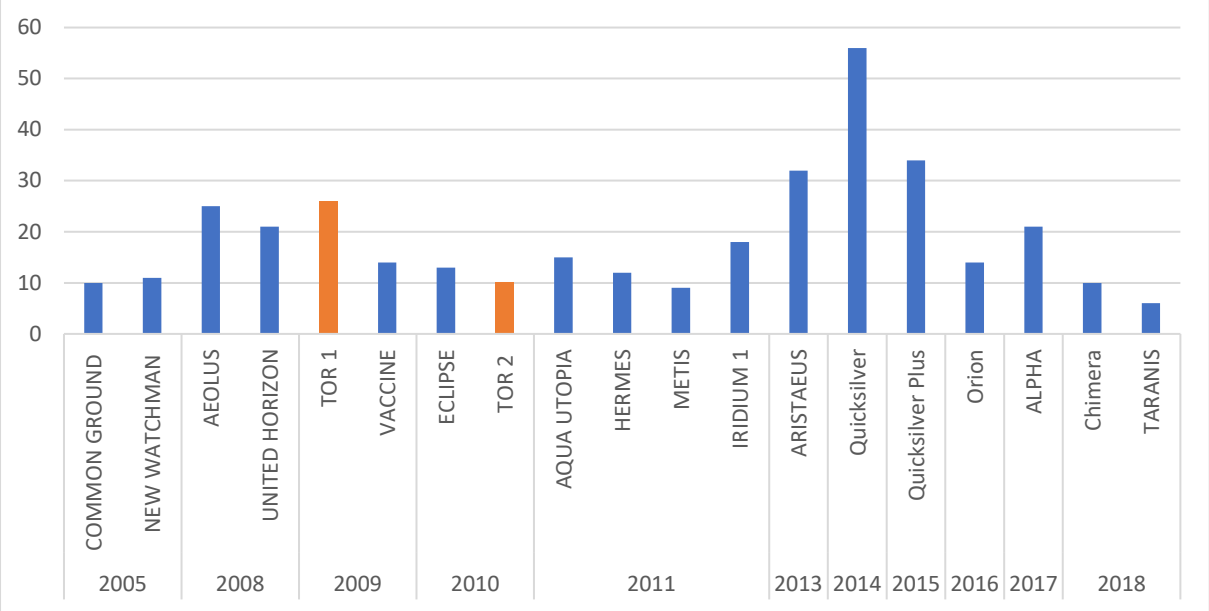
exercise scenarios/IAR were either biological events (n=14), including two food safety event and one zoonotic event, chemical events (n=3) or radiological events (n=2). The health events of the SimEx were either of natural cause (n=9), deliberate causes (n=4), accidental causes (n=2), or both deliberate and accidental causes (n=2). A summary of the exercise scenarios is presented in **Annex I**.

Figure 2: Data included - number of recommendations per SimEx (blue) and IAR (orange) in chronological order (total N=357)



3.1.2. Participants

The number of countries participating in the exercises/IAR (including EU MS, EEA and other countries) ranged from 4 to 30 countries (median 21 countries). The number of individual participants in the exercises varied by type of exercise, with 8 to 95 participants (including facilitators) in the tabletop exercises, while the CPX exercises had between three to four hundred registered participants.

For all the exercises public health specialists, among others the Health Security Committee (HSC) members, were in the participant target group. For eight of the exercises at least one other target group was specifically invited to participate, including specialists in communications/ members of the HSC COMNET (n=5), chemical sector (n=2), environmental health (n= 2), food safety (n=2), veterinary health (n=1), civil protection/security (n=1), transportation (n=1) and energy (n=1). For the CPX, participating countries were able to invite other sectors as relevant. The most represented agencies were WHO Euro and/or HQ (n=15), ECDC (n=13), DG SANCO (n=10), CHAFEA (n=5), DG HOME (n=4), DG SANTE (n=5), JRC (n=4), DG ECHO (n=4), EMEA (3) and EFSA (n=3). The mandates of these agencies can be seen in Annex 4.

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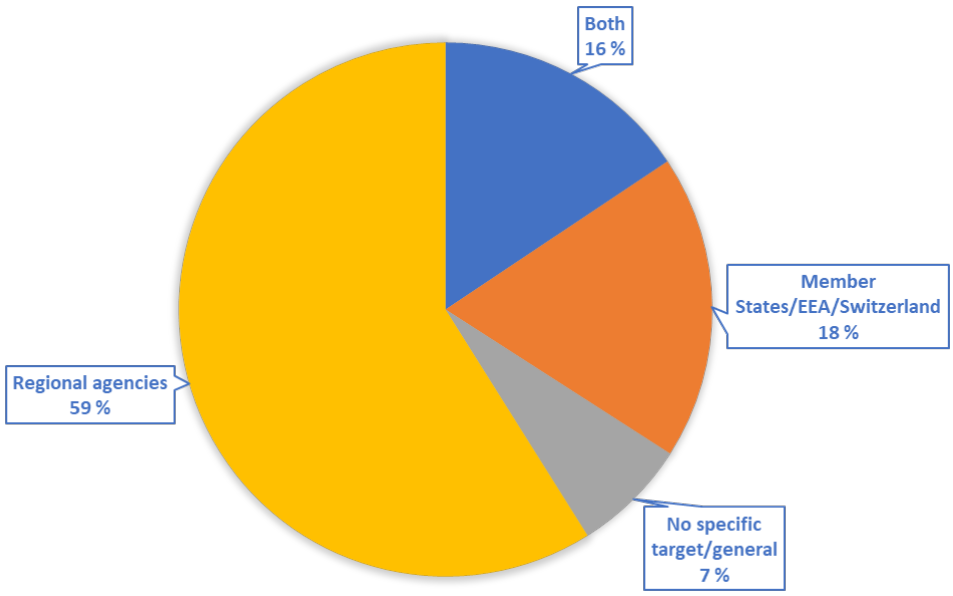
3.1.3. Target audience

Recommendations from the exercises were worded to target either EU agencies, Member States, or both. Figure 3 shows the proportion of recommendations to Member States, regional agencies, both, or none.

Figure 3: Recommendations per responsible entity, as a proportion (N=357)



In many instances it was difficult to assess who was responsible for following up on the recommendation. Out of the 19 exercise reports, only 6 had tables that directly stated the agency or organisation responsible for following up the recommendation. In other reports, some of the recommendations were worded as addressing a particular entity. For the rest, we deducted based on other content of the reports. Where no deduction was possible, the recommendation was classified as having no specific target/general.

3.2. SimEx and IAR results

3.2.1. Most common weaknesses identified

Many SimEx, while specifying a particular aim and focus of the exercise, highlight a variety of additional issues that may impact the response in each situation. For example, Chimera (2018) aimed to assess systems and communications tools but discovered a lack of both common response guidelines and defined leadership in that type of event. Classifying all the recommendations individually by IHR capacity thus gave an overview of which capacities were the most concerned in the reports. Some

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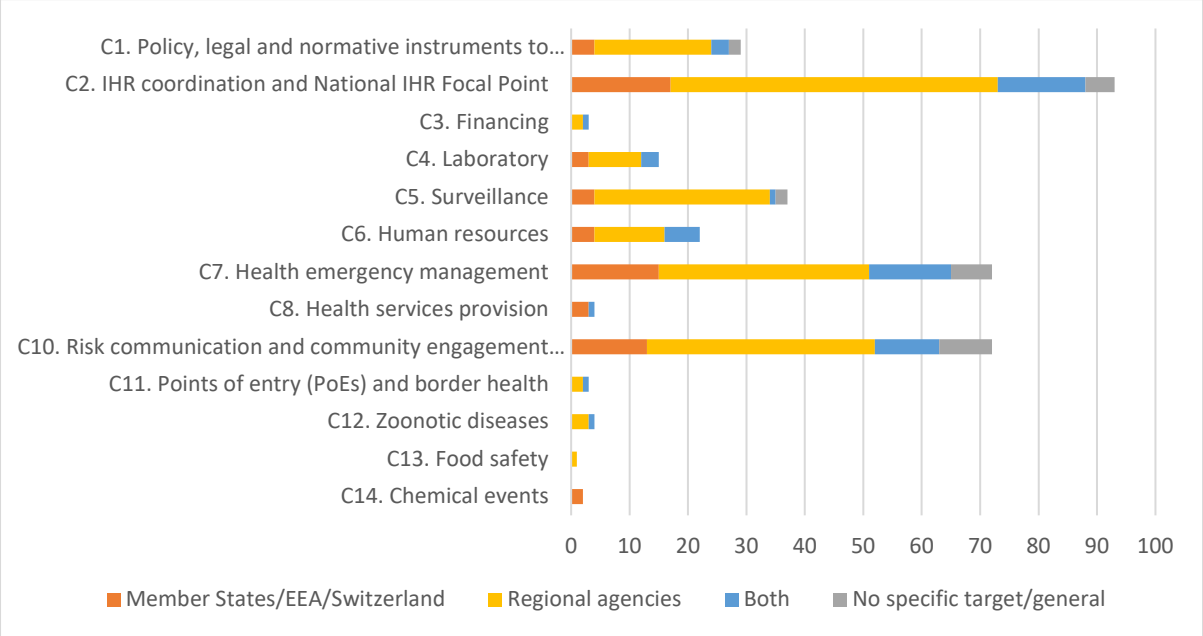
recommendations were relevant for several core capacities – in which case the most relevant one was selected. There were recommendations concerning all capacities except C15: Radiation emergencies. Recommendations pertaining to coordination, health emergency management and risk communications were the most recurrent in this dataset, and least recurrent were recommendations concerning the capacities C13: Food safety and C14: Chemical events.

Figure 4: Number of recommendations per IHR capacity, by target audience (N=357)



Using SHINY language tool across capacities, certain issues emerged. The crude results can be seen in Annex 5. The following extraction was done:

Collection, exchange and sharing of information: 34 recommendations stipulated the importance of regular information flow and improving ways of information exchange. Information flow across borders was especially underscored as an essential element in managing events (another 27 recommendations concern the role and use of EWRS alone), but intersectoral communication on a national level was also mentioned repeatedly. Another group of recommendations pertained to the challenges related to risk communication- interaction between authorities and media and social media and how to ensure transparent, coherent, scientifically correct, and timely information to the public.

Systems, procedures, and protocols (SOPs): Recommendations across capacities highlighted a need to streamline and standardise procedures to facilitate international collaboration. Defining strategies and processes in standardised SOPs during “peace time” will further gain time in a crisis.

