



Transboundary disease data exchange: proposal for a “Data Interface Protocol”

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SUMMARY

Data on disease outbreaks and related information are exchanged between different offices and services both within and between countries. Because outbreaks do not stop at national borders, information needs to be transmitted and understood regardless from where they originate but unfortunately data sharing remains a challenge. The challenges faced by institutions required to exchange data may be technical, organizational, political or legal (e.g. data ownership, compliance with national legislations and EU legislation etc.). In addition, the lack of tangible benefits or scientific or economic incentives to share the data with other parties does not encourage research institutes or other bodies to share the data and information generated by their routine efforts. The fact that outbreaks of transboundary animal diseases can have trade (and therefore economic) implications or even, for zoonotic diseases, can be a cause for public health concern, adds even more complexity to the international sharing of such sensitive information.

As part of the ANIHWA project SPARE, the technical and organizational challenges of data exchange between organizations and countries are to be discussed. The objective is to identify and discuss practices and procedures that promote a rapid, timely and efficient **access, use** and **sharing** of relevant data (i.e. diagnostic and epidemiological data related to outbreaks of diseases with intra-community trade impact) and to identify the critical aspects along the process of data access and sharing, suggesting solutions to address the identified hurdles. To fulfil this objective, a **Technical Advisory Group for Data Exchange (TechADE)** has been established. The TechADE group consists, in addition to the SPARE consortium members, of experts belonging to veterinary institutes from Belgium (CODA-CERVA), Germany (Friedrich-Loeffler-Institut, FLI), Netherlands (Wageningen Bioveterinary Research, WBVR) and from FAO and the EFSA.

Three case studies (**rabies, bluetongue** and **classical swine fever**) were selected by the SPARE consortium to develop a spatial model to assess the risk of introduction and spread of transboundary diseases in EU. Data are being collected to parameterize the model. The obstacles faced to data access/use and sharing process were analyzed, discussed within the TechADE framework, and key findings and elements related to data sharing were described in the **Data Interface Protocol** available for downloading from: <https://www.spare-europe.eu/>

A data interface protocol typically defines the procedures and format for exchanging data. Such a protocol needs to be explicit and agreed by all partners. **A long-term objective of a protocol is to become accepted as a standard operating procedure.**

KEY PRINCIPLES FOR DATA SHARING

The process of data sharing should be based on the following general **key principles**:

1. Data generated by routine surveillance activities or research projects should be accessible in a timely fashion to the international scientific community (veterinary and public health);
2. All data, either collected through paper or electronic questionnaires, should be stored in electronic databases and the use of paper register alone should be discouraged;
3. Data access should be regulated according to pre-defined rules to protect privacy and anonymity without limiting the benefit of accessing them;
4. Data providers should be able and encouraged to submit their data in a timely manner to a data management system such that the integration of data from different databases is facilitated;
5. All institutes involved in the data sharing process should be responsible for the respective quality assurance and quality control of data generated and shared .

The following sections describe the key technical, legal and organizational elements that are required for the implementation of a **sustained, reliable and rapid data exchange** for the purpose of trans-boundary disease management.

DATA SHARING OBJECTIVES AND RISK/BENEFITS ASSESSMENT OF DATA SHARING

Each institute calling for or called to share existing data with a third party should consider the following aspects to optimize the data sharing process:

- 1. Define the objectives for data sharing**
 - Definition of main and specific objectives for data sharing (statutory requirements or not) considering also the Institute mandate
- 2. Ascertain own capacity to fulfil the requirement of data sharing**
 - Are the relevant data requested available?
 - Are extra resources (IT, hardware, personnel, time) needed for data management?
 - Who is responsible for data management?
 - Who is responsible for quality assurance and quality control?
- 3. Assess the costs/benefits of data sharing**
 - What are the costs (time) to share data?
 - What benefits derive from this process?

ORGANIZATIONAL SOLUTIONS/RESPONSIBILITIES

- 1. Signing of a “data sharing agreement” which shall contain the following information:**
 - Motivation and objectives for data sharing
 - Which data/information are to be shared
 - Organizations to be involved:
 - o Data providers:
 - Characteristics, mandate and responsibilities’
 - o Data users:
 - Characteristics, mandate and responsibilities’
 - Limit for data usage
 - Data access policy (including external stakeholders access or data disclosure)

- Measures to ensure adequate security to protect the data
- Agreed common retention periods of data
- Management of data after use
- Availability of incentives to share data (see point 3)

2. Availability/development of technical guidelines/best practices to share the data

- Are best practices for data sharing available?
- If not, is it necessary to develop best practices for the current specific project?
- To develop best practices, consider the standards requirements (see also point 2, under Technical component)

3. Incentives to share the data

- Are there any incentives (financial, technical) to share the data?
- Incentives can be in the forms of:
 - specific trainings organized by EC for the Member States active in data submission and sharing
 - financial incentives for data sharing
 - financial support for publications
 - acknowledgement the contribution of data providers in publications and/or other works
 - priority in projects engagement

LEGAL ASPECTS (OWNERSHIP, MANDATE)

1. Sensitivity of data

- Nature of data
- Confidentiality and needs to anonymise data
- Consensus to share data to be obtained from data providers (MSs)

2. Mandate and power to share data

- Is data sharing in line with the Institute mandate?
- Is data sharing justified?
- Data copyright issues
- Consensus to share data to be obtained from data providers (MSs)

3. Obligations of data submission

- Legal obligations to share the data (statutory requirement)

4. Regulate use of data for publication

- Define a time boundary under which scientific publication that used the data may be submitted (embargo concept)

TECHNICAL COMPONENTS

1. Data

- Source of data (i.e. routine surveillance, research project)
- Consider level of access (unrestricted, restricted) to data
- Nature of data (i.e. diagnostic or epidemiological)
- Format of data and data standardization
- Language (English language, in addition to national language) is recommended

2. Quality assurance of data before sharing:

- Data quality
- Data needs in term of checking, verification and cleaning
- Completeness of data annotation
- Availability of metadata

- Needs to create metadata
- Requirement in terms of data standardization for data sharing
 - quality standards
 - format standards
 - origin of standards (available or standards have to be generated?)

3. Data sharing/submission

- Is a common data sharing platform needed?
- Is a common data sharing platform with the necessary functionalities available and ready to use?
- Definition of technical characteristics and requirements of the common data sharing platform (i.e. establishment of a server platform for access to common data) and/or of the functionalities needed to link country specific databases to the common data sharing platform (i.e. development of algorithms)
- Is a data submission interface to facilitate data sharing process available?
- IT requirements
- Data storage space needs
- Consider the need to transfer data from mobile devices
- Plan for regular back-up of data

4. Data user management system

- Definition of access rules for user (access rights to be configured independently for different users, and different data types, respectively)
- IT requirements