Impact of a Pharmacist-included Mobile Geriatrics team intervention on potentially inappropriate drug prescribing: protocol for a prospective feasibility study (PharMoG study)

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ABSTRACT

Introduction Research has shown that potentially inappropriate drug prescription (PIDP) is highly prevalent in older people. The presence of PIDPs is associated with adverse health outcomes. This study aims to evaluate the impact of a PHARmacist-included Mobile Geriatrics (PharMoG) team intervention on PIDPs in older patients hospitalised in the medical, surgical and emergency departments of a university hospital.

Methods and analysis The PharMoG study is a prospective, interventional, single-centre feasibility study describing the impact of a PharMoG team on PIDPs in older hospitalised patients. Pharmacist intervention will be a treatment optimisation (clinical medication review) based on a combination of explicit and implicit criteria to detect PIDPs. The primary outcome is the acceptance rate of the mobile team’s proposed treatment optimisations related to PIDPs, measured at the patient’s discharge from the department. This pharmacist will work in cooperation with the physician of the mobile geriatric team. After the intervention of the mobile geriatric team, the proposals for improving therapy will be sent to the hospital medical team caring for the patient and to the patient’s attending physician. The patient will be followed for 3 months after discharge from the hospital.

Ethics and dissemination This study was approved by the South-West and Overseas Territories II Ethics Committee. Oral consent must be obtained prior to participation, either from the patient or from the patient’s representative (trusted person and/or a family member). The results will be presented at national and international conferences and published in peer-reviewed journals.

Trial registration number NCT04151797.

INTRODUCTION AND BACKGROUND

In patients aged ≥75 years, comorbidities are common and a cause of polypharmacy. Multiple prescriptions, combined with physiological changes in pharmacokinetic and pharmacodynamic parameters that occur with age, make older adults more susceptible to adverse drug reactions. Each new drug prescribed is thought to increase the rate of adverse effects by 12%–28% and the risk of hospitalisation by 11%.

The term ‘potentially inappropriate drug prescription’ (PIDP) refers to

- overuse (use of prescription drugs that are not indicated or whose efficacy has not been demonstrated),
- misuse (use of drugs whose risks exceed the expected benefits),
- underuse (failure to use effective drugs in patients with conditions for which one or more drug classes have been proven effective).
Several tools have been developed to make it easier to identify PIDPs using an explicit or implicit approach, or a combination of both. The implicit approach is based on clinical judgement: the risk/benefit ratio of each drug is analysed in light of the patient’s history, concomitant illnesses, laboratory tests and coprescribed drugs (eg, the Medication Appropriateness Index (MAI)). The explicit approach is based on criteria generally determined by expert consensus. They consist of standardised lists of drugs to be avoided in older subjects (eg, the European list of potentially inappropriate medications for older people (EU(7)-PIM list)) or more complex rules combining drugs and clinical parameters (eg, STOPP/START (Screening Tool of Older Persons’ Prescriptions/Screening Tool to Alert to Right Treatment) criteria).5

Many studies on the prevalence of PIDPs, their health impact and interventions to reduce them have been published. The prevalence of PIDPs varies considerably depending on the context and tools used to detect them.8 The Gallagher et al study conducted in six European university hospitals evaluated the prevalence of PIDPs in older patients admitted for acute care to be 59.4% using the START criteria, 51.3% using the STOPP criteria and 30.4% using the Beers criteria.10 In our facility, a cross-sectional, descriptive, observational study performed on outpatients in 2015 showed 71.2% of the 229 subjects to have a PIDP.11 Concerning the health impacts of PIDPs, a recent meta-analysis showed evidence of a connection between PIDPs and the risk of adverse effects and hospitalisations in older subjects.11 Finally, concerning strategies for avoiding PIDPs, a Cochrane literature review recently established that the presence of a pharmacist, especially as part of a multidisciplinary team, reduces PIDPs.12

Regarding the role of pharmacists, several studies have shown that a pharmaceutical analysis of prescriptions and treatment optimisation has a positive impact on reducing adverse effects, length of hospitalisation, readmission rate, quality of life and mortality.5 14–16 The impact of a multidisciplinary intervention involving nurses, pharmacists and physicians is also well established in the hospital,17 especially on PIDPs and adverse events linked to drug therapy.18–21 The impact of this type of multidisciplinary approach has rarely been evaluated in France.

