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Burden of disease of Alzheimer disease in Italy: a real-world data analysis

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Abstract

Background Alzheimer Disease (AD) represents a growing global health concern with profound socioeconomic implications, with predictions indicating a potential 50% increase in AD cases in Italy over the next 30 years. Timely diagnosis remains challenging due to the slow progression of symptoms and limited accessibility to advanced diagnostic tools, yet it remains one of the few tools available to prevent and alter the clinical course of the disease. The aim of this study is to build a cost-of-illness model to estimate the number of AD patients managed by the National Health Service, analyzing their use of hospital care, and estimating the social costs through real-world data.

Methods The analysis encompassed a multifaceted approach, combining real-world data analysis from different sources for the period 2014–2019. Health direct costs related to AD in Italy were estimated thanks to the Italian database of all hospital discharges and a Local Health Unit database (400,000 residents) collecting all information on resource consumption related to AD. The National Social Security System database was used to estimate social security costs (disability compensations) related to Attendance Allowance (AA) recognitions.

Results In Italy a prevalence of 413,715 AD patients was estimated, with annual health direct costs per patient equal to €3,779. Annual social security costs related to AA recognitions amounted to 240 million euros. Overall, the analysis estimated an annual total cost exceeding 1.8 billion euros.

Conclusions This study provides a comprehensive exploration of the multifaceted burden of AD in Italy, shedding light on its economic dimensions. The results underscore the urgency of prioritizing AD on political agendas, especially in the face of the projected global surge in AD cases. The study advocates for proactive policy interventions and informed healthcare decision-making to address the complex challenges posed by AD.

Keywords Alzheimer disease, Social costs, Real world evidence, Italy, Economic burden

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Introduction

Dementia is defined as a clinical syndrome characterized by memory deficits, language impairments, and other cognitive function disorders, along with behavioral changes significant enough to interfere with the patient's usual abilities [1]. Alzheimer disease (AD) represents 54% of cases of dementia [2]. Previous studies estimated that in Italy, over the next 30 years, the number of cases of dementia may increase by about 50%, from the current 1.5 million cases to around 2.3 million patients by 2050 [3].

AD is a progressive neurodegenerative disorder with an unknown etiology. Due to the slow progression of the disease and the risk of attributing symptoms to other conditions such as depression or normal cognitive decline, making a timely diagnosis of AD is very challenging [4, 5]. In recent years, cutting-edge diagnostic tools (instrumental tests, biological markers) have become available, yet their use is limited, partly due to high costs, restricted accessibility, and complexity in execution and interpretation. Therefore, diagnosis in most cases still relies on clinical and neuropsychological evaluations, with small contribution from instrumental investigations [6]. A meta-analysis highlighted a dementia underdiagnosis rate of 53.7% in Europe, a figure that has not decreased over the years [7]; nevertheless, early diagnosis remains one of the few tools available to prevent and alter the clinical course of the disease [8, 9].

The WHO estimated that the annual cost of a dementia patient in Europe amounts to \$31,144, with 12% attributed to direct healthcare costs, 42% to formal care, and the remaining 46% to informal care [10].

Literature provides with several cost-of-illness analyses of AD in Italy, trying to approximate the real economic impact of the disease. A study conducted by the Centro Studi Investimenti Sociali (CENSIS) in 2007 estimated an average annual expenditure of over €60,900 per patient, 75% of which attributed to indirect costs [11]. The analysis, based on interviews conducted with 401 patients, has the limitation of collecting indirect information and now represents an outdated estimate.

More recently, a study involving 198 patients estimated the average monthly costs per patient based on the severity of the disease (mild, moderate, and severe). This analysis showed that patients with mild AD incur costs equal to €1,850 per individual, while the expense for a severe patient amount to approximately €2,730 (81% of which is due to indirect caregiver costs) [12].

The aim of this study is to build a cost-of-illness model capable of estimating the number of AD patients managed by the National Health Service (NHS), analyzing their use of hospital care, and estimating the social security costs through real-world data.

Data and methods

Data sources

Italian hospital discharges record (SDO)

The Italian SDO records all hospital discharges (HD), both ordinary and day-hospital (DH), from public and accredited hospitals. Each record contains, together with a patient specific anonymous code, patient's demographic (age, sex, residence) and clinical information (primary and up to five secondary diagnoses and procedures, Diagnosis-Related Groups – DRG). Data were available from 2014 to 2019.

