ECDC – TESSy data access policy

Working Group Data protection and data linkage

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Introduction

- The Founding Regulation calls on ECDC to "*develop with the competent bodies of the Member States and the Commission appropriate procedures to facilitate consultation and data transmission and access*"
- The document MB16/7 "*Access to ECDC MS Data in TESSy by Third Parties*" was approved in 2009 and was revised in a new document MB20/15 "*Policy on Access and Use of Data from TESSy*" in 2010.
- The policy provided for considering a revision after one year based on performance and experience.
- The document was revised by the ECDC Management Board and approved the 10th November 2012 as MB23/17 "*Policy on data submission, access, and use of data within TESSy (2011 revision)*"

Legal framework

Article 15(3) of the Treaty on the Functioning of the European Union, EC Regulations 45/2001, 1049/2001, 178/2002, 726/2004, 851/2004, 1907/2006, Commission Decision 2119/98/EC, 2008/721/EC.

European Commission - Directorate-General Health and Consumers Brussels, 10 November 2008 "*Common guidelines on practical arrangements for the sharing of scientific data between the scientific committees and panels of European Agencies and the scientific committees of the Commission*".

Opinion of the European Data Protection Supervisor 03.09.2010 (Case 209-0474) on TESSy.

Opinion 01/2010 of Data Protection Working Party.

MB16/7 "Access to ECDC MS Data in TESSy by Third Parties"

MB20/15 "Policy on Access and Use of Data from TESSy"

Categories - 1

Nominated TESSy Users:

ECDC personnel, MS contact points, EC and EU Agencies Staff, WHO-EURO Staff*,

may have direct access to TESSy data and downloads after training and awareness of confidentiality issues

** Only for diseases under joint surveillance*

Categories - 2

EU Agencies:

(e.g. EMEA, EFSA, ECHA and the Commission Scientific Committees)

may also request downloads (with a standard form) of subset of data for own use directly after signature of confidentiality declaration

Please note that already published data will not be subject to any limitation apart from acknowledgement to ECDC and MS

Categories - 3

Third parties:

(e.g. Universities, PH institutions, Private Companies)

May request downloads (with a standard form) of subset of data for own use after approval by ECDC (internal review group) and signature of specific agreement including confidentiality declaration

Please note that already published data will not be subject to any limitation apart from acknowledgement to ECDC and MS

Additional information- 1

1) **The policy is consistent with the ECDC-MB decision about one Coordinating Competent Body per Member State** (i.e. nominations for TESSy users follow requests of the National Coordinator of each national coordinating competent body)**.**

2) **Data requested for scientific purposes will not be withheld if there is scientific disagreement on the study protocol.** The internal review group will not judge the scientific validity of the study proposed, but will make only comments on the adequacy of the data for the purpose. As the current regulations stand a European Agency cannot withhold data on the bases of scientific disagreement, any possible complaint to the European Ombudsman is likely to be resolved in favour of the applicant.

Additional information- 2

3) The Member States are informed of any data release concerning data of their country and allowed to comment.

4) The data request form has been designed with many details to facilitate extraction from TESSy and to be "client oriented" (like this is clear what the requester wants and what he or she can get).

Additional information- 3

5) **The data is released together with a note from our experts on the source, completeness and "fit for purpose" of the extracted information and accompanied by the metadata.** A disclaimer clarifies the limits of the dataset and of ECDC, Member State liability.

6) **The publication of data is subject only to acknowledgements and disclaimer.** ECDC and the MS will have to be informed of all publications timely to allow possible comments .

7) **A "peer review group" will advise on controversial cases** (mainly when questions on intellectual property, confidentiality or on possible impropriety of the request arise).

Peer Review Group - 1

- **Composition** (*3 national surveillance coordinators and 2 ECDC experts)*
- **Nomination** (*the national ones sequentially selected among the volunteers and MS nominated and the ECDC experts appointed by the Director)*
- **Privileges** *(consultative body)*
- **Terms of Reference** *(advise Director on release or on conditions, propose refusal)*
- **Procedures** *(may be consulted via e-mail or teleconference has 6 weeks to reach a decision)*

Peer Review Group 1

Examples of reasons considered by the Peer review Group to suggest refusal

- There is the possibility of breach of confidentiality on "personal data"
- The data is claimed as intellectual property
- The request for data is made by a disreputable body or individual or it is made in an anonymous manner

Definition of *INTELLECTUAL PROPERTY*

Knowledge, creative ideas, or expressions of human mind that have commercial value and are protectable under copyright, patent, servicemark, trademark, or trade secret laws from imitation, infringement, and dilution.

Examples:

Intellectual property includes brand names, discoveries, formulas, inventions, knowledge, registered designs, software, and works of artistic, literary, or musical nature.

Records

A record of all requests dealt with is retained. All requests and subsequent procedures and documentation are recorded and maintained in the ECDC Intranet. All requests are also recorded in "Chrono" and a specific e–mail address (data.access@ecdc.europa.eu) is used for correspondence and data provision.

An annual revision of the policy is envisaged based on performance and eventual new legislation or guidelines.

http://www.patentgenius.com/patent/7840421.html

(12) **United States Patent**
Gerntholtz

(10) **Patent No.: US 7,840,421 B2**
(45) **Date of Patent: Nov. 23, 2010**

(54) **INFECTIOUS DISEASE SURVEILLANCE SYSTEM**

(76) Inventor: **Otto Carl Gerntholtz**, B302 Sea Spray, Marine Drive, Bloubergrand, 7441 (ZA)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1352 days.

(21) Appl. No.: **10/209,542**

(22) Filed: **Jul. 31, 2002**

(65) **Prior Publication Data**

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G06Q 10/00 (2006.01)
G06Q 50/00 (2006.01)
A61B 5/00 (2006.01)
G06F 19/00 (2006.01)

(52) **U.S. Cl.** **705/3**; 705/2

(58) **Field of Classification Search** 705/2, 705/3, 4

See application file for complete search history.

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(57) **ABSTRACT**

An infectious disease surveillance system is disclosed, which comprises a database system for storing data relating to at least one infectious disease; input means for providing data to the database system; a complex adaptive system associated with the database system; processing means for processing the data of the database system and converting the data into surveillance data; and output means for displaying the surveillance data.

28 Claims, 2 Drawing Sheets