ISSN 0120-4157

Biomédica

Revista del Instituto Nacional de Salud

Citación provisional:

Pineda E, Fernández A, Curcio CL, de Souza JF, Vafaei A, Gómez JF. Medicación potencialmente inapropiada en adultos mayores de la comunidad: Análisis longitudinal del estudio IMIAS. Biomédica. 2024;44 (2).

Recibido: 27-04-23

Aceptado: 15-03-24

Publicación en línea: 18-03-24

Medicación potencialmente inapropiada en adultos mayores de la comunidad: Análisis longitudinal del estudio IMIAS

Potentially inappropriate medication on community-dwelling older adults: Longitudinal analysis of IMIAS study

Edison Pineda [1,2], Alejandra Fernández [3], Carmen Lucía Curcio [1,2], Juliana Fernandes de Souza [4], Afshin Vafaei [5], José Fernando Gómez [1,2]

[1] Facultad de Ciencias para la Salud, Universidad de Caldas, Manizales, Colombia

[2] Grupo de Investigación en Gerontología y Geriatría, Facultad de Ciencias para la Salud, Universidad de Caldas, Manizales, Colombia

[3] Hospital Alma Mater de Antioquia, Medellín, Colombia

[4] Laboratório de Fisioterapia e Saúde Coletiva, Departamento de Fisioterapia da Universidade Federal de Pernambuco, Recife, Brasil

[5] School of Health Studies, Western University, Kingston, Ontario, Canada

Corresponding author:

José Fernando Gómez, Facultad de Ciencias para la Salud, Universidad de Caldas, Manizales, Colombia, Edificio Miguel Arango Soto, Carrera 25 N° 48-57, Manizales, Colombia

Telephone: (57) 878 3060, extension 31261.

gomez.montes@ucaldas.edu.co

Author contributions:

All authors participated in the interpretation of study results, and in drafting, critically revising, and approving the final version of the manuscript. All authors agree to be accountable for all aspects of the work.

Introducción. Los fármacos son parte fundamental del tratamiento de múltiples patologías, sin embargo, a pesar de sus beneficios algunos son considerados medicamentos potencialmente inapropiados (MPI) en los ancianos dado su perfil de seguridad. Las diferencias en los datos epidemiológicos relacionados con los MPI contribuyen a la dificultad de determinar los efectos de estos en los ancianos.

Objetivo. Estimar la prevalencia longitudinal y los tipos de MPI utilizando los criterios Beers 2019 en adultos mayores de 65 años en una cohorte.

Materiales y métodos. Estudio observacional, multicéntrico, retrospectivo, longitudinal de 4 años de seguimiento de los MPI en adultos mayores de la comunidad.

Resultados. 820 participantes, de 5 ciudades diferentes, fueron seguidos durante 4 años (*m1*= 2012, *m2*= 2014 y *m3*= 2016), la edad promedio fue 69,07 años, 50,9% fueron mujeres. La prevalencia de MPI en los participantes fue de 40,24%. El promedio de MPI entre los sujetos estudiados en *m1* fue de 1,65 (DE: 0,963), en *m2* de 1,73 (DE: 1,032) y en *m3* de 1,62 (DE: 0,915), no hubo diferencias estadísticas entre las mediciones (valor de p prueba de Friedman = 0,204). Las categorías de MPI más frecuentes fueron: gastrointestinal (39,4%), analgésicos (18,8%), medicamentos relacionados con delirium (15,4%), benzodiacepinas (15,2), y cardiovasculares (14,2%).

Conclusiones. La prescripción de MPI estuvo presente de manera sostenida y sin variabilidad importante en el tiempo en cerca de la mitad de la población de adultos mayores de la comunidad, principalmente medicamentos gastrointestinales, analgésicos, relacionados con delirium, benzodiacepinas y uso cardiovascular.

Palabras clave: lista de medicamentos potencialmente inapropiados; polifarmacia; anciano; vida independiente; prevalencia; estudios longitudinales.