Local health unit (LHU) Umbria2

The LHU Umbria 2 health information system (HIS) routinely collects information on hospitalizations, drug prescriptions, outpatients care and laboratory tests for each patient registered in the Regional Health Care Assistance Registries (approximately 97% of residents). Each patient was identified in the HIS by an anonymous code that allowed deterministic linkage between the databases. Data were available from 2014 to 2018.

National Institute for Social Security

The database of the National Social Security System (INPS) collects all applications related to welfare benefits; for this study, only applications resulting in the recognition of the Attendance Allowance (AA) were considered. The AA is a financial benefit for individuals who are severely disabled or totally incapacitated, necessitating permanent assistance for walking or carrying out daily life activities. This benefit is irrespective of age and income status but requires a total disability (100%) to be recognized, leading to the need for constant care. Data were available for the period 2016–2019 and only for adult subjects.

Methods

To assess the economic and social burden of AD, we considered both the NHS perspective and the social perspective, by including direct healthcare costs and social security costs (disability compensations).

National analysis

Identification of the population with AD occurred by selecting all acute and post-acute (rehabilitation and long-term care) hospital admissions in ordinary or day hospital regimen, with discharge dates between January 1, 2014, and December 31, 2019. AD related hospital admissions were identified by the presence, either in primary or secondary diagnosis, of one of the following diagnoses:

Alzheimer's disease (ICD9CM code 331.0)
Dementias (ICD9CM 290.xx)
Pick's disease (ICD9CM 331.11)
Other frontotemporal dementia (ICD9CM 331.19)
Dementia with Lewy bodies (ICD9CM 331.82)

For the selected population, the distribution of subjects, hospital admissions, and average cost per patient per year of admission was calculated.

LHU Umbria2 analysis

To define the population with AD in the regional analysis, all subjects meeting at least one of the following criteria were selected:

- At least one hospitalization with discharge in 2018 for AD (identified by the codes mentioned in the previous section)
- Recognition of the exemption code 029 (AD)
- At least one prescription of a drug included in one of the following Anatomical Therapeutic Chemical (ATC) codes:
 - Rivastigmine (ATC N06DA03)
 - Galantamine (ATC N06DA04)
 - Donepezil (ATC N06DA02)
 - Memantine (ATC N06DX01)

The selection process from the different data sources was described using the Venn Diagram [13]. The distribution by sex (% of men and women) and age (mean, 1st, 25th, 50th, 75th, 99th percentile) was estimated. By linking the data sources previously described, it was possible to estimate the expenses covered by the NHS. Voices of expense considered were hospital admissions, direct drugs and specialist outpatient visits for the year 2018. The cost of hospital admissions was estimated through the DRG code, the cost of drugs was determined using the regional reimbursement price at the time of dispensation, while expenses related to specialist outpatient services were calculated using the year specific regional tariff. The costs related to hospitalizations and drugs were stratified based on whether they corresponded to one of the codes related to AD (ICD 9 CM for hospitalizations, ATC for drugs) or not.

All results were replicated by stratifying the subjects based on the source of origin (hospital care, pharmaceutical, specialist care).

Predicting direct costs at national level

The estimated average annual cost per subject at the regional level for drug consumption, hospital admissions

and outpatient visits was multiplied by the estimated number of prevalent patients with AD at the national level. The number of prevalent patients with AD at the national level was obtained by dividing the number of patients with a hospital admission with a diagnosis of AD in 2018, by the proportion of patients identified in LHU Umbria 2 through hospital admissions. Since the only source used for Italy is hospital care, when projecting the number of AD cases at the national level, the hypothesis was made that the proportion of subjects identified in LHU Umbria 2 by the different sources (hospital admissions, drug prescriptions, exemption code) was valid for Italy as well.

Social security costs

To estimate the beneficiaries and costs related to social security benefits for individuals affected by AD, all new applications submitted during the period 2016–2019, with a prevalent diagnosis of AD and recognition of Attendance Allowance (AA) were selected. The ICD9 CM codes listed previously were used to identify applications for AD. Following a method described elsewhere [14], social security beneficiaries were estimated through a probabilistic model with a Monte Carlo simulation, as to obtain the number of prevalent cases from the incident ones. Briefly, the percentage of incident AD recognitions was estimated in relation to the total incident recognitions for AA. This percentage was applied to the number of total prevalent benefits by year in order to estimate the prevalent benefits related to AD. The assumption was made that all recipients received the social benefit across the whole year, since no information was available on the potential revocation of the benefit. To account for potential bias associated with this assumption, a Monte Carlo simulation was conducted; specifically, for the benefits provided and the yearly values we assigned a gamma distribution, while we used the beta distribution for the percentages.

