Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Protocol for an overview of national approaches to stockpiling of medical countermeasures for public health emergencies

16 October 2023

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.

- **Regulating social care services** — The Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.

- **Regulating health services —** Regulating medical exposure to ionising radiation.

- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.

- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.

- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.

- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

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1 Purpose and Aim

The purpose of this protocol is to outline the process by which the Health Information and Quality Authority (HIQA) will conduct a descriptive analysis of national approaches to stockpiling of medical countermeasures (MCMs) for public health emergencies in selected countries. The information will be summarised in a report in order to inform the development of a national stockpiling strategy in Ireland, through supporting the work of the Health Security Unit in the Department of Health.

2 Process outline

It is important that a standardised approach to the process is developed and documented, to allow for transparency, aid project management and to mitigate risks.

Four distinct steps in the process have been identified and will be completed. These are listed below and described in more detail in sections 2.1-2.4:

1. Defining the scope
2. Interview of key representatives from selected countries
3. Analyse and describe interview results
4. Summarise the findings.

2.1 Defining the scope

The COVID-19 pandemic highlighted the need for countries to improve their preparedness for emerging health threats. The European Union (EU) Health Emergency Preparedness and Response Authority (HERA) was established to prevent, detect, and rapidly respond to health emergencies at European level.[(1)] HERA has a role in addressing vulnerabilities and strategic dependencies within the Union related to, development, production, procurement, stockpiling and distribution of medical countermeasures. The European Commission defines MCMs as vaccines, medicines, medical equipment and diagnostics.[(2)] The top three key threats to our health security as described by HERA include:

- pathogens with high pandemic potential
- chemical, biological, radiological and nuclear threats
- threats resulting from antimicrobial resistance.[(3)]

At national level, the World Health Organization and HERA have also recommended that individual countries develop national MCM stockpiling strategies.[4] This review will focus on approaches taken to the stockpiling of MCMs for public health emergencies in selected countries. Information on national approaches to MCM stockpiling for a select group of countries will be identified from government resources and resources from other relevant national, European and global bodies (websites, reports and press releases). The associated resources that will be searched are detailed in Appendix 1. This list is not exhaustive and will be expanded as necessary should relevant information be available elsewhere. However, as publicly available information relating to national stockpiling of MCMs is limited, information will be obtained primarily via semi-structured interviews which will be conducted with key representatives in selected countries.

2.2 Interview of key representatives in selected countries

The following countries have been selected for inclusion in this review:

- France
- Latvia
- Lithuania
- the Netherlands
- Norway

These countries were selected based on their varying levels of experience with MCM stockpiling. The list of countries may be updated to include additional countries should this information be deemed relevant to the review. Similarly, countries may be removed from the list if key representatives are not available for interview. This will be documented.

Key representatives in the selected countries will be identified by the Department of Health. Each key representative will be initially contacted by the Department of Health via email and invited to participate in a semi-structured interview. HIQA will subsequently make contact with key representatives who agree to participate. An interview topic guide will be developed, piloted and refined as necessary (see Appendix 2). Key representatives will be provided with the interview topic guide and the participant information leaflet (see Appendix 3) for information prior to undertaking the interview. Key representatives will be asked to provide informed consent prior to participation (see Appendix 4).

Interviews will focus on the following areas in relation to national approaches to stockpiling of MCMs:

- past and current national approaches
- scope (for example, is the MCM stockpile focused on general medicine shortages or on serious cross-border health threats)
- risk assessment (in relation to public health threats)
- the interaction of national MCM stockpiling strategies and other strategies (such as national preparedness plans)
- efficiency (for example, efficiency of stockpiling in comparison to direct procurement of MCMs)
- management and governance (for example, what ministries are leading on operational delivery)
- cost considerations (for example, how do countries assess the cost implications of specific MCM stockpiling approaches)
- EU coordination (for example, how do national MCM stockpiling approaches align with EU directives).