Introduction. Medications are a fundamental part of the treatment of multiple pathologies, however, despite their benefits, some are considered potentially inappropriate medications (PIM) in the elderly given their safety profile. Differences in the epidemiological data related to PIMs contribute to the difficulty of determining the effects of these in the elderly.

Objective. Estimate the prevalence and types of PIM using the 2019 Beers criteria in adults older than 65 years in a cohort.

Materials and methods. Observational, multicenter, retrospective, longitudinal study of 4 years of follow-up of PIM in community-dwelling older adults.

Results. 820 participants from 5 different cities, were followed for 4 years (*m1*= 2012, *m2*= 2014 and *m3*= 2016), the mean age was 69.07 years, 50.9% were women. The PIM prevalence in the participants was 40.24%. The mean PIM among the subjects studied in *m1* was 1.65 (SD: 0.963), in *m2* it was 1.73 (SD: 1.032) and in *m3* was 1.62 (SD: 0.915), there were no statistical differences between measurements (Friedman test p value = 0.204). The most frequent PIM categories were: gastrointestinal (39.4%), analgesics (18.8%), delirium-related drugs (15.4%), benzodiazepines (15.2), and cardiovascular (14.2%).

Conclusions. The prescription of PIM was present in a sustained manner and without significant variability over time in about half of the population of community-dwelling older adults, mainly gastrointestinal drugs, analgesics, delirium-related drugs, benzodiazepines, and cardiovascular use.

Keywords: Potentially inappropriate medication list; polypharmacy; aged; independent living; prevalence; longitudinal studies.

The number of older people and life expectancy worldwide has significantly increased. It is estimated that the global geriatric population will grow at a rate close to 3% annually, a higher rate than any other age group (1). The significant increase in the elderly population in recent decades, especially in low- and middle-income countries, is a well-recognized situation. In 1990, the elderly population was approximately 6%, which increased to nearly 14% in 2020 and is expected to reach around 30% in 2050 (2). Aging is characterized by a progressive inability to maintain homeostatic balance and is associated with the decline of organ functions, which translates into a predisposition of the elderly population to develop multiple comorbidities (3). In recent decades, the continuous use of medications has increased along with the number of non-communicable chronic diseases and life expectancy (4). Despite their benefits, some prescriptions are considered potentially inappropriate medications (PIM) in older adults. PIMs are those in which the risks of harm outweigh the potential benefits, i.e., those that are not indicated or lack evidence of efficacy and those that do not align with patients' goals/preferences and values (5,6). The Beers criteria have been used for identifying PIMs in multiple studies, and its most recent update was made in 2019 by the American Geriatrics Society (AGS) (7). Previous studies have investigated the risk of adverse reactions caused by PIM in the treatment of chronic diseases, the safety of single-category PIM (anticholinergics) used by elderly patients, and the hazards of PIM use in elderly patients in continuous care (8). Results are variable, showing that PIM prescriptions may be associated with potential risks for the elderly. However, it is postulated that this variability may be related to discordance of parameters such as prevalence given the variability in the methodology used in different studies (cross-

sectional, longitudinal), or the place of evaluation of the elderly (institutionalized, hospitalized in general ward or ICU, or living in the community) (9-15). Therefore, the purpose of this study is to determine the prevalence of PIM in community-dwelling elderly individuals with sustained exposure to PIM and to characterize the most frequently prescribed PIM groups.

Materials and methods

Study population

A longitudinal analysis was conducted using data from the International Mobility in Aging Study (IMIAS), a population-based study of 2002 community-dwelling older adults in five different social and cultural contexts: Kingston (Ontario, Canada), Saint-Hyacinthe (Quebec, Canada), Tirana (Albania), Manizales (Colombia), and Natal (Brazil). The objective of IMIAS was to understand how factors throughout life affect mobility in older adults. The characteristics and details of the study have been described elsewhere (16). The present study followed the guidelines of the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement for reporting observational studies (17). For this study, we used data from older adults who were assessed in 2012 (*m1*), re-evaluated in 2014 (*m2*) and 2016 (*m3*). To identify the cohort of older adults exposed to PIM, the AGS 2019 Beers criteria (7) were operationalized into categories and recommendations identifying PIMs. Participants considered for follow-up were older adults who had all their demographic and clinical data recorded in the database, and in whom the presence of PIM was identified in *m1* and *m2* and *m3* (exposed). Additionally, a group of older adults without the presence of PIM at any of the the evaluation timepoints (*m1*, *m2*, and *m3*) were developed (unexposed) for illustrative purposes. The

