TERROR
Strengthened preparedness and response to biological and chemical terror attacks

NIPH

Co-funded by the Health Programme of the European Union

Novel Threats

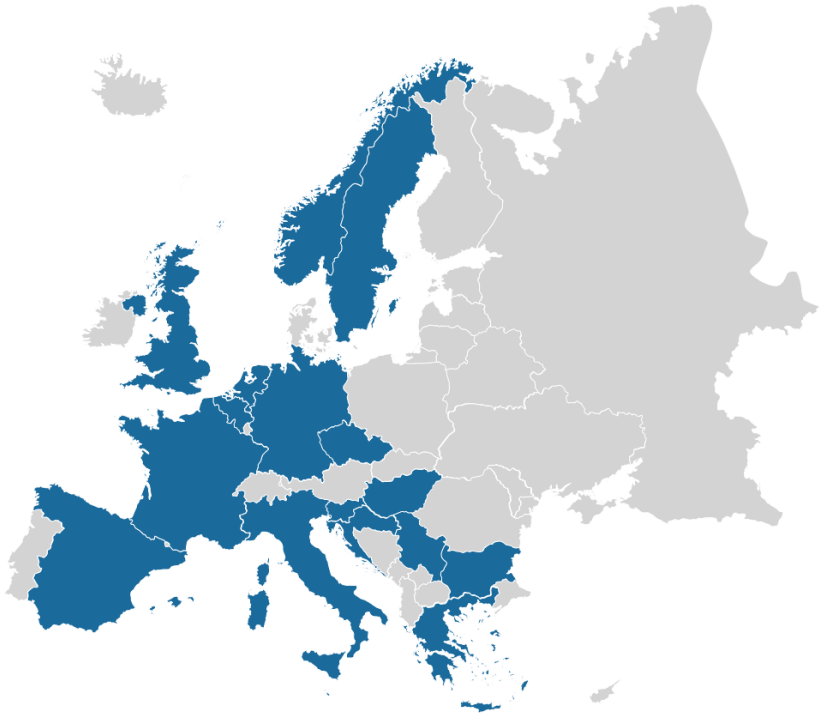
The dual-use risk of synthetic biology

Tone Bjordal Johansen
Senior Scientist, DVM, PhD

Department of Preparedness and Infection Prevention and Control
Norwegian Institute of Public Health
NORWAY
www.fhi.no
Tone.Johansen@fhi.no

JA TERROR

- Aims to address gaps in health preparedness and cross-sectoral work in response to biological and chemical threats
- Public health, law enforcement and civil protection organizations from 17 European countries.
- Coordinated by The Norwegian Directorate of Health



- Norway
- Belgium
- Bulgaria
- Czech Republic
- Croatia
- France
- Germany
- Greece
- Hungary
- Italy
- Netherlands
- Slovenia
- Spain
- Sweden
- United Kingdom
- Malta
- Republic of Serbia

- WP 1 – Coordination of the project
- WP 2 – Dissemination of the project
- WP 3 – Evaluation of the project
- WP 4 – Sustainability and integration in national policies
- WP 5 – Health preparedness & Response planning to biological and chemical terrorist attacks
- WP 6 – Cross-sectoral collaboration: Law enforcement, Civil protection and Health
- WP 7 – Risk and crisis communication (internal and public)
- WP 8 – Novel threats

Synthetic biology

Photo: Colourbox

Concepts, approaches, and tools used to modify living organisms or to create new ones