Among the multidisciplinary teams intervening in health facilities are mobile geriatric teams (MGTs). There are more than 200 MGTs in France. They intervene in non-geriatric medical, surgical and emergency department services to provide geriatric evaluation and advice through a multidisciplinary evaluation. In 2013, a meta-analysis showed that MGTs have a positive impact on the mortality rate at 6 months (relative risk (RR): 0.66; 95% CI: 0.52 to 0.85) and 8 months (RR: 0.51; 95% CI: 0.31 to 0.85) after hospital discharge.24 We have found no published studies evaluating the impact of MGTs on drug prescriptions specifically, particularly inappropriate ones. However, the characteristics of patients seen by MGTs match those most at risk of adverse drug reactions and PIDPs.25 In other countries, geriatric consultation teams that are multidisciplinary but do not include pharmacists have helped reduce PIDPs both for inpatients26 and for hospitalised patients.27

In summary, the published data show the following:

► The relationship between PIDPs, frequent adverse effects and risk of hospitalisation.
► The impact of MGTs on the mortality rate, 6 and 8 months after hospital discharge.
► The impact of clinical pharmacy activities and multidisciplinary treatment optimisation on PIDPs, length of hospitalisation and the rate of unscheduled readmissions.
► The relationship between iatrogenic risk and a lack of coordination between professionals.

There are currently no data, either French or international, on the following:

► The impact of MGTs on PIDPs in France.
► The impact of including a pharmacist in the MGT (ie, a PHARmacist-included MOBILE Geriatrics (PharMoG) team).

We hypothesise that a PharMoG team intervention including a clinical medication review improves the quality, safety and relevance of drug treatment in older patients by decreasing exposure to potentially inappropriate drugs and improving cooperation between pharmacists and doctors caring for older patients.

METHODS AND ANALYSIS

Design

The PharMoG study is a prospective, interventional, single-centre feasibility study describing the intervention of a PharMoG team on PIDPs in older patients hospitalised at Toulouse University Hospital, France. The checklist items from the ‘Standard Protocol Items Recommendations for Interventional Trials’ and the ‘Consolidated Standards of Reporting Trials extension for the reporting of randomised pilot and feasibility studies’ (only items regarding feasibility studies) were used to report this study protocol.28 29

Patients

Consent and inclusion

The MGT intervenes only at the request of the patient’s hospitalist for a geriatric opinion. The request is made by telephone or through the hospital’s software.

During the screening visit, if the inclusion criteria are met, the investigator (geriatrician or pharmacist) gives the subject or the subject’s representative (trusted person or family member) a copy of the information sheet and answers any questions about the purpose, constraints, foreseeable risks and expected benefits of the study. The investigator also specifies the subject’s rights in a research protocol.28

The PharMoG (PharMoG) team consists of a geriatrician, a clinical pharmacist, a pharmacy technician, an administrative assistant and a research assistant. The subject or the subject’s representative (trusted person or family member) met, the investigator (geriatrician or pharmacist) gave a detailed explanation of the study protocol.28

Informed consent is obtained according to the French research law. The subject or the subject’s representative (trusted person or family member) was informed of his or her right to withdraw from the study at any time and that the investigator would respect his or her oral refusal as an consent. The subject or the subject’s representative (trusted person or family member) was informed of his or her right to withdraw from the study at any time. If the patient agrees to participate in the study, he or she consents orally as well as in writing. The subject or the subject’s representative (trusted person or family member) or family member) is informed of the study protocol.28

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of 5 March 2012 on human research trials (the Jardé Act). Oral consent is sufficient because according to French law (the Jardé Act), this is a minimal-risk research project. If the patient does not have the cognitive or physical capacity to read the information sheet, the investigator will address the patient’s trusted person and/or family member, who will consent orally on behalf of the patient. A copy of the information sheet and consent form for the patient or the patient’s trusted person and/or family member (translated into English) is provided as online supplemental file 1. The investigator will record the representative’s consent in the patient’s medical file. The investigator assigns an enrolment number to the subject and keeps an up-to-date key (with the name and enrolment number), separate from the electronic case report form (e-CRF).

Sample size and duration
As this is a feasibility study to describe the intervention of a PharMoG team and to obtain preliminary results and feasibility outcomes, we did not calculate a sample size based on assumed efficacy. The number of patients and the duration of the study are given for information only and have been estimated to have a sufficient sample of patients to evaluate feasibility.

The enrolment period is expected to allow sufficient time to gather data on approximately 250 patients, ensuring that the prescriptions analysed and clinical situations are representative in the context of a descriptive study. Knowing that the MGT of Toulouse University Hospital treats approximately 1000 patients per year, we can estimate that it would take 1 year to enrol 250 patients, taking into account the inclusion criteria and availability of the pharmacist in the MGT. Knowing that each patient is followed for 3 months after the PharMoG intervention, we can estimate that the whole study would take around 15 months, assuming a maximum hospital stay of 2 months. We chose a 3-month follow-up because it would be consistent with a new general practitioner visit and also because this duration was used in another study on the effects of a clinical medication review.

Inclusion criteria
Participants with the following criteria will be included in the study:

- Man or woman aged ≥75 years.
- Hospitalised at Toulouse University Hospital in a medical, surgical or emergency department, with admissions having requested the MGT.
- Having five or more prescription drugs before the intervention (including all routes of administration and as-needed prescriptions).
- Having given oral consent to participate in the study (or oral consent given by the representative: a trusted person and/or a family member of the patient, if necessary).
- Belonging to a social security scheme or equivalent.

