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Optimising medication management for polymedicated home-dwelling older adults with multiple chronic conditions: a mixed-methods study protocol

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ABSTRACT

Introduction Optimal medication management is one of the basic conditions necessary for home-dwelling older adults living with multiple chronic conditions (OAMCC) to be able to remain at home and preserve their quality of life. Currently, the reasons for such high numbers of emergency department visits and the very significant rate of hospitalisations for OAMCC, due to medication-related problems (MRPs), is poorly explored. This study aims to reveal the current state of the medication management practices of polymedicated, home-dwelling OAMCC and to make proposals for improving clinical and medication pathways through an innovative and integrated model for supporting medication management and preventing adverse health outcomes.

Methods and analysis A mixed-methods study will address the medication management of polymedicated, home-dwelling OAMCC. Its explanatory sequential design will involve two major phases conducted sequentially over time. The quantitative phase will consist of retrospectively exploiting the last 4 years of electronic patient records from a local hospital (N ≈ 50 000) in order to identify the different profiles—made up of patient-related, medication-related and environment-related factors—of the polymedicated, home-dwelling OAMCC at risk of hospitalisation, emergency department visits, hospital readmission (notably for MRPs), institutionalisation or early death. The qualitative study will involve: (a) obtaining and understanding the medication management practices and experiences of the identified profiles extracted from the hospital data of OAMCC who will be interviewed at home (N ≈ 30); (b) collecting and analysing the perspectives of the formal and informal caregivers involved in medication management at home in order to cross-reference perspectives about this important dimension of care at home. Finally, the mixed-methods findings will enable the development of an innovative, integrated model of medication management based on the Agency for Clinical Innovation framework and Bodenheimer and Sinsky's quadruple aim.

Ethics and dissemination Ethical approval has been obtained from the Human Research Ethics Committee of the Canton Vaud (2018-02196). Findings will be disseminated in peer-reviewed journals, professional conferences and other knowledge transfer activities with primary healthcare providers, hospital care units, informal caregivers' and patients' associations.

Strengths and limitations of this study

- ⇒ This mixed methodology will rely on a closely coordinated combination of methods and on the utilisation of valuable existing data underexploited to date (patients' electronic hospital records and Resident Assessment Instrument-Home Care (RAI-HC) data).
- ⇒ The investigation draws on an interprofessional and interdisciplinary approach, which associates general practitioners, community healthcare nurses, pharmacists and researchers in health psychology, old age psychiatry, nursing and survey methodology.
- ⇒ Our findings will contribute to the development of an evidence-based and innovative, cooperative model of medication management for polymedicated, home-dwelling older adults with multiple chronic conditions.
- ⇒ Although patients' electronic hospital records and RAI-HC data provide a broad range of patient-related, medication-related and environment-related information, they rarely highlight factors that may influence the occurrence of medication-related problems.

INTRODUCTION

The number of older adults living at home with multiple chronic conditions (OAMCC) rises considerably around the world and has been estimated to affect 25.2% of people aged from 65 to 79% and 41.3% of those aged 80 and over.[1] Multiple chronic conditions is a comprehensive concept used to properly cover the diverse definitions of multimorbidity[2 3] and therefore the complexity of older adults' health statuses. The concept encompasses the simultaneous presence of an individual's diseases and their chronic physical, mental or behavioural health problems requiring ongoing management over years or decades.[4]

These long-term health conditions require taking multiple medications,[5] known as polypharmacy (PP) when the daily intake

corresponds to five or more medicines.[6] PP places older adults at higher risk of medication-related problems (MRPs), including adverse medication reactions, medication errors and potentially inappropriate medications.[7 8] Potentially inappropriate medications are the intake of medicines for which the associated risks outweigh the potential benefits, particularly when more effective alternatives are available.[9] Consequently, MRPs can lead to a degradation of the patient's clinical condition, physical and cognitive decline, an exacerbation of chronic medical conditions and avoidable health costs.[10 11] Moreover, up to 25% of emergency department visits by home-dwelling OAMCC are due to MRPs.[10] However, 60% of MRPs in patients visiting the emergency department with non-specific complaints (such as weakness) may go undiagnosed, whereas 83% of those MRPs may be responsible for acute morbidity.[10] MRPs are also a frequent cause of readmission, and they were the most frequent cause in one study that followed older patients for 6 months after hospital discharge.[12] Care-coordination problems, associated with low or suboptimal medication management, are all the more evident in the sensitive period of discharge home from hospital.[11 13] The complexity of OAMCC's care needs leads them to be significant users of health services and to consult many different healthcare professionals.[14] The number of healthcare professionals consulted by home-dwelling OAMCC has been directly associated with fragmented and uncoordinated care.[13] Moreover, different healthcare professionals may have different treatment preferences. Failure to coordinate care among home-dwelling OAMCC contributes to MRPs.[13]

