General information about the myCare Start-I study: Evaluating the myCare Start service to support patients starting a new medicine in Switzerland

Project Overview

myCare Start is a new service to support people starting a new long-term treatment. It includes two consultations with your pharmacist within six weeks of the first dispensing of the new medication. This service gives patients like you the opportunity to learn more about your new medications and ask questions. This new service does not replace a consultation with your physician; it is designed to complement ongoing care, and the physician will be notified when an individual participates in the service.

Why are we conducting the myCare Start-I study?

To establish myCare Start in routine practice, we need to assess the relationship between its cost and its effectiveness by comparing it with everyday practice. To examine these aspects, the University of Geneva has set up a study called the *myCare Start – Implementation project (myCare Start-I).* The study has two study arms (patients receiving usual care and patients receiving the myCare Start service). Allocation to one of the two study arms is defined at random, neither you, your pharmacist or your physician can choose it.

Who can take part in this study?

- You must be at least 18 years old.
- You have a mandatory basic health insurance in Switzerland.
- You are able to self-manage treatment *(i.e. without a home nurse).*
- Your physician prescribes a new medication for cardiovascular disease, hyperlipidaemia (high cholesterol levels in the blood), diabetes, respiratory disease (asthma or chronic obstructive pulmonary disease (COPD) or depression.
- You will have to take this medication for a long-time duration.
- You have not taken part in any similar educational program related to your new treatment since the last 3 months.

Why take part in this study?

Medication initiation is a crucial but underestimated stage in the patient's therapeutic pathway. The myCare Start service can assist you, your pharmacist and your physician in optimising your treatment collaboratively at treatment initiation. This study will evaluate the myCare Start service.

What does participation in the study involve?

Participating in the study will involve sharing your health data. All data collected will be coded, which means you cannot be identified by this information. Data collected will include information about the medications you are taking, how you take them, your quality of life and health insurance data. Health insurance data allows us to measure if the service leads to cost savings to the Swiss health system. More detailed information follows.

Detailed information

We are asking you to take part in this evaluation project because you are over 18 and have started a new long-term medication.

In the following, we refer to you as participant.

1. Aim of the study and selection of participants

This study will assess the cost and the effectiveness of the myCare Start service, and in addition, will help to implement it in the Swiss healthcare system.

2. General information about the myCare Start service

Please note that depending on the study arm you are allocated to, you may or may not receive the myCare Start service. Your pharmacist will inform you accordingly.

myCare Start is a service for people taking a new treatment for cardiovascular disease, hyperlipidaemia (high cholesterol levels in the blood), diabetes, respiratory disease (asthma or chronic obstructive pulmonary disease (COPD) or depression. It is based on a service already in place in the UK called the *New Medicine Service*. myCare Start includes two successive consultations with the pharmacist within six weeks of the first dispensing of a new medication; the two successive consultations build upon each other. The topics covered during these consultations are:

- *Information and context*: open talk about treatment to assess patients' understanding of their new medications, the expected effects and their timing, as well as identification of any gaps of information.
- *Motivation/readiness for treatment*: assessment of motivation and confidence regarding starting or taking the treatment and evaluation of any concerns.
- *Self-management skills*: evaluation of fit between new medications and daily life activities.
- *Symptoms and sides effects:* identification and monitoring of potential unexpected symptoms or side effects

myCare Start supports patients in the learning process about the newly prescribed medications. This service is designed to complement and reinforce the usual care receive from the physician.

3. General information about the study

This study is a national study led by the University of Geneva. The study involves 30 to 40 pharmacies that have been recruited throughout Switzerland. It will take place in 2025 and 2026.

This study is carried out in accordance with Swiss legislation. We also follow all internationally recognised guidelines. The study has been reviewed and approved by the Cantonal Research Ethics Committee of the Canton of Geneva (CCER) (study number: 2024-02559).