rest of the participants, those who presented PIM in only one or two of the evaluation timepoints, were excluded from the analysis.

Data collection

The information was collected in the participants' homes by trained interviewers and physicians using structured questionnaires in *m1*, *m2*, and *m3*. The questionnaire included information about the medications used daily by each participant, and the data were recorded according to the protocol of the IMIAS study. Participants were interviewed and assessed after reading and signing the informed consent.

Main measurement

For the identification of PIMs, operationalization of the AGS 2019 Beers criteria (7) was performed. These criteria have been previously validated and have better performance for detecting potentially inappropriate medications in community-dwelling individuals compared to other strategies (18,19). Using the recorded information, 36 categories and 256 PIM identifying recommendations were developed; however, it was necessary to exclude 40 recommendations due to the absence of data to stratify the renal function of the participants, resulting in the utilization of 81.5% of the recommendations. Subsequently, based on the 216 recommendations used, specialized software was designed and developed using the Synthax® programming language to identify the presence or absence of PIMs in each of the 4350 prescriptions (1 per participant in each of the 3 evaluation moments; *m1*, *m2*, and *m3*) and the category to which the PIM belonged. Sustained exposure was defined as the presence of at least one PIM in all three evaluation timepoints.

Covariates: Sociodemographic: The investigated sociodemographic data was represented by a dichotomous variable for sex, a discrete variable for age, and polytomous variables for marital status and recruitment city.

Clinical variables: The explored clinical variables were the number of chronic diseases, the number of prescribed medications, and the number of falls in the last year. The number of chronic diseases was estimated by summing up the pathologies explored in the structured questionnaire (hypertension, diabetes, cancer, chronic pulmonary disease, heart disease, stroke, osteoarthritis, and osteoporosis). The number of prescribed medications was obtained by reviewing all the formulas and recording the total number of drugs consumed daily by each participant. The number of falls in the last year was estimated by asking the question: "How many times have you fallen in the last 12 months?" The use of health services was explored using the variable "number of visits to the doctor in the last year," defined by the question "How many times have you seen a doctor in the last year?"

Statistical analysis

A descriptive analysis was performed (frequencies, distribution, means, and standard deviation). We conducted a cross-sectional bivariate analysis using Student's T-test and Mann-Whitney U test according to the distribution of the variables, and Chi-square and Fisher's exact test for categorical variables collected in *m1*. The normality of the variables was measured using the Kolmogorov-Smirnov test. A longitudinal bivariate analysis was performed to estimate the change in the proportions of PIM over the 4 years using Cochran's Q test and Friedman test in participants exposed to PIM. All

statistical analyses were carried out using the IBM SPSS version 24.0 for MacOS (SPSS® Inc., Chicago, IL, USA) statistical package.

Ethical considerations

Approval was obtained from the ethics review committees of research centers at the University of Montreal Hospitals (CR-CHUM), Queen's University (Kingston), the Institute of Public Health of Albania, the Federal University of Rio Grande do Norte (Brazil), and the University of Caldas (Colombia). Likewise, in accordance with Resolution 8430/1993 of the Ministry of Health of Colombia regarding studies with human subjects, the study was considered of minimal risk since the participants had a very low probability of suffering harm as a result of the study.

Results

Out of the initial 2002 participants, 25.57% (512) were considered lost to follow-up, resulting in a total of 1490 older adults to whom AGS 2019 Beers criteria were applied in *m1*, *m2*, and *m3*. Among these, 610 individuals were excluded either because they had PIM present in only one or two of the three evaluation timepoints, or because of absence or PIM in one or two of the three evaluation timepoints. This left 820 participants: 330 for analysis, and 490 for comparison purposes (figure 1).