The total expenditure was calculated by multiplying the number of beneficiaries of AA by the annual amount granted to them, based on the 2018 rate (€6,180).

In both analyses (direct and social security costs) costs were not adjusted for inflation, nominal values were used.

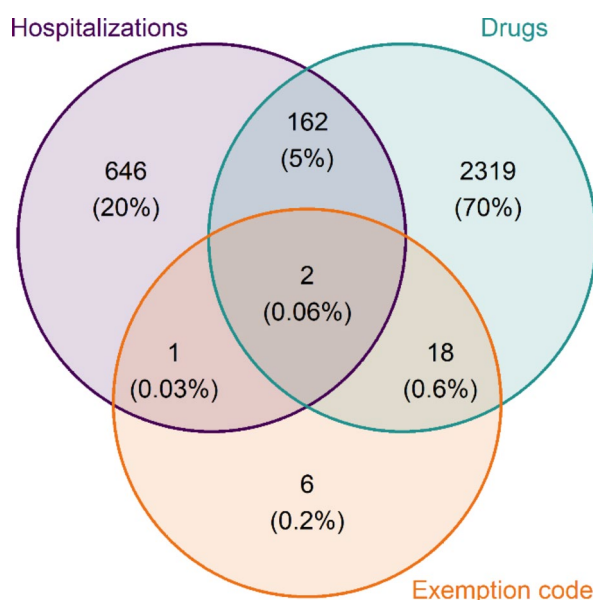
Results

National analysis

From 2014 to 2019, an average of 107,356 individuals per year were hospitalized due to AD, with an average cost per individual of €4,141, resulting in a total of 125,601 annual admissions (Table 1). The number of admissions remained stable over time, as did the readmission rate per patient within the year (1.2

Table 1 Patients hospitalized, hospitalizations and mean cost per patient in Italy

Year	Patients	Hospitalizations
2014	104,846	122,576
2015	110,580	128,646
2016	106,109	123,207
2017	109,183	128,123
2018	106,380	124,373
2019	107,035	126,683
Mean	107,356	125,601

**Fig. 1** Distribution of patients by source of selection in LHU Umbria 2

admissions). A slight increase was noted over time in the average annual cost per patient (+ 4.3%). In 2018, 106,380 patients had at least a hospital admission with a diagnosis of AD, with a mean cost per patient equal to €4,178.

LHU Umbria2 analysis

In 2018, 3,154 patients with AD were identified. The Venn diagram (Fig. 1) describes the sources from which these patients were selected: 2,501 individuals (79.3%) were identified through pharmaceutical records, 811 (25.7%) through hospitalizations, and 27 (0.9%) through

exemptions. Only 2 subjects were present in all sources, while 164 individuals experienced at least one hospitalization and received a prescription for AD related drugs in 2018. Patients identified exclusively through exemptions (6 subjects, corresponding to 0.2% of the study population) were excluded from the analyses stratified by source, to avoid results biased due to the small sample size.

The age and sex distribution of the cohort is presented in the (Table 4 in [Appendix](#)). The median age of the population was 83 years (1st percentile 78 years, 99th percentile 97 years), with men representing 35% of the total. Patients selected solely through hospitalizations were older than those selected through pharmaceutical records (with a median age of 87 and 82 years, respectively), while no significant differences were observed in the sex distribution.

The analysis of costs reveals that, on average, a patient in 2018 incurred expenses of €3,779 (Table 2); of these, €2,551 originated from hospitalizations, €375 from outpatient specialist visits and €854 from drug prescriptions. Only 39.6% of the hospitalization costs is related to admissions with a diagnosis of AD, while spending on AD specific medications accounted for 15.3% of the total costs related to drugs.

Results stratified by source of selection show that patients selected through hospitalizations are those associated with higher costs (€8,564); this is not only due to admissions for AD (in this population, by definition, each patient experienced at least one), but also to admissions for other causes (expenditure amounts to €3,469 compared to the average of €1,540). On the other hand, costs associated with drug prescriptions were lower in these patients, with the highest expense observed in patients selected by both sources. No significant differences were observed in costs for outpatient specialist visits. Distribution of total costs show positive skewness: the 25 th percentile of total costs ranged from €662 in the cohort selected only by drug prescriptions, to €4,022 in the cohort of patients identified by both hospitalizations and drug prescriptions. The 75th percentile range from € 1,963 (only drug prescriptions) to €10,898 (only hospitalizations), with values closer to the mean than the 25th percentile.