In addition to the role of healthcare professionals in medication management, informal caregivers play a vital role in ensuring safe and appropriate medication use by home-dwelling OAMCC, especially among those who may also have cognitive impairment.[15–17] Despite the important role of informal caregivers in medication management, several complications to do with their activities have been documented in relation to the time spent, anxiety making a mistake and the uncooperative behaviour of the home-dwelling OAMCC.[18] They are also confronted with difficulties in maintaining continuous supplies of medication, assisting with administration, making clinical judgements (eg, in response to side effects and about over-the-counter medication), and solving conflictual communications or disagreements with the older adult,[18] or even with healthcare professionals, with regard to ineffective and addictive medication practices.[15 18]

Nonetheless, many MRPs are preventable.[8 10 19] Studies about medicine-related hospitalisations suggest that up to 58% may be preventable with appropriate primary care.[8] An essential strategy for medicine-related hospitalisations prevention and medication safety is medication reconciliation—the process of creating and maintaining a single list of the patient's current list of medications.[20] This process allows a systematic and comprehensive review of all the medications the patient is taking, reducing medication errors by a consistent communication across transitions of care.[21]

Therefore, optimising medication management among home-dwelling OAMCC requires regular monitoring of MRPs, interprofessional collaboration across different health and social care providers, organisations and departments[13] and medication reconciliation at every transition of care including changes in the clinical setting, practitioner or level of care.[22]

Aim and objectives

This study's aim is to document the current state of medication management practices of polymedicated, home-dwelling OAMCC and to make proposals for improving evidence-based clinical and medication pathways through an innovative, integrated model intended to support medication management and to prevent adverse health outcomes related to MRPs (recurrent hospitalisation, emergency department visits, institutionalisation in nursing homes and early death). To achieve this aim, three main objectives will guide this project:

The first objective is to carry out a *retrospective analysis of patients'* hospital records, their medication and environment-related factors in order to identify those that increase the risk of hospitalisation, emergency department visits, hospital readmission (notably due to MRPs), institutionalisation or early death, among home-dwelling polymedicated OAMCC—factors that prevent OAMCC from staying at home.

The second objective is to use *a prospective qualitative study* to explore and better understand *the medication experiences and practices of home-dwelling OAMCC with different profiles*. We seek to identify the skills and strategies developed by them to manage polymedication within their social contexts and health trajectories despite possible cognitive impairment and particularly after a recent hospitalisation.

The third objective is to better understand the *roles and coordination of the different caregivers involved in the medication management of home-dwelling OAMCC*. We seek to investigate the perspectives of both professional caregivers (community healthcare nurses, pharmacists, general practitioners or specialist physicians) and non-professional/informal caregivers (family members, friends or neighbours).

METHODS

Study design

To enable us to meet our objectives, a mixed-methods study will address the medication management of polymedicated, home-dwelling OAMCC.[23] Two major phases will be conducted sequentially from February 2019 to January 2022: a quantitative data collection phase followed by a qualitative phase. The reasons for using an explanatory sequential design are, first, that existing data in electronic patient records from a local hospital will enable us to identify profiles affected by similar patient-related, medication-related and environment-related factors

among the polymedicated, home-dwelling OAMCC at risk of hospitalisation, emergency department visits, hospital readmission (notably due to MRPs), institutionalisation or early death. Second, the identified profiles extracted from the hospital data will allow proceeding to a purposive sampling—of those polymedicated, home-dwelling OAMCC who present with more risk factors—for the qualitative data collection focused on medication management at home. Thus, the analysis of the results from the retrospective quantitative phase will be integrated with the data collected from the prospective qualitative phase. Finally, phase 3 will develop a Medication Management Model based on interpreting the quantitative and qualitative findings.

