How a Patient Personalised Clinical Pharmacy Programme Can Secure Therapeutic Care in an Orthogeriatric Care Pathway (5P Project)?

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Background: A new model was developed for integrating a personalised clinical pharmacy programme (5P project) into the orthogeriatric care pathway.

Objective: To secure the therapeutic care of orthogeriatric patients.

Design and Setting: Prospective descriptive study in a multisite teaching hospital from June 2019 to January 2020.

Subjects: Patients aged ≥75 years admitted for hip fracture.

Methods: A prescription review was performed for all patients at inclusion. Other clinical pharmacy activities (additional prescription review, pharmaceutical interviews, medication reconciliation) were dedicated to “high-risk” patients. Potential medication errors (ME), either pharmaceutical interventions (PI) or unintentional discrepancies (UID), were recorded. The potential clinical impact of PI was evaluated by a pluriprofessional expert panel using a validated tool.

Results: In the 455 patients included, 955 potential ME were detected, that is ≥1 potential ME for 324/455 (71%) patients. In acute care, 561 PI were formulated during prescription review for 440/455 (97%) patients and 348/561 (62%) were accepted by physicians. Medication reconciliation was performed for 213 patients, 316 UID were identified. In rehabilitation units, a second prescription review was performed for 112/122 (92%) “high-risk” patients, leading to 61 PI. The clinical impact was evaluated for 519/622 (83%) PI. A consensus was obtained for 310/519 (60%) PI: 147/310 (47%) were rated as having minor clinical impact, 138/310 (45%) moderate, 22/310 (7%) major, 2/310 (0.6%) vital, and 1/310 (0.3%) null.

Conclusion: The 5P project secured the orthogeriatric care pathway by detecting a great number of potential ME, including PI mostly considered as having a significant clinical impact.

Keywords: hip fracture, frail elderly, pharmaceutical services, medication errors, clinical relevance

Introduction

Hip fractures mostly affect older people (annual incidence of 620,000 in Europe in 2010) and induce high morbidity and mortality (18–33% one-year mortality rate), functional decline, and sometimes postoperative complications.1,2 Recently, several studies have reported the benefits on both short- and long-term clinical outcomes of a pluriprofessional and integrated care pathway for older people with hip fractures (orthogeriatric care), such as fewer confusion episodes and postoperative complications, as well as lower mortality.3–5 Orthogeriatric care aims at organising patient...
care management before and after surgery in order to optimise medical and paramedical assessments, discharge planning, and to initiate enhanced recovery after surgery. This approach improves the quality and security of care due to collaboration between healthcare professionals.3–5

Previous studies have found that clinical pharmacy activities prevent between 1.2 and 4.2 medication errors (ME) per patient especially in older patients.6–10 Clinical pharmacy activities consist of prescription reviews, medication reconciliation, and patient or caregiver pharmaceutical interviews. Prescription review consists of an analysis and optimisation of a patient’s medication prescription considering medical and laboratory data, therapeutic objectives, and guidelines. During this activity, pharmaceutical interventions (PI), corresponding to “any action initiated by a pharmacist directly resulting in a change of the patient’s management or therapy” according to Dooley et al,11 could be addressed to physicians. Medication reconciliation is a standardised process based on an exhaustive medication history using multiple sources; it permits to share complete information between healthcare professionals, to analyse and justify any discrepancies between usual medications and any new prescriptions, and so to detect potential ME. Finally, various pharmaceutical interviews conducted with patients or caregiver exist: admission interviews are a major source of information for medication reconciliation; discharge interviews consist of pharmaceutical advice regarding discharge prescription and any therapeutic change during hospitalisation; and targeted pharmaceutical informative interviews consist of giving pharmaceutical advice on a specific medication.

Although their interest has been highlighted in geriatric and/or orthopaedic units,6,7,12,13 to our knowledge, there is no data regarding any clinical pharmacy programmes developed all along this care pathway. Thus, a new model was created for integrating a patient personalised clinical pharmacy programme (5P project) into the orthogeriatric care pathway. The main objective was to optimise and secure therapeutic care of orthogeriatric patients, by describing the clinical pharmacy activities performed and evaluating the potential clinical impact of PI using a validated tool.