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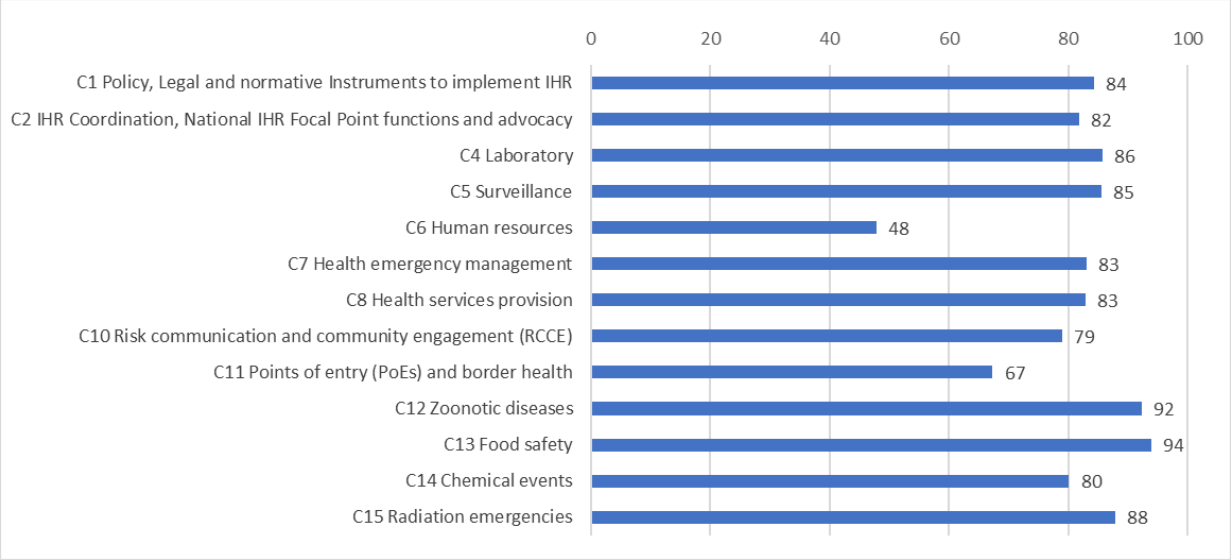
Clarification and awareness of roles: A recurrent issue across capacities was the review, clarification and awareness of roles and responsibilities of different entities, particularly EU entities. 33 recommendations stipulated this need, 29 of which specified a need to clarify roles of EU agencies, most often the EU commission itself or DG SANTE. The remaining 4 recommend clarification of roles on national level within Member States.

Aside from the recommendations on technical issues, a recurrent statement in the summary of the execution of the exercise is that participants felt that the exercise itself was useful and that it allowed them to practise skills and identify gaps in preparedness and response.

3.2.2. Recommendations to states and SPAR/JEE scores

Figures 5 and 6 give an overview of the average SPAR and JEE scores for the period when the SimEx in the sample were carried out but starting in 2010, when states started reporting on national IHR core capacities through SPAR.

Figure 5: Average SPAR scores per capacity in EU/EEA countries and Switzerland, 2010-2018



In the latest SPAR report from 2021, the capacities with the poorest performance on average in the EU/EEA/Switzerland were C1 Policy, legal, financing (69 points), C6 Human resources (69 points) and C11 Points of Entry (67 points).

Complementary to SPAR are the JEE. Reports were available for 9 JEE done in the European region, in Belgium, Slovenia, Latvia, Finland, Switzerland, Liechtenstein, Montenegro, Serbia and Lithuania. All were carried out in 2017 and 2018. Average scores from these are presented below.

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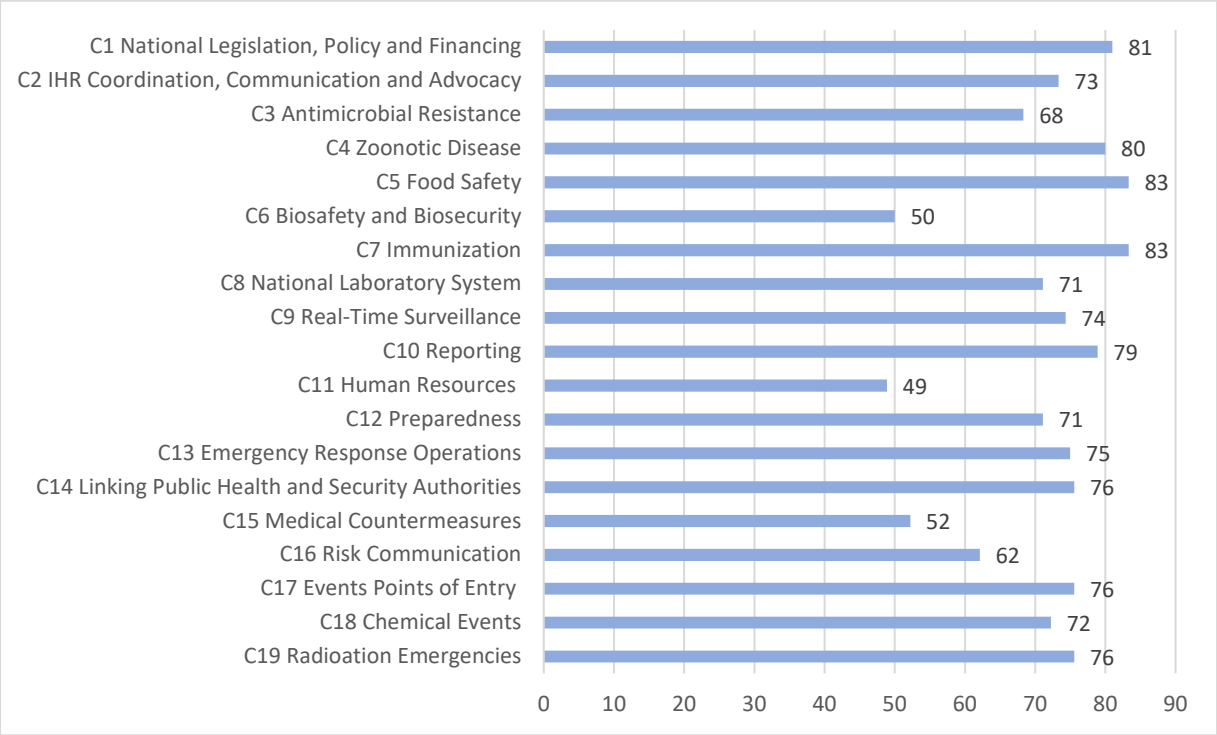
Figure 6: Average JEE score per capacity in 9 countries.



Throughout the period, the low scoring areas in SPAR and JEE are Human Resources (C6/C11), Points of Entry (C11/C17), Risk Communication (C10/C16), Biosafety/biosecurity (C6), and to some extent Legislation, Policy and Financing (C1). The SimEX conducted between 2005 and 2018 did not focus on the low scoring areas from the SPAR, except for Risk Communication which has been prioritised in the EU and was the main objective of three exercises in the dataset.

34% of the recommendations targeted states, either exclusively or in addition to regional agencies. They focused on the same capacities as the overall recommendations, as seen in figure 4. These were compared with SPAR indicator for the corresponding capacity, to assess whether and how they add value to the SPAR framework. The comparison is detailed in Annex 3. For most of the capacities, the recommendations provide added value in the form of identification of specific gaps, either in terms of a particular type of event or disease. Numerous recommendations also point out that despite the implementation of a tool, role or mechanism, there are weaknesses such as lack of awareness or incorrect use. In other words, despite the existence of required technical or infrastructural capacities, they were not considered to be functioning optimally.

3.2.3. Recommendations to EU agencies

59% of the recommendations targeted EU agencies. A summary of the recommendations can be seen in table 3. The reports assessed in this study do not

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contain action plans for implementation. Below follows a short summary of recurrent recommendations and the most relevant recent development in health security in the EU.

Information exchange tools are frequently mentioned in the recommendations. The need to upgrade, improve and integrate them, as well as to train users is mentioned in various exercises. There are recommendations on the need to streamline and create integrated platforms for sharing information during public health crises. Emergency coordination is another recurrent topic, both in terms of roles and responsibilities as well as multisectoral coordination depending on the type of event. There is a recurrent call for a clearer mandate for coordination. It also includes recommendations on joint procurement and regional stockpiling of medical countermeasures. A series of recommendations on how to strengthen the HSC and HSC COMNET came in 2011. Streamlining public communication is another frequent recommendation, including how to engage on social media. Some recommendations were specific to the coordination and intersectoral collaboration of hybrid and chemical events.

Main objective	Exercises	Summary of recommendations
Influenza preparedness	2005 COMMON GROUND 2009 TOR 1	1- Develop a generic national plan for emergency frameworks 2- Investigate and clarify international regulations on travel and border control during international infectious disease outbreaks – aim for a coordinated approach across EU MS. 3- Review, define, improve and train on communications tools for both epi data and business continuity (**HEDIS**, **EWRS, MedISys** and others) 4- Establish secured digital platform for EU communication 5- Engage with pharma and vaccine manufacturers to ensure access to MCM for the EU during public health emergencies 6- Clarifications of roles of ECDC, EC, WHO and WHO EURO 7- Streamline key EC-wide media responses 8- Enhance coordination and reporting mechanisms between WHO, EU agencies and MS. 9- Develop a strategy for HSC COMNET with clear roles, responsibility, line of communication, trigger points and coordination mechanism
Vaccination during an infectious disease emergency	VACCINE WORKSHOP (2009) TOR 2 (2010)	1- Develop an EU joint procurement protocol which ensures equitable distribution between MS and addresses national requirements, logistics and legal issues 2- Develop a regional stockpiling mechanism managed by EU or WHO. 3- Enhance collaboration and coordination between DG SANCO, EMEA, ECDC, HSC communicators and WHO
Communication during a biological health threat of an infectious agent.	2005 NEW WATCHMAN	1- Develop SOPs in case of public health emergency with defined roles and responsibilities of MS and ECDC, EC, WHO and WHO EURO. 2- Establish minimum standard of equipment needed for teleconferences during crises 3- Develop secure system for sharing information across EU 4- EC to ensure streamlined alert level definitions across MS 5- Ensure coordinated key EU wide responses to media 6- Conduct routine exercise to enhance coordination between MS and ensure that identified issues are addressed