Interviews will be conducted remotely via Zoom or Microsoft Teams. The duration of each interview will be approximately 60 minutes. Three team members will be present during the interview. One team member will conduct the interview while two others will take written notes, electronically or by hand. The same interviewer will conduct all of the interviews to ensure consistency. The interview will not be audio or video recorded. A follow-up interview may be conducted to clarify points raised during the initial interview. Following the interview, a single summary interview note will be compiled from the researchers' notes. Each participant will be provided with the summary note of their interview for their information and asked to verify it and, where necessary, to provide clarifications. Participants will be given up to five working days to query the summary; after this time, the summary will be considered to be an accurate representation of the interview.

2.3 Analyse and describe interview results

Interview summaries will be pseudonymised, that is, country names and or information which may identify a key representative and or their associated country (such as, organisation titles or named public officials) will be removed and replaced

with values that do not allow participants to be directly identified. Primary data collected from interviews will be stored on a secure server in HIQA for seven years (as per the HSE data retention policy[5]), and will only be accessible to members of the HTA directorate.

Using a deductive approach, thematic analysis will be conducted, following the six-step process described by Braun and Clarke:[6]

- Step 1 — Familiarisation: Three researchers will familiarise themselves with the interview data, through reading and re-reading of the data collected.
- Step 2 — Coding: The researchers will independently generate initial codes. These initial codes will be discussed and then finalised to create a codebook which will subsequently facilitate data coding.
- Step 3 — Theme development: Using a deductive approach, initial themes will be identified based on the interview topic guide. All researchers will sort coded data into these initial themes. Additional themes and or sub-themes may be identified by the researchers during this step also.
- Step 4 — Theme review: All themes will be reviewed in detail, modified and refined to ensure they are accurate.
- Step 5 — Theme refinement: All themes will be defined and further refined to derive the finalised set of themes and identify sub-themes and categories (where required).
- Step 6 — Write up: Data write-up will be undertaken.

2.4 Summarise the findings

A descriptive report will be prepared by HIQA in which findings will be summarised and compared across the selected countries. Findings will be based on interviews with key representatives and any relevant documents which are identified. Limitations of the data will also be described.

3 Quality assurance process

The review question will be undertaken in accordance with the HTA directorate's Quality Assurance Framework and led by an experienced member of the team. All interview summaries will be compiled by at least two members of the research team and checked by the relevant participant for inaccuracies. All deliverables will be

reviewed by at least two members of the senior management team, to ensure processes are followed and quality is maintained. Key representatives will be offered the opportunity to review the report and provide feedback.

References

1. European Health Emergency preparedness and Response Authority (HERA): Getting ready for future health emergencies [press release]. 2021.
2. European Commission. COMMISSION DECISION of 16.9.2021 establishing the Health Emergency Preparedness and Response Authority: 2021 [Available from: https://health.ec.europa.eu/system/files/2021-09/hera_2021_decision_en_0.pdf.
3. European Commission. Health Union: HERA delivers list of top-3 health threats to prepare against: 2022 [Available from: https://ec.europa.eu/commission/presscorner/detail/en/ip_22_4474.
4. World Health Organization (WHO). WHO updates critical medicines list for radiological and nuclear emergencies: 2023 [Available from: https://www.who.int/news/item/27-01-2023-who-updates-critical-medicines-list-for-radiation-and-nuclear-emergencies.
5. Health Service Executive (HSE). HSE National Policy for Consent in Health and Social Care Research. 2023. Available from: https://hseresearch.ie/wp-content/uploads/2023/02/HSE-National-Policy-for-Consent-in-Health-and-Social-Care-Research-compressed.pdf
6. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology. 2006;3(2):77-101.