Exclusion criteria
Participants with the following criteria will be excluded from the study:

- Man or woman <75 years of age.
- Not hospitalised in any of the departments targeted by the study (medicine, surgery, emergency).
- Not having had the MGT called.
- Having fewer than five prescription drugs before the intervention (including all routes of administration and as-needed prescriptions).
- Legally protected adults (under guardianship or protection of the court).
- Patient participating in another research protocol.

Intervention
All the pharmacists in the PharMoG team have specific training in clinical pharmacy and pharmacology applied to geriatrics achieved through a university diploma programme (‘Optimization of drug management of the elderly patient’). The pharmacists of the PharMoG team review the patient’s medical file to look for the following information: medical and surgical history, comorbidities, the reason for hospitalisation, the reason the PharMoG team was called, medicines prescribed, and information important to analysing the prescription and left to the pharmacist’s discretion (falls, malnutrition, insomnia, urinary incontinence, frailty or dependence, adverse effects, laboratory results, etc). As the usual care provided by pharmacists is not uniform at our hospital (pharmaceutical analysis, medication reconciliation, pharmaceutical interview), the pharmacist in the PharMoG team contacts the department’s pharmaceutical team and collects information on the actions already carried out.

Based on the information gathered through a routine medication reconciliation, the study pharmacist conducts a clinical medication review as recommended by the French Society of Clinical Pharmacy based on both explicit and implicit approaches. As there are many explicit criteria tools available, we chose the EU(7)-PIM list and the STOPP and START V.2 criteria because they were the most recent tools in Europe, they were validated for both inpatients and outpatients, and the combination of the two allowed us to detect situations of overuse, misuse and underuse. They were supplemented by the French Alert and Mastering of drug Iatrogenicity (AMI) indicators, ‘medical benefit’ assessed by the French National Authority for Health (HAS) and Summary of Product Characteristics of the drugs. For the implicit approach, we took into account the patient’s comorbidities, laboratory test results, adverse events reported and questions from the MAI. Appropriateness or inappropriateness is assessed by calculating the number of PIDPs for each drug prescription line.

The study pharmacist discusses the proposed pharmaceutical inventions with the MGT and then writes them up. The geriatrician adds these proposals to the computerised report and sends it to the hospital physician in
charge of the patient and the attending physician, and then to the community pharmacist by secured electronic messaging. The PharMoG team’s therapeutic optimisation proposals are transmitted to the community pharmacist to relay the pharmaceutical interventions carried out by the team and to reinforce them by carrying out a postdischarge clinical medication review in primary care.

**End points**

**Primary end point**
The primary end point is the acceptance rate of the PharMoG team’s proposed treatment optimisations related to PIDPs, measured at patient’s discharge from the department.

**Secondary end points**
The secondary end points are the following:

- The change in the average number of PIDPs per patient, before the intervention, at the time of discharge and 3 months after the intervention by the mobile team.
- The percentage of PIDPs per patient, before the intervention, at the time of discharge and 3 months after the intervention by the mobile team.
- The percentage of patients with at least one PIDP before the intervention, at the time of discharge or 3 months after the intervention by the mobile team.
- The number of prescription medicines per patient, before the intervention, at the time of discharge and 3 months after the intervention by the mobile team.
- The acceptance rate of the mobile team’s proposed treatment optimisations on the entire drug prescription, at the time of discharge and 3 months after the intervention by the mobile team.
- The number of postdischarge clinical medication reviews performed by community pharmacists.
- Falls within 5 months after the mobile team’s intervention.
- Mortality 3 months after the mobile team’s intervention.
- Hospitalisation, emergency department visits—whether or not admitted to the hospital—and institutionalisation within 3 months after the mobile team’s intervention.
- Changes in the cost per patient of medications prescribed before the intervention, at the time of discharge and 3 months after the PharMoG team’s intervention, according to the rates reimbursable by national health insurance, or failing that, according to the price of hospital purchases.

The end points will be assessed 3 months after the mobile team’s intervention only for patients whose hospitalisation within 3 months after the mobile team’s intervention.

**Secondary end points**

- The time it takes for treatment optimisation of drug prescriptions (calculated as the difference between the time the pharmacist arrives and the time the pharmacist leaves the ward).
- The proportion of patients enrolled/number of patients meeting the inclusion criteria.
- The number of patients lost to follow-up 3 months after the mobile team’s intervention.
- Satisfaction of the physicians in the PharMoG team and of the departments involved according to the Likert scale (satisfaction questionnaire will be sent at the end of the study).

**Data collection**
The data collection methods are detailed in **table 1**. The data are collected in a CRF and then in an e-CRF.