Materials and Methods

The clinical pharmacy programme was developed and described by Hoegy et al.14 Briefly, a Delphi technique was used with surgeons, geriatricians, paramedics, and pharmacists involved in the orthogeriatric care pathway in order to define criteria for prioritization of patients based on adverse events, and to position clinical pharmacy activities at the most relevant steps of the pathway.

Design and Setting

A prospective study was carried out in a French multi-site teaching hospital over eight months, from June, 3rd 2019 until January, 31st 2020. Patients were recruited from four sites. Two of them had a surgical emergency department, orthopaedic or geriatric units, and rehabilitation units. The two others had only rehabilitation units.

Patients and Levels of Risk

Consecutive patients aged 75 or older admitted to the participating hospitals for hip fracture during the study period were included. These patients were divided in two groups by clinical pharmacists according to their level of risk of adverse event: “low-risk” (LR) or “high-risk” (HR). HR patients presented at least two of the following criteria: being aged ≥90 years, being obese (body mass index ≥30) or diabetic, being prescribed a potentially inappropriate medication (PIM) for older people (list defined in Laroche et al15), suffering from at least one cardiovascular disease. The level of risk of patients was regularly revaluated by checking their medical records for an intercurrent event (postoperative complications or newly diagnosed diseases), or upon medical or pharmaceutical request.

Clinical Pharmacy Programme

The 5P project is summarized in Figure 1. In acute care (post-surgery step), a prescription review was performed for all patients, either in orthopaedic or geriatric units. No additional clinical pharmacy activity was performed for LR patients. Medication reconciliation at admission and transfer/discharge was conducted for HR patients. Whenever possible, ie, absence of cognitive impairment or postoperative confusion, admission and/or discharge interviews with patients were performed.

In rehabilitation units, a second prescription review was performed for HR patients. If appropriate, a targeted pharmaceutical informative interview about oral anticoagulant and/or discharge interviews were proposed to eligible patients. For instance, HR inpatients initiating an oral anticoagulant treatment, or patients already treated with oral anticoagulants and requiring more information were eligible to a targeted informative interview.
Descriptive Analysis and Outcomes

A descriptive analysis per protocol was performed for the following outcomes: number of inpatients who experienced at least one potential ME, which can be either PI during prescription review or unintentional discrepancies (UID) during medication reconciliation; number of potential ME detected (PI and/or UID); number of PI, and for each, the type of drug-related problem (DRP) and pharmacist recommendations according to the French Society of Clinical Pharmacy (SFPC) criteria; PI acceptance rate; number of UID at admission and at transfer/discharge; prescription modification rate following UID.

The potential clinical impact of PI was retrospectively assessed by a pluriprofessional expert panel composed of an anaesthetist, a geriatrician, a surgeon, and a pharmacist, using the clinical dimension of the CLinical, Economic, and Organizational (CLEO) tool (harmful, null, minor, moderate, major, vital, not determined; Table 1), developed and validated by Vo et al. The Economic and Organizational dimensions of this tool were not considered in the 5P project, consequently PI such as “non-conformity to the hospital formulary” (medications unavailable at the hospital) which were made essentially because of their organizational impact, were excluded. Firstly, PI were reviewed by two pharmacists (MB and EC). Secondly, PI were classified in “DRP and medication categories” by two pharmacists (JM and AJD). Thirdly, PI were rated by each expert independently. The pharmacist rating corresponded to a majority in opinion of individual ratings performed by five pharmacists (MB, EC, DH, AJD, and JM) independently. Finally, ratings from each expert were compared: the final rating was defined as “no consensus” (4 different ratings or in case of 2 times 2 identical ratings) or according to the majority rating (≥3 identical ratings, or in case of 2 identical ratings and the 2 other ratings different).

Data Collection

Patient data (level of risk of adverse event, risk criteria, intercurrent event, and date of death) and their care pathway (origin before hospital admission, destination after discharge, and length of stay –LOS– in each unit) were collected from medical records.
Data regarding clinical pharmacy activities were collected prospectively by each pharmacist. For prescription review, PI were rated according to the SFPC criteria. The name of the medication concerned by PI and the PI acceptance by physicians were recorded. For medication reconciliation, the number of medications prescribed before hospitalization, at admission, and discharge, and the number of UID were gathered. Any prescription modification by physicians was collected for UID.