Phase 1: retrospective quantitative analysis

To fulfil the first objective, the purpose of the quantitative phase is to identify the different profiles—made up of patient-related, medication-related and environment-related factors—of the polymedicated, home-dwelling OAMCC at risk of hospitalisation, emergency department visits, hospital readmission (notably for MRPs), institutionalisation in nursing homes or early death (before the average age of death described by the Organisation for Economic Cooperation and Development in 2018).[24] A systematic, retrospective chart analysis of the electronic patient records from a local hospital over the last 4 years using the evidence-based methodology developed by Vassar and Holzmann will provide substantial clinical information.[25] Motheral *et al*'s standardised extraction sheets will be adapted to explore and assess the data of older inpatients or emergency department-visiting home-dwelling older adults.[26] The 4-year analysis was selected based on the availability of systematic, well-coded patient data using the Swiss-Diagnostic Related Groups[27] and the Swiss Classification of Surgical Interventions (CHOP).[28]

Research population

All home-dwelling OAMCC with somatic and/or mental health disorders who were hospitalised, rehospitalised or who consulted the emergency department (for MRPs or other reasons) at the partner hospital between 2015 and 2018 (estimated n=50 000) will be included. The estimated sample of 50 000 older adults' electronic inpatient charts are part of the 40 000 yearly adult inpatients in acute care units and more than 40 000 adult emergency department consultations yearly at the partner hospital. To explore generalisability, we will compare their sociodemographic and health status characteristics with those of the national sample of hospitalised older adults in Swiss hospitals for the same period.

Data collection

Data from the hospitalisation and emergency admissions databases will be collected on patient-related, medication-related and environment-related factors that could have influenced the occurrence of MRPs that resulted in hospitalisation, rehospitalisation or emergency department admission.

Patient-related factors comprise sociodemographic characteristics, the International Classification of Diseases 10th version (ICD-10) diagnostics (main diagnosis and comorbidities), the Swiss Classification of Surgical Interventions (CHOP) category and the reason for hospitalisation, rehospitalisation or emergency department admission. Supplementary filters will be added to discriminate polymedication, multimorbidity (secondary ICD-10 diagnosis), physical and cognitive impairment documented in the clinical data files (Function Independence Measure, Mini-Mental State Examination and Activities of Daily Living).

Medication-related factors include the number, types and changes in medication at admission, during hospitalisation and at discharge.

Environment-related factors include the presence of formal and/or informal caregivers, patient's provenance (rural or urban), hospital pathways (wards and eventual transfers), length of stay, readmissions (number of admissions in the previous year, 30-day readmission and unplanned readmission), discharge destination and, potentially, death during hospitalisation. A unique patient identification number will allow us to analyse rehospitalisations via the emergency department during the period from 2015 to 2018. Retrospective data collection began in April 2019.

Data analyses

The data set of polymedicated, home-dwelling OAMCC will be analysed using multivariate regression analysis, in order to identify the patient-related, medication-related and environment-related factors that can increase the risk of hospitalisation, emergency department visits, readmission (notably due to MRPs), institutionalisation or early death. Furthermore, the profiles of polymedicated, home-dwelling OAMCC hospitalised or visiting the emergency department due to MRPs, and identified via multicluster analysis, will serve to guide the qualitative study and lead to a purposive sampling of polymedicated, home-dwelling OAMCC presenting with more risk factors. A draft of the cluster analysis strategy is available as an online supplementary file.

Phase 2: prospective patient-centred qualitative analysis

To meet the second and third objectives, a qualitative investigation, based on purposive sampling, will draw on work done in a feasibility study.[29] This qualitative investigation will consist of collecting and understanding the medication practices and experiences of OAMCC presenting with the risk factors identified in the first phase. The focus will be on identified OAMCC who were recently hospitalised and are at risk of hospital readmission. The older adult will be interviewed at home on two separate occasions. This methodology is a way to analyse changes in their medication practises and their experiences following their recent hospitalisation. The data

collection tools include a walking-interview[30] based on a medication journal and household photographs of where medication is stored. This allows us to focus on the tangible practices of OAMCC and contextualises them within the private space of their daily lives.