Table 1 presents the baseline characteristics of the study subjects, highlighting statistically significant differences between participants exposed and not exposed to PIM. Just over half of the participants (50.9%) were women, however, the proportion of women between groups was different and higher in the exposed group (58.5% vs 45.7%; p=0.000). The average age was 69.07 years. Approximately 63.9% of study subjects reported their health as good, and when comparing exposure groups, the non-

exposed group reported their health as good more frequently than the exposed group (66.7% vs 59.7%; p=0.022). Exposed older adults had on average more chronic diseases than the non-exposed group [2.3 (SD: 1.3) vs 1 (SD: 1.18); p=0.000]. Overall, the average number of medications per formulation was 4.08 (SD: 2.99), and when evaluating by exposure group, the average was higher in the exposed group than the non-exposed group [(6.18 (SD: 2.87) vs 2.66 (SD: 2.12); p=0.000]. In the non-exposure group, no participants reported falls in the last year. The mean number of doctor visits in the last year was higher in the exposure group than the non-exposure group [6.13 (SD: 5.16) vs 3.86 (SD: 4.2); p=0.000]. Non-exposed participants to PIM had on average better quality of life than those exposed to PIM [7.49 (SD: 2.24) vs 7.21 (SD: 2.16); p=0.027]. The average score on the SPPB test was lower in older adults exposed to PIM than in the non-exposed group [9.56 (SD: 2.1) vs 10.13 (SD: 1.82); p=0.000]. Of the participants exposed to PIM, 7% presented frailty, twice the percentage of their non-exposed counterparts (p=0.018). In *m1*, 12 different categories of PIM were used by older adults, with the most frequently consumed being gastrointestinal (39.4%), analgesics (18.8%), delirium-related drugs (15.4%), benzodiazepines (15.2%), and cardiovascular (14.2%). Four years later (*m3*), 11 categories of PIM were identified and the following were the most common: gastrointestinal (43.1%), analgesics (14.8%), cardiovascular (14.5%), delirium-related drugs (14.2%), benzodiazepines (13.1%). About half of exposed participants received at least one PIM (prevalence: 40.24%). The average PIM among exposed subjects in *m1* was 1.65 (SD: 0.963), in *m2* was 1.73 (SD: 1.032) and in *m3* was 1.62 (SD: 0.915), with no statistically significant differences between measurements (p-value Friedman test = 0.204). Table 2 shows the number of

PIM used per person during the 4-year follow-up, with no statistically significant differences in the distribution of PIM during the three evaluation periods and the results were not modified when adjusted for the different covariates (figure 2).

Discussion

A longitudinal analysis of sustained exposure to potentially inappropriate medication (PIM) was conducted, establishing its prevalence, distribution, and classification in a community-dwelling population of older adults. During the study period from 2012 to 2016, approximately half of the participating older adults received at least one PIM, consistent with estimates made using different versions of the Beers criteria of the AGS (9-12). Chinthalpudi et al. reported a prevalence of PIM using Beers 2019 criteria of 54% in a third-level center (10). Recently, a longitudinal study was published with participants from a US center that used Beers 2019 criteria, finding a prevalence of PIM of 34.4%. Furthermore, there was a significant decrease in the prevalence, from 35.3% in 2011 to 32.5% in 2015 (13). In the present analysis, no change in the proportion of PIM per participant was found in the 4-year follow-up, which could be explained by the presence of participants from various cities with different modifying factors of PIM exposure, contributing to the homogenization of the global sample. This is confirmed by reviewing the results of the population-based study by Roux et al., who applied Beers 2015 criteria in a 1-year follow-up study and showed that 25.1% of PIM users prescribed at the beginning continued to use them one year later and the risk of being persistent with PIM increased by 10% for the most socially deprived individuals (RR 1.10, 95% CI 1.05-1.15) while there was no significant difference between the different quintiles of the material deprivation index (except for the first quintile, least deprived