Statistical Analyses
Statistical analyses were performed per protocol using SAS software version 9.4 (SAS Institute Inc., Cary, NC, USA). If clinical pharmacy activities were not performed, a dedicated implementation analysis was done by Martin et al (unpublished data). Categorical variables were expressed as frequency (percentage); continuous variables were expressed as mean ± standard deviation (SD) or median (interquartile, [IQR]).

Results
Patients and Care Pathway Characteristics
A total of 455 patients were included in the study, 284/455 (62%) were considered as HR patients. Among them, 255/284 (90%) were HR at inclusion, and 29/284 (10%) patients were LR at inclusion and were reassessed as HR during orthogeriatric care pathway. A total of 202/455 (44%) patients were ≥90 years, 375/455 (82%) had at least one cardiovascular disease, 82/455 (18%) were either obese or diabetic, and 67/455 (15%) received at least one PIM. Most HR patients met two risk criteria (204/255, 80%), 44/255 (17%) met three, and 7/255 (3%) met all four criteria.

Most patients were admitted directly from home (272/455, 60%), nursing homes (126/455, 28%), or healthcare facilities (52/455, 11%). In acute care, the median [IQR] LOS was 8 [6–12] days. A total of 191/455 (42%) patients were transferred to 5P project rehabilitation units, their median [IQR] LOS was 35 [25–51] days. Among patients admitted to the hospital directly from home, 122/272 (45%) were discharged home. A total of 36/455 (8%) patients died during their hospitalization.

Outcomes of 5P Project and Clinical Relevance of PI
Regarding the 455 included patients, 955 potential ME (PI + UID) were detected, corresponding to a mean ± SD of 2.1 ± 2.5 ME per patient, and at least one ME was noticed for 324/455 (71%) patients. Regarding the 284 HR patients, 755 ME were detected, corresponding to a mean ± SD of 2.7 ± 2.8 ME per patient, and at least one ME was noticed for 225/284 (79%) HR patients.

Clinical Pharmacy Activities in Acute Care (Orthopaedic or Geriatric Units)
A total of 561 PI were made corresponding to 440 prescription reviews performed (440/455, 97%) for all patients, and at least one PI was made for 287/440 (65%)
patients. Medication reconciliation at admission was performed for 213/284 (75%) HR patients, and identified 316 UID, and at least one UID was detected for 116/213 (54%) patients (Table 2). Admission interviews were conducted with 107/284 (38%) HR patients.

The most common medication classes identified by PI were nervous system medications (291/561, 52%) including a majority of analgesics (morphine, acetaminophen … etc.), medications for blood and blood-forming organs (83/561, 15%) including antithrombotic and infusion fluids, cardiovascular system medications (65/561, 12%), and medicinal products for the alimentary tract and metabolism (63/561, 11%). Most common DRP detected were “supratherapeutic dosages” (90/561, 16%), “non-conformity to guidelines” (90/561, 16%), “supratherapeutic dosages” (9/61, 15%), and “unjustified medications” (9/61, 15%). Main pharmacist’s recommendations were “medication switch” (19/61, 31%), “dosage adjustment” (15/61, 25%), or “addition of a medication” (12/61, 20%).

Targeted pharmaceutical informative interviews were conducted with 13/64 (20%) HR patients treated with oral anticoagulants, 9/13 (69%) had direct oral anticoagulants, and 4/13 (31%) had anti-vitamin K anticoagulants.

Clinical Pharmacy Activities at Discharge
Medication reconciliation at discharge was completed for 105/213 (49%) patients who benefitted from an admission medication reconciliation and identified 17 UID. At least one UID was detected for 11/105 (10%) patients (Table 2).

Among them, 29/105 (28%) had a discharge interview, either in acute or rehabilitation units.

Potential Clinical Impact of PI
The potential clinical impact of 519/622 (83%) PI gathered in 127 “DRP and medication categories” was rated by the pluriprofessional expert panel (Figure 2). The 20 most common “DRP and medication categories” are presented in Tables 3 and 4, and correspond to 302/519 (58%) PI.