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Main objective	Exercises	Summary of recommendations
	2008 UNITED HORIZON	DG SANCO should upgrade the **HEDIS** system by: 1- End user survey to understand needs and requirements 2- SOPs, guidance document and training on how to use HEDIS 4- Clarify role of HEDIS in relation to EWRS and other EU and WHO systems 5- Address technical and security issues 6- Develop a mechanism for instant sharing of urgent information
Communication in addressing a radio-nuclear threat.	2011 AQUA UTOPIA	**HSC and HSC COMNET should** 1- Develop and update TORs governing the mandates of HSC and HSC COMNET 2- Reinforce knowledge internally of mandates and procedures 3- Define triggers, actions and joint criteria for information sharing during crises 4- Receive training on use of HEDIS 5- Improve overview and access to specialist advice, including on CBRN threats 6- Develop use of social media as a tool 7- Map communication processes in MS and share best practises
Communication in mitigating a chemical event.	2011 IRIDIUM 1	**DG SANCO should:** 1- Use updated contact list and e-mail protocol for incident notification 2- Define a process for developing a case definition of chemical incidents 3- Rapidly provide and share an overarching picture of incidents with EU and MS 4-Coordinate scientific advice for chemical incidents with MS to avoid conflicting advice 5- Consider agreements on rapid collaboration and info sharing in border regions 6- Ensure involvement of both health and other sectors in preparedness planning 7- Review mutual aid plans between EU countries to streamline processes and ensure rapid deployment of assistance to neighbouring countries 8- Define protocols for RAS-CHEM 9- Consider joint public messaging communications
Intersectoral coordination in addressing biological threat with a direct impact on food safety.	2008 AEOLUS	1- Establish a European coordination mechanism for health events that <u>are not</u> due to a communicable disease, and define which European scientific body would lead on risk assessment and epidemiological investigation 2- Review protocols for exchange of information during health threats of criminal/terrorist nature, and establish guidance on management, access and transfer of sensitive data during such crises 3- Establish an EU-wide timeline for audio-conferences, reporting, risk assessments and communications - HEDIS provides a Common Recognized Information Picture. 4- DG SANCO and HSC COMNET should ensure consistency of public messages by establishing a framework for sharing information about public statements. 5- Develop a policy for EU information systems HEDIS, EWRS, RAS-BICHAT - Define function, usage and interplay between systems, and who has access - Review and improve user friendliness, security and resilience of the systems - Establish verification of shared information.
	2013 ARISTAEUS	**DG SANCO should:** 1- Develop EU-wide SOPs on emergency management of food-borne outbreaks, defining roles and responsibilities, coordination mechanisms, lines and tools of communication 2- Secured digital cross-sectoral platform for cross communication between MS and relevant EU agencies to share information, actions to take, epi and lab data. 3- Secured digital platform for public dissemination 4- A protocol for coordination enables exchange of expertise between HSC members and HSC CommNet members. 5- Define EFSA's mandate and develop SOPs for joint ECDC/EFSA food borne outbreaks 6- Review needs and access to technical assistance and training on outbreak response

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Main objective	Exercises	Summary of recommendations
Intersectoral coordination during a radio-nuclear event	2010 ECLIPSE	1- Develop a European 'uncertainty' communication strategy for the early stages of an incident with generic messages to be used 2- Study, monitor and utilise social media platforms for community engagement 3- Defined trigger points for inclusion of technical expertise 4- Ensure awareness and training for senior officials
Intersectoral coordination in facing a biological threat of zoonotic nature.	2017 ALPHA	1- Multisectoral coordination protocol between the EU commission, and OIE on emerging diseases in animals which defines - Multisectoral coordination between animal and human health authorities - Roles and responsibilities of relevant EU agencies and lines of communication. C- SOPs for surveillance data on emerging diseases, and AMR. 3- Development of joint dashboard or information sharing system for zoonotic threats. 4- Increased awareness and training on the One Health interface.
Intersectoral coordination in mitigating a hybrid threat.	2018 Chimera	1- Develop common EU guidelines on hybrid threats 2- A secure system for exchanging information in case of hybrid threats. 4- An emergency management protocol for hybrid threats including roles, responsibilities, coordination mechanism, line and mode of communication, and contingency plan. 5- Address the need to communicate and coordinate with non-EU states
Cross-border coordination in mitigating a chemical event.	2014 Quicksilver	1- Develop and strengthen the HEOF 2- Improved process for the timely sharing of information and use of tools such as EWRS and RASCHEM between the relevant institutions at the EU and MS to ensure rapid risk assessment and crisis communication 3- Continued development of the HSC Communicator's Network and awareness of its role and responsibilities, to ensure coherent messaging at European level. 4- Implement procedures for sharing technical information between EU agencies and WHO to ensure unified and scientifically based advice to MS
	2015 Quicksilver Plus	1- DG SANTE to develop its role as a European coordinator during cross border threats 2- Improve awareness of roles, responsibilities and communication mechanisms between EU agencies, WHO, MS. 3- Establish SOPs between DG SANTE, DG ECHO, DG HOME. 4- Upgrade and train on functionality of RASCHEM and EWRS. 5- Review and increase awareness of HEOF roles and responsibilities 6- Develop HSC COMNET and a unified communication platform
Intersectoral coordination in a biological threat	2018 TARANIS	1- Improve business continuity planning, resilience, intersectoral and cross-border cooperation during disruptive events 2- Improve collaboration between public health and other critical sectors for the maintenance of public services
Preparedness and response facing biological threats due to climate change	2016 Orion	1- Improve preparedness in terms of response coordination, scientific evidence of vector control measures, medical countermeasures, communication and public health adaptation to climate change 2- Develop European guidelines on how to disinfect airplanes in case of PHE 3- Develop a European universal communication tool for all hazards 4- Enhance intersectoral collaboration by conducting further exercises and trainings
Laboratory capacities during a biological threat of an infectious agent.	2011 HERMES	**Review the legislative framework for transport of dangerous goods between EU MS** 1- Define roles and responsibilities between MS, EU agencies, IATA and others. 2- Establish a list of EU accredited 'Expert labs' 4- Review border restrictions to enable movement of biological samples between MS 5- Establish standardized protocol on labs biosafety and biosecurity on packaging and transportation of infectious substances, 6- Implement online trainings and accreditation.

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3.2.4. Impact and COVID-19

The EU Commission identified 10 lessons learnt after more than one year of responding to COVID-19 in Europe and proposes some concrete amendments or solutions (European Commission, 2021). These lessons are related to international surveillance, coordination of scientific advice and measures, emergency preparedness, health systems strengthening, supply chains, clinical research, and risk communication. There is a strong focus on regional coordination and joint approaches.

TOR1 (HPA, 2010b) and TOR2 (HPA, 2010a) are IAR from 2009 reviewing the response and the vaccination strategies during the H1N1 pandemic.

A step-by-step comparison of the 10 lessons learnt with the SimEx recommendations found that among the SimEx in our sample, some of the recommendations are in line with the lessons learnt during COVID-19. In the following are eight of the COVID-19 lessons and similarities with previous SimEx/IAR highlighted. For the lessons not presented, there were no obvious similarities.

Table 3: Comparison between SimEx recommendations and lessons learnt from COVID-19

Covid-19 lesson 1: ***"Faster detection and response depends on stronger global surveillance and more comparable and complete data."*** Report highlights that current international alert system did not operate with sufficient speed and recommends implementation of a new global surveillance system and a new and improved European pandemic information gathering system.		
SimEx/IAR (type of event)	**Year**	**Similar recommendations**
COMMON GROUND Influenza preparedness	2005	Established that efficient on-line, real-time data input and access by the relevant bodies is needed in a crisis situation and would alleviate the duplication of case reporting.
TOR 1 Influenza preparedness	2009	Review and define the use of EWRS, HEDIS, and MedISys. A review of reporting processes should be undertaken by ECDC and WHO Euro *of the case reporting system and other similar systems to ensure an efficient process is developed for use between multiple receiving agencies.*
ARISTAEUS biological threat (food safety)	2013	Identified the need to organise central collection, collation, analysis and dissemination of data and information during multi-state outbreaks, facilitated by timely provision of data from Member States.
ALPHA biological threat (zoonotic)	2017	*The Commission should implement the interactive information system referred to within Animal Health Regulation (EU) 2016/429.* *The Commission should develop procedures to support intersectoral sharing of information on emerging diseases when the disease is not notifiable.*
TARANIS biological threat (pandemic flu)	2018	*Strengthen the role of information sharing, risk identification and surveillance between EU agencies, in particular ECDC, and national / EU / international partners.*

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Covid-19 lesson 2: ***"Clear and coordinated scientific advice facilitates policy decisions and public communication."***		
More coordination at EU level on scientific advice was identified in the report as a need to ensure consistent, coherent and factual communication. A new European Chief Epidemiologist was proposed to address this.		
SimEx/IAR (type of event)	**Year**	**Similar recommendations**
IRIDIUM Chemical event	2011	MS and DG SANCO should coordinate the provision of scientific advice for response to chemical incidents to ensure that conflicting advice is not given.
Quicksilver Chemical event	2014	Series of recommendations on how to ensure coherent public messaging from MS and the EU. For example: • EU and MS should coordinate crisis communications • Communicators and scientific staff should collaborate on communications, and to share public information before releasing it. • *MS should consider the advice of the EU Scientific Committee in the context of cross-border health threats as the one to be used (coherence of messages and increased safety for the public)*
Orion Biological treat (chikungunya virus outbreak)	2016	• *Develop a protocol to enable daily key messages to be released to MS to aid coordination including intersectoral during an incident* • *Implement a system to facilitate interaction and sharing of information to inform decision-making between MS*
Covid-19 lesson 3: ***"Preparedness needs constant investment, scrutiny and review"***		
It was concluded in the report that even if there were many preparedness plans, there was a lack of systems and means to put these into action. Need for stepping up investment was acknowledged, and an annual State of Preparedness Report was suggested.		
SimEx/IAR (type of event)	**Year**	**Similar recommendations**
TOR 1 Influenza preparedness	2009	• MS, the Commission and EU Agencies *should continue to evaluate pandemic preparedness for sectors and services identified as potentially at risk, (health and cross-sectoral), particularly as not all sectors experienced similar levels of pressure.* • MS and EU Agencies should *undertake a pandemic "lessons identified" review process and the outcomes, where appropriate, are shared across MS and the EU. Outputs of this process should be inputted into the development of pandemic plans at MS and EU level.* • The Commission and EU Agencies should *refine and publicise estimates of pandemic planning assumptions for a new pandemic as early as possible to enable other sectors to prepare and ensure these are reviewed as the pandemic progresses.*
Quicksilver, Quicksilver Plus, Chimera Chemical event/Hybrid threat	2014 2015 2018	Training including at Member States and/or EU level was mentioned in three exercises, including *continual programme or regular training and exercises.*

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Covid-19 lesson 5: ***"Coordinated measures should become a reflex for Europe"***

The report highlights further strengthening of inter-institutional cooperation, coordinate decision and combine necessary expertise and propose building of the European Health Union.