Appendix 1 List of grey literature resources

The resources listed below will be searched for relevant data relating to national approaches to stockpiling of medical countermeasures for public health emergencies (this list is not exhaustive and will be added to as necessary):

Selected countries:

- France
  - The Ministry of Health and Prevention
  - Public Health France
- Latvia
  - Ministry of Health
  - State Emergency Medical Service of Latvia
- Lithuania
  - Ministry of Health
  - National Public Health Centre under the Ministry of Health
- The Netherlands
  - Ministry of Health, Welfare and Sport
  - National Institute for Public Health and the Environment
- Norway
  - Directorate of Health (Helsedirektoratet)
  - Institute of Public Health (Folkhelseinstituttet)

Europe:

- European Commission

Worldwide:

- World Health Organization
- Global Health Security Index

Appendix 2 Interview topic guide

Questions:

a) Opening the interview

Thank you for agreeing to participate in this interview. This interview will focus on your country's national approach to stockpiling of medical countermeasures for public health emergencies.

b) Questions around national stockpiling of medical countermeasures

Past and current national approaches:

1. What is your country's current national approach to stockpiling of medical countermeasures?
2. How and when was this national approach developed?
3. Prior to the development of your national stockpiling approach or policy, how did your country ensure the availability of medical countermeasures nationally?

Scope, threat identification and risk assessment:

4. Is your national stockpiling approach focused on specific threats such as Serious Cross-Border Health Threats, or does your strategy address more general medicine shortages?
5. How does your country decide on what risks to stockpile for?
6. How is your country's assessment of national stockpiling needs linked to other national or international risk assessment measures?
7. Once threats are identified as requiring a stockpiling approach, how does your country assess what medical countermeasures are included and what quantities are required?

Interaction with other strategies:

8. How does the country's national stockpiling approach interact with preparedness plans for specific health threats? For example, do pandemic preparedness plans also address stockpiling requirements?

Efficiency:

9. For individual threats, how does your country examine if stockpiling is the most efficient way to ensure the availability of medical countermeasures?

10. How does your country evaluate the role of stockpiling versus other ways of accessing medical countermeasures? For example, national stockpiling versus joint procurement or direct procurement or access to EU stockpiles.

Management and governance:

11. What Ministries, agencies or structures are leading on the operational delivery of MCM stockpiling in your country?

12. Where there are shared responsibilities for stockpiling across various sectors, how do the relevant Ministries, agencies and or other bodies work together?

13. What governance structures are in place to provide oversight of stockpiling?

Cost considerations:

14. What disadvantages to stockpiling approaches have been identified at a national level (such as waste, for example)?

15. How does your country assess the costs and benefits of stockpiling approaches?

EU coordination:

16. How does your country ensure that stockpiling at a national level complements EU initiatives in this area?

c) Closing the interview

Thank you for participating in this interview. The research team will now summarise the notes collected during this interview. You will be provided with a copy of the summary notes for your information, and will have the opportunity to clarify anything you feel necessary. We will be in further contact with you in the coming days.

Appendix 3 Participant information leaflet

Information leaflet

An overview of national approaches to stockpiling of medical countermeasures for public health emergencies

Evaluation Team:

Dr Máirín Ryan, Director of Health Technology Assessment, Health Information and Quality Authority

Dr Eimear Burke, RCPI Aspire Fellow, Health Technology Assessment, Health Information and Quality Authority

Dr Michelle Norris, Senior Health Technology Assessment Analyst, Health Technology Assessment, Health Information and Quality Authority

Dr Valerie Power, Health Services Researcher, Health Technology Assessment, Health Information and Quality Authority

Dr Louise Larkin, Health Technology Assessment Programme Manager, Health Technology Assessment, Health Information and Quality Authority

Dr Susan Spillane, Deputy Director of Health Technology Assessment, Health Information and Quality Authority

Ms Michelle O' Neill, Deputy Director of Health Technology Assessment, Health Information and Quality Authority

Funder: HIQA

Data controller: Dr Máirín Ryan

Data protection officer: Dr Lydia Buckley

Introduction

You are being invited to take part in a project that aims to explore national approaches to stockpiling of medical countermeasures for public health emergencies. Before you decide whether or not you wish to take part, you should read the information provided below carefully. Take time to ask questions – do not feel rushed or under pressure to make a quick decision. You should clearly understand the risks and benefits of taking part in this project so that you can make an informed decision. You do not have to take part. A decision not to take part will not affect your relationship with any of the evaluation team. If you agree to take part, you are free to withdraw at any time. You are not required to give a reason for your withdrawal.