Table 2 Mean annual direct healthcare costs per patient in LHU Umbria 2, nominal values

	Subjects	Drug prescriptions		Outpatient visits	Hospitalizations		Total		
		Alzheimer	others		Alzheimer	others	Mean	25th pct	75th pct
Total	3,154	131 €	723 €	375 €	1,011 €	1,540 €	3,779 €	796 €	4,471 €
Only hospitalizations	647	0 €	796 €	323 €	3,976 €	3,469 €	8,564 €	3,977 €	10,898 €
Only drug prescriptions	2,337	164 €	694 €	391 €	0 €	932 €	2,182 €	662 €	1,963 €
Hospitalizations + drug prescriptions	164	184 €	841 €	350 €	3,754 €	2,625 €	7,754 €	4,022 €	9,120 €

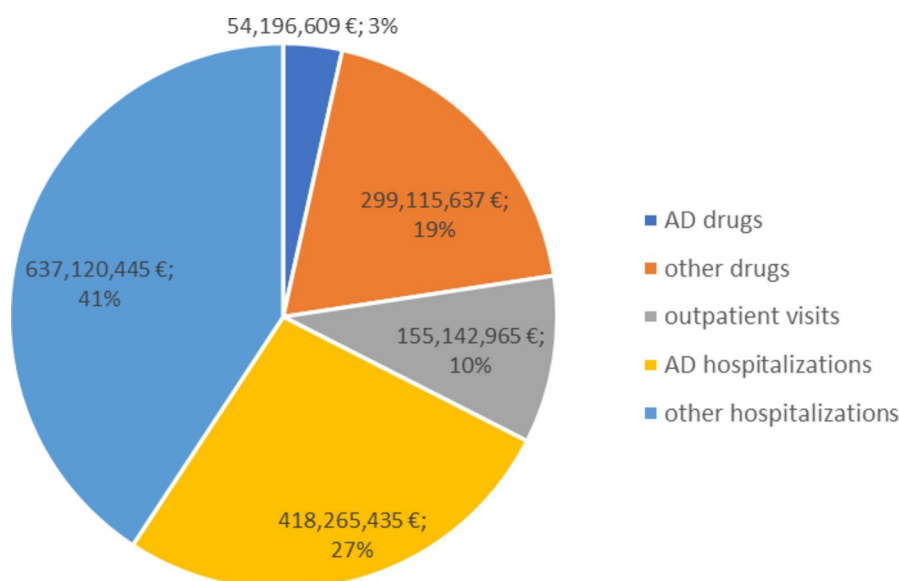


Fig. 2 Estimate of total direct costs related to AD in Italy in 2018, nominal values

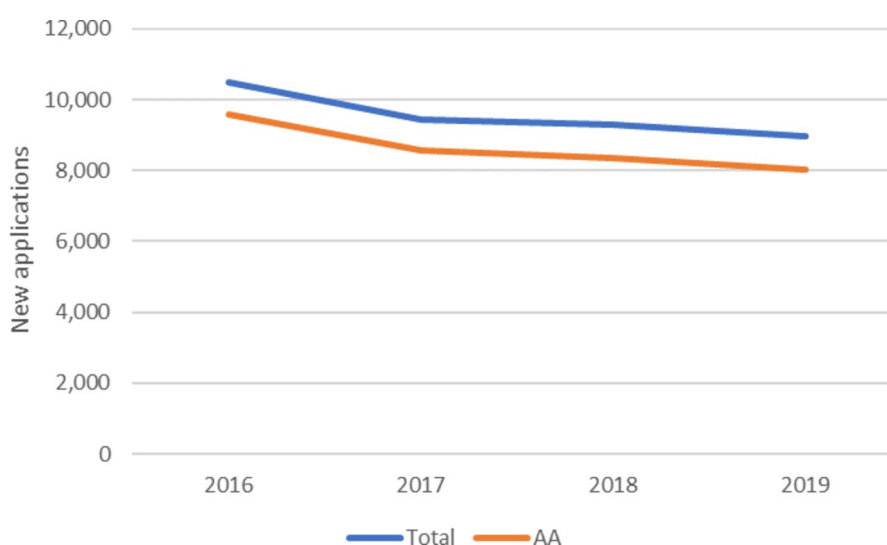


Fig. 3 Annual time series of new applications for social security benefits with a diagnosis of AD in Italy, stratified by outcome (total and with AA recognition)

Predicting direct costs at national level

In Italy in 2018, a prevalence of 413,715 AD patients was estimated, with a total expenditure amounting to over 1.5 billion euros (Fig. 2).