SimEx/IAR (Type of event)	Year	Similar recommendations
COMMON GROUND Influenza preparedness	2005	Clarifying the roles of organisations such as ECDC, EC WHO Europe and WHO HQ so that Member States could make coordinated and informed decisions concerning, for example, the movement of individuals.
TOR1 Influenza preparedness	2009	Share information regarding travel advice and have a coordinated approach and share contact tracing policies.
Quicksilver Plus chemical event	2015	Recommended that *DG SANTE to consider including roles and responsibilities of partner organisations within HEOF SOPs and emergency plans.*
TARANIS biological threat (pandemic flu)	2018	Recommended to *Clarify roles and responsibilities of all stakeholders during the crossborder intersectoral response to disruption during a pandemic.*

Covid-19 lesson 6: ***"Reinforced public-private partnerships and stronger supply chains are needed for critical equipment and medicines"***

The need to increase resilience of supply chain for critical supplies was addressed in the report. Joint procurements and stockpiles were mentioned as some of the measures EU has taken during the pandemic. The establishment of HERA to ensure preparedness and response in terms of medical countermeasures, and IPCEI to enable breakthrough innovation in pharmaceuticals were advised.

SimEx/IAR (type of event)	Year	Similar recommendations
COMMON GROUND Influenza preparedness	2005	Highlighted the need to engage with vaccine manufacturers and pharmaceutical companies to resolve "issues of availability and suitability of containment measures", specifically development and procurement of vaccines, the quantities required and the projected timeframes, as well as co-ordinated distribution and use of anti-virals and vaccines, and mechanisms to allocate vaccines and anti-virals between Member States.
TOR1 Influenza preparedness	2009	Recommended that MS incorporate planning for the provision of mutual aid as part of generic business continuity planning for health services, including health sector supply and support services.
TOR 2 influenza vaccination	2010	Joint procurement enables stronger negotiation power, lower costs, and equitable access, and that these JP should adapt to national requirements, logistics, context and legality.
TARANIS biological threat (pandemic flu)	2018	Identified the critical reliance on supply chains and the need to have contingency plans in cases of disruptions, where all countries would be demanding similar limited resources, including medical counter-measures and personal protective equipment. The loss of such services could quickly make the provision of the effective response unsustainable. A thorough review into the resilience of key supply provision was recommended as well as more coordination and guidance on EU level.

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Covid-19 lesson 7: ***"A pan-European approach is essential to make clinical research faster, broader and more effective"***

The report state that the approach to clinical trials in Europe were fragmented and divided in the beginning of the pandemic. An EU wide trial network has been supported by the Commission and a large scale EU platform for multi-centre trials is recommended to set up.

SimEx/IAR	Year	Similar recommendations
TOR 2 influenza vaccination	2010	The IAR on vaccine strategies established *need for public clinical research capacity (e.g., carry out comparative effectiveness studies) in the EU, (…) this should be coordinated by an existing EU agency.*

Covid-19 lesson 8: ***"Capacity to cope in a pandemic depends on continuous and increased investment in health systems"***

Structural weakness in health systems, like lack of surge capacity, and the need for health systems in Europe to become more resilient was concluded in the report. It is advised to support MS in this process.

SimEx/IAR	Year	Similar recommendations
TOR 1 Influenza preparedness	2009	*Appropriate that MS incorporate planning for the provision of mutual aid as part of generic business continuity planning for health services, including health sector supply and support services.*
TARANIS biological threat (pandemic flu)	2018	Frontline and support staff shortages in emergency and community-based care, e.g., in a pandemic situation, would severely hamper capability and capacity. Recommend considering the impact on the health sector and to identify and prioritise services to assign staff to critical services.

Covid-19 lesson 10: ***"A more coordinated and sophisticated approach to tackling misinformation and disinformation should be developed"***

Misinformation and disinformation have been spread with great speed and the report highlights the need for standby capacity to combat these risks and recommends improved tools for better coordination to detect and react at EU level.

SimEx/IAR	Year	Similar recommendations
VACCINE WORKSHOP influenza vaccination	2009	Raise the issue of how to counter the "anti-vaccine lobby" and recommending that scientific evidence will be important in this.
TOR 1 Influenza preparedness	2009	Considered important that MS monitor the accuracy of public health messages issued by the media during a crisis and develop systems that assess the level of public understanding of the issued messages.
TOR 2 influenza vaccination	2010	In relation to vaccination strategy during a pandemic, the recommendations were among others: • to tackle any vaccination fears and or criticisms 'head on' through an open debate • use specialised communication for at risk groups • consider targeted communications • use social media, newspaper and mass media sites to gain information of antivaccination campaigns.
ALPHA biological threat (zoonotic)	2017	Active role for risk communicator was highlighted *Future exercises should include an active role for communicators from Animal Health and Public Health services to clarify or test the requirements of risk and crisis communication.*

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4. Discussion

4.1. Summary of findings

The analysis is based on reports from 17 SimEx and 2 AAR between 2005 and 2018 where multiple countries and EU agencies participated. From these reports 357 recommendations were extracted and classified according to IHR capacity and target group. The exercise scenarios included biological events, chemical events and radiological events.

Major issues for improvement pointed out in the SimEx/IAR on EU level are within the areas of information sharing, standardisation of procedures across sectors and countries, clarity and awareness of the roles of the different national and EU agencies and availability of medical countermeasures. Several of the recommendations from the exercises were in line with lessons learned from the covid-19 pandemic. In a crisis, valuable time can be gained from having established streamlined structures and strategies in different countries, as it facilitates collaborative efforts across borders. This was addressed in part by the ECDC as a result of lessons learnt from the 2009 influenza pandemic, in the “Guide to revision of national pandemic influenza preparedness plans”(European Centre for Disease Prevention and Control, 2017). This can contribute to more streamlined preparedness plans in member states. Further, formalising operating procedures is a way of ensuring efficient, predictable, and coherent responses during international crises. The need for clarification and awareness of roles also arises especially in times of crises when swift reactions hinge on a thorough understanding of the roles and responsibilities, and roles may change.

The recommendations from the exercises targeted towards the Member States complement SPAR and JEE in that they identify specific gaps in the functionality of existing systems and propose amendments. They do not focus particularly on low scoring capacities in the SPAR. The most addressed IHR core capacities were C2 IHR coordination, C7 Health Emergency Management and C10 Risk communication. This corresponds exactly to the findings in a WHO review of SimEx and AAR globally from 2016-2019 (Copper et al., 2020). The review hypothesises that this is because such cross-cutting capacities are more likely to be in the foreground of the response in a real-life event. We can make the same hypothesis in this review. In addition, the participant groups had international, intersectional and EU agency representation, which would equally facilitate evaluation of capacities that involve coordinated actions from several entities and sectors.

About two thirds of the recommendations target EU agencies only. They address issues related to the international collaborative operations in the EU which are not covered by any other part of the IHR monitoring and evaluation framework. There was therefore no existing measure to compare with, like the SPAR on national level. Over the years, some recommendations have been implemented, but many of the

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recommendations were still relevant now during the covid-19 pandemic. The pandemic has now had a triggering or accelerating effect on many of these processes. Some relevant recent developments have happened in relation to the **European Health Union**, which has as a goal to improve preparedness and response capacity and resilience of health care systems in the EU. A **new regulation** has been proposed, which will repeal the Decision on cross border health threats and provide a strengthened framework for regional coordination of health emergencies in the EU. The proposal includes "clear provisions for the EU and Member States to adopt similar and interoperable plans at national and local levels. To ensure these plans are actually operable in times of crisis, regular full-scale exercises and carry-out after-action reviews to implement corrective measures will be organised" (European Commission, 2020a). These specific elements will be highly relevant to address the challenges with interoperability and standardisation, which was raised numerous times in our data.

In terms of communication tools, a relevant new platform is **EPIPULSE**, launched by ECDC in 2021, which integrates several communication platforms related to infectious diseases. The establishment of **HERA** in 2021 is meant to ensure a coordinated approach to ensuring access to medical countermeasures during crises. The extended mandate of **ECDC** aims to, among others, improve and integrate real-time surveillance, provide recommendations and options for risk management, and deploy an EU Heath Task Force to MS. The **EMA** has also got a stronger mandate to be a coordinating agency on monitoring risk of medicine shortages and provide advice on medicines and vaccines. In terms of hybrid threats, this is a strategic priority in the **EU Security Union Strategy** (European Commission, 2020b), with DG DEFIS mandate to coordinate a response and a hybrid toolbox was recently launched including a communication tool.

Indeed, when compared to the lessons learnt from COVID-19, we find that most of the challenges that the EU met responding to COVID-19 had already been identified during the SimEx/IAR between 2005 and 2018, and amendments had been proposed. This indicates that the qualitative tools assessed here are topically relevant and pertinent and identify important gaps in the national and international response. We also observe that the challenge is rather to ensure the recommendations are followed up and implemented and not merely identified. It may be discussed if a better implementation of recommendations throughout the years could potentially have strengthened the early response to COVID-19 in Europe.

On that note, another main finding is that we did not find consistent assignment of responsibility to implement the recommendations. The exercises and resulting reports have been commissioned from exercise management teams, which do not have the authority to develop action plans for implementation of the recommendations. There is frequent use of passive language, and some recommendations are too general or vague for it to be possible to assign responsibility for follow up or measure whether improvements have been made. This means on the one hand that important

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improvements may be left undone. On the other hand, it means that the output and impact of the exercises themselves is reduced or impossible to measure.

4.2. Strengths and weaknesses of using exercises as an IHR monitoring tool

The European Union is unique in that, in addition to national policies, plans and capabilities of Member States, there is an overarching operational structure, which is the European Commission and its DGs such as DG SANTE, which "play[s] a leading role in managing health crises at EU level, such as the COVID-19 pandemic, and in preventing and managing the EU's response to food safety crises and threats to human, animal and plant health."(European Commission, 2020c). There are also several EU agencies that are mandated to have an operational or advisory role in international public health events. Further, legislative structures such as Decision No 1082/2013/EU which requires prevention and control of the spread of severe human diseases across the borders of the EU countries; and combat other serious cross-border threats to health and contribute to a high level of public health protection in the EU.

This regional level of health management is not measured by SPAR or in JEE, which focus on national level capacities. Even if the EU was a WHO region, regional scores are mere averages of country scores and do not reflect the state and functionality of regional agencies and collaborative efforts. SimEx and AAR on EU level can contribute to evaluating the functionality and effectiveness of these agencies and collaborations. This is true also on a global level: An analysis of IHR annual reports data from 182 countries suggest that countries' capacities to prevent, detect and respond to outbreak vary widely and that capacity building and collaboration between countries are needed to strengthen global readiness for outbreak control (Kandel et al., 2020).