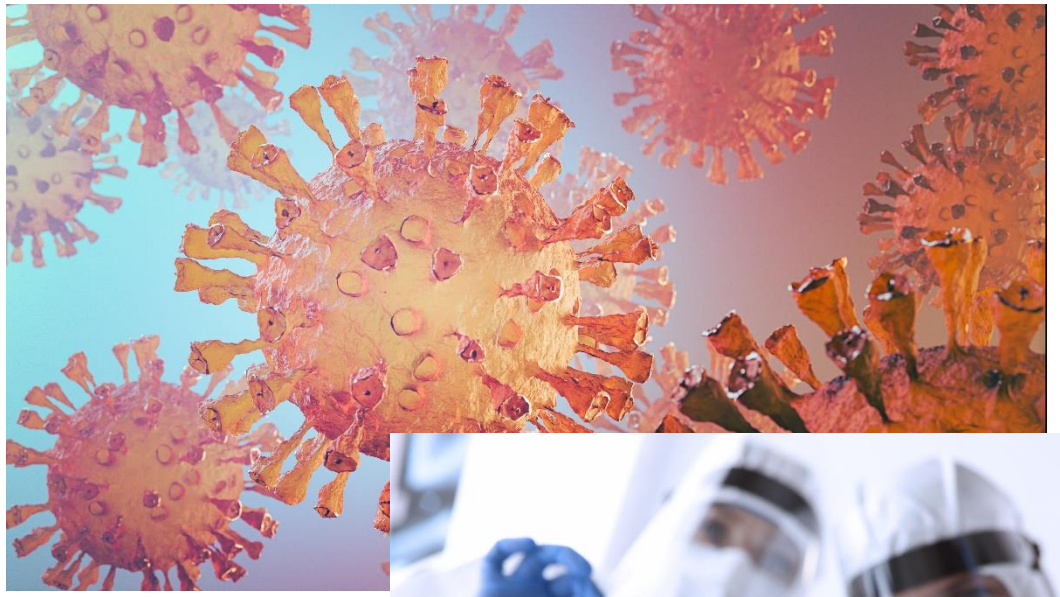
Techniques and methods developed for beneficial purposes (new vaccines, medicines, gene therapy)

Can be adapted for malicious purposes **Dual-Use Research of Concern (DURC)**

WP8: Novel threats

WP8: Health preparedness for novel threat agents, including synthetic biology, synthetic opioids and dual use technology.

- The consequences of biological threats can be equally serious regardless whether a disease is naturally occurring, accidental or intentional
- The COVID-19 pandemic demonstrated the enormous effects a pandemic can have worldwide
- Recent developments within synthetic biology cause growing concerns



