#### ARTICLE IN PRESS

Geriatric Nursing xx (2017) 1-5



Contents lists available at ScienceDirect

## **Geriatric Nursing**

journal homepage: www.gnjournal.com



#### Feature Article

### Adverse drug events reported by rural older adults

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#### ARTICLE INFO

# Article history: Received 21 December 2016 Received in revised form 14 April 2017 Accepted 24 April 2017 Available online xxx

Keywords:
Adverse drug events
Rural
Older adults
Health status
Potentially inappropriate medications

#### ABSTRACT

Adverse drug events (ADEs) impact the health and safety of older adults. ADEs may lead to unplanned medical visits that influence health and related costs. The purpose of this study was to explore ADEs reported by rural, community-dwelling older adults. Data were collected on 138 participants' demographics, physical and mental health, sleep, medications, and ADEs. One or more ADEs were reported by 48% of participants, including central nervous symptom disturbances (16%), dry mouth (12%), hoarseness, gastrointestinal irritation, and decreased libido (all 8%). Poor sleep and poor physical health were associated with higher reported ADEs (p < 0.05). Older adults (ages 79–99) and those with higher physical health were 60% less likely to report ADEs. Those with poorer sleep quality were 50% more likely to report ADEs. Viable strategies are needed to monitor and reduce ADEs in community-dwelling older adults who use multiple medications to manage poor health and poor sleep.

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#### Introduction

The prevention of adverse drug events (ADEs) has become a national priority. An ADE is any physical or mental harm that results from a medical intervention related to medications. ADEs include side effects, medical errors, adverse drug or allergic reactions, and overdoses. ADEs contribute to nearly 280,000 of U.S. annual hospital admissions and have been shown to result in high medical expenditures. Estimates of ADEs in outpatients vary, with a higher incidence occurring in adults ages 65 and older. Older adults are susceptible to pharmacokinetic and pharmacodynamic changes and become more sensitive to medications, which in turn increases the risk of drug—drug interactions and ADEs.

The prevalence of ADEs estimated to be attributed to prescribed medications has been as high as 30% in older adults. <sup>7,8</sup> Medication categories such as cardiovascular, hypoglycemic, and anticoagulants have been associated with over 27% of preventable ADEs in U.S. community-dwelling older adults. <sup>1,9,10</sup> In the ambulatory setting, older adults who took non-opioid analgesics and diuretics had an increased risk for ADEs. <sup>11</sup> Other studies reported that ADEs were predicted by warfarin, benzodiazepines, and the use of a

higher number of overall medications.<sup>12–14</sup> The Beers Criteria is a clinical resource to promote safety and reduce the occurrence of ADEs by targeting potentially inappropriate medications (PIMs) that have evidence of increasing the risk of drug—drug and drug—disease interactions in older adults. Published in 1997, the Beers Criteria classifies medications as PIMs if the risk of use outweighs the benefit in general populations of ambulatory elderly adults.<sup>15</sup> A rigorous update of the criteria was published in 2012.<sup>16</sup>

The relationship between ADEs and the use of PIMs is complex. Community-dwelling older adults taking PIMs have reported ADEs and geriatric syndromes, such as falls.  $^{17-21}$  An increase in the use of inappropriate medications predicted the increased odds of an ADE.  $^{22}$  Researchers also have reported the use of PIMs results in fewer ADE emergency department and acute visits when compared to other medications such as warfarin and insulin.  $^{23-25}$ 

Older adults with decreased homeostatic responses related to poor health may be more susceptible to the negative events of medications.<sup>6</sup> Poor health may manifest as self-reported poor physical and mental health functioning, pain, and disrupted sleep.<sup>26–29</sup> The comprehensive view of health in older adults includes not only the physical and mental components, but also functioning and sleep quality.<sup>30</sup>

Those living in rural communities have been reported to have more chronic illness burden and use more medications than those in urban areas.<sup>31</sup> PIMs such as benzodiazepine receptor agonists

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have been reported to be prescribed to older adults in rural settings more often than in urban settings. <sup>32</sup> In rural areas, older individuals self-manage symptoms by taking over-the-counter (OTC) products that increase polypharmacy. <sup>27</sup> Not only are there health provider shortages in rural settings, <sup>33</sup> but primary health care providers may not be aware of all prescribed and additional OTC medications used, increasing the risk for ADEs. <sup>34,35</sup> ADEs are difficult to recognize and present additional challenges in rural-dwelling older adults with less access to emergency medical care. <sup>28,36</sup> The overall use of prescribed and OTC medications, that have drug—drug interactions has increased since 2005, placing older adults at additional risk for ADEs. <sup>37</sup>

Medical and pharmaceutical research has emphasized the importance of ADEs related to specific medications and prevalence rates. Patient-centered concepts such as medication beliefs and perceived illness and symptoms have been associated with self-reported ADEs. The perceptions an older adult has about his/her medicines may influence expectations and how he/she interprets symptoms. <sup>38,39</sup> We chose to explore self-reported ADEs using a nursing model among rural, community-dwelling older adults. The use of a nursing model may guide nurses in recognizing and reducing ADEs. The purpose of this study was to explore the characteristics of self-reported ADEs and their relationships with individual health characteristics of rural, community-dwelling older adults. We also examined predictors of self-reported ADEs. We hypothesized that older adults who used PIMs and considered their health status as poor would have a higher probability of ADEs.