To discriminate the older adults' health profile, we will use the Resident Assessment Instrument-Home Care (RAI-HC) introduced by the Swiss Association for Home Care Services for all home care services in 2004. Based on a comprehensive geriatric assessment, the RAI-HC both allows for the establishment of an individualised care plan and generates quality indicators, plans resource use, optimises the medication management process by monitoring and documenting the number and types of medication and the persons involved in preparing medication, and regularly assesses adherence to the medication prescribed.[31] This instrument will provide information on the patient-related, medication-related and environment-related factors which may influence the occurrence of MRPs, and it will be used to recruit OAMCC at risk of or already presenting with MRPs.

Furthermore, we will also collect and analyse the perspectives of the formal and informal caregivers involved in medication management at home to cross-reference perspectives about this important dimension of care at home.

Research population

The profiles of the polymedicated OAMCC hospitalised/rehospitalised or consulting the emergency department, as identified in the retrospective investigation, will be used to select participants for the qualitative investigation. A theoretical, purposive sampling will be carried out. Based on Guest *et al*, the principal investigator will recruit about 30 polymedicated OAMCC (until saturation of data), all recently hospitalised (within the last 90 days) and at risk of hospital readmission.[32] For each OAMCC participant, an informal caregiver will also be integrated into the investigation. We defined informal caregivers as any family member, neighbour or friend assisting a dependent older adult with certain activities in their daily life. That assistance, help, care or physical presence must be given on a regular basis, for at least two basic activities or instrumental activities of daily living or to ensure patient safety, and for 6 months or more.[33] The informal caregiver will be included in the study if the recruited older adult identifies that person as being significant in their medication management and if they give informed written consent to participate.

Furthermore, a formal caregiver will be integrated into the investigation for each participant. Professional caregivers are those employed to provide professional healthcare services (ie, nurses, nursing assistants, general practitioners, pharmacists and social workers). They will be included in the study if the recruited OAMCC identifies them as the professional most involved in their medication management.

Table 1 presents the specific inclusion/exclusion criteria for each group of participants.

Participant recruitment

Polymedicated, home-dwelling OAMCC will be recruited via two paths so that all of the participants meet the eligibility criteria and fit corresponding profiles established in the quantitative phase. Some OAMCC will be receivers of care from Community Healthcare Centres and others will be functioning without that day-to-day support.

Table 1 Phase 2 inclusion and exclusion criteria

Participants	Inclusion criteria	Exclusion criteria
OAMCC	► Aged 65 or above ► Man or woman ► Hospitalised within the last 90 days ► Managing at least five different medications (prescribed and over-the-counter medications explored during recruitment) ► Suffering from multiple chronic conditions[4] ► Living alone or in a couple, in a rural or urban area ► With or without support from a Community Healthcare Centre	► Not able to speak and understand French
Informal caregiver	► Designated by the OAMCC as the most significant informal caregiver involved in medication management ► Aged 18 or above	► Not able to speak and understand French
Professional caregiver	► Designated by the OAMCC as having a key role in medication management	► Student ► Apprentice

OAMCC, older adults living with multiple chronic conditions.

- For OAMCC who do not receive support from a Community Healthcare Centre, recruitment will be based on variables in their patient files and carried out in collaboration with different nursing departments from the partner hospital.
- For OAMCC who do receive support from a Community Healthcare Centre, recruitment will be based on the clinical and health data documented in the RAI-HC and carried out in collaboration with community healthcare nurses from Sion Community Healthcare Centre.

Research nurses partnering the project, from a hospital or a Community Healthcare Centre, will briefly explain the study to the patient. Potential participants will be asked for permission to give their name to the researchers. The principal investigator will contact the older adult by telephone during the week following hospital discharge and ask for their agreement to participate in the study. In case of agreement, a first meeting will be organised at the older adult's home in the next few days. Participant recruitment will start in October 2019.