individuals)(14). It should be noted that the high frequency observed may have been influenced by the inclusion of new medications in the Beers 2019 list and the classification of Potentially Inappropriate Medications in this study based on the amount of PIM. Additionally, this approach may have influenced the stability in the prevalence of PIM use over time. Among participants who had sustained exposure to PIM, just over half received one PIM, nearly a quarter received two PIM, and a little over 10% received three PIM at each of the three time points analyzed. These proportions of PIM are consistent with those reported in a population-based study from Malaga conducted by Blanco-Reina et al., who indicate a distribution of 46.2%, 28.5%, and 13.7% for 1, 2, and 3 PIM by Beers 2015 criteria, respectively (12). The PIM categories most frequently used by participants were gastrointestinal, analgesics, delirium-related drugs, benzodiazepines, and cardiovascular drugs, which are comparable to those described by Moriarty in 2020, who indicated high usage of proton pump inhibitors, strong anticholinergics, benzodiazepines, and nonsteroidal anti-inflammatory drugs identified using the Beers criteria 2012 (20). In a literature review, no other studies were found that use PIM categories to characterize the use of these inappropriate medications, probably due to the difficulties in grouping medications that have been associated with different risks, such as anticholinergics that have been linked to delirium, risk of falls, and cognitive impairment (20-22). An important strength of this study is the use of an international database with detailed sociodemographic and clinical characteristics of the participants and their 4-year follow-up. Additionally, the presence of culturally diverse cities from middle- and high-income countries allowed for the study of the relationship between PIM and the health of older adults, which may be considered more

representative of the global population compared to single-center or single-country studies. Another strength is the use of standardized tools in the five cities of the IMIAS study, which reduces the variability of data collection. Moreover, the use of specialized software for the identification of PIM reduces errors in quantification and characterization. Several limitations were identified, including the inability to identify interruptions in PIM use over the four-year period or to determine when other PIMs were added to participants' treatment. Some recorded variables were self-reported, and there were no other sources to formally validate the information, which could result in underreporting due to poor recall, which may differ between cities. Finally, analysis of medications requiring dose adjustment based on renal function using Beers 2019 criteria will be necessary. In conclusion, sustained use of PIM was present in more than half of the older adult population in the community, primarily gastrointestinal medications, analgesics, delirium-related drugs, benzodiazepines, and cardiovascular use, with little variability over time. Reducing PIM use is part of the World Health Organization's global health agenda and has been a priority since 2017, which proposed reducing potential risks associated with medication use (23). The results reinforce the need to intervene in the medication prescribing process to prevent the continued formulation of inappropriate and unnecessary medications for older adults (24–26). Additionally, the findings of this study will help identify particularly vulnerable individuals who should be targeted for prevention and deprescribing strategies.

Acknowledgments

We would like to express our gratitude to the members of the International Mobility in Aging Study (IMIAS) and the University of Caldas for their support of this study.

Conflict of Interest Statement

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest or conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

Funding

This study did not receive specific funding from public or private agencies or non-profit organizations.

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Table 1. Characteristics of the study sample in 2012.