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**Table 2 Clinical Pharmacy Activities and Outcomes in the Orthogeriatric Care Pathway**

|                          | Acute Care, n = 455 Patients | Rehabilitation, n = 122 Patients | Total |
|--------------------------|-----------------------------|----------------------------------|-------|
|                          | At Admission | At Transfer or Discharge | 112   | 622  |
| Prescription review      | 440          | NA            | 552  |
| PI                       | 561          | NA            | 622  |
| Number of PI per patient, mean ± SD | 1.3 ± 1.3 | NA            | 0.5 ± 0.8 |
| Acceptance rate, n/N (%) | 348/561 (62%) | NA          | 40/61 (66%)  |
| Medication reconciliation| 213          | 105           | 318  |
| Number of medications per patient, mean ± SD | Before admission: 8.0 ± 3.7 | At discharge: 7.3 ± 3.7 | NA       | NA   |
| UID                      | 316          | 17            | 333  |
| Number of UID per patient, mean ± SD | 1.5 ± 2.2 | 0.2 ± 0.5 | NA       | NA   |
| Acceptance rate, n/N (%) | 210/316 (66%) | 11/17 (65%) | 221/333 (66%) |

**Abbreviations:** NA, not applicable; PI, pharmaceutical intervention; SD, standard deviation; UID, unintentional discrepancy.
A consensus was obtained for 94/127 (74%) “DRP and medication categories” corresponding to 310/519 (60%) PI.

Among “DRP and medication categories” for which a consensus was reached, the potential clinical impact was mainly minor (147/310, 47% PI), or moderate (138/310, 45% PI). It should be noted that the expert panel rated 22/310 PI (7%) with a major impact: 10 PI were related to anticoagulant treatment (enoxaparin, calciparin, or dabigatran) with either a DRP of duplication (4 PI), an absence of postoperative anticoagulation (2 PI), a non-conformity to guidelines (3 PI), or a supratherapeutic dosage (1 PI); 10 PI were related to the use of non-steroid anti-inflammatory medication (3 PI) or nefopam (7 PI) in older patients; and
| N° | Medication                  | Drug-Related Problem                                      | Number of PI per DRP/Medication Category | Examples                                                                 | Result of Clinical Impact by Expert Panel |
|----|-----------------------------|-----------------------------------------------------------|------------------------------------------|--------------------------------------------------------------------------|-------------------------------------------|
| 1  | Morphine                    | Absence of corrective medication                          | 66                                       | Association of an osmotic laxative medication with a morphine-type treatment in order to prevent iatrogenic constipation | No consensus: 2 moderate/2 minor          |
| 2  | Acetaminophen               | Supratherapeutic dosage related to the age of the patient  | 39                                       | Maximal daily dose of acetaminophen recommended is 3g in elder patients   | No consensus: 2 moderate/2 minor          |
| 3  | Acetaminophen               | Duplication                                               | 21                                       | Duplication of acetaminophen on the prescription (often intravenous and per os, or sometimes 2* intravenous or 2* per os) | Moderate                                  |
| 4  | Calciparin                  | Non-conformity to guidelines                              | 21                                       | Considering the normal renal function of the patient, the utilization of a low molecular weight heparin is recommended as a first line of treatment | Minor                                     |
| 5  | Acetaminophen               | Intravenous/oral switch                                   | 17                                       | A switch from intravenous acetaminophen to an oral form seems possible as the patient is treated with other oral medications | Minor                                     |
| 6  | Acetaminophen               | Supratherapeutic dosage related to the patient's renal function | 16                                       | Considering the altered renal function of the patient (< 50 mL/min/1.73m²), the maximal daily dose of acetaminophen recommended is 3g (instead of 4g) | No consensus: 2 moderate/2 minor          |
| 7  | Antidepressant              | Absence of medication for a valid medical indication (omission) | 13                                       | Omission of the usual antidepressant taken by the patient (Citalopram, escitalopram, mianserin, mirtazapine, venlafaxine, fluoxetine) ≤ not prescribed on hospital prescription after the operation | Moderate                                  |
| 8  | Morphine                    | Duplication                                               | 11                                       | Duplication of morphine on the prescription (often intravenous and per os, or sometimes 2* intravenous or 2* per os) | Moderate                                  |
| 9  | Bronchodilators and inhaled corticoids (± in association) | Absence of medication for a valid medical indication (omission) | 11                                       | Omission of the usual bronchodilators taken by the patient (for example Beclometasone 100 mcg + formoterol 6 mcg powder for inhalation) considering nursing home prescription ≤ not prescribed on hospital prescription | No consensus: 2 moderate/2 minor          |
| 10 | Morphine                    | Intravenous/oral switch                                   | 9                                        | A switch from subcutaneous morphine to an oral form seems possible as the patient is treated with other oral medications | Minor                                     |