WP8: Novel threats

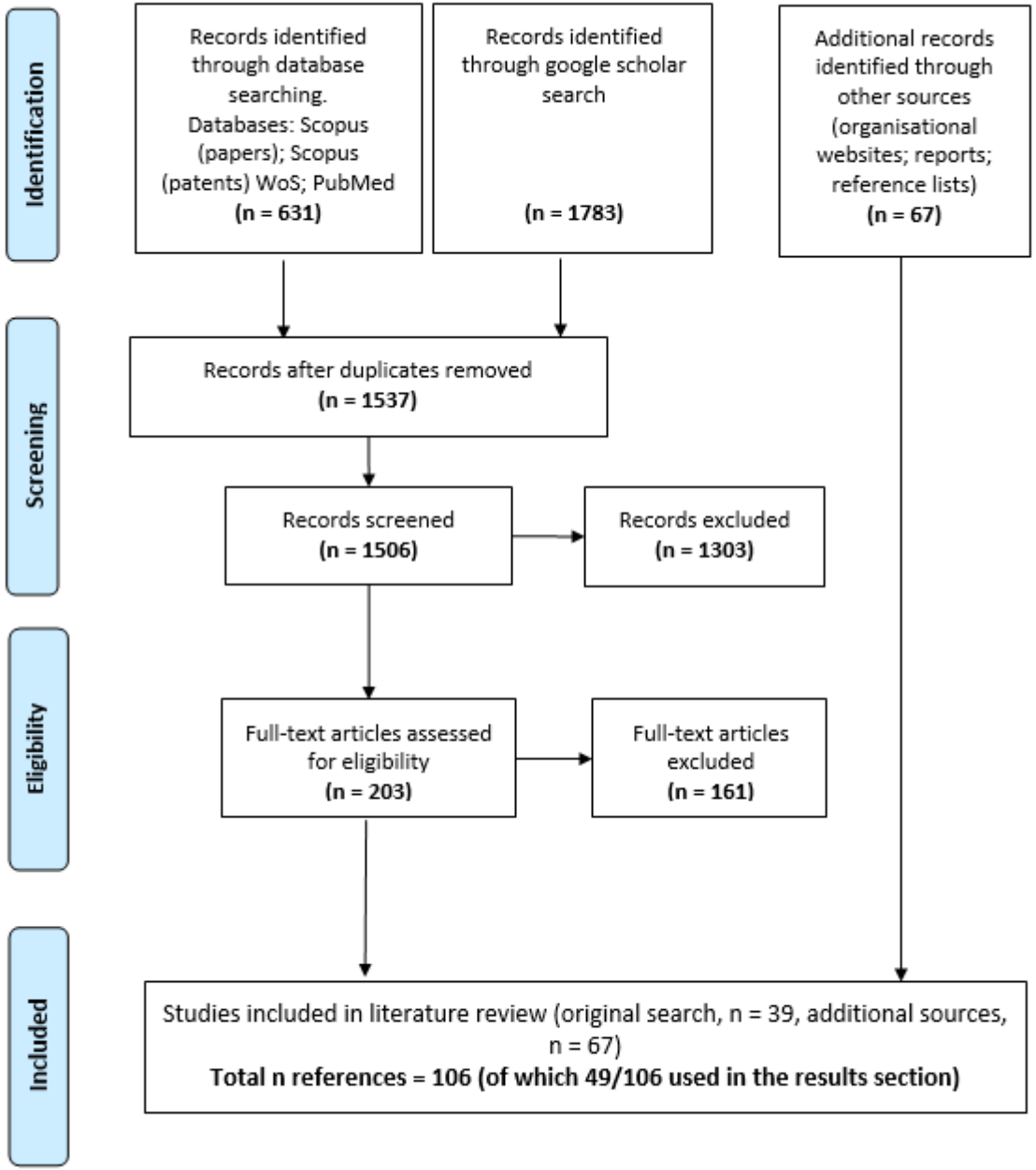
Literature review to map and describe novel technologies (2016 - 2022)

Survey to evaluate existing knowledge, guidelines and regulations on dual-use aspects in EU