Why is this project being conducted?

The COVID-19 pandemic highlighted the need for countries to improve preparedness for emerging health threats. The European Union (EU) Health Emergency Preparedness and Response Authority (HERA) was therefore established to prevent, detect, and rapidly respond to health emergencies at European level. The top three key threats to health security as described by HERA include: pathogens with high pandemic potential; chemical, biological, radiological and nuclear threats; and threats resulting from antimicrobial resistance. Actions to improve preparedness to respond to such threats include increasing medical, or medical countermeasures, stockpiling capacity. Medical countermeasures include items such as vaccines, medicines, medical equipment and diagnostics. At a national level, the World Health Organization and HERA have also recommended that individual countries develop national strategies for stockpiling of medical countermeasures.

We are conducting this project to inform the development of a national strategy for stockpiling of medical countermeasures in Ireland, through supporting the work of the Health Security Unit in the Department of Health. The Health and Information Quality Authority (HIQA) Health Technology Assessment (HTA) team will perform reviews of organisation websites, published and grey literature in order to identify any documents of relevance. As publicly available information relating to stockpiling of medical countermeasures is limited, semi-structured interviews will be conducted with key representatives in selected countries.

Why am I being asked to take part?

You have been asked to take part because you are a key representative within your country's public health system with expertise in relation to stockpiling. The evaluation team would like you to share information about your country's national approach to stockpiling of medical countermeasures for public health emergencies. This will inform the report we will prepare for the Department of Health in Ireland.

What will happen if I agree to take part?

If you decide you are happy to take part, we will provide you with the project protocol and the interview questions so that you can review these prior to scheduling an interview. Then, we will invite you (via email) to take part in a semi-structured interview. The interview will be with three members of the evaluation team and you will be asked to share your thoughts on the specific questions we have in relation to stockpiling. No sensitive or personal data will be collected during the interview.

The interview will be via Zoom or Microsoft Teams and should take approximately 60 minutes. With your permission, we will take notes during the interview so that we can we can analyse the information. Interview note summaries will be pseudonymised and any information that may make you, or your country, identifiable to others will be removed. The notes will be stored on a secure server in HIQA and will only be accessible to members of the HTA directorate. You will have the opportunity to review the notes of the interview to correct any inaccuracies and ensure that the notes accurately reflect what you wished to say.

We will summarise the findings in a HIQA report which we will make available to the Department of Health and publish on the HIQA website. No personal data will be included in this publication.

What are the benefits of taking part?

The findings will help the team complete a report on an overview of national approaches to stockpiling of medical countermeasures for public health emergencies. This will help to inform the development of a national stockpiling strategy in Ireland.

What are the risks of taking part?

One potential risk is a breach of confidentiality. As the evaluation team will not collect sensitive/highly personal information as part of this project, and have put in place several steps to protect participants' confidentiality (including pseudonymisation of interview summaries), the risk is deemed very low.

Is the study confidential?

The evaluation team have put in place several steps to make sure the project is confidential. Only members of the evaluation team will know your identity or be able to match your name with the information you provided. Any information that might make you identifiable to others will be removed before the data is shared with the rest of the evaluation team for analysis.

The data collected (interview notes) will not be stored with your name on it. We will assign a pseudonym to you, e.g. 'Participant 1', and this will be used to name any data files relating to your interview.

All your information will be encrypted and stored in secure restricted folders used specifically for this project. Access will be managed by the evaluation team to ensure that your identity and data are protected. Any reports or presentations arising from this project will not identify you in any way.

The period for which the data will be retained will not exceed 7 years. Once the retention period is complete, all data relating to the project will be deleted from the secure folders by a member of the evaluation team.

Who is organising and funding this study?

This study is being organised by researchers from HIQA as requested by the Department of Health. No external funding has been obtained to conduct this project.