Data collection from OAMCC

During the first home meeting with the OAMCC, the principal investigator will provide all the study details and will suggest two semistructured interviews, each lasting about an hour, starting on the first meeting and spaced 2–3 weeks apart. According to participants' levels of tiredness, it may be necessary to subdivide the interviews. The older adult will be invited to sign the informed written consent form, allowing the researcher to collect sociodemographic and health data (RAI-HC and the patient's hospital records). Eligible home-dwelling OAMCC from both recruitment paths will be screened using the RAI-HC Minimal Data Set (MDS), which includes information on polymedication (section P), multiple chronic conditions (sections J and K) and recent hospitalisation (section Ac). Research team members trained on the RAI-HC will also carry out this evaluation for participants who do not have an RAI-HC. The following multidimensional clinical data will be retrieved from the RAI-HC MDS: cognitive status, hearing, vision, mood status, functional and physical status, continence, healthcare problems and nutritional state. The MDS will aid interviews with OAMCC and the exploration of the facilitators and barriers to daily medication management.

The first semistructured interview will collect the perspectives of OAMCC with regard to their medication management, the return home, information received about their treatment and its possible modifications, whether their opinions and preferences were taken into account in the prescription of medications, and the informal and professional caregivers involved. OAMCCs will be interviewed alone or with an informal caregiver, if necessary. The principal investigator will then ask the participant to complete a week-long medication journal,[34 35] either alone or with the help from informal or professional caregivers, emphasising that any information on daily medication routines is helpful, even if the OAMCC feels unable to complete the journal for the full 7 days. The instructions will mention the importance of noting all the medicines taken—those prescribed by general practitioners or specialist physicians, but also any others taken at their own initiative (over-the-counter medications). Participants will be asked to note their perceptions of and satisfaction with their treatment in a week-long medication journal. This will provide information on the daily routines associated with the participant's medication and will form the basis of the second interview.

The second interview will be based on the participant's medication journal and will take the form of a walking-interview[36] using household photographs.[35] The principal investigator will ask the participant to explain their medication practises while pointing out the locations within their home where drugs are stored, prepared and taken. The hypothesis underlying this methodology is that the physical presence of drugs promotes discussion.[37 38] We will identify and photograph, with the participants' agreement, the places where medication, contact details for medical professionals and other information are stored as well as the locations of any other objects involved in daily care practises. The collection and analysis of photographs provide a better understanding of the complexity of medication management in home settings. They help to capture the interviewee's concerns or strategies when they are pointed out to the interviewer. The interview guide will also investigate the issue of self-medication in order to reveal the extent and influence of this practice.

Data collection from informal caregivers

Sociodemographic data and information related to medication management will be collected. When possible and appropriate, a joint third interview[39] with the OAMCC and their principal informal caregiver[34] will be organised at the older adult's home 1–2 weeks after the walking interview. This type of interview provides access to the interactions between OAMCC and their informal caregivers with regard to medication management. We hypothesise that the main informal caregiver is deeply involved in the older adult's experience of medication management, but the caregiver's ideas about this may be similar to, overlapping with or different from those of an OAMCC.

Data collection from professional caregivers

A semistructured interview of about 1 hour will be conducted with a professional caregiver in order to explore their point of view on the OAMCC's medication management and other issues associated with the return home after hospitalisation. In agreement with the project's field partners and stakeholders, these interviews will take place in professionals' workplaces (Community Healthcare Centre, medical practice office or pharmacy), during working hours, 1–2 weeks after the interview with the OAMCC and their informal caregiver.

Qualitative data analyses

A database will be prepared using the RedCap software platform to record and store the participants' sociodemographic, health and interview data. Information on their health statuses will be collected using the RAI-HC data and will be analysed using the IBM-Statistical Package for Social Sciences V.25.0.

Data collected via the interviews will be examined according to an analytical plan that integrates and compares two different methods. First, thematic content analysis,[40 41] using NVivo V.12 software, will be used to identify the themes emerging from the data, and this will provide a rich, detailed account of the data set. Themes will be compared by different members of the analysis team until a consensus is reached. Second, lexicometric analysis, using Iramuteq software—a technique derived from the Alceste method[42]—will allow a very fine exploration, both within each interview and across the whole corpus of interviews, of the structures underlying the discourse. Each older adult's medication journal will be analysed and categorised according to the same principles as the interviews. The data collected from these documents will be put into perspective by the analysis of the interviews. In the final data analysis, links will be made between the interviews, the medication journal, the older adult's RAI-HC data and the photos of the medicines' locations.