Data will be collected based on the patient’s computerised record, the patient’s paper record and if, appropriate, an interview with the patient or the trusted person and/or family member of the patient. If the department in which the patient is hospitalised normally has a pharmaceutical team, the study pharmacist will contact them to inform them that the patient has been enrolled and to gather information about what has already been done (medication reconciliations on admission, previous pharmaceutical interventions). In addition, if necessary, the investigator will contact the community pharmacist to find out which treatments are usually taken at home by the patient.

For the callback at the time of discharge, the data will be collected by the pharmacist of the mobile team or the clinical research associate by telephone, and/or by a visit to the department in question, and/or from data in the patient’s computerised file. For the 3-month callback (±15 days) after discharge from the hospital, the data are collected by the pharmacist of the MGT or the clinical research associate by a telephone call to the patient (and/or the patient’s trusted person and/or family member, if necessary) and from the community pharmacist. The following data will be collected: drugs prescribed, falls, hospitalisations, emergency department visits and institutionalisation. A fall is defined as ‘an event which results in a person coming to rest inadvertently on the ground or floor or other lower level’ by WHO.35 The occurrence of falls is collected by consulting different sources: patient records and interviews with the patient, family and general practitioner.

A participant may stop participating in the study at any time without any consequences for him or her or for his or her subsequent care. If withdrawal from the study occurs before hospitalisation (death, withdrawal of consent, etc), the main end point is not calculated. In the event of withdrawal from the study, there is no provision for replacement of participants.

**Data analysis**
Concerning the statistics regarding the primary and secondary end points:
## Table 1  Data collection steps

<table>
<thead>
<tr>
<th>Steps</th>
<th>Screening</th>
<th>Enrolment and intervention day 0</th>
<th>Discharge callback (on the patient's discharge from the department)</th>
<th>Three-month callback (3 months±15 days after the intervention of the mobile team)</th>
<th>Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Give information sheet and obtain oral informed consent</td>
<td>√</td>
<td></td>
<td></td>
<td></td>
<td>Patient or patient’s representative</td>
</tr>
<tr>
<td>Check inclusion and exclusion criteria</td>
<td>√</td>
<td></td>
<td></td>
<td></td>
<td>Patient or patient’s representative</td>
</tr>
<tr>
<td>Medical history</td>
<td>√</td>
<td></td>
<td></td>
<td></td>
<td>Medical record and physicians</td>
</tr>
<tr>
<td>Medications (INN, pharmaceutical form, dosage, length of prescription)</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td></td>
<td>Medical record and phone call to the dispensing pharmacy</td>
</tr>
<tr>
<td>Identification of PIDPs</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td></td>
<td>Pharmaceutical knowledge</td>
</tr>
<tr>
<td>Treatment optimisation recommendations</td>
<td>√</td>
<td></td>
<td></td>
<td></td>
<td>Discussion with the geriatric team</td>
</tr>
<tr>
<td>Implementation of recommendations</td>
<td>√</td>
<td></td>
<td>√</td>
<td></td>
<td>Prescription and/or hospital report</td>
</tr>
<tr>
<td>Number of falls in the past 3 months</td>
<td>√</td>
<td></td>
<td>√</td>
<td></td>
<td>Patient and/or phone call to the family</td>
</tr>
<tr>
<td>Mortality</td>
<td>√</td>
<td></td>
<td>√</td>
<td></td>
<td>Medical record and phone call to the patient or family</td>
</tr>
<tr>
<td>Hospitalisations, emergency department visits and institutionalisations</td>
<td>√</td>
<td></td>
<td></td>
<td></td>
<td>Medical record and phone call to the patient or family</td>
</tr>
</tbody>
</table>

√, done; INN, international non-proprietary name; PIDP, potentially inappropriate drug prescription.
The quantitative variables are described in terms of the mean and SD or as a range and compared using Student’s t-test for paired data if the distributions are normal and a Wilcoxon signed-rank test if they are not.

The qualitative variables will be described as numbers and percentages and compared using a McNemar test if the validity conditions are met and a Fisher exact test if they are not.

For economic data, the results will be presented in the form of incremental costs per patient and 95% CIs from a bootstrap. The economic analysis will be done from a national health insurance point of view using a time horizon of 1 month.

The significance threshold will be set at 0.05, and all the tests will be two-tailed.

A mixed model will be used to explain the acceptance rate of the PharMoG team’s proposed treatment optimisations and the changes in PIDPs before and after the intervention of the PharMoG team by the following:

- The patients’ characteristics: age, gender, weight, number of medicines before the intervention, comorbidity index (Charlson) and adverse drug event risk score in geriatrics (Trivalle score).
- The type of department (surgical vs medicine vs emergency, and the presence and level of pharmaceutical analysis according to the French Society of Clinical Pharmacology).
- SAS software V.9.3 (SAS Institute) will be used to produce the statistical outcomes.

Patient and public involvement

It was not possible to involve patients or the public in the design, or conduct, or reporting, or dissemination plans of our research.

Discussion

This feasibility study aims to obtain preliminary results on the impact of a PharMoG on PIDPs in older, hospitalised patients and to ensure the feasibility of this type of intervention.