Health emergencies often involve several countries at once, as for example the flu pandemic which was analysed in TOR 1 and 2. Cross-border collaboration are equally an important feature of SimEx. The recommendations from the SimEx and IAR focus on information sharing, interoperability and streamlining of setup, protocols, and strategies across countries. This is not covered in SPAR reporting which is limited to national capacities. Further, the management of a complex situation is intersectoral and necessitates capacities and collaboration in various sectors, both on a regional and national level. Where the SPAR indicators mostly assess these one by one, the SimEx assesses how they work together. The ability to assess functionality despite the complexity of both international and intersectoral aspects of public health events is a major strength of the qualitative tools.

However, it is important to separate between "monitoring" and "evaluation" when comparing quantitative tools i.e., SPAR/ JEE and qualitative tools i.e., SimEx/AAR/IAR. Monitoring implies regular data collection to assess progress against a defined target. Evaluation aims at assessing the overall functionality and response

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time. In the IHRMEF, the SPAR annual reporting constitutes monitoring, and its' strengths are regularity and completeness of reporting allowing to map the structures in place and assess development of capacities over time. SimEx and AAR tend to be a punctual evaluation of the functionality and effectiveness of the structures in place, and thus a complement to SPAR and JEE. For monitoring, these qualitative tools would therefore not be suitable, but will be appropriate to conduct evaluations.

The results of any SimEx will be influenced by the choice and quality of the scenario, as well as the participants, and this should be considered when planning exercises and interpreting the results. Both the frequency, participants and the choice of scenarios are therefore important for the usefulness of SimEx as a tool to assess and improve state of health preparedness in the EU. For example, even though 6 scenarios in our sample were based on deliberate events, national representatives of civil protection/security only participated in one of them. This could leave out important perspectives from the recommendations given.

4.3. How to improve use of results from SimEx and AAR

One of the main challenges with SimEx and AAR is follow-up and implementation of recommendations. This is not a new finding : During the AAR/SimEx global consultation in 2019, it was also highlighted that the implementation of AAR & SimEx recommendations and findings "remains challenging" (WHO, 2019). One of the outcomes of the consultation was thus a recommendation to "Draft an implementation framework integrating recommendations and action plan into operational planning that should be shared with the Member States to enhance accountability and national ownership and develop a 1-2-page strategy for the implementation of AAR & SimEx finding." It was also one of the main conclusions in the CIARA report on Covid-19 Intra Action Reviews, where they recommend to "identify a reliable and systematic approach to monitor IAR recommendations to ensure they progress within the proposed timeline and meet the desired outcomes."(WHO, 2022a).

However, there are already some initiatives underway to amend this. In 2018, the WHO issued a guideline for implementing SimEx and AAR. It includes a detailed guide on how to develop recommendations to facilitate implementation: "specific, feasible, time bound, measurable, and adequately translated into an action plan" (WHO, 2018). All the SimEx/AAR in this report are from 2018 or before and as no EU level SimEx have been carried out since the manual was published, it will be important that future exercises use this manual in future planning.

A database for SimEx is currently being developed by the EC. This database should include possibilities to follow progress on implementation of recommendations to EU agencies. Following the Country Implementation Guidance, the database should include a time frame, indicator and responsible agency/unit for each recommendation, as well as possibility to "complete" the recommendation. For recommendations to

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Member States, a different model of follow up can be considered, where participating countries report back to the EC within the set time frame and using the set indicator.

The choice of scenario for any given exercise depends on the aims and objectives as set by the Commission. The exercise design team will develop the scenario according to the aims. This group has not considered the rationale behind aims, scenarios and timings for EU level exercises. It seems reasonable to suggest that an analysis of SPAR and JEE scores and the European annual state of preparedness report should inform the choice of exercise scenario, with identified areas of improvement and a clear objective. An exercise would clarify further what improvements are needed.

4.4. Limitations of this review

In addition to description, this report is offering a comparative analysis of data from different sources and different times, that is not designed to be compared. Recommendations from SimEx and AAR are not conceived according to the IHR core capacities, and there is therefore some subjectivity in the interpretation of the recommendations and classification according to IHR capacities. As a mitigation, the attribution of a core capacity to a recommendation was done by one person and then reviewed by a second person. Inconsistencies were discussed and a decision reached by consensus.

The review was conducted as a desk exercise and is based on the information found in the reports. We do not have secondary sources of information to triangulate our findings. To mitigate this, we have invited key persons in the EC and other EU agencies to review the draft report, and have presented preliminary findings to peers in the Joint Action.

The group had no access to internal processes in the EC whereby follow-up of exercises may have been done. The timeline of the included SimEx/IAR is long (2005-2018), during which time preparedness within the EU has been also evolving and developing. Numerous EU agencies, organisations, tools, SOPs and guidance documents have been produced which are difficult to capture and contextualise from the outside. Thus, we have no evidence of causal links and have not been able to evaluate the impact of the exercises.

Only EC level exercises were included in this analysis, which means only a small number of exercises were reviewed. Exercises at national level have been carried out in the same time period, and might show a stronger focus on low-scoring capacities at national level, and produce other types of recommendations.

The topics of the exercises and selection of invited participants, as well as the selection of participants who actually participate, may impact the nature and quality of

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recommendations. Selecting common events or rare events as exercise scenarios can influence the result as some participants may be more familiar with scenarios that occur relatively frequently than those who do not, which might influence the nature and quality of recommendations.

5. Conclusion and recommendations

This study has assessed the added value of conducting SimEx and AAR at regional level in the EU. It finds that these qualitative tools provide valuable insight in the state of public health preparedness at EU level and is as such a highly useful evaluation tool. At the regional level there are few other mechanisms in place to assess IHR compliance. These SimEx and AAR are therefore valuable instruments to assess the functionality of preparedness and response mechanisms, point out important gaps as well as to train and raise awareness on health emergencies. It should be regarded as complementary to existing IHR monitoring tools at national level and possibly other monitoring tools at regional level in the EU.

The recommendations from the SimEx and AAR from the period in this report was found to be highly relevant in identifying important gaps in health preparedness in the EU, seen in the light of the lessons learned from Covid-19.

Better system for follow up and implementation of recommendations will have a positive impact on the EUs ability to respond effectively to public health crises and should be prioritised for future exercises.

With the new European Health Union, the EU will have an even more important role in coordinating health emergencies, and evaluating the capacity at that level will only get more important in the future.

<u>Recommendations</u>

1) SimEx should be carried out at EU level according to a clearly defined programme, as an opportunity both to evaluate functionality and to practise response mechanisms. AAR should be carried out routinely after public health events.

2) It should be considered to include the main lessons/recommendations/ from exercises and after-action reviews in the report on state of preparedness in the EU, which summarize the status in the member states based on their reporting under decision 1082/2013 (and now under the new regulation).
3) Regional SimEx should be designed to target key gaps and challenges for regional preparedness, based on previously identified issues both from monitoring tools, risk analyses and previous evaluations.

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4) To ensure national ownership, each regional SimEx should be followed by national ones with a similar, adapted scenario in the native language. The combination of regional and national exercises could contribute to better harmonization of preparedness plans as described in the new regulation.

5) Future exercises and AAR should follow WHO's 2018 Guideline for SimEx and AAR, or similar guidance from ECDC. Based on the recommendations in the reports, the commissioner of the exercise should establish a plan for follow up and implementation, including assigned responsibilities and a plan for accountability. Assessment of whether improvements have been made regarding follow-up of SimEx conducted after 2018 should be done.

6) The EC should, as the organiser of the SimEx at EU level, centralise information about the implementation of recommendations to identify the areas where progress have been done and not.

7) A simulation exercise repository should, in addition to documenting exercises and recommendations, include the possibility to assess progress in implementation of the recommendations, to ensure improvement and accountability in public health preparedness as well as to inform the cost/benefit of carrying out exercises.

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Annex 1: Table of reports included

Exercise	Year	Hazard	Event scenario	N of MS	Other agencies	Main theme	Main aim
Chimera (SimEx)	2018	Hybrid	Deliberate release of plague + cyber-attack on power supplies and hospitals	27	DG SANTE; SG; DG Home; DG ECHO; JRC; ECDC; CHAFEA; CERT-EU; EU INTCEN; EEAS; Council Secretariat; WHO; NATO	intersectoral coordination	To challenge the use and usability of the existing systems and communications tools in response to a hybrid threat through 11 objectives.
TARANIS (SimEx)	2018	Infectious	Pandemic influenza + space weather event	21	DG SANTE; DG ECHO; DG ENER; ECDC; WHO EURO; EACCC; UK Met Office; CHAFEA	cross-border and intersectoral coordination	To rehearse response capacities and mechanisms to a serious cross-border health threat but also to review planning for disruptive events that go beyond the health sector focussing on business continuity
ALPHA (SimEx)	2017	Zoonosis	Outbreak of Nipah virus with animal and human cases	20	DG SANTE; CHAFEA; ECDC; EFSA; WHO EURO; UN FAO	intersectoral coordination	To engage the key sectors of public health and veterinary authorities in testing the use and usability of the existing systems and communication tools in outbreak response.
Orion (SimEx)	2016	Infectious	New variant of chikungunya; schistosomiasis	22	DG SANTE; CHAFEA; ECDC; DG CLIMA; WHO EUROPE	Preparedness and response	To test the preparedness and response aspects towards health hazards caused by climate change.
Quicksilver Plus (SimEx)	2015	Chemical	Unidentified illness from chemical exposure at transportation hubs and mass gathering + chemical release from oil refinery	16	C3; CHAFEA; DG HOME; DG SANTE; DG ECHO; JRC; ECDC; SCHER; WHO EURO	cross-border coordination	To test the implementation of Decision (1082/2013/EU) on serious cross-border threats to health resulting from chemical, environmental and climate change related incidents; especially in the areas of preparedness, monitoring, surveillance, risks, crisis communications, coordination and response."