The aim of the myCare Start study is to compare the myCare Start service with everyday practice, which means that some participants will receive usual care while others will benefit from the myCare Start service. In both cases, the research team will need to collect information from you. You will be randomly assigned to one of the two study arms.

4. How does it work?

Patients Receiving myCare Start Service

The pharmacist has informed you about the myCare Start service when you were dispensed your new medication and has organised an initial interview with you 7 to 14 days after the start of the new treatment.

The study is structured around the myCare Start service as follows:

myCare Start Consultation One

myCare Start Consultation One has taken place in the pharmacy in a confidential area or by telephone. The consultation will last about 10 minutes. The pharmacist and you have discussed your new medication, your need for information and the way to manage it on a day-to-day basis. A second appointment will be scheduled 14 to 28 days after this initial consultation to continue and reinforce the discussion.

Inclusion in the study:
At the end of myCare Start Consultation One, the pharmacist will tell you about the study. You are free to decide whether or not you want to take part.

myCare Start Consultation Two

This consultation will take place in the pharmacy in a confidential area or by telephone. It will last about ten minutes. The pharmacist will discuss your latest experience with the new treatment, your evolving needs and the goals you have set for the next phase of treatment.

To ensure that information is passed on, a brief report of the two myCare Start consultations will be sent to your physician at the end of each consultation. The data will be transmitted via secured e-mail addresses to comply with data protection rules.

You may be invited to utilise the myCare Start service by your physician, pharmacist, or pharmacy assistant. Consultations are conducted by pharmacists.

Patients receiving Usual Care

The pharmacist will inform you about the myCare Start study when you are dispensed your new medication and have received usual initial dispensation counselling. You are free to decide whether you want to take part.

5. Data collection

5.1. Purpose of data collection

The myCare Start service is new. Researchers need to assess whether this service is cost-effective for the healthcare system. If so, myCare Start can be maintained for future users. This means that the research team will need to collect information about you.

5.2. Type of data collected: Data will be collected for the duration of the study period. All the data collected is then transmitted to the researchers in a **coded and secured** form. It is stored on secure servers at the University of Geneva.

Consultation Data (Patients receiving the myCare Start Service only): All data assessed during myCare Start Consultations One and Two will be collected for study purposes.

Surveys (All patients): you will receive an e-mail, containing a link to an online survey, at five different times: 2 weeks, 6 weeks, 3, 6 and 12 months after the dispensation of your new medication. Each survey will take no longer than 10-15 minutes. If you prefer, you can also complete the questionnaire over the phone with a member of our research team.
The content of the survey will include:

- Questions on how you have been taking the new medication
- Questions about your quality of life.
- Questions about your opinion on the myCare Start service (for those receiving the myCare Start service only).

Health insurance data

The researchers will ask for your consent to extract your health insurance data. Health insurance data from patients is essential for determining whether the myCare Start service can generate savings for the Swiss healthcare system.

The data collected includes your personal details (year of birth, gender, postcode, nationality, marital status, type of insurance contract, deductible), medication costs (name, dosage, box size, and number of boxes, and dispensing dates) and healthcare utilisation costs (medical visits, nursing visits, emergency room visits, hospitalisations, and laboratory tests, and dates).

6. Benefits for participants

When you start a new treatment for a long-term illness, myCare Start can assist you, your pharmacist and your physician in optimising your treatment collaboratively. The myCare Start service provides structured and tailored information on your medication. The myCare Start service supports you in the learning process about your new medications. It could also improve your health and quality of life. Therefore, your participation in the evaluation will allow the researchers to inform the healthcare system whether myCare Start is useful for the population of patients initiating a long-term medication.

7. Rights and duties of participants

Your participation is entirely voluntary. If you decide not to take part, or if you decide to take part and change your mind during the study, you will not have to justify your decision. This will not affect your usual medical or pharmaceutical care.

Your medical and pharmaceutical care is guaranteed throughout the process, whether you choose to take part in this study or not.

If you take part in this study, you must respect the agreed deadlines and answer the questions honestly.