Characteristics	Total (N=820)	PIM (n=330)	No PIM (n=490)	P-value
Sex (n, % women)*	417 (50,9)	193 (58,5)	224 (45,7)	0,000
Age (years, SD)	69,07 (2,85)	69,23 (2,97)	68,97 (2,78)	0,258
Marital status (n, %)				0,654
Single	50 (6,1)	22 (6,7)	28 (5,7)	
Married	557 (67,9)	218 (66,1)	339 (69,2)	
Widowed	117 (14,3)	48 (14,5)	69 (14,1)	
Separated/Divorced	96 (11,7)	42 (12,7)	54 (11)	
Highest level of education (n, %),				0,093
Primary/illiterate	334 (40,7)	114 (34,5)	220 (44,9)	
Secondary	112 (13,7)	47 (14,2)	65 (13,3)	
Post-secondary	374 (45,4)	169 (51,2)	205 (41,8)	
Recruitment site (n, %)				0,000
Kingston	172 (21)	79 (23,9)	93 (19)	
Saint Hyacinthe	184 (22,4)	89 (27)	95 (19,4)	
Tirana	156 (19)	77 (23,3)	79 (16,1)	
Manizales	183 (22,3)	69 (20,9)	114 (23,3)	
Natal	125 (15,2)	16 (4,8)	109 (22,2)	
Number of chronic illnesses (mean, SD)*	1,81 (1,3)	2,3 (1,3)	1 (1,18)	0,000
Number of prescribed medications (mean, SD)*	4,08 (2,99)	6,18 (2,87)	2,66 (2,12)	0,000
Number of falls in the last year (mean, SD)*	0,27 (1,605)	0,67 (2,479)	0 (0)	0,025
Number of visits to the doctor in the last year (mean, SD)*	4,77 (4,75)	6,13 (5,16)	3,86 (4,2)	0,000
Self-reported health (n, % good health)*	524 (63,9)	197 (59,7)	327 (66,7)	0,022
Quality of life (mean, SD)*	7,38 (2,21)	7,21 (2,16)	7,49 (2,24)	0,027
Life-space (n, % not restricted)	640 (78)	251 (76,1)	389 (79,4)	0,134
Depression (n, % without depression)*	668 (81,5)	258 (78,2)	410 (83,7)	0,035
Cognitive function (n, % without cognitive impairment)	795 (97)	318 (96,4)	447 (97,3)	0,273
SPPB (mean, SD)*	9,9 (1,97)	9,56 (2,1)	10,13 (1,82)	0,000
Frailty in 2012 (n, % not frail)*	780 (95,1)	307 (93)	473 (96,5)	0,018

Notes: PIM = potentially inappropriate medications, SPPB = *Short Physical Performance Battery*.

* p value< 0,05 for Chi-Square, Student's t-test or Mann-Whitney U test depending on the characteristics of each variable.

Table 2. Number of PIM per person.

Variable	m1 (2012)	m2 (2014)	m3 (2016)	P value *
1 potentially inappropriate medication	56,4%	54,6%	59,1%	0,291
2 potentially inappropriate medications	22,3%	27,8%	25,4%	0,151
3 potentially inappropriate medications	12,4%	12,1%	10,6%	0,382
4 potentially inappropriate medications	8,9%	3,9%	3,6%	0,094
5 potentially inappropriate medications	1,2%	0,9%	0,9%	0,073

Notes: m1 = moment 1; m2 = moment 2; m3 = moment 3.