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Exercise	Year	Hazard	Event scenario	N of MS	Other agencies	Main theme	Main aim
			explosions and freight train derailments				
Quicksilver (SimEx)	2014	Chemical	Collision of chemical cargo ship + forest fire and chemical plant explosion + deliberate release of chemical at transportation hub	22	ECDC; WHO EURO; DG SANCO; DG ECHO; DG HOME; JRC	cross-border coordination	To test the communication channels and the procedures in place for reporting, monitoring and scientifically assessing the risks and threats, to examine risk and crisis communication capacities in place and to investigate the coordination of the management of the response following major chemical and environmental incident(s) which pose serious cross border threats to health in the context of the new Decision"
ARISTAEUS (SimEx)	2013	Food safety	Contamination of powdered milk with Salmonella	27	ECDC; EFSA; DG SANCO; WHO EURO	intersectoral coordination	To explore outbreak co-ordination and response to a food-borne incident involving public health and food safety authorities at the national and international level.
AQUA UTOPIA (SimEx)	2011	Radio-nuclear	Contamination of illicit drug with a radiological substance	19	DG SANCO; DG Home; WHO HQ; WHO EURO; EFSA; EMA; ECDC; Media Consulta	Communication	To test existing working arrangements between the HSC COMNET members and HSC policy makers during a health crisis (CBRN incident) in order to examine ways of developing and strengthening those arrangements.
HERMES (SimEx)	2011	Infectious	Outbreak of human monkeypox	19	DG SANCO; transport experts by phone	Laboratory	To strengthen the coordination and response of microbiology laboratories in public health events in the EU.
IRIDIUM 1 (SimEx)	2011	Chemical	Leakage of hydrofluoric acid on ferry	4	ECHA; EMSA; DG SANCO	Communication	To examine how public health and clinical personnel recognise, detect and alert EU stakeholders regarding a chemical incident and its impact
METIS (SimEx)	2011	infectious	Re-emergence of SARS CoV-I	17	ECDC; WHO EURO; DG SANCO	Laboratory	To strengthen the coordination and response of microbiology laboratories in public health events in the EU.
ECLIPSE (SimEx)	2010	Radio-nuclear	Deliberate contamination	11	EC; WHO;	intersectoral coordination	To test international communication in the early 'uncertainty' stages of the response to a

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Exercise	Year	Hazard	Event scenario	N of MS	Other agencies	Main theme	Main aim
			with radioactive material at international airport				potential CBRN threat affecting the GHSAG members.
TOR 2 (IAR)	2010	infectious	Pandemic influenza	30	HSC communication network, DG SANCO	vaccine	To capture the diverse pandemic vaccine strategies (with special emphasis on communications issues) developed by the Member States, and their experiences in implementing them, in order to provide a point of departure for improving MS and EU preparedness for future pandemics.
TOR 1 (IAR)	2009	infectious	Pandemic influenza	21	ECDC; EMA; DG SANCO	influenza preparedness	To examine the response at MS and EC level to the first four months of the pandemic (H1N1)
Vaccine Workshop (SimEx)	2009	infectious	Pandemic influenza vaccine adverse events + efficacy issues	17	DG SANCO; WHO; EMEA; CHMP; PhVWP; EVM; Pharmaceutical Vaccine Manufacturers	vaccine	To test the flow of information between EU MS and agencies to respond to public concerns of potential (H1N1) 2009 pandemic vaccine adverse events or efficacy issues.
AEOLUS (SimEx)	2008	Food safety	Contamination of a protein supplement drink	27	ECDC; Europol; DG SANCO; WHO EURO	Information sharing	To examine the capability of departments and institutions at Member State and Commission level to work together and share information during a fast-evolving health threat which cuts across departmental responsibilities. The exercise addressed cross-sectoral communication and collaboration at national and EU level.
United Horizon (SimEx)	2008	Infectious	Measles-like illness in Asia	20	ECDC; JRC; DG SANCO	HEDIS tool	To explore whether the HEDIS tool can be established as the reference hub for verified,

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Exercise	Year	Hazard	Event scenario	N of MS	Other agencies	Main theme	Main aim
COMMON GROUND (SimEx)	2005	Infectious	Pandemic influenza	28	DG SANCO; ECDC: EMEA; EVM; WHO; pharmaceutical countries	influenza preparedness	To test the execution of the national plans of the Member States and examine their compatibility and inter-operability; Examine the role and availability of countermeasures; Determine the availability and suitability of containment measures; Examine the role of the EC during an influenza pandemic
NEW WATCHMAN (SimEx)	2005	Infectious	Deliberate malicious release of smallpox	28	ECDC; Europol; EMEA; WHO	Communication	To evaluate communication between the Member States, and between the Member States and the European Commission, in response to a deliberate release incident

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Annex 2: IHR capacity conversion from 2010 and 2018 to 2021.

Capacities have been grouped together as per the colour code, to fit in the 2021 framework.

The IHR Annual Reporting Questionnaire (2010)		The State Parties Annual Reporting (V1) (2018)		State Parties Annual Reporting (V2) (2021)	
C1	National legislation, policy & financing	C1	Legislation and Financing	C1	Policy, Legal and normative Instruments to implement IHR
C2	Coordination and NFP Communications	C2	IHR Coordination and National IHR Focal Point Functions	C2	IHR Coordination, National IHR Focal Point functions and advocacy
C3	Surveillance	C3	Zoonotic Events and the Human–animal Interface	C3	Financing
C4	Response	C4	Food Safety	C4	Laboratory
C5	Preparedness	C5	Laboratory	C5	Surveillance
C6	Risk Communication	C6	Surveillance	C6	Human resources
C7	Human Resource Capacity	C7	Human Resources	C7	Health emergency management
C8	Laboratory	C8	National Health Emergency Framework	C8	Health services provision
C9	Points of Entry	C9	Health Service Provision	C9	Infection prevention and control (IPC)
C10	Zoonotic Events	C10	Risk Communication	C10	Risk communication and community engagement (RCCE)
C11	Food Safety	C11	Points of Entry	C11	Points of entry (PoEs) and border health
C12	Chemical Events	C12	Chemical Events	C12	Zoonotic diseases
C13	Radiation Emergencies	C13	Radiation Emergencies	C13	Food safety
				C14	Chemical events
				C15	Radiation emergencies

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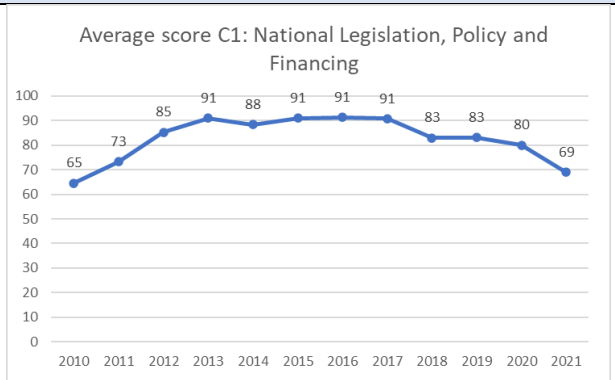
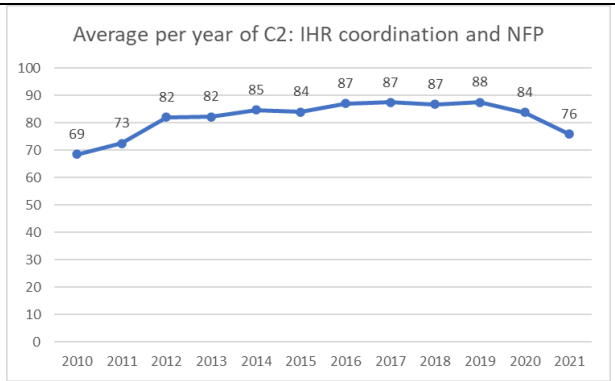
Annex 3: Comparison between recommendations to Member States, and SPAR indicators

Recommendations to Member States	SPAR scores for EU/EEA/Switzerland
C1/C3: Policy, legal, financing 7 recommendations from 4 different SimEx. They identify a need to clarify roles, responsibilities and mandates of different actors, as well as collaboration, through written agreements or SOPs. Three of them are about defining cross-border sharing and protection of information. One recommendation is about separating between political and technical meetings. The recommendations indicate that necessary systems are in place but the awareness of these systems and how they function needs to be improved. This is an aspect that the SPAR does not cover, as it is more focused on identifying gaps and legally covering them. The recommendations thus provide detail and context in relation to the legal framework for IHR, and identify specific issues where SOPs are needed.	
C2: IHR coordination and National IHR Focal Point 31 recommendations from 12 SimEx. The majority, 16, concern intersectoral or international communication, including the use of information exchange platforms such as HEDIS or EWRS. Mostly, it is about improving the awareness and use of the channels, and improving information exchange between sectors and countries. Many recommend reconsidering which actors have access to which channels. 7 of them pertain to encouraging cross-sectoral collaboration, by including different sectors in both preparedness and response to incidents. The remaining 8 are about how to clarify mandates of stakeholders, and improve the organisation and quality of responses to events. SPAR scores cover multisectoral coordination and communication well, however do not assess international comms and collaboration. This is an added value of the recommendations. Further, the recommendations identify specific gaps in the coordination, providing more details than the SPAR.	

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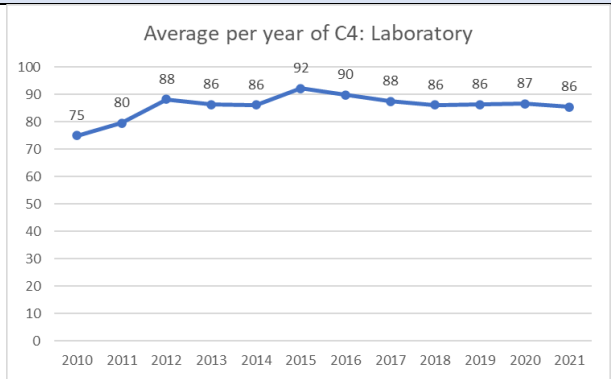
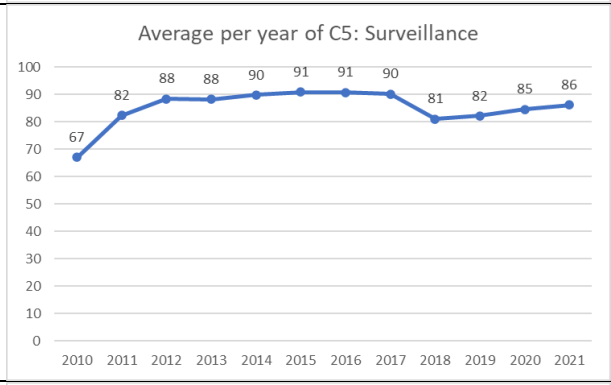
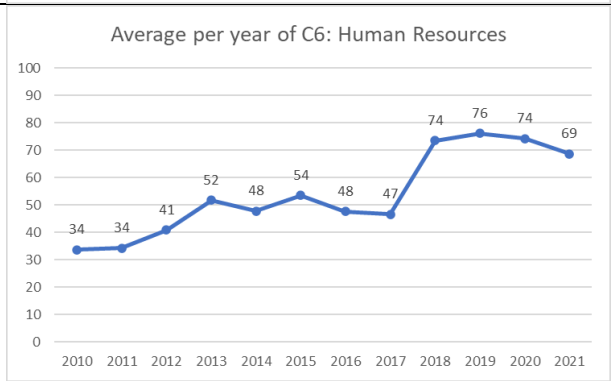
Recommendations to Member States	SPAR scores for EU/EEA/Switzerland
C4: Laboratory 6 recommendations from 4 SimEx. Better understanding of roles and responsibilities of natl/intl reference laboratories during crises, as well as sharing information about their capacities. Trainings on epidemic intelligence for labs. Agree international methodologies for strain comparison. Develop directory of carriers of dangerous goods. Establish procedures and advice to private laboratories about sample management of notifiable diseases. SPAR indicators are focused on systems being in place for specimen referral and transport, as well as a biosafety and biosecurity regime. The recommendations indicate that information sharing and interoperability needs to improve, and identify specific areas of improvement, thus complementing SPAR.	
C5: Surveillance 5 recommendations in 4 different exercises. They include recommendations on protocols relating to climate change related illness and vector control. Two of the recommendations concern the access to medical and epi data for other actors during events. One is about international coordination of contact tracing policies. The SPAR scores are based on the existence of national surveillance systems and protocols to define them, whereas the recommendations focus also on the exchange of information between the surveillance system and other actors as well as internationally. The SimEx thereby covers an area of functionality that SPAR does not cover.	
C6: Human resources 10 recommendations in 7 different exercises. Four of the recommendations concern ensuring an appropriate workforce during crises through preparatory trainings, in particular to ensure forensic epidemiologists. The remaining points recommend specific trainings, often for a wide group of stakeholders. Whereas the SPAR details whether a workforce is available, most of the recommendations specify skills that need improvement or knowledge gaps in different workforces or in general. The SimEx is thereby a complement to the SPAR scores providing specific qualitative input.	