#### Materials and methods

The Interaction Model of Client Health Behavior (IMCHB) guided this study because no pharmacologic or medical models were identified that examined ADEs in a holistic manner. The IMCHB is a unique approach to examine ADEs in independent older adults and can guide nursing research and practice. The original IMCHB by Cox is a theoretical nursing model developed to characterize the interactions that occur between a patient's needs, interventions, and health care outcomes following an experience with a nurse. The main components of the IMCHB are client singularity, client—professional interaction, and health outcomes. 40

Client singularity is made up external and internal factors that are transformed into measureable variables. The external variables of client singularity in the IMCHB model are background demographic characteristics, social influence, health experience, and environmental resources. The internal variables of client singularity include: intrinsic motivation, cognitive appraisal, and the affective response. The health outcome variables include: utilization of health care services, clinical health status indicators, severity of the health care problem, adherence, and care satisfaction. The elements of the client—professional interaction in the model represent interventions that may influence the elements of client singularity and the health outcome. 40

In this descriptive study, the IMCHB was adapted and used as a holistic and patient-centered approach to exploring ADEs. In conjunction with the original IMCHB, demographic characteristics and health experiences were measured as background external variables. Internal variables included the older adult's cognitive appraisal of health status. Self-reported ADEs were assessed as the outcome.

#### Sample/setting

A convenience sample of independent older adults was recruited from a rural Midwestern family practice clinic from January to October 2015. Rural urban commuting area (RUCA) codes 7 and 10 were assigned to zip codes to classify small rural versus isolated rural status. Men and women were screened for participation according to inclusion and exclusion criteria. Inclusion criteria were: adults  $\geq$ 65 years of age, living independently, taking  $\geq$ 3 prescribed medications, scoring  $\geq$ 26 on the Montreal Cognitive Assessment (MOCA),<sup>41</sup> and available during the data collection period. Exclusion criteria were: those not responsible for taking their own medications, unable to complete forms or read and speak English, or currently taking prescriptions for cognitive impairment.

#### Measures

Demographic data were comprised of age, gender, zip code, and income. Health experience data included the current number of health providers, medications, medical diagnoses, and comorbidity severity. Data on medications taken in the last month included prescribed, OTC, herbal, vitamin, and supplements. Names of drugs, dosage, frequency, and length of use were verified with each participant's medical records. Additional information was recorded, such as the routine for taking medications and pharmacy use. Participants' medications were compared to the 2012 Beers Criteria in order to document PIMs use. 16 The 2015 Beers Criteria update was not used because it was published in November 2015 after data collection ended. 42 PIMs were recorded on an investigator-derived log derived from medications to avoid on the 2012 Beers Criteria. Chronic medication use was defined as at least weekly use of a medication for the past 3 months. Medical diagnoses were recorded from each participant's medical record, and the Charlson Comorbidity Index was used to assess comorbidity severity.<sup>43,44</sup>

Health status data included self-reported physical and mental health and sleep quality and disturbance. The 12-Item Medical Outcomes Survey (MOS) Short Form (SF-12) was used to measure self-reported physical and mental health status<sup>45</sup>; the Cronbach's alpha in this study was 0.82. The Pittsburgh Sleep Quality Index (PSQI) and Patient Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance SF-8A measured self-reported sleep quality, sleep depth, and sleep restoration.<sup>46,47</sup> The Cronbach's alphas in this study were 0.74 and 0.88, respectively.

ADEs were defined in this study as any harm resulting from a pharmacological intervention.<sup>2,4</sup> Currently, we are unaware of reliable and valid tools to operationalize ADEs. The Naranjo Algorithm has been a popular criterion for determining the probability of an adverse drug reaction. The algorithm may be unethical to apply among older adults because it requires intense monitoring of medication use, along with the measurement of medication concentrations in the blood or bodily fluids.<sup>36</sup> ADEs were described to participants as any unintended, undesirable, or harmful effect resulting from the treatment of a medication, and participants were given an adapted version of the clinical Questionnaire for Detecting Potential Adverse Drug Reactions. 48 The questionnaire provided a way to categorize participants' self-reported symptoms by body system for methodical assessment of side effects. The original questionnaire was composed of 24 questions, with multiple examples of symptoms listed to correspond with each body symptom. In the effort to reduce participant burden, the questionnaire was adapted to 23 dichotomous (yes/no) questions that assessed each participants' self-reported ADEs for each body system during the last month. A response of yes was followed by an additional question that assessed whether the participant believed the symptom was related to a medication. For example, "Did you have any symptoms (complaints/irritation) related to your stomach or digestive system?" and "If yes, do you believe it was related to a edication you took?" A pharmacist with expertise in geriatrics reviewed all self-reported data on ADEs and PIMs.

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