GDPR Compliance Sentinelles Network

Legal framework and requirements for data protection - data collected at the Sentinelles network for the I-MOVE-COVID-19 primary care surveillance and primary care risk factor study in France

French data used for the I-MOVE-COVID-19 primary care surveillance and primary care risk factor study collected within the virological surveillance of respiratory infections in primary care in France has received approval from French Data Protection Agency (CNIL, registration number #471393). An authorization issued by the CNIL is valid as long as data collection and processing is implemented in accordance with what the organization has previously declared. As long as the processing does not undergo any modification (no change) and as long as it is not deleted (or suspended), the authorization issued is valid.

Information to patient included in the study and informed consent

During consultation, the patient is informed by the physician on how the data collected will be processed. Before the beginning of each influenza season, all Sentinelles physicians are invited to participate in the seasonal virological surveillance. Physicians' registration is recorded via an electronic form confirming their understanding and engagement to respect the 'patient's consent' assessment procedure. Physicians registered to participate at the study receive by mail and by telephone the instructions on the study protocol before the start of the study (in September 2019). They also receive information on the protocol, the sample form and laboratory swabbing procedures.

At the moment of swabbing, physicians are requested to ask patients (or, for those unable to provide consent, their relatives) for informed consent (oral) regarding potential uses of data collected. A paper document (Annex 3) explaining patient's rights and the potential uses of collected data is available and will be handed by the physician to each patient.

Oral informed consent is documented by the physician and noted on the paper questionnaire filled at the moment of swabbing. Three answers are possible for the 'patient consent' variable:

- Patient (or legal representative) was informed and is not opposed to the secondary use of its sample and associated data, for research purposes in the context of the pathology for which he/she consults

- Patient (or legal representative) was informed and is opposed to the secondary use of its sample and associated data, for research purposes in the context of the pathology for which he/she consults
- Patient could not be informed due to the following reason... [Free text field]

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

Security measures consist of secure IT infrastructure with periodical external security audits. Data center is located in restricted area with logical security with firewall, intrusion detection, logging and physical protection (intrusion, flooding, fire, electricity & environment management), managed at the research institute level (UMR S 1136). Database is hosted in separated network with restricted access. Only restricted people & application have access to the database. Automatic Database backup is done in a secured area with periodical restoration tests.

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

Data are collected at the physician's office. Physicians interview the patients using a standardised questionnaire (see Annex 1). The questionnaire and the swab are sent by the physician by post mail to the laboratory assigned to their geographic area. Epidemiological data collected along with the corresponding virological results are entered by the laboratory on a secured database. Then, anonymised datasets are regularly transmitted by the laboratories to the *Sentinelles* network using standardized procedures and secured informatics platforms. An unique sequential number assigned by each laboratory is used to identify samples. A second unique sequential number (unique across all seasons & laboratories) is assigned in the centralized *Sentinelles* database and used as a swab identifier in the I-MOVE-COVID-19 primary care surveillance and primary care risk factor study. All exchanges on patient's information are done via secured dedicated web platform hosted in our institute, transmitted by each laboratory. Transmissions are encrypted by SSL connection.

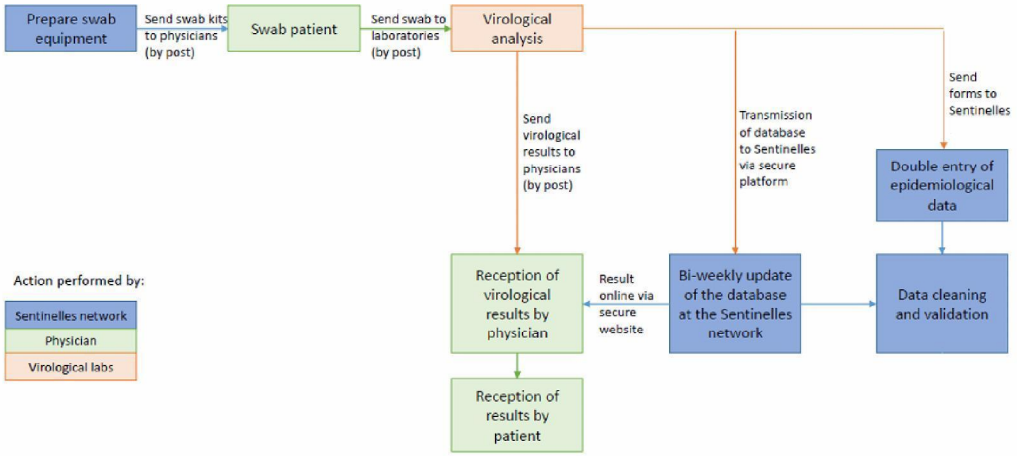
In parallel, scans of the paper forms are transmitted by laboratories to the *Sentinelles* network via a secured platform, on a weekly or biweekly basis, depending on the laboratory and period.

The secretary of the *Sentinelles* network double enters the data collected on the paper

forms using a dedicated tool. An algorithm compares in real time the two databases in order to detect potential inconsistencies in data collection. Detected inconsistencies are verified by a third person (statistician or epidemiologist at the *Sentinelles* network) and a database of corrections to be applied is stored on a secured platform.

All steps of data collection and processing are summarised in Figure 2.

Fig 2. Data flow diagramme



Information on health professionals participating to the study

Information on health professionals participating to the study are collected for other research purposes (such as representativeness studies), out of the scope of I-MOVE-COVID-19 primary care surveillance and primary care risk factor study, and are not available for external entities. Such data are collected during physician subscription at the Sentinelles surveillance, via a secured platform and with the consent of the health professional. These data are restricted for internal use.

GDPR implementation

Our institute has implemented the actions required to comply with GDPR. A DPO has been designated at the government agencies' level on which belongs the research institute, respectively Sorbonne University and French Medical Research Institute. Local DPO is under discussion but not designated yet.

Impact assessment was done for the technical infrastructure. Institute level is currently under discussion.