First, regarding the main end point, we chose to detect PIDPs using a method combining several explicit criteria and an implicit approach. On one hand, this choice is consistent with current practice and provides patients with pharmaceutical care that is as personalised as possible. On the other hand, this approach is less reproducible than the application of explicit criteria from a single tool, even if all the pharmacists involved in the PharMoG team were provided with clinical pharmacy training applied to geriatrics. It should be emphasised that in this feasibility study, the PIDPs are evaluated by the pharmacist included in the MGT. To overcome this problem, in the future we could compare the number of PIDPs related to each drug prescription either via a computerised algorithm only for explicit criteria or by another clinical pharmacist.

Finally, as there is no control group, the results of this study cannot be used to assess the pharmacist’s own added value within the MGT. We can hypothesise that the main added value of having a pharmacist on the PharMoG team compared with usual care therefore lies in the clinical medication review. To validate this hypothesis, if the results of this feasibility study are conclusive, we can consider launching a multicentre randomised study to demonstrate the efficacy and cost-effectiveness of this approach for older patients. To ensure the consistency of the intervention, we will provide clinical pharmacy training in geriatrics to all pharmacists involved in the study as well as a detailed description of the intervention (gathering information with a medication reconciliation and carrying out a clinical medication review with the tools to be used). The study design would be a comparison of two groups with cluster randomisation by medical wards to avoid contamination bias: a group of wards with MGT intervention without a pharmacist and a group of medical wards with a pharmacist-included MGT (PharMoG team).

Ethics and dissemination

The sponsor and investigator(s) agree to conduct this study in compliance with French Law No. 2012-300 of 5 March 2012 on human research trials (the Jardé Act), as well as with Good Clinical Practice (ICH version 4 of 9 November 2016 and the decision dated 24 November 2006) and the Helsinki Declaration. The study is conducted in accordance with this protocol. Other than in emergency situations requiring the use of specific therapeutic procedures, the investigator(s) agree to abide by the protocol in its entirety, particularly with regard to obtaining consent, and the notification and follow-up of serious adverse events. In this study, adverse events will have to be declared according to various health vigilance procedures (pharmacovigilance, medical device vigilance, haemovigilance) in accordance with the regulations in force. This study was approved by the South-West and Overseas Territories II Ethics Committee (2-19-041 id5236). The Toulouse University Hospital, the sponsor of this study, took out a liability insurance policy in accordance with French public health code provisions. An audit will be scheduled before including the 50th patient. The next audit will be carried out at the end of the study. The article is based on version 2.2 of the protocol dated 16 December 2019. The study started in December 2019.

The data recorded at the time of this study are processed in a computer at Toulouse University Hospital in accordance with French Law No. 78-17 of 6 January 1978 amended by Law No. 2018-493 of 20 June 2018 on Data Processing, Data Files and Individual Liberties (the French Data Protection Act) and Regulation No. 2016/679 adopted by the European Parliament on 16 April 2016, the General Data Protection Regulation.

This study is governed by Reference Methodology (MR-001) under the provisions of Article 54, paragraph 5, of the General Data Protection Regulation.
French Data Protection Act. This change was ratified in a decision dated 5 January 2006 and updated on 21 July 2016. Toulouse University Hospital has signed an agreement to comply with this ‘Reference Methodology’. The results will be presented at national and international conferences and published in peer-reviewed journals. This study is registered in the European Union Clinical Trials Register (IDRCB 2018-A00180-55) and at clinicaltrials.gov.

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6 This study is registered in the European Union Clinical Trials Register (IDRCB 2018-A00180-55) and at clinicaltrials.gov.

**Collaborators**

**Contributors**
All authors made substantial contributions to the conception or design of the protocol and approved the final version of the protocol. Specifically, ABA, CMC, MH, MR, OT, PC and TV were involved in the conception of the protocol. AP and BJ-C led the overall writing of the protocol and designed the database. SO and CR reviewed the protocol and validated the methods of data collection. AB contributed to the ethical and regulatory aspects of the research. The PHARmacist-included MObile Geriatrics (PharMoG) study group represents all persons involved in the implementation of the PharMoG study.

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**Competing interests**
None declared.

**Patient consent for publication**
Not required.

**Provenance and peer review**
Not commissioned; externally peer reviewed.

**Supplemental material**
Includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

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Supplementary file
INFORMATION SHEET AND CONSENT FORM FOR THE PATIENT

Impact of a PHARmacist-included MOBILE Geriatrics team intervention on potentially inappropriate drug prescribing

PharMoG
31/17/0353

Version No.2 dated 16/12/2019
Sponsor: CHU Toulouse
Principal Investigator: Philippe CESTAC PharmD, PhD

Dear Sir or Madam,

A pharmacist or geriatrician from the Toulouse CHU geriatrics team has invited you to participate in a research trial sponsored by the CHU of TOULOUSE. Before deciding, please take the time you need to carefully read this document. It will provide you with all the relevant information about the various aspects of this research. Please feel free to ask the pharmacist or geriatrician any questions you may have about what you have read.

