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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.

Strengths and limitations of this study

► This prospective study is the first to describe the intervention of a mobile geriatric team including a pharmacist in France.

► The pharmacist intervention consists of a clinical medication review based on both implicit and explicit criteria, which reproduces current practices.

► The acceptance rate of the mobile geriatric team propositions related to potentially inappropriate drug prescriptions is measured both at discharge and after 3 months to assess the long-term effects of the intervention.

► Our feasibility study is not randomised, with no control group.

► The detection of potentially inappropriate drug prescriptions is carried out by the pharmacist involved in the study and not by an external assessor (clinical pharmacist not involved in the study or computer algorithm).

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with age,[2] 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%[3] and the risk of hospitalisation by 11%.[4]

The term 'potentially inappropriate drug prescription' (PIDP)[5] 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).

INTRODUCTION AND BACKGROUND

In patients aged ≥75 years, comorbidities are common[1] and a cause of polypharmacy. Multiple prescriptions, combined with physiological changes in pharmacokinetic and pharmacodynamic parameters that occur

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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))[6] 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).[7]

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*[9] 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.[12] 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.[13]

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.[22 23]

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 inpatients[26] 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 study and verifies the eligibility criteria. After this information session, the subject or the subject's representative is given time (1 day) to think it over. If the patient agrees to participate in the study, he or she consents orally as recommended by French law (French Law No. 2012-300

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.[30] 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.[31]

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 review, 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[32] based on both explicit and implicit approaches. As there are many explicit criteria tools available, we chose the EU(7)-PIM list[6] and the STOPP and START V.2 criteria[7] 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.[33] 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.[34] 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 3 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 hospital stay does not exceed 2 months after the mobile team's intervention.

The other end points for judging the feasibility of the study and satisfaction of health professionals are the following:
► The number of enrolments per day.

► 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/the 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

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

√, 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)[36] and adverse drug event risk score in geriatrics (Trivalle score[37]).

► 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 (2-19-081 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

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 clinical-trials.gov.

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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. SQ 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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