Surveillance of severe acute respiratory infections (SARI) by the network of sentinel hospitals

INFORMATION FOR THE PATIENT HOSPITALIZED FOR FLU-LIKE SYMTPOMS

Dear Madam,
Dear Sir,

What is the purpose of this survey?

Every year, on average, more than half a million Belgians contract the flu or another respiratory infection, requiring consultation with their GP, hospitalisation, or sometimes even death from the infection. This places a heavy burden on the healthcare system in Belgium.

Sciensano is the national public health institute. Through a network of hospitals, it constantly monitors how many new respiratory tract infections there are, how well vaccines protect against flu or COVID-19 infections and whether drugs against the virus infection are still working properly. To investigate this, it is necessary to take a test from a group of people who are admitted to hospital with signs of acute respiratory infection to show exactly which virus they are infected with.

A network of hospitals therefore test all patients admitted for a severe acute respiratory infection. The hospital you have been admitted to belongs to that network.

It is important to know which respiratory viruses are currently causing infections in Belgium, because this has consequences for the approach to testing and for monitoring the effect of vaccines.

Furthermore, for the patients themselves, it is also important to know exactly which virus is involved, as treatment can be different.

Finally, the international health organisations "European Centre for Disease Prevention and Control" (ECDC) and the World Health Organisation (WHO) also need information on which flu viruses are causing infections now, in order to choose the right composition of the next flu vaccine and to estimate the severity of the epidemic in Europe.

Your physician participates in the surveillance of acute respiratory infections, sending anonymous data on the number of admissions to Sciensano. In every patient admitted to hospital for a respiratory infection, the doctor also takes an airway sample to be tested for a number of respiratory viruses by the National Influenza Reference Centre. Additional data, anonymous to the researchers, on symptoms, risk factors, influenza and COVID-19 vaccination and treatment (antiviral and antibiotic) and complications are recorded in these patients in order to best estimate the effectiveness of the vaccines.

Who organizes and reviews this research?

This research is organized by Sciensano and funded by the Federal Government. The study was approved by the Medical Ethics Committee of the Vrije Universiteit Brussel (VUB). Sciensano is acting in this study as a data controller and processor.

Why was I (or the person I represent) chosen?

This hospital takes a sample from all patients who are admitted because of an acute respiratory infection to test for the flu virus, SARS-CoV-2 and some other respiratory viruses. This ensures that a representative proportion of patients are tested, which will ultimately make the results more applicable to the overall Belgian population.

Do I have to participate and does this study affect my rights as a patient?

For the value of the study, it is important that as many eligible individuals as possible participate. However, the decision whether or not to participate in the study lies entirely with you. If you participate, you are free to withdraw from the study at any time, without having to provide a reason or without affecting the quality of care you receive.

What will happen to me (or the person I represent) if I participate and what is expected?

If you (or the person you represent) exhibit symptoms of influenza during the surveillance period, you will be asked by your physician to sign a consent form confirming your understanding of the study and desire to participate.

The physician will collect from you (or the person you represent) a nasal swab. The sample will then be sent to the Sciensano reference lab to see if it is positive for influenza virus or another respiratory virus. The health care provider will also fill out a questionnaire. This questionnaire will collect information about your health status (or that of the person you represent): age, gender, signs/symptoms of the influenza illness, any antiviral or antibacterial treatments for the respiratory infection, vaccination against influenza and COVID-19, complications and existing chronic conditions (including liver or kidney dysfunction, diabetes, respiratory disease).

Your sample will then be kept for a period of 2 years for possible future analyses.

What are the disadvantages of this study for me (or the person I represent)?

Other than the inconveniences associated with taking the sample, there are no disadvantages associated with this study. The costs associated with the studies are fully covered by the research team.

What if something goes wrong?

It is very unlikely that anything will go wrong as a result of participating in this study. In fact, in accordance with the Belgian law of May 7, 2004 on experiments on the human person, the

commissioning authority is liable without fault for any damage incurred by the participant or his/her beneficiaries that is directly or indirectly related to the experiment. For this reason, insurance has been taken out to cover this liability. Consequently, should you (or the person you represent) suffer damage as a result of your participation in this study, such damage will be compensated in accordance with the Belgian law of May 7, 2004.

What will be done with the results?

The results of the studies as well as the personal information will be processed in a coded manner. Each participating patient will be assigned a study number, of which only the attending physician and the clinical biologist validating the test result will know the corresponding patient identity. Only this study number (not your name) is communicated to the research team. Sciensano communicates the result of the sample collection directly to your treating physician.

The results of this surveillance will be used in a coded and non-identifiable way to produce statistics for the benefit of the federal and regional health authorities (Vlaams Agentschap Zorg en Gezondheid, Agence wallonne pour une vie de qualité en Gemeenschappelijke Gemeenschapscommissie van Brussel-Hoofdstad) and of the international organizations WHO and ECDC. The overall results of this study will also be published in the weekly flu bulletin and in a scientific report and/or journal for other physicians to read.

Your rights

This study respects the new European General Data Protection Regulation (May 25, 2018) and the Belgian law on the protection of privacy[1] and on experiments on the human person.[2]

- In the context of the study, personal data will be collected from you. We, Sciensano, are responsible for the correct processing and the information obligation associated with it. Therefore, we would like to draw your attention once again to the fact that in addition to ordinary personal data, such as data about your age and gender, "special categories" of personal data are also collected. Examples are:
    - your health status and medical conditions;
    - your treatments;
    - your biological samples (nasopharyngeal swab) and the results of their analysis.

  Of course, we may only use your personal data for the scientific research purposes described in this informed consent form.

- You have the right to withdraw from this study at any time and no longer consent to the use of your data.[3] If you withdraw from the study, all your data will be deleted from all Sciensano files within a period of 3 weeks to respect your "right to be forgotten."

[1] Belgian law of July 30, 2018 on the protection of privacy in relation to the processing of personal data and the law of August 22, 2002 on patient rights.
[2] Belgian law of May 7 2004
[3] You can do so by sending an email to ppmv@sciensano.be.

- If you wish, you may access your data during the period of data collection.[3]
- After all data has been collected, the link between your name and study number will be deleted.
- The research team will treat the collected data strictly confidential. This means that the involved researchers commit themselves to never disclose your study number in the context of any communication related to the research project.
- The research data will be kept by Sciensano for a period of 30 years after the end of the study. If you have any questions about this, please contact the data protection officer of the research center, Sciensano, at the following e-mail address: dpo@sciensano.be.
- Your data will only be used for the purpose for which it was collected and will also not be passed on to a third party.
- If you have a complaint about the way your data is processed, please contact the Belgian Data Protection Authority: Drukpersstraat 35- 1000 Brussel - Tel.: 02 274 48 00 - e-mail: contact@apd-gba.be website: www.gegevensbeschermingsautoriteit.be

Additional questions?

If you have additional questions about the study, please contact the investigators (see contact information below) or report it to your doctor.

Thank you in advance for taking the time to read this information and to consider participating in our study.

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