The decision to participate in the trial is entirely yours. If you do not want to participate, you will continue to receive the best possible medical care based on today’s knowledge.

Why this research?

From 65 years of age, the number of chronic diseases increases and is a source of polypharmacy, that is to say the “administration of several drugs simultaneously or the administration of too many drugs”.

Elderly people are more sensitive to adverse drug reactions. According to studies, 5% to 25% of hospitalizations and 10% of emergency visits are due to adverse drug reactions. Each new prescription increases adverse events from 12% to 18% and the risk of hospitalization to 11%.

Also, the difficulties inherent in the packaging or the complexity of the treatment plan increase the risk of not taking the drugs and therefore therapeutic failures.

To reduce these risks, a collaboration between healthcare professionals is essential. Pharmacists, thanks to their knowledge about drugs and their proper use, can help optimise the impact of the treatments prescribed by your doctor.

To our knowledge, a study that evaluates the impact of a pharmacist-included mobile geriatrics team on potentially inappropriate drug prescribing has not been performed yet in France.

What is the objective of this research?

The main objective of the PharMoG study is to compare the average number of a patient’s potentially inappropriate drug prescriptions before the intervention of a mobile geriatric team that includes a pharmacist and after the intervention, when the patient is discharged from the hospital department in which they were admitted.

The secondary objectives will be to evaluate the impact of the pharmacist included mobile geriatric team 3 months after the intervention on potentially inappropriate prescriptions, polypharmacy, falls, and hospitalizations.

How will this research be conducted?

PHARMOG is a local, single-centre, prospective study. It will take place in all the departments of the CHU of TOULOUSE and will last 15 months. It is a descriptive study. It will not change your usual medical care, except that your prescriptions will be analysed and optimised. Your participation in the study will last 3 months. A total of 250 participants will be included.
**Who can participate?**

You can participate if:

- You are 75 years or older
- You are hospitalized at the Toulouse University Hospital in a medical, surgical, or emergency department, for which the mobile geriatric team was requested
- You have been prescribed at least five drugs before the intervention
- You gave your oral consent to participate in the study (or oral consent given by a representative: trusted person and/or a family member, if necessary)
- You are affiliated to a social security scheme or equivalent

You cannot participate if:

- You are less than 75 years old
- You had fewer than five prescription drugs before the intervention
- You are legally protected (under guardianship or prescription of the court)
- You are already participating in another research protocol

**What will be asked of you?**

During the first visit, called the inclusion visit, you will confirm that you agree to participate in the study in the presence of the investigator (pharmacist or geriatrician). The participation criteria will be checked, and you will be included as a participant if your eligibility is confirmed. Your agreement for participating in the study will be recorded in your medical record.

The pharmacist of the mobile geriatric team will ask you about how you take your medications, the difficulties you may have encountered, and the potential adverse drug reactions. The pharmacist will also ask for your community pharmacist’s contact information to collect information about your usual treatment. This inclusion visit will last about 30 minutes.

The second study visit will be a telephone call 3 months after your inclusion. We will collect information about your latest prescriptions and ask about possible falls, if you went to the emergency room or if you were hospitalized during these 3 last months. This call will last about 15 minutes.

Your participation in this study is entirely voluntary. You can end it any time and for any reason without consequences on your medical and pharmaceutical care.

You must be affiliated to a social security scheme or equivalent.

**What are the expected benefits?**

The expected benefits are a reduction in hospitalizations, the number of potentially inappropriate prescriptions, adverse drug reactions, and health insurance costs.

**What are the possible disadvantages?**

You will have to make yourself available for the 3-month follow-up phone call and answer the pharmacist’s questions. There are no known risks connected to the research procedures given that all the decisions will be based on validated (national or international) medical recommendations and these decisions will be taken with your doctors. The studied intervention will therefore not incur any additional risk.

**What are your rights?**

The doctor is required to give you all necessary explanations concerning this research. If you wish to withdraw your consent at any time and regardless of the reason, you will continue to receive the best medical care and your decision will not affect his or her future medical supervision.

In the framework of this biomedical research, your data will undergo computer processing to analyse the research results relative to the research objectives that you are hereby informed of. The body responsible for the data processing is the University Hospital (CHU) of Toulouse, represented by its legal representative in office.
The study physician and other study staff will gather information about you, your health, your prescriptions, and your participation in the study. This information, called "personal information", is recorded on forms, referred to as the case report forms, provided by the sponsor or, on secure online forms dedicated to the study. Only information needed for your treatment and the research aims will be collected; these data will be kept for 15 years after the study and archived. You will only be identified by a code and your initials. The code is used so that the study doctor can identify you if necessary. This data processing is based on Article 6 of the General Data Protection Regulation (GDPR), namely the execution of a public interest mission vested in the data controller and the legitimate interests pursued by it. In addition, under article 9 of the GDPR, the data controller may extraordinarily process specific categories of data, including health data, specifically for scientific research purposes.