Risk- and recommendations-report

Results

Photo: Colourbox



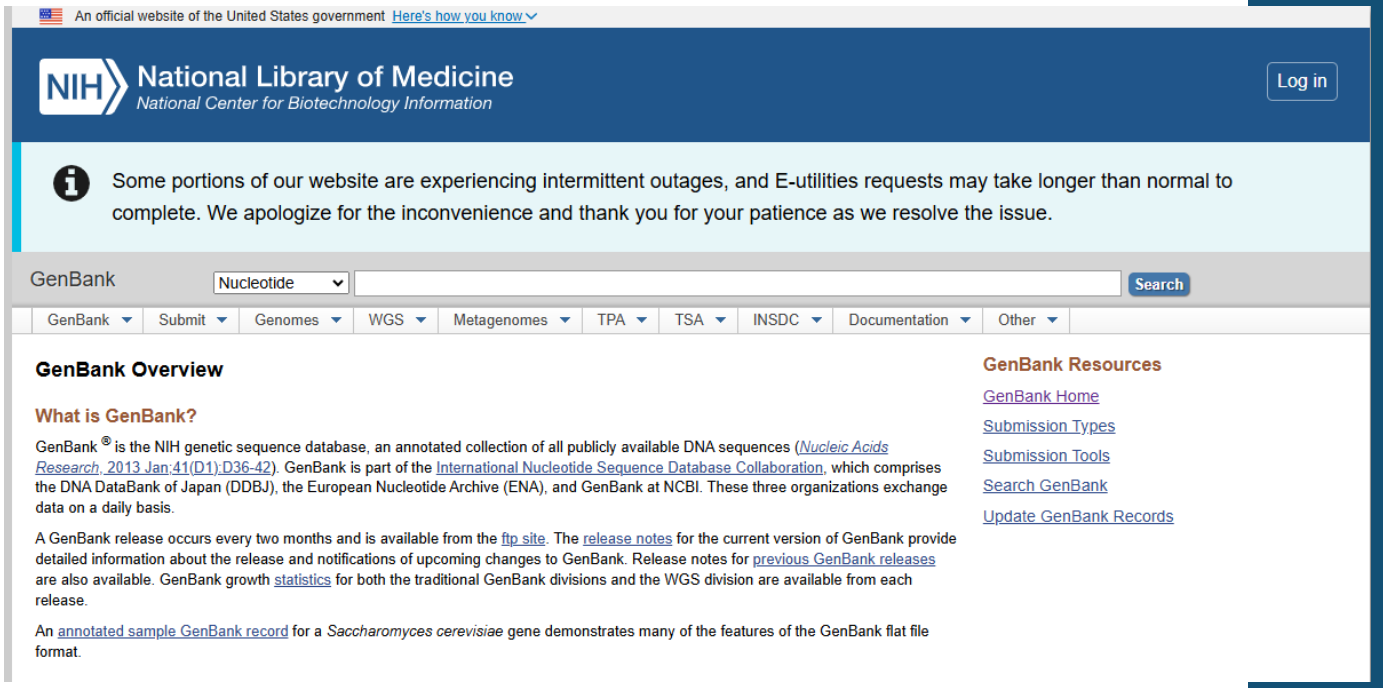
Whole genome sequencing

Findings

- Most studies focused on beneficial aspects of using WGS and NGS in response to bioterrorism

Risks

- Publicly available databases, including genomes of highly virulent pathogens
- Potential misuse of sensitive genomic data



Genetic engineering (DNA synthesis, CRISPR/Cas, TALEN, Gibson Assembly etc)

Findings

- Several examples in relation to specific pathogens
  - Synthetic horsepox virus (Noyce, Lederman et al. 2018)
  - Outbreak strain of Ebola virus (McMullan, Flint et al. 2019)
  - Genetic modifications of *Yersinia pestis* (Wang et al., 2019)

Risks

- Editing microorganisms to increase their pathogenicity
- Modify to escape diagnostic assays
- Reconstruction of known pathogens
- Construction of new pathogens

Risks across technologies

Findings

- DIY-labs
- Availability of advanced technology at lower cost
  - Desktop DNA synthesizer and 3D printers
  - CRISPR bacterial gene editing kit

Risks

- Increased accessibility of technology and knowledge
- Lower cost and increased simplicity of use

Literature review

No examples of synthetic biology being used to cause harm

Several examples of synthetic biology being used to recreate or modify highly pathogenic agents

Publicly available databases, including genomes of highly virulent pathogens

Rapidly technological development, availability and lower cost.

Machine learning and artificial intelligence

Changing global CBRN threat landscape

Dual-use technology - desk review and questionnaire

A substantial number of guidance documents on the governance of dual-use is available

Export control regulation is often the only legal framework to control dual-use (EU Regulation 2021/821)

Biological Weapons Convention, Contained Use of Genetically Modified Organisms or import laws of biological materials

Many, but not all institutes and universities have, on a voluntary basis, implemented a system for the detection of potential dual-use risks

→ Develop a framework at EU level to comply with international regulations and guidance, to secure dual-use related risk mitigation

https://iris.who.int/bitstream/handle/10665/362313/9789240056107-eng.pdf?sequence=1