* Cochran's Q

Figure 1. Participant Selection

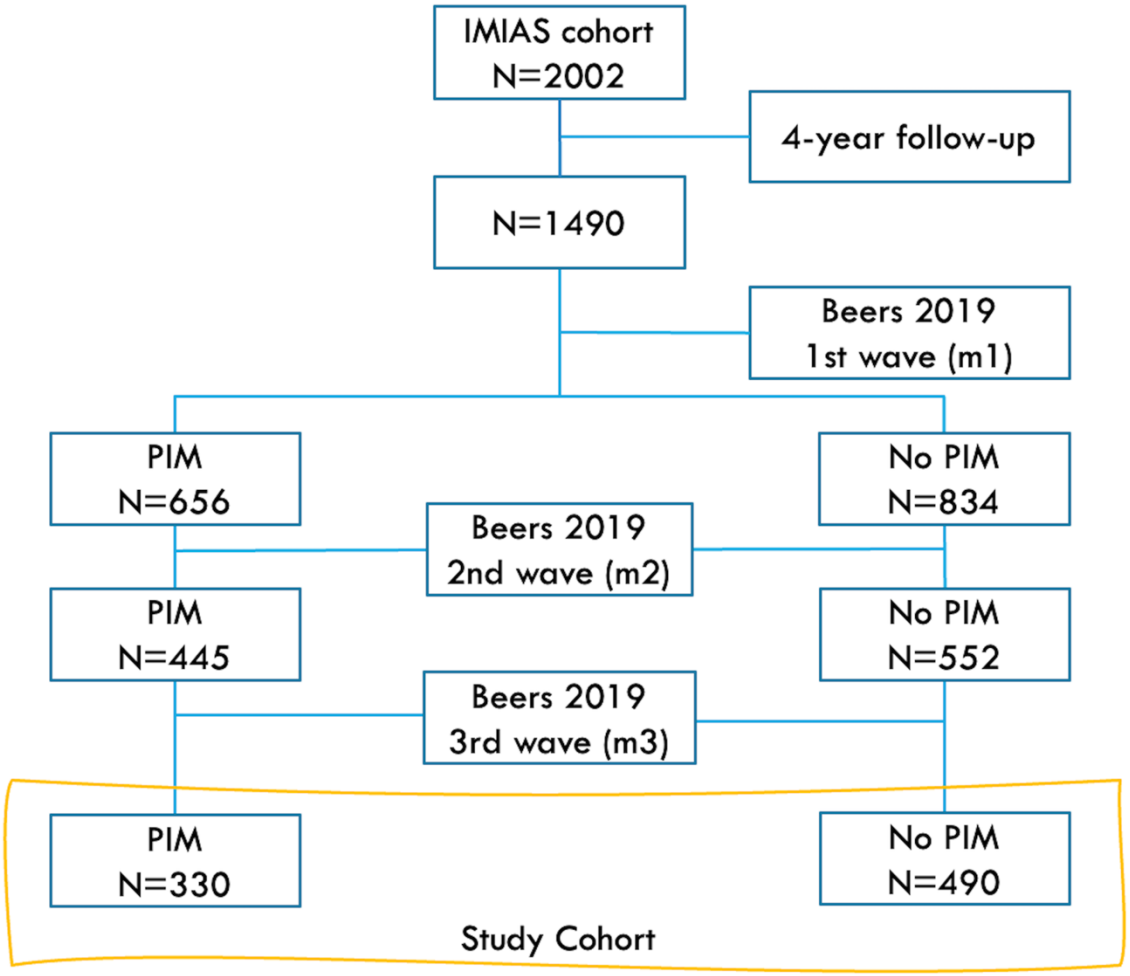
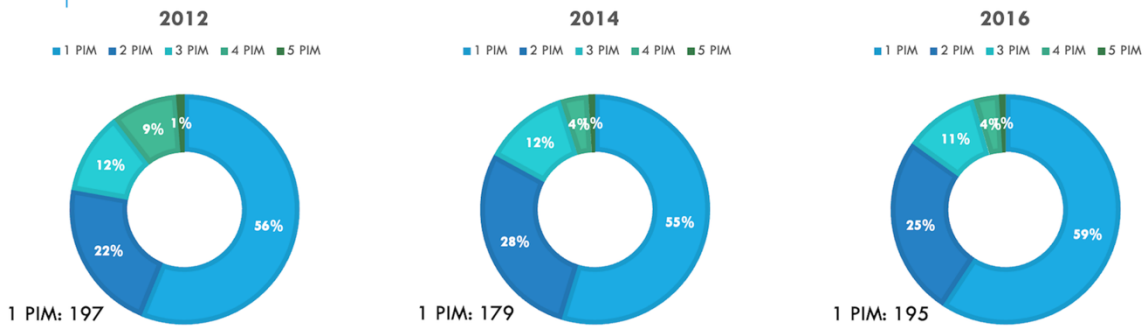


Figure 2. Distribution of the number of PIM per person per year.



1 PIM: 197
2 PIM: 76
3 PIM: 41
4 PIM: 10
5 PIM: 4

1 PIM: 179
2 PIM: 92
3 PIM: 40
4 PIM: 13
5 PIM: 3

1 PIM: 195
2 PIM: 84
3 PIM: 35
4 PIM: 12
5 PIM: 3