In accordance with the provisions of the law relating to data processing, files and freedoms (French law No. 78-17 of January 6, 1978 relating to data processing, files and freedoms modified by law No. 2018-493 of 20 June 2018 on the protection of personal data) and the GDPR (EU Regulation 2016/679), you have the right to access and rectify your personal information. You may also request a restriction on the processing of your personal information, oppose certain types of processing of such personal information, or request that personal information be deleted. However, some previously collected data may not be deleted under Articles 17.3.c and 17.3.d. GDPR, if this deletion is likely to make it impossible or seriously jeopardize the achievement of the research objectives. You may also request that personal information about you be provided to you or a third party in a digital format (portability right).

You can exercise these rights by asking the study doctor in writing. The Sponsor will respond to your requests to the extent possible in accordance with its other legal and regulatory obligations and where required by law.

The data analysis may be carried out within your country, in other countries of the European Economic Area (EEA), in the United States and in countries outside the EEA.

The sponsor may disclose personal information to regulatory agencies or research partners in order to apply for marketing authorizations and reimbursement agreements. These individuals, companies and agencies may be in your country, in other countries of the EEA, in the United States and in countries outside the EEA. Some countries outside the EEA may not offer the same level of privacy protection as your country. The Sponsor will however maintain as much as possible the confidentiality of all the personal information received within the limits of the law.

The sponsor will adopt the appropriate contractual measures, including its Privacy Shield certification and standard data protection clauses, to ensure that relevant recipients outside the EEA provide an adequate level of protection for your personal information as set out in this form and in accordance with the law.

You also have the right to oppose the transmission of data covered by professional secrecy that may be used in the context of this research and to be processed. You can also access all your medical data in accordance with the provisions of Article L1111-7 of the French Public Health Code directly or through the doctor of your choice. These rights are exercised with the doctor who follows you during the research and who knows your identity. The competent authorities and the sponsor or its authorized representatives may also need access the medical records to verify the data collected as part of the study. Your coded personal information may be used for further scientific research with applicable laws and regulations.

If you have any other questions about the collection and use of your personal information or the rights associated with this information, please contact the Data Protection Officer of the University Hospital of Toulouse (DPO@chu-toulouse.fr) or the study doctor.

If, despite the measures put in place by the Sponsor, you believe that your rights are not respected, you can file a complaint with the data protection supervisory authority in your country of residence (the CNIL for France on the website https://www.cnil.fr/fr/donnees-personnelles/plaintes-en-ligne).

In accordance with French law No 2012-300 of 5 March 2012 relating to research involving human persons:
- This research has received a favourable opinion from the the South-West and Overseas Territories II Ethics Committee and authorization from the National Agency for the Safety of Medicines and Health Products (ANSM).
- The sponsor of this research – the CHU of Toulouse – has taken out civil liability insurance with Lloyd’s Insurance Company SA
- Persons who have suffered damage after participating in a research study may make a claim with the regional commissions for conciliation and compensation of medical accidents.
- Once this research is completed, if you wish to, you will be personally informed about the overall results by the study doctor as soon as they become available.

After reading this information sheet, do not hesitate to ask your doctor any questions you may have. After thinking about it, if you agree to participate in this research, you must complete and sign the consent form. A copy of the completed document will be provided to you.

**Contact information for the pharmacist or physician at the study site:**

Name and Surname: …………………………………………………………………………………………………..

Phone number: …………………………………………………………………………………………………..

Professional address: …………………………………………………………………………………………..

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*We thank you for taking time to read this document.*
Certification by the pharmacist or physician who obtained the patient consent to participate in the study:

PharMoG

31/17/0353

I, the undersigned, doctor: .................................................................

pharmacist or physician investigator at the CHU of TOULOUSE certify to having obtained oral consent from

Mr/Mrs (patient name)

.................................................................................................................... for his/her

participation in the PHARMOG study on the (date of oral consent) ___/___/___.

A copy of the information letter and of this certification was given to the patient on ___/___/___.

Physician’s or Pharmacist’s signature / Date
INFORMATION SHEET AND CONSENT FORM FOR THE PATIENT'S LEGAL REPRESENTATIVE

Impact of a PHARmacist-included MOBILE Geriatrics team intervention on potentially inappropriate drug prescribing

PharMoG
31/17/0353

Version No.2 dated 16/12/2019
Sponsor: CHU Toulouse
Principal Investigator: Philippe CESTAC PharmD, PhD

Dear Sir or Madam,

A pharmacist or geriatrician from the Toulouse CHU geriatrics team has invited you to participate in a research trial sponsored by the CHU of TOULOUSE. Before deciding, please take the time you need to carefully read this document. It will provide you with all the relevant information about the various aspects of this research. Please feel free to ask the pharmacist or geriatrician any questions you may have about what you have read.