PREVENTIVE MEASURES

POTENTIAL CAUSES

Access to laboratories/ selected B agents (biosecurity gaps)	◦ Biosecurity measures/ management (local level) ◦ Biosecurity guidance and regulations (national/ international level)
Access to molecular building blocks (DNA/ RNA sequences, kits)	◦ Dual-use measures (local level) ◦ Dual-use guidance and regulations (national/ international level) ◦ Screening of sequences and customers (DNA synthesis services and manufacturers) ◦ Implement traceability systems (DNA synthesis services and manufacturers)
Access to sensitive knowledge (how to increase virulence of pathogens, increase transmissibility, create de-novo agents)	◦ Risk assessment and ethical review of dual-use research at institutional level, also taking new technology into account (AI, ML) ◦ Risk assessment and ethical review of dual-use research at funding level, also taking new technology into account (AI, ML) ◦ Editorial polices for scientific journals ◦ Biosecurity screening of preprint servers
Access to technology (DIY labs, online kits, DNA synthesizers)	◦ Dual-use measures (local level) ◦ Dual-use guidance and regulations (national/ international level) ◦ Screening of customers ◦ Implement traceability and control systems of equipment
Access to data (DNA/ RNA databases etc)	◦ Dual-use measures (local level) ◦ Dual-use guidance and regulations (national/ international level)
Lack of awareness/ ignorance	◦ Education, training and awareness ◦ Regular exercises ◦ Regular risk assessment on dual-use ◦ Encouragement of culture of openness ◦ Engagement in professional societies
Lack of international collaboration and harmonization	◦ Enhance interdisciplinary cooperation at European and international levels ◦ Establish European biosecurity platform ◦ International cooperation building on existing initiatives ◦ Establish harmonized approach for risk assessment ◦ Develop strategies for surveillance and monitoring of synthetic biology threats
Lack of surveillance systems being able to detect and identify potential synthetic biology threats	◦ Epidemic intelligence ◦ Strengthen the capacity for rapid detection and identification of synthetic biology threats ◦ One Health approach on surveillance and monitoring
Actors with unethical intentions	◦ Intelligence ◦ Acceptance for reporting of suspicious behaviour /"whiste blowers"

Hazard:
Modified known pathogen or novel pathogen

Event:
Bioterror attack caused by misuse of synthetic biology

MITIGATION MEASURES

CONSEQUENCES

◦ Research, development and stockpiling of medical countermeasures including PPE ◦ Epidemic intelligence and surveillance ◦ Rapid detection and identification of synthetic biology threats ◦ Global notification systems/ warnings systems (IHR) ◦ National and international cross-sectoral collaboration* ◦ One Health approach on surveillance and monitoring	Human disease, outbreaks/ epidemics/ pandemic
◦ One Health approach on surveillance and monitoring	Animal disease/ outbreaks
◦ One Health approach on surveillance and monitoring	Environmental consequences
◦ Promote open and transparent communication among all stakeholders, including the public**	Mistrust
◦ Preparedness planning and regular exercises* ◦ National and international cross-sectoral collaboration*	Societal disruption and economic losses

**See recommendations on cross-sectoral collaboration by WP6: National and international cross-sectoral collaboration, Guiding Document (D6.5) and Preparedness planning and regular exercises, SimEx reports (D6.2) and (D6.6).*

***See recommendations on risk communication by WP7: Biological and Chemical Terror Attacks: Risk and Crisis Communication Guidance Tool (D7.1) and Guidelines for Community Resilience at Major CB Health-Threats (D7.3)*