Social security costs

During the study period, an average of 9,552 applications for social security benefits with a prevalent diagnosis of AD were submitted each year (Fig. 3). In 90.5% of cases, a total disability and Attendance Allowance (AA) was recognized. Over the years, a significant decrease has been

observed both in the number of applications (– 14.7%) and in the recognition of AA (– 16.2%).

From these values, an average annual number of 40,914 recipients of AA was estimated, with mean costs amounting to 253 million euros (Fig. 4). The expenditure trend follows a pattern similar to that of the number of applications/recipients. In 2018, costs amounted to 240 million euros.

Summary of cost-of-illness

Combining all the aforementioned costs, an attempt was made to estimate direct and social security costs incurred

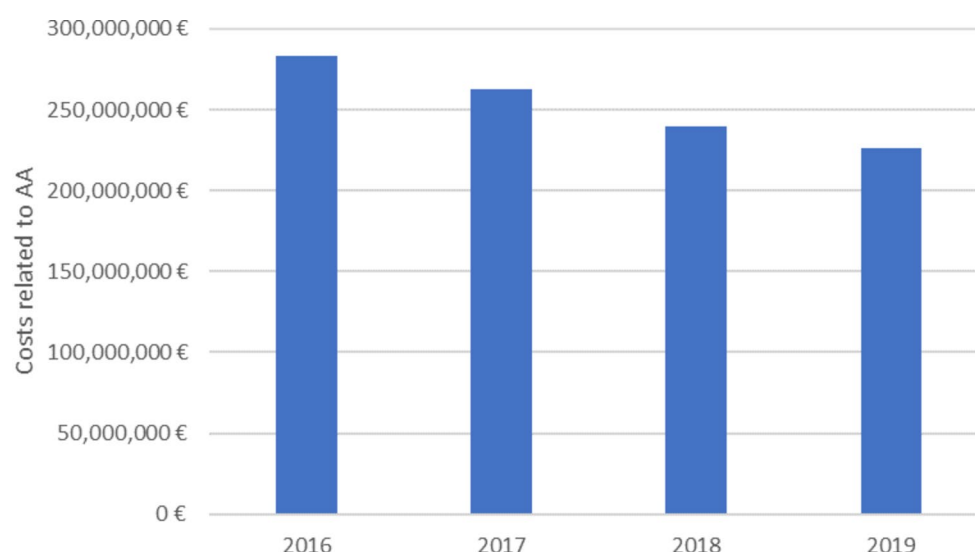


Fig. 4 Estimated annual time series of costs related to social security benefits for AD patients in Italy, nominal values

Table 3 Estimated annual costs related to AD in Italy, nominal values

Direct healthcare costs	€ 1,563,841,092
Social security costs	€ 239,572,421
Cost-of-illness	€ 1,803,413,513

by healthcare for the management and treatment of patients with AD in Italy in 2018. The analysis estimated an annual overall cost exceeding €1.8 billion, of which 87% were costs related to hospital admissions (Table 3).

Discussion

The aim of this study was to estimate the economic burden of AD in Italy from both the NHS perspective and the social perspective. The analysis estimated an annual overall cost exceeding €1.8 billion, two-thirds of which were associated with the role of the caregiver.

The regional analysis highlighted that two out of three patients are women, with an overall average age of 82 years. Literature confirms the distribution by sex, although the discussion remains open regarding the possibility that both age (the primary risk factor for AD) and the higher life expectancy observed in women could act as confounding factors [15].

The extrapolation of regional data to the national level led to an estimate of approximately 400,000 prevalent cases of AD in Italy. A study from CENSIS reported a prevalence of around 600,000 cases in 2016 [11]; therefore, our analysis might suffer from an underestimated number of patients. However, a systematic review of studies on dementia prevalence in Italy highlighted

significant variability in results and considering difficulty in defining the dimension of the AD population [16]. Additionally, literature indicates a substantial underestimation of AD diagnosis, estimated to range between 30% and 50% [9].