The decision to participate for the person you represent in the trial is entirely yours. If you do not want the person you represent to participate, he or she will continue to receive the best possible medical care based on today's knowledge.

Why this research?

From 65 years of age, the number of chronic diseases increases and is a source of polypharmacy, that is to say the “administration of several drugs simultaneously or the administration of too many drugs”.

Elderly people are more sensitive to adverse drug reactions. According to studies, 5% to 25% of hospitalizations and 10% of emergency visits are due to adverse drug reactions. Each new prescription increases adverse events from 12% to 18% and the risk of hospitalization to 11%.

Also, the difficulties inherent in the packaging or the complexity of the treatment plan increase the risk of not taking the drugs and therefore therapeutic failures.

To reduce these risks, a collaboration between healthcare professionals is essential. Pharmacists, thanks to their knowledge about drugs and their proper use, can help optimise the impact of the treatments prescribed by your doctor.

To our knowledge, a study that evaluates the impact of a pharmacist-included mobile geriatrics team on potentially inappropriate drug prescribing has not been performed yet in France.

What is the objective of this research?

The main objective of the PharMoG study is to compare the average number of a patient’s potentially inappropriate drug prescriptions before the intervention of a mobile geriatric team that includes a pharmacist and after the intervention, when the patient is discharged from the hospital department in which they were admitted.

The secondary objectives will be to evaluate the impact of the pharmacist included mobile geriatric team 3 months after the intervention on potentially inappropriate prescriptions, polypharmacy, falls, and hospitalizations.

How will this research be conducted?

PHARMOG is a local, single-centre, prospective study. It will take place in all the departments of the CHU of TOULOUSE and will last 15 months. It is a descriptive study. It will not change your usual medical care, except that your prescriptions will be analysed and optimised. Your participation in the study will last 3 months. A total of 250 participants will be included.
Who can participate?
You can participate if:
- You are 75 years or older
- You are hospitalized at the Toulouse University Hospital in a medical, surgical, or emergency department, for which the mobile geriatric team was requested
- You have been prescribed at least five drugs before the intervention
- You gave your oral consent to participate in the study (or oral consent given by a representative: trusted person and/or a family member, if necessary)
- You are affiliated to a social security scheme or equivalent

You cannot participate if:
- You are less than 75 years old
- You had fewer than five prescription drugs before the intervention
- You are legally protected (under guardianship or prescription of the court)
- You are already participating in another research protocol

What will be asked of you?
During the first visit, called the inclusion visit, you will confirm that you agree to participate in the study in the presence of the investigator (pharmacist or geriatrician). The participation criteria will be checked, and you will be included as a participant if your eligibility is confirmed. Your agreement for participating in the study will be recorded in your medical record.

The pharmacist of the mobile geriatric team will ask you about how you take your medications, the difficulties you may have encountered, and the potential adverse drug reactions. The pharmacist will also ask for your community pharmacist’s contact information to collect information about your usual treatment. This inclusion visit will last about 30 minutes.

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Your participation in this study is entirely voluntary. You can end it any time and for any reason without consequences on your medical and pharmaceutical care.

You must be affiliated to a social security scheme or equivalent.

What are the expected benefits?
The expected benefits are a reduction in hospitalizations, the number of potentially inappropriate prescriptions, adverse drug reactions, and health insurance costs.

What are the possible disadvantages?
You will have to make yourself available for the 3-month follow-up phone call and answer the pharmacist’s questions. There are no known risks connected to the research procedures given that all the decisions will be based on validated (national or international) medical recommendations and these decisions will be taken with your doctors. The studied intervention will therefore not incur any additional risk.

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- Once this research is completed, if you wish to, you will be personally informed about the overall results by the study doctor as soon as they become available.

After reading this information sheet, do not hesitate to ask your doctor any questions you may have. After thinking about it, if you agree to participate in this research, you must complete and sign the consent form. A copy of the completed document will be provided to you.

**Contact information for the pharmacist or physician at the study site:**

Name and Surname: …………………………………………………………………………………………………..

Phone number: …………………………………………………………………………………………………..

Professional address: …………………………………………………………………………………………..
………………………………………………………………………..…………………

*We thank you for taking time to read this document.*
Certification by the pharmacist or physician who obtained the patient’s representative oral consent to participate in the study:

PharMoG

31/17/0353

I, the undersigned, doctor: .................................................................

pharmacist or physician investigator at the CHU of TOULOUSE certify to having obtained oral consent from the legal representative (trusted person or relative) of Mr/Mrs (patient name) .................................................................

........ for his/her participation in the PHARMOG study on the (date of oral consent) |__|__|

|__|__| |__|__|.

A copy of the information letter and of this certification was given to the patient’s legal representative on |__|__| |__|__| |__|__|.

Physician’s or Pharmacist’s signature / Date