Produced by JA TERROR
Work Package 8 - Novel threat

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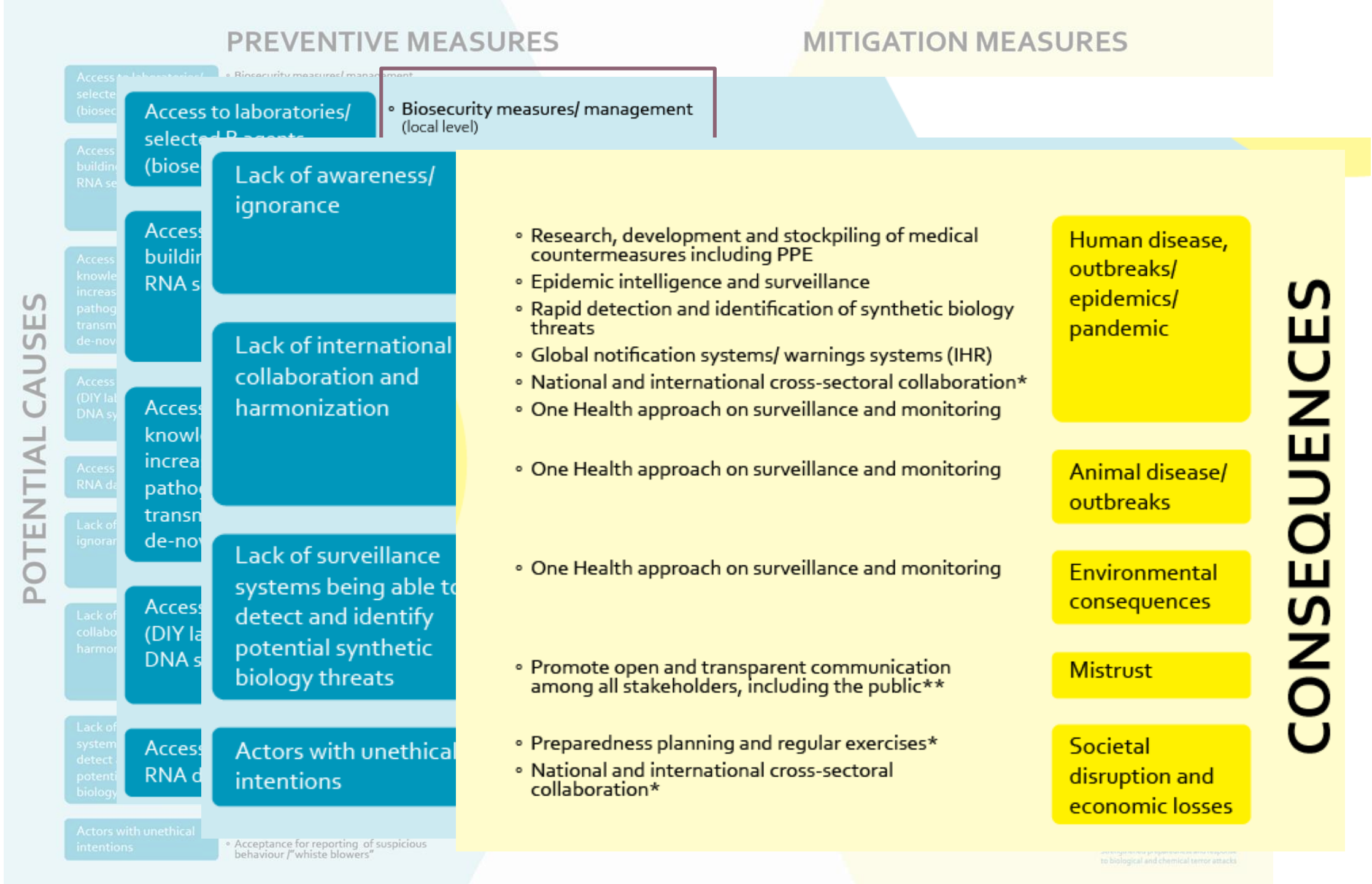
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MITIGATION MEASURES
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Lack of international collaboration and harmonization
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Human disease, outbreaks/ epidemics/ pandemic
Animal disease/ outbreaks
Environmental consequences
Mistrust
Societal disruption and economic losses
CONSEQUENCES

Risk mitigation strategies and recommendations

Established biosecurity measures not sufficient to prevent malicious use of synthetic biology

Interdisciplinary and intersectoral approach reaching all stakeholders

Control the spread of "know- how" and improve awareness

Access to technology and sensitive genomic data

Rapidly detect and identify synthetically engineered pathogens

Surveillance, intelligence gathering and threat assessment

Therapeutics/ vaccines

Oversight and governance frameworks

Thank you!

- Jessica Jones and Jackie Duggan (UK Health Security Agency; United Kingdom)
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- JA TERROR WP8 project working group

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https://www.jaterror.eu/