The analysis estimated an average annual cost per patient with AD of approximately €4,359, resulting in a total expenditure of over 1.8 billion euros. A study conducted in 2015 on a cohort of 438 subjects with moderate AD reported an annual expenditure of around €4,534 in terms of public costs [17]. In the same study, the primary expense (related to public costs) was “state care allowances”, while the share of direct healthcare costs was 48.7% (compared to 86.7% in our study). Other economic impact analyses of AD have been conducted in Italy, but these studies are now outdated and based on small cohorts [18, 19].

In this study we didn't consider direct costs different from the ones reported and costs borne by families. The study from CENSIS estimated direct costs related to formal care, admissions to healthcare and welfare facilities, and outpatient activities to be around €3,425 per patient annually [11]. Another study attributed a significantly higher expenditure to families, amounting to €21,317 per year, with caregiver-related expenses (both in terms of personal time and loss of productivity) accounting for 84.9% of the total [12]. By including these estimates in our analysis, the total burden of AD would have amounted to over 11 billion euros.

Italy is not the only country registering such high caregiver costs: a study on the economic burden of dementia in Germany highlighted how the costs of ‘informal

care' exceed those of patient care at home by specialized personnel [20]. An American study estimated that family caregiving, along with out-of-pocket expenses, covers 70% of the total costs associated with AD [21]. Generally, in Europe, it is estimated that the burden of informal care on the total expenditure for a patient with dementia ranges from 50–90% [22].

Despite the significant contribution of this analysis to understanding the phenomenon of AD in Italy, some limitations need to be addressed. The estimation of direct healthcare costs and social security costs was obtained from administrative databases. These data sources are meant for accounting and reimbursement purposes; hence, their primary intent is not to support research, potentially leading to missing pertinent information for the study objectives. Additionally, the population residing in LHU Umbria 2 is 400,000; therefore, the cohort used to estimate direct healthcare costs represents 0.7% of the Italian population. However, none of the referenced studies are based on such a large population. Furthermore, for the study period, the age and sex distribution of LHU Umbria 2 are comparable to that of Italy [23]. Other potential sources of bias must be acknowledged, such as the autonomy of Italian regions in managing healthcare services. This independence can result in significant variability in how patients with the same condition are managed, including differences in the care setting (hospital vs. outpatient), availability of treatments, and overall healthcare approaches. These regional disparities could influence the generalizability of our findings and should be considered when interpreting the results. Finally, to the best of our knowledge, no study on the economic impact of AD had the chance to analyze

Hospital Discharge Records data at the national level. Another potential limitation of this study is the inclusion of costs related to hospitalizations not including a diagnosis code related to AD in the analysis. While these hospitalizations may not always be directly attributable to AD, their inclusion reflects an effort to capture the broader economic impact of the disease. Patients with AD often experience comorbidities or complications that necessitate hospitalization, contributing to the overall healthcare burden. However, we acknowledge that not all "other hospitalizations" are necessarily related to AD, which may lead to an overestimation of the costs directly associated with the disease. Future studies could aim to refine the methodology by identifying hospitalizations more specifically linked to AD, enabling a more precise estimation of its economic burden. Additionally, patients with AD were identified through an algorithm that has not been tested in other studies, albeit it was approved by an expert panel.

Conclusions

The study analyzed the burden of Alzheimer's disease (AD) in Italy using real world data. This study provides a detailed overview of the AD burden in Italy, including direct healthcare and social security costs. The information collected can be valuable in assessing the economic impact of the disease and guiding policy and healthcare decisions concerning the management and care of AD patients. In light of the estimated expenditure (€1.8 billion annually) and the projected significant increase in AD cases worldwide in the coming years, AD must become a priority on both the Italian and global political agendas.

Appendix

Table 4 Age and sex distribution by source of selection in LHU Umbria 2

	Subjects	Age						Sex	
		1° pct	25° pct	median	mean	75° pct	99° pct	M	F
Total	3,154	73	78	83	82.3	87	97	34.9%	65.1%
Only hospitalizations	647	77	83	87	86.5	91	98	35.1%	64.9%
Only drug prescriptions	2,337	72	78	82	81.1	86	95	34.7%	65.3%
Hospitalizations + drug prescriptions	164	75	81	84	83.5	88	96	36.0%	64.0%

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Not applicable.

Authors' contributions

All authors contributed to the study conception. MS, FSM, AM and PS developed the study design, MS and PS conducted the statistical analysis and derived the analytical results. The first draft of the manuscript was written by FSM and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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