8. Risks and constraints for participants

The medical instructions to be followed are those given by the attending physician and pharmacist, and the intervention is a support tool that presents no additional risks. Your medical treatment is guaranteed at all times.

9. Data protection

9.1 Data processing

As part of this study, your personal data and data relating to your health will be collected and analysed (see part 5.2. Type of data collected). All data is coded at the time of collection. Coding means that personal information that can directly identify you is kept separate from other collected data, in the form of a list (identification list) that identifies each person with a unique participant number. This means that neither your name (nor that of your pharmacy or your physician), neither your date of birth or address appear directly with the data collected. This means that it will not be possible to link the data collected to your identity. Your data will be transmitted to the University of Geneva using this unique participant number. Only two members of the University of Geneva research team have access to the identification list, i.e. will see your data in uncoded form, exclusively to enable them to retrieve your data from health insurers. These staff members are bound by professional secrecy. As a participant, you have the right to consult your data at anytime until it has been anonymised at the end of the study. Coded data will be analysed by the investigative team members from the University of

Geneva and University Centre for Primary Care and Public Health (Unisanté), University of Lausanne,

Anonymisation: At the end of the data analysis, we will permanently delete the code linking your person to the data assessed for the study. This means that no one will ever again know that the data belonged to you. The main aim of this procedure is to protect your personality.

9.2. Data protection

We carry out this study in accordance with the laws in force in Switzerland (law on research on human beings, data protection laws). In addition, we comply with all internationally recognized guidelines. The relevant ethics commission has reviewed and approved the study (BASEC ID: 2025-00715)

A description of the study can also be found on the website of the Swiss Federal Office of Public Health at www.kofam.ch, under registration number SNCTP [NCT07036471].

The principal investigator is responsible for the security of your data in this study. All data collected during myCare Start-I study will be stored on a secured server at the University of Geneva. If you have any questions on this subject, please contact the investigators (see paragraph 15 – Contact Person).

9.3 Data protection in the event of re-use

The data collected during this study is very important for future research. It is possible that the data collected in the myCare Start-I study may be made available to other researchers in a grouped and totally anonymised form to assist and support similar studies. Health insurance datasets will not be shared outside of Switzerland.

9.4 Consultation rights during inspections

The study may be subject to inspections. These inspections may be carried out by the relevant ethics committee. The universities are obliged to provide your data for the purposes of these inspections.

As pharmacies are taking part in the study, they may also be subject to checks by the competent authorities. All those involved are bound by the strictest professional secrecy.

10. Withdrawal of the project

You may withdraw from the study at any time. However, the data collected up to that point will be analysed in coded form.

To withdraw from the project, please contact the pharmacy that included you in the project or the investigative team (see paragraph 15).

11. Compensation

Your participation will have no financial consequences for you or your health insurance. Patients who receive Usual Care, and therefore do not receive the myCare Start service, will receive a voucher to the value of 15CHF, upon successful completion of the online surveys. Patient who receive myCare Start will receive the intervention and no compensation for taking part in the study.

12. Liability

Although there are no foreseeable risks associated with this research, the University of Geneva is legally responsible for any damage resulting from the study. If you suffer any damage as a result of participating in this study, please contact your pharmacy team or the investigative team (see paragraph 15).

13. National collaboration

This project is the result of a research collaboration between the Universities of Geneva, Basel, Lausanne and Bern. The Swiss pharmacists' association (pharmaSuisse) and the University of Barcelona (sharing expertise in the analysis of medicines use) are partners in this research.

14. Financing

The study is funded by the Swiss National Science Foundation, the Federal Quality Commission, the University of Geneva and the Research Foundation of Swiss Pharmacist Association (pharmaSuisse) and the health insurers.

15. Contact person

You can ask questions about the study at any time. If you have any doubts or concerns during or after the study, you can visit https://www.unige.ch/mycarestart/ or contact the researchers at the University of Geneva at the following address: mycarestart@unige.ch.

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