Phase 3: development of a medication management model

Connecting retrospective and prospective findings, using an explanatory sequential design and participants' different perspectives, will contribute to a deep understanding of the current state of medication management practices of polymedicated, home-dwelling OAMCC. This mixed-methods study corresponds to the 'diagnostic' phase of the process of developing a Model of Care, as presented by the Agency for Clinical Innovation (ACI).[43] It will guide the 'solution design' phase—the next step in the creation of an innovative, integrated model for supporting medication management and preventing adverse health outcomes. In addition to the ACI's framework, the development of a proposed Medication Management Model will consider the quadruple aim of enhancing the patient's experience, improving population health, reducing costs and improving the working lives of healthcare providers.[44]

Finally, our mixed-methods research findings will be completed with those of an ongoing systematic review of Medication Management Models.[45]

The study phase outcomes are summarised in table 2.

Table 2 Outcomes for each study phase

Phase 1 outcomes	Patient-related, medication-related and environment-related factors which can increase the risk of hospitalisation, emergency department visits, hospital readmission (notably due to MRPs), institutionalisation or early death. Profiles of polymedicated, home-dwelling OAMCC hospitalised or visiting the emergency department due to MRPs based on the previously identified patient-related, medication-related and environment-related factors.
Phase 2 outcomes	For OAMCC participants: ► Patient-related, medication-related and environment-related factors for MRPs (defined by phase 1's outcomes) extracted from the RAI-HC MDS and the patient's electronic hospital records (number and types of medication, multiple chronic conditions, recent hospitalisations, cognitive status, hearing, vision, mood status, functional and physical status, continence, healthcare problems and nutritional state). ► Medication practices and experiences of OAMCC following their recent hospitalisation, facilitators/barriers to medication management, informal and professional caregivers involved. For informal caregivers: ► Sociodemographic profiles. ► Practices and experiences related to medication management. For professional caregivers: ► Sociodemographic and professional profiles. ► Role and perspectives on OAMCC medication management. ► Coordination activities related to returning home after hospitalisation.
Phase 3 outcomes	Three first steps in the process of developing a Model of Care[43]: ► 'Project initiation'. ► 'Diagnostic'. ► 'Solution design' considering the quadruple aim. Proposals for the Medication Management Model's 'Implementation' and 'Sustainability' steps[43] to support medication management and to prevent adverse health outcomes related to MRPs.

MDS, Minimal Data Set; MRPs, medication-related problems; OAMCC, older adults living with multiple chronic conditions; RAI-HC, Resident Assessment Instrument-Home Care.

Patient and public involvement

This study and the feasibility study on which it is based were developed in collaboration with representatives from a Community Healthcare Centre, a regional hospital, medical and pharmacy associations and an informal caregivers association. They shared their expertise on the study's relevance and the feasibility of data collection with the research team. Patients' priorities, experiences and preferences, collected during the feasibility study, were the drivers for the development of the research question and outcome measures.

A steering committee will involve these different actors at various stages in the project, both to contribute to data collection and to provide their expertise to the coconstruction of a Medication Management Model and its future implementation. As regards data collection, the hospital's medical informatics department will provide the appropriate data based on a data extraction protocol (phase 1) and the Community Healthcare

Centre will help with OAMCC recruitment and access to participants' RAI-HC and professional caregivers (phase 2).

Results will be disseminated to study participants through presentations to associations of patients and informal caregivers and at professional training sessions.

ETHICS AND DISSEMINATION

With the approval, the medical informatics department of partner hospital will provide the appropriate data for the retrospective phase based on a data extraction protocol. Extracted data will be delivered and stored in the ReDCap data platform via a secure coded data file. In coherence with the Data Management Plan submitted to the Swiss National Science Foundation, the collected data will be securely stored for future research.

The autonomy of the participants will be respected. Participation in the prospective phase in this research is free. It will be possible for participants to refuse to record the interview or to request the deletion of the recorded data. Participating in a structured effort to understand medication practises and the posthospital return home experience can contribute to improvements in health management in the community at large, and particularly in the area of home support.

Findings will be disseminated in peer-reviewed journals, professional conferences and other knowledge transfer activities with primary healthcare providers, hospital care units, informal caregiver and patient associations.

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Contributors FP, PR and HV had the original idea. MSD, AVG, BW, MMM and HV provided conceptual and methodological expertise to the design of the research protocol. FP, PR and HV were major contributors to writing the manuscript. All authors read, edited and approved the final manuscript.

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