Data Protection

1. We will be using the information you provide in our research to complete a report on national approaches to stockpiling of medical countermeasures for public health emergencies. This will help to inform the development of a national stockpiling strategy in Ireland.

2. We will be processing your data for scientific research purposes under Article 6 and 9 of the General Data Protection Regulation (GDPR) 2016.

3. Only the evaluation team will have access to information with your name on it. The wider HTA directorate will only have access to the information which has any identifiers removed.

4. The data you provide will be encrypted and stored in stored in dedicated secure restricted HIQA institutional folders. The data will be retained for 7 years after which it will be deleted.

5. The data collected will be managed carefully as described in line with Data Protection and GDPR requirements. As the data will not contain any personal details, impact of any breach is not expected to cause you any harm.

6. You are entitled to change your mind about taking part in this research. If you wish to withdraw consent you can contact a member of the evaluation team.

7. As a participant in this study, you have a right to lodge a complaint with the Data Protection Commissioner in Ireland if you are not happy with how your data is managed. Contact details are available upon request.

8. You can request access to your information and for a copy of it to be provided to you if you wish. This will be possible until the identifiable data has been removed.

9. You can request that your data is not processed for analysis until the point that the identifiable data has been removed.

10. You will be given the opportunity to view the notes of your interview in order to correct any inaccuracies and ensure that the notes accurately reflect what you wished to say. You have the right to request that your information be deleted if you wish. This is possible until the point that the identifiable data has been removed.

11. You have a right to data portability, which means you can move the information held about you to another data controller. This is possible until the point that the identifiable data has been removed.

12. There will be no automated processing of data as part of this research.

13. Your personal data will not be used for any purpose other than in the completion of this research.

14. In order to complete this research, the notes which have any identifiable data removed will be shared securely with researchers in HIQA. It will be shared as encrypted files in a restricted folder on HIQA's secure server. Access to the study folder will be granted to named evaluation team members. Logging in to their account requires an individual password and dual-factor authentication.

15. Data will remain with the project team at HIQA.

Where can I get further information?

If you need any further information about the project, now or at any time in the future, please contact:

Name: Dr Eimear Burke

Address: HIQA, George's Court, George's Lane, Dublin, D07 E98Y

Phone No: +353 (0)1 8147400

Appendix 4 Participant consent form

Consent form

An overview of national approaches to stockpiling of medical countermeasures for public health emergencies

Please tick as appropriate:

I have read and understood the **Information Leaflet** about this project. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	**Yes** ☐	**No** ☐
I understand that I don't have to take part and that I can opt out at any time. I understand that I don't have to give a reason for opting out and I understand that opting out won't affect me in any way.	**Yes** ☐	**No** ☐
I am aware of the potential risks, benefits and alternatives of this project.	**Yes** ☐	**No** ☐
I have been assured that information about me will be kept private and confidential.	**Yes** ☐	**No** ☐
I have been given a copy of the Information Leaflet and this completed consent form for my records.	**Yes** ☐	**No** ☐
I consent to take part in this project having been fully informed of the risks, benefits and alternatives.	**Yes** ☐	**No** ☐
I understand that any data collected for this project will be stored securely in a dedicated encrypted and password-protected folder for no longer than 7 years.	**Yes** ☐	**No** ☐
I consent to be contacted by researchers as part of this project.	**Yes** ☐	**No** ☐
FUTURE CONTACT		
I consent to be re-contacted by researchers about future research *related to* the current project for which I may be eligible.	**Yes** ☐	**No** ☐

Participant Name (Block Capitals): _____

Participant Signature: _____

Date: _____

I the undersigned, have taken the time to fully explain to the above participant the nature and purpose of this project. I have explained the risks involved as well as the possible benefits. I have invited them to ask questions on any aspect of the project.

Name (Block Capitals): _____

Signature: _____

Date: _____

Published by the Health Information and Quality Authority (HIQA).

For further information please contact:

Health Information and Quality Authority

George's Court

George's Lane

Smithfield

Dublin 7

D07 E98Y

+353 (0)1 8147400

info@hiqa.ie

www.hiqa.ie