VACCIN SURVEILLANCE PLAN: USE OF VACCINE REGISTRY DATA

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The present document summarizes Sciensano COVID-19 vaccine surveillance plan, focusing on use of data collected within the foreseen vaccine registry, Vaccinnet. A complete protocol is available upon request (chloe.wyndhamthomas@sciensano.be; lucy.catteau@sciensano.be)

1. Background

Post-authorization monitoring and surveillance includes the monitoring of vaccine uptake & coverage, vaccine effectiveness, and vaccine safety. The recording of these post-authorization vaccine surveillance indicators is a public health priority, both at the national and international level, and strongly encouraged by EU, EMA, WHO and ECDC. To achieve this objective, it is essential that COVID-19 testing data be coupled with the COVID-19 vaccine registry Vaccinnet, in addition to other national datasets (COBHRA, IMA, STATBEL).

2. Objectives

To monitor, in Belgium, the following key indicators of COVID-19 vaccine post-marketing surveillance:

2.1. NATIONAL VACCINE UPTAKE AND COVERAGE

- by vaccine brand
- by age, gender, geographical region
- by target group[1](HCW, >65y, 45-65y & co-morbidities, nursing-home residents)
- by socio-economic indicators

2.2. IDENTIFICATION OF BREAKTHROUGH CASES (Covid-19 confirmed cases occuring in fully vaccinated individuals)

- Primary objective: Incidence rates of break-through cases:
  - by vaccine-brand
  - by age, gender, target group
  - by time since vaccination
  - by severity
- Secondary objective :
  - Conservation of samples of breakthrough cases for ulterior whole genome sequencing (identification of mutations)

2.3. VACCINE EFFECTIVENESS (VE)

- Primary objective:
  - To measure pandemic COVID-19 vaccine-effectiveness (CVE) against laboratory-confirmed SARS-CoV-2 in patients of all ages, by vaccine-brand.
- Secondary objectives:
  - To estimate pandemic CVE against laboratory confirmed SARS-CoV-2:
    - by target group (HCW, >65y, 45-65y with co-morbidities)
    - by age-group
    - by gender
    - by risk-group (ex by specific co-morbidities)

[1] As defined by Superior Health Council. https://www.health.belgium.be/fr/vaccination . May evolve in time

- by time since vaccination and regularly over calendar time
- by vaccine-dose (one vs two dose), if applicable
- if documentation of prior COVID-19 infection
- by specific genetic variant, if feasible

2.4. VACCINE SAFETY (IN SUPPORT OF AFMPS/FAGG)

- Identification of clustering of break-through cases, as possible safety signal (quality control)
  - by lot number
  - by location
- Detection of probable cases of Vaccine-Associated Enhanced Disease (VAED)
- Monitoring of certain Adverse Effects of Specific Interest (AESI)
- Descriptive analysis of side-effects occurring in vaccinees *(if field with drop down list of side effects is added to VACCINNET)*
  - by vaccine-brand
  - by age, gender, target group
  - by time since vaccination

2.5. CONTACT-TRACING

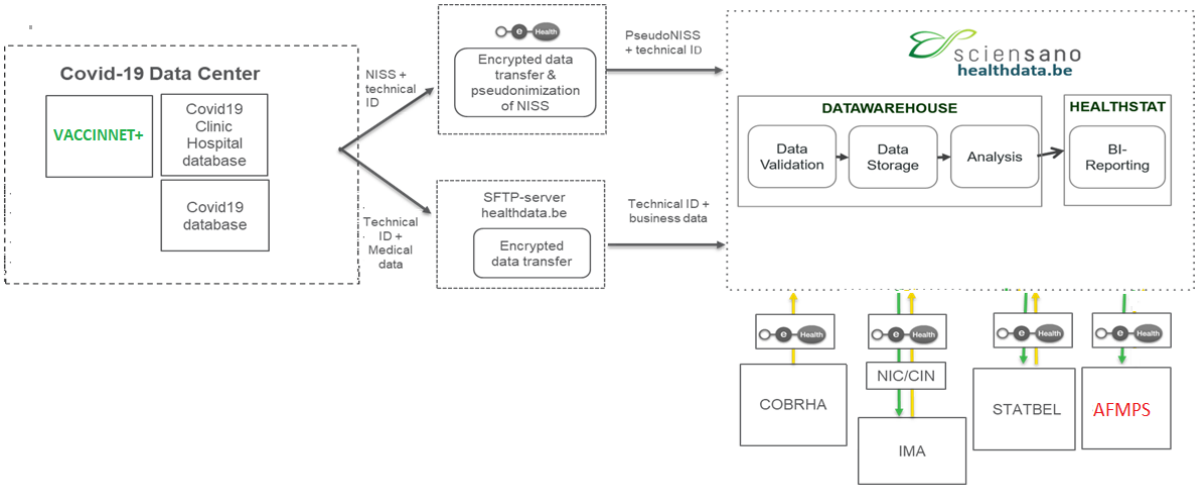
Testing and tracing policy may be affected and modified as we progress throughout 2021. For example, if high vaccine effectiveness on transmission risk is shown, high-risk contacts that are vaccinated may not need to be tested and/or placed in quarantine. Thus, an additional objective for the use of vaccination data from Vaccinnet would be to adapt testing and tracing tools.

3. Methods

Linking of Health COVID-19 Database registry to multiple other registries.