Notes: *All PI were exclusively made in acute care, except “DRP and medication categories” number 2, 4, and 5 in which one to three PI were formulated in rehabilitation unit.  
Abbreviations: DRP, drug-related problem; PI, pharmaceutical intervention.
### Table 4 Most Common PI by DRP/Medication Categories Encountered in the Orthogeriatric Care (11–20)

| N° | Medication                      | Drug-Related Problem                  | Number of PI Per DRP/Medication Category* | Examples                                                                                                                             | Result of Clinical Impact by Expert Panel |
|----|---------------------------------|---------------------------------------|--------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| 11 | Tiapride                        | Contraindication                      | 9                                          | The association of tiapride and escitalopram (or citalopram or hydroxyzine) is contraindicated because of the increased risk of torsades de pointes | Moderate                                  |
| 12 | Infusion fluids with electrolytes| Unjustified medications               | 9                                          | Considering that the patient has an hyperkalemia (> 5.5 mmol/L), revaluation of the administration of Glucidion containing potassium supplementation: switch with another hydration if still necessary | No consensus: 4 different ratings, minor/ moderate/ major/vital |}
| 13 | Acetaminophen                   | Supratherapeutic dosage related to the patient's weight | 8                                          | Considering the patient’s weight of 40 kg (<50 kg), the maximal daily dose of acetaminophen recommended is 3g (instead of 4g/day) | No consensus: 2 moderate/2 minor          |
| 14 | Benzodiazepines and Z drugs     | Supratherapeutic dosage               | 8                                          | In older patients, it is recommended to prescribed zopiclone at half-dose                                                      | Moderate                                  |
| 15 | Benzodiazepines and Z drugs     | Not recommended in older patients     | 8                                          | As bromazepam is a benzodiazepine with a long half-life, its prescription is not recommended in elder patients. Switch to benzodiazepine with shorter half-life such as oxazepam | No consensus: 2 moderate/2 minor          |
| 16 | Tiapride                        | Drug-drug interaction other than contraindication | 8                                          | The association of tiapride and amiodarone is contraindicated because of the increased risk of torsades de pointes (5 not recommended, 3 precautions for use) | No consensus: 2 major/2 moderate          |
| 17 | Enoxaparin                      | Infratherapeutic dosage               | 8                                          | Actual prescription of enoxaparin is unclear, in between a prophylactic and a curative dosage (patient of 58 kg with a prescription of 4000 UI twice a day). | Moderate                                  |
| 18 | Nefopam                         | Not recommended in older patients     | 7                                          | As nefopam is a central analgesic with anticholinergic properties, its prescription in elder patients is not recommended. Nota bene: the patient has already other analgesic treatments (acetaminophen + morphine) | Major                                     |
| 19 | Calcium ± vitamin D             | Absence of medications for a valid medical indication (omission) | 7                                          | The patient takes an oral chronic calcium ± vitamin D supplementation ≤ not prescribed on hospital prescription | Minor                                     |
| 20 | Morphine                        | Therapeutic optimization              | 6                                          | Morphine is systematically prescribed whereas acetaminophen is prescribed only if needed.                                        | Minor                                     |

**Notes:** *All PI were exclusively made in acute care, except "DRP and medication categories" number 15, 17, 19 and 20 in which one to three PI were formulated in rehabilitation unit.

**Abbreviations:** DRP, drug-related problem; PI, pharmaceutical intervention.
2 PI were related to metformin prescribed at a supratherapeutic dosage in patients with impaired renal function. Two PI were rated as having a vital impact (2/310, 0.6% PI), which consisted in a contraindication of the association of digoxin with infusion fluids containing calcium ions (ringer lactate). One PI was rated as having a null clinical impact (1/310–0.3% PI).

