GDPR Compliance Primary Care Surveillance - RIVM

Legal framework and requirements for data protection - data collected by RIVM for the I-MOVE-COVID-19 primary care surveillance in the Netherlands

The Dutch contribution to the COVID-19 European primary care surveillance, in the context of the I-MOVE COVID-19 project, builds on the well-established influenza primary care sentinel surveillance. This is a joint effort by the National Institute for Public Health and the Environment (RIVM) and Nivel (Netherlands institute for health services research).

Nivel holds the integral monitoring and information services for primary care, called 'Nivel Primary Care Database'. The database contains routinely recorded, pseudonymised health data from general practices. The use of these data for research does not require ethical approval according to the Dutch Medical Research Involving Human Subjects Act (see the statement by Nivel d.d. 7 September 2020).

A proportion of the general practitioners participating in Nivel Primary Care Database collect a throat swab and nose swab from patients with influenza-like illness or other acute respiratory infections and send it to RIVM for virological laboratory diagnostics (influenza virus, RSV, rhinovirus, enterovirus, and SARS-CoV-2).

Information to patient included in the study and informed consent

General practitioners (GPs) participating in sentinel surveillance are in close contact with Nivel for information, instructions, and training. For direct contacts between Nivel and sentinel GPs, a GP is employed by Nivel. Before the beginning of each influenza season, all participating GPs receive information on the protocol, the sample form and laboratory swabbing procedures.

If a patient is eligible for swabbing, the GP asks the patient (or, if unable to provide consent, their relative or caregiver) for informed consent (oral). The questionnaire that is completed at the time of consultation contains the statement that "Patient/caregiver is informed about the significance for him/her of participating in the national surveillance. Patient/caregiver

agrees with participation and processing of personal data for this purpose", with possible answers Yes or No.

The next statement on the form pertains to secondary use and says: "Remains of sample material, not traceable to the person, may be used for preparation of control materials or for evaluation of new laboratory methods. Laboratory results, combined with other data on the form, not traceable to the person can be used for further research". If the patient/caregiver objects against this secondary use, the GP is supposed to indicate this on the form by entering a check in the statement "Patient /caregiver objects: ☐ Yes".

The form (in Dutch), with the mentioned statements can be found as Annex 1. The statements have been developed with the RIVM lawyers to comply with GDPR and with the national Dutch privacy legislation.

GDPR implementation

RIVM maintains a register of the information that is processed for all research and surveillance activities. This is accessible to the Dutch Data Protection Authority (Autoriteit Persoonsgegevens), which can thereby supervise RIVM and check how we deal with personal data. The Data Protection Officer (Functionaris Gegevensbescherming) also monitors compliance with the GDPR.

For laboratory-confirmed COVID-19, there is a different situation because COVID-19 is according to Dutch legislation, a notifiable disease. Medical doctors and medical-microbiological laboratories must notify cases to the Public Health Services, who subsequently report these to the RIVM via the online registration programme Osiris. Arrangements have been made that in case of a positive SARS-CoV-2 laboratory result, the responsible RIVM virologist first contacts the GP by phone before notifying the Public Health Service. The Osiris system of notifiable infectious diseases is GDPR compliant, and a Privacy Impact Assessment is available (Annex 2).

Data flow: who, when, how - steps of data processing, from data collection to data analysis

Data are collected at the GP practice. The GP interviews the patient using a standardised questionnaire (see Annex 1). The questionnaire and the swab are sent by the GP by postal

mail to the Centre for Infectious Disease research, diagnostics and laboratory Surveillance at RIVM (IDS-RIVM). Data from the sample form and the laboratory results are entered by IDS-RIVM in the secured Laboratory Information Management System (LIMS) of IDS-RIVM. The Centre for Infectious Diseases Epidemiology and Surveillance at RIVM (EPI-RIVM) will receive anonymized datasets from the LIMS for data analyses. Based on these anonymized datasets, EPI-RIVM will prepare and send data for the pooled analysis to EpiConcept on a monthly basis.

The RIVM laboratory reports the virological results to the GPs, according to its regular role in individual patient diagnostics.

The IDS-RIVM laboratory is accredited for all virological analyses by the national Dutch Accreditation Council (RVA) (see Annex 3).

Data risk management - the security measures to protect the security of the study database

All digital files are stored in a secure environment according to general governmental, and RIVM-specific information safety rules. These consist amongst others, of a secure IT infrastructure with periodical external security audits. Data centre is located in restricted area with logical security with firewall, intrusion detection, logging and physical protection, managed at the institute level. Automatic Database backup is done in a secured area with periodical restoration tests.
In addition, EPI-RIVM has a centre-specific 'In Control' data safety declaration (Annex 4).

Data for the I-MOVE COVID-19 projects is hosted in a separate network site with restricted access. Only authorized people have access to the database. Any new staff member (or intern) must sign a confidentiality declaration before first day of employment. Any data leakage or breach of confidentiality is notifiable by law.