NAME	CONTENT USED FOR PROJECT	Frequency
VACCINNET	COVID-19 vaccine registry Identification of patients vaccinated against COVID-19 and information about the received vaccine (brand, lot number, date of vaccination…) See full list of variables and justification in annex)	Continuous
HEALTHDATA COVID-19 Databases	Data on patients tested for COVID-19. Informations on test prescriptions, test results (including rapid tests), suspected false negatives, false positives as well as unidentified suspected cases of COVID-19.	Continuous
HEALTHDATA COVID-19 CLINIC Database	Data on hospitalized patients with a confirmed COVID-19 diagnostic.	Continuous
COBHRA	Identification oh healthcare workers	Continuous
STATBEL	Socio-economic informations (civil status, employment status, income decile,…)	2x/year
IMA	Data on reimbursed care and medicines of citizens insured in our country: Pseudopathologies (as comorbidities), Nursing home resident status, Pregnancy status, Influenza vaccination , Treatments	2x/year

Dataflow Sciensano :



4. Outputs

4.1. REPORTING OF RESULTS:

- All results, whether in public health reports or scientific article, will only contain aggregated data and/or anonymous data on individual level (cfr §5 Ethical considerations below)
  - Reports to health authorities on vaccine effectiveness and coverage
  - Reports to health-care professionals (Sciensano website) on vaccine effectiveness and coverage
  - Vaccine uptake numbers and coverage percentages may be added to Sciensano dashboard
  - Scientific articles on in-depth analysis of results

4.2. DATA SHARING:

- Transmission of data to AFMPS/FAGG for safety monitoring purposes:
  - Aggregated data and/or pseudonimysed data will be shared with AFMPS/FAGG as defined in their specific request to ISH-SSH.
  - Data transfer of safety data to international instances, such as EMA, will be coordinated and managed by AFMPS/FAGG.
- International collaborations (ECDC, EU, WHO foreseen):
  - Vaccine uptake/coverage data: aggregated data
  - Break-through cases: aggregated data
  - Vaccine effectiveness: international pooling (in discussion)

5. Discussion

Vaccine uptake and coverage, as well as vaccine safety signals and detection of break-through cases must approach real time monitoring, to meat post-marketing surveillance basic requirements. It is therefore very important that for optimal functioning, Sciensano can receive the data via the existing covid19 architecture where the identity of the vaccinated person is known, and thus can guarantee the necessary links, both operationally and for the researchers. It should also be possible to maintain data for longer than 6 months, because adverse events, for example, may manifest themselves even after that period.

6. Annex

Table: Vaccinnet variables required and justification:

DATA	DESCRIPTION	PURPOSE
Patient identifier	NISS of vaccinated person	Linking of databases only. Not available to researcher => pseudomonized to ICD_PAT of other databases below
Date of birth	Year of birth, except for children <24 months where month and year required)	Vaccine uptake and coverage by age group. Identification of gaps/groups of lower vaccine uptake for adaptation of policy + communication. Month required in addition to year for Children <24months Data cleaning (check for correct matching of databases, exclusion of doubles)
Postcode	Patient postcode	Vaccine uptake by geographical region
Date of death	Patient date of death	Effect of vaccination on COVID-specific mortality, taking into account delay between vaccination and outcome.
Gender	Patient Gender	Vaccine uptake by gender. Identification of gaps/groups of lower vaccine uptake for adaptation of policy + communication Data cleaning (check for correct matching of databases, exclusion of doubles)
Vaccinator type	Type of vaccinator who register the vaccination : Doctor, Doctors Practice, Organization Possible values for organizations are in function of the in Vaccinnet existing entities: Industrial medicine, hospital,...	Descriptive assessment of vaccine prescription distribution for authorities Cluster of break-through cases based on administrator
Vaccinator identification	Doctor or entity which register the vaccine For doctor's practice: RIZIV number For doctor group practice: Vaccinnet code of practice For organization: Vaccinnet entity code	Cluster of break-through cases based on administrator
Vaccinator Postcode	Postcode of the vaccinator	Cluster of break-through cases based on location
Vaccine Identification Code	CNK/ATK vaccine code : CNK code if known, otherwise ATC code. CNK and ATC codes can also be used as separate fields will be delivered.	Vaccine uptake by vaccine type
Vaccine Description	Description of the vaccine : Vaccine description (description CNK code if known, otherwise description ATC code)	Vaccine uptake by vaccine type
Vaccine Lot Number	Lot number of the administered vaccine	Cluster of break-through cases based on Lot n°
Vaccine dose*	Dose number (1st dose, 2nd dose…)	To extrapolate vaccine status: complete or partially vaccinated
Date of administration	Date of vaccine administration	To establish that vaccine administration prior of after COVID-19 disease. To define time between vaccine administration and various outcomes (disease, hospitalization, VAED, AESI etc)
Record date	Date of recording in the registry	To use as proxi date if administration date unknown
Infectious disease	Infectious disease for which vaccine was administered	COVID-19 vaccine specific surveillance
Indication*	Target group to which person belongs (HCW, >65y old, 45-65y old with comorbidity)	To calculate Vaccine coverage by target group
Adverse event Y/N	Yes/No value	Incidence of adverse events
Adverse events*	Description of adverse event/Drop down list of adverse events of various levels of severity	Descriptive analysis of AESIs occuring in vaccine cohort –Support of AFMPS

* *Data currently unavailable but that we would like to use if they do become available*

COVID-19 vaccinations are collected.
If available, Influenza vaccine status in previous season (date) and last pneumococcal vaccine (type + year) for all persons included in the Vaccine effectiveness study, being effect modifiers.