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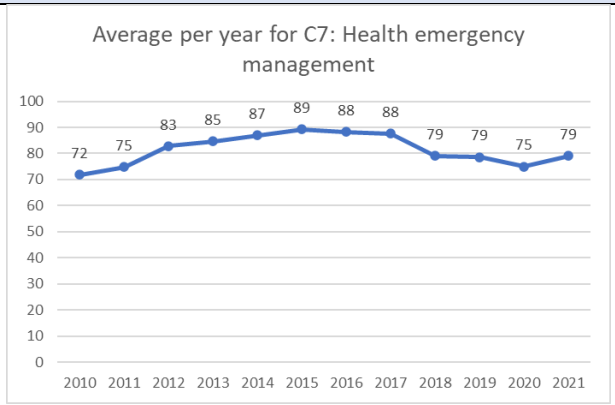
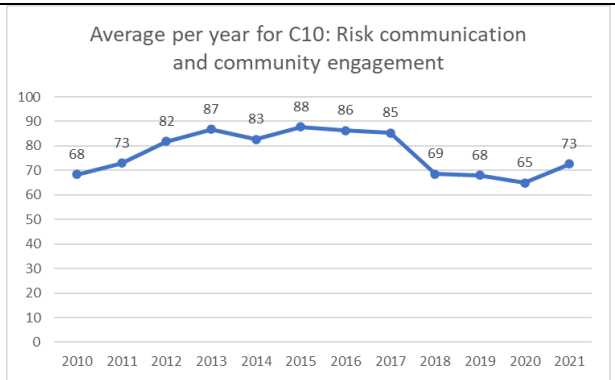
Recommendations to Member States	SPAR scores for EU/EEA/Switzerland
C7: Health emergency management 29 recommendations in 13 exercises. 8 of them concern how to share information and communicate across sectors, countries and EU organisations. 7 are about sharing and streamlining practises and strategies, such as alert level definitions and response mechanisms. 4 pertain to the organisation and quality assurance of the EOC. 5 are about planning for specific types of emergencies. Three recommend writing or reviewing SOPs for cross-sectoral collaboration, and two pertain to vaccination during pandemics. SPAR scores are focused on the presence of plans and management systems at the national level. The recommendations are more focused on the fact that health emergencies often involve several countries, highlighting the importance of information sharing and coherence between countries.	
C8: Health services provision 4 recommendations in 3 SimEx. Pertain to preparedness for cyber-attacks on hospitals, improving business continuity during pandemics in light of the impact it may have on health services, and management of antiviral drugs.	New capacity since 2018, scores have been 81 and 82 up to 2021.
C10: Risk communication and community engagement 23 recommendations from 10 SimEx. 8 of these are about organisation and strategy in communication work, including protocols and SOPs to develop/review, as well as intelligence gathering. 5 concern the specific communication tools used to reach the public or specific groups in order to have the best possible impact. A further 6 are about how to improve the quality of the content of messages, in particular how to ensure technical accuracy and coherence of messages across countries. 4 recommendations pertain to specific topics: climate change and anti-vaccine issues. SPAR indicators for C10 are fairly detailed and include a variety of factors to take into account. In this sense, the recommendations do not provide much further value, as they are quite general and cover more or less the same issues as the SPAR indicators.	

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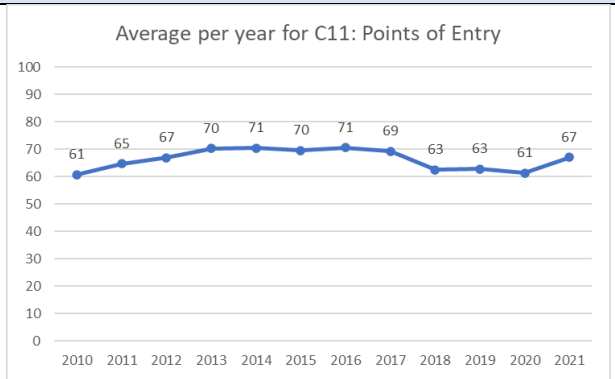
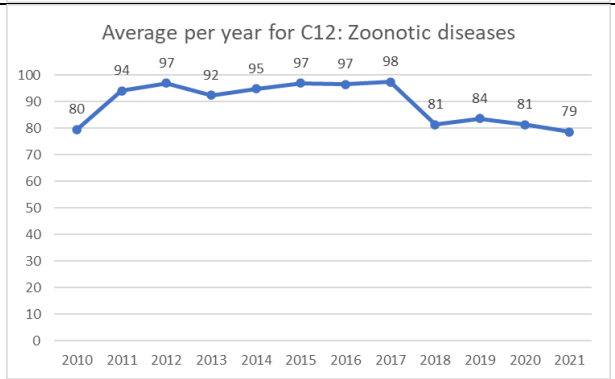
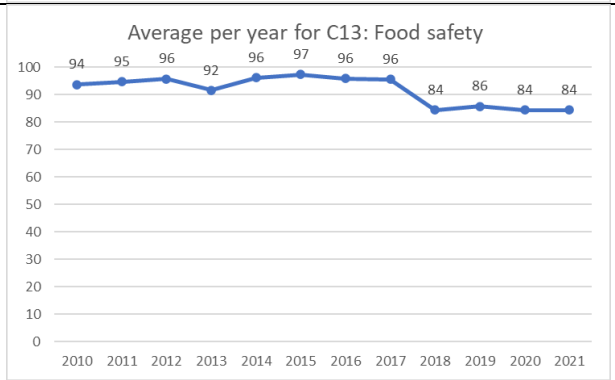
Recommendations to Member States	SPAR scores for EU/EEA/Switzerland
C11: Points of Entry One recommendation. Member states should share information regarding travel advice and the Commission aim for a coordinated and common approach to travel information and restrictions across Europe.	
C12: Zoonotic diseases One recommendation: Consider how veterinary practices and human health practices in the private sector can be more engaged in the One Health approach at the national level, as envisaged under Animal Health Regulation (EU) 429/2016. Other recommendations stress the importance of improving collaboration between the human and animal health sectors, but fall under other categories.	
C 13: Food safety No recommendations given to states within this capacity.	

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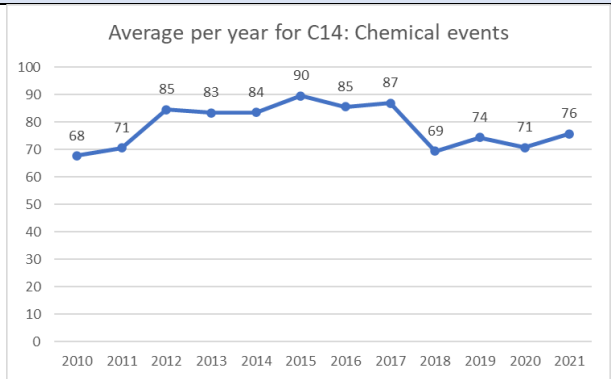
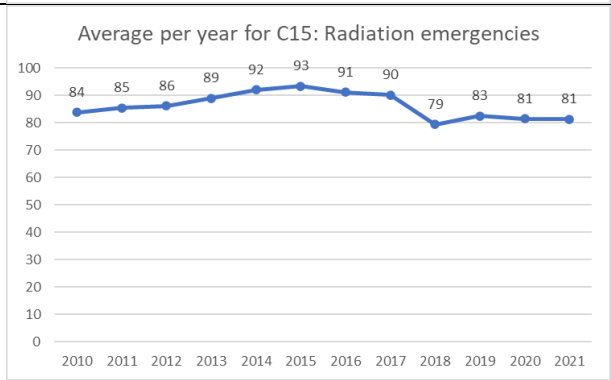
Recommendations to Member States	SPAR scores for EU/EEA/Switzerland
C14: Chemical events Three of the SimEx in the dataset had scenarios about chemical events. Most of the recommendations in the exercises however fall under other capacities. Two recommendations from one SimEx recommend reviewing the capacity of poison centres to provide advice, and to facilitate access to notifications of chemical events in EWRS	
C 15: Radiation emergencies No recommendations given to states within this capacity.	