Discussion

Even though the implementation of clinical pharmacy activities was not fully reached, at least one potential ME was detected for almost three quarters of included patients. The results obtained herein are similar to previous reports in terms of potential ME per patient, either with PI or UID in geriatric or orthopaedic units. Furthermore, the most frequent medication classes involved in PI in the present study (central nervous system, antithrombotic, and cardiovascular system medications) have also been found in studies led in orthopaedic units. However, among the central nervous system medication class, the proportion of analgesics compared to antidepressants was slightly different between acute care and rehabilitation facilities which illustrated the fact that PI made in orthopaedic units were different to the ones made in geriatric or rehabilitation units. Indeed, orthopaedic surgeons and anaesthetists do not revaluate the usual medications taken by the patient, because LOS in orthopaedic unit are often short. Consequently, some PI regarding reevaluation of usual medications of patients were made exclusively in geriatric or rehabilitation units.

Furthermore, four “DRP and medication categories” almost exclusively made in acute care were of particular interest by the relative number of PI, despite the existing institution postoperative protocol for older patients: “absence of an osmotic laxative medication with a morphine-type treatment” and “supratherapeutic dosage of acetaminophen” either based on the patient’s age, weight or renal function. Thereby, PI permitted to promote the use of this protocol in this specific population throughout our multi-site hospital, which seemed to be underused in acute care. Beyond 5P project, this protocol will be reviewed, regarding heparin and acetaminophen. The latter needed to be discussed in the context of the acute postoperative management of pain and the debate of reducing the dosage to 3g per day only based on the patient’s age. Henceforward, it will be important to raise awareness of this institutional protocol at each turnover of surgery or anaesthetist residents.

Most PI performed in the orthogeriatric care pathway were evaluated by the expert panel as having a significant clinical impact from improving patient’s quality of life (almost one-third of PI rated as “minor”) until preventing major or even vital damage that could have led to hospitalization or death. Similar results have been reported in a previous study using the same tool (CLEO), even if performed only in orthopaedic units with planned and unplanned surgeries, and rating only for a sample of 10% of PI. A strength of the present study is that the evaluation of the potential clinical impact of PI relied on a pluriprofessional and independent expert panel, which permitted to limit the interindividual variations that would have been induced by an evaluation performed by a single expert. No consensus was reached for almost half of PI, which highlights the importance of adapting PI to the step of the orthogeriatric care pathway. Indeed, the priorities of therapeutic management are slightly different between orthopaedic units (where the focus is made on pain and thromboprophylaxis management) and geriatric units including rehabilitation facilities (where a global reevaluation is performed). Further investigations on these differences of clinical impact rating should be conducted in order to increase the clinical relevance of pharmacists towards the prescriber, and so improve even more the quality of care of patients.

The present study has several limitations. Firstly, not all the patients benefitted from all the clinical pharmacy activities, therefore the number of potential ME may have been underestimated, especially in medication reconciliation at discharge. Indeed, an implementation study was conducted and a full-blown analysis of motives of non-realization is being performed. Moreover, according to Mekonnen et al, medication reconciliation seems to be less effective during multiple transitions of care. So it could have been interesting to analyse whether the clinical impact of medication reconciliation was more important at discharge compared to transfer. A limitation of this study is that medication reconciliation at transfer (between units) and at discharge were not distinguished, which could explain the weak proportion of patients who had at least one UID at discharge. Furthermore, the potential clinical impact considered was evaluated only for PI related to prescription reviews, whereas it should also have been evaluated for UID to emphasise the relevance of clinical pharmacy
activities. However, name of medications concerned by UID was not included in the initial data collection plan.

Conclusions
The present study showed that the patient personalised clinical pharmacy care programme permitted to secure the orthogeriatric care pathway by detecting a great number of potential ME, including PI mostly considered as having a significant clinical impact. Thus, the 5P project should be sustained as it permits to improve security and quality of patient therapeutic care throughout the multisite teaching hospital. Indeed, it required to coordinate our practices across units, better communicate between sites if patients were transferred, and enhance collaboration in daily routine between physicians, and with pharmacists and the paramedical teams. Regarding this positive impact on the securitisation of the therapeutic care, we could imagine to develop this new care pathway model of clinical pharmacy to other care pathways.

Ethics Approval and Informed Consent
This study was approved by the ethics committee of the Hospices Civils de Lyon on February, 26th 2019 and the Commission nationale de l’informatique et des libertés (CNIL, French national commission on data protection) following MR004 requirements n°18–314 on May, 1st 2019.

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Author Contributions
All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure
The authors report no conflicts of interest in this work.

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