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Annex 4: EU agencies in public health preparedness and their mandates

Year established	EU agency /committee	Mandate / objectives / mission	Reference
1995	European Medicines Agency (EMEA/EMA)	1- Facilitate development and access to medicines. 2- Evaluate applications for marketing authorisation. 3- Monitor the safety of medicines across their lifecycle. 4- Provide information to healthcare professionals and patients. 5- Monitoring medicine shortages and report shortages of critical medicines during a crisis. 6- Coordinate responses of MS to shortages of critical medical devices and in-vitro diagnostics in crisis situations.	https://www.ema.europa.eu/en/about-us/what-we-do
1999 (DG SANCO until 2014)	European Commission Directorate-General, Health and Food Safety (DG SANTE)	Responsible for EU policy on food safety and health and for monitoring the implementation of related laws. Including: 1- Build a strong European Health Union to protect and improve public health 2- Ensure Europe's food is sustainable and safe 3- Protect the health and welfare of farm animals 4- Protect the health of crops and forests	https://ec.europa.eu/info/system/files/sante_sp_2020_2024_en.pdf
2001	Health Security Committee (HSC)	A European forum for coordination during an emergency. Mandate to reinforce the coordination and sharing of best practice and information on national preparedness activities. Including: 1-Consultation between MS with a view to coordinating national responses to serious cross border threats to health, including PHEIC. 2-Deliberates on communication messages to health care professionals and the public.	https://health.ec.europa.eu/health-security-and-infectious-diseases/preparedness-and-response/health-security-committee-hsc_en
2002	European Food Safety Authority (EFSA)	To Develop scientific advice on food safety. Including: 1- Risks assessment to the entire food chain. 2- Deliver the scientific basis for laws and regulations to protect European consumers from food-related risks.	https://www.efsa.europa.eu/en/about/mission-values
2002	European Aviation Safety Agency (EASA)	Ensuring safety and environmental protection in civil aviation in Europe.	https://www.easa.europa.eu/light/safety
2005	European Centre for Disease Prevention and Control (ECDC)	To identify, assess and communicate current and emerging threats to human health posed by infectious diseases. Including: 1- Search for, collect, collate, evaluate and disseminate relevant scientific and technical data2- Provide scientific opinions and scientific and technical assistance including training 3- Provide timely information to other relevant organisations. 4- Coordinate the European networking of bodies operating in the fields within the Centre's mission. 5- Exchange information, expertise and best practices, and facilitate the development and implementation of joint actions.	https://www.ecdc.europa.eu/en/about-us/what-we-do
2007	European Chemicals Agency (ECHA)	A European agency to implement the EU's chemicals legislations and not to regulate EU response in case of chemical events.	https://echa.europa.eu/legislation

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Year established	EU agency /committee	Mandate / objectives / mission	Reference
Reorganisation in 2015	Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) (Managed by DG SANTE)	Provides opinions on questions concerning health, environmental and emerging risks. Including: 1- Emerging or newly identified health and environmental risks. 2- Broad, complex or multidisciplinary issues that require a comprehensive assessment of risks to consumer safety or public health. 3-Related issues not covered by other European Union risk assessment bodies.	
2021	European Commission Directorate-General, Health Emergency Preparedness and Response Authority (HERA)	**Preparedness mode** 1- Coordinate the European preparedness with national and regional stakeholders 2- Perform risk assessment and collect intelligence 3- Address gaps in medical countermeasures including research and development, manufacturing, supply chain and logistic issues. **During emergency** 1. Ensure the availability, supply and deployment of medical countermeasures 2. Acting as a central purchasing body 3. Monitoring medical countermeasures 4. Activating emergency measures for research, EU FAB manufacturing surge capacity and emergency funding	**https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/overview_en**

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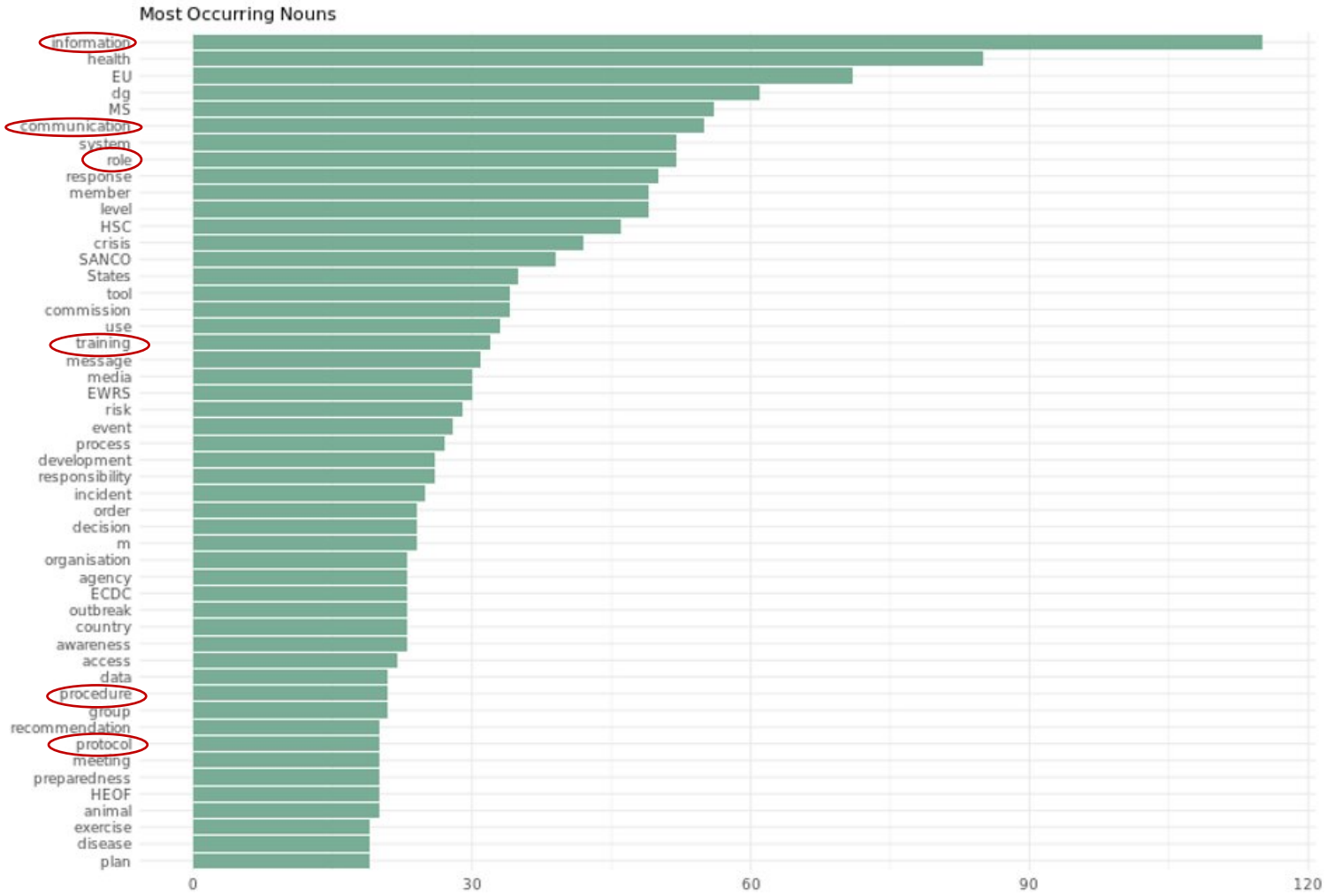
Annex 5: Crude results from SHINY



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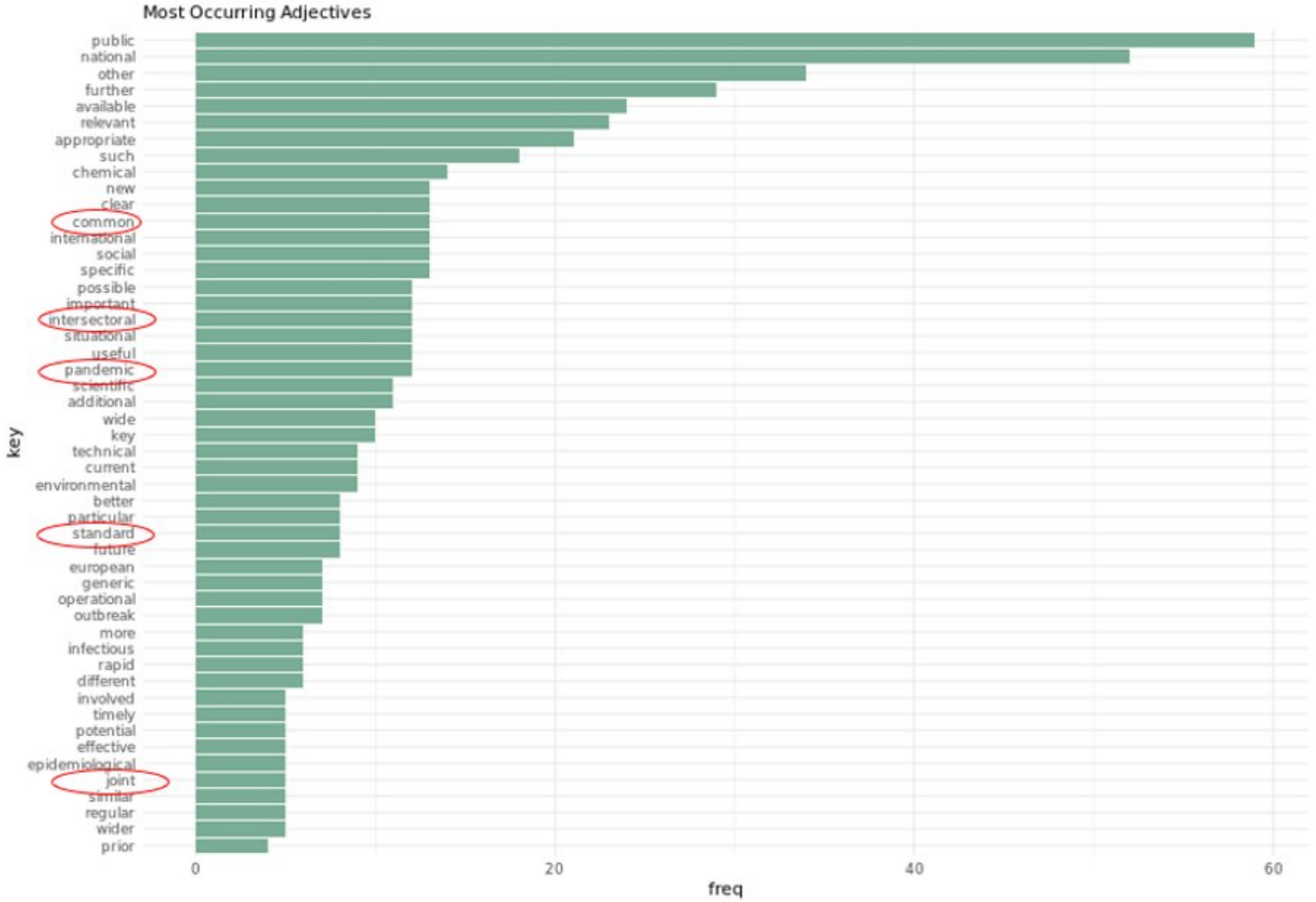

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