# BACKGROUND

Medicines are increasingly consumed both in developed and developing countries[1]. There are many reasons for this trend and the high drug consumption: difficult access to preventive health services, growing number of places where medicines can be easily bought, better health expectations and an aggressive pharmaceutical marketing (in)directed to the consumer, that has been shown to increase patient's demands for medicines[2]. High drug use is of special concern if it goes without medical prescription or any other type of expected health professional supervision. Several studies have suggested that much prescribing may be unnecessary, inappropriate or irrational. It is also known that there is a disparity between the prescription and the taking of medicines and that both physicians and users are aware of it. The way how medicines are being used have obvious consequences for individuals and populations health and for efficient health resources utilization[3].

Pharmacoepidemiology was first mentioned in the early 1980's, as the application of epidemiology methods to the study of the effects of drugs in the society[4]. Nowadays it is defined as the study of the distribution and determinants of drug-related events in populations and the application of this study to efficacious drug treatment[5]. The main goal of pharmacoepidemiology is to estimate the effects of drugs in communities when they are prescribed after marketing. It may be drug-oriented, with an emphasis on safety and effectiveness of individual drugs or group of drugs, or utilization-oriented, aiming to improve the quality of drug therapy by educational intervention[6].

The most difficult issue in pharmacoepidemiology is dealing with the dynamics of drug exposure, with little being usually known about remote-past exposures, which can act as a risk modifier[4]. Cross-sectional assessment of exposure at baseline implicitly assumes that drug exposure during the interview is a proxy of chronic use during follow-up. This is a direct consequence of using a statistical model like the Cox proportional hazard model in which a baseline characteristic is assumed to remain present during the follow-up. However, as exposures status usually changes over time, this assumption is rarely met[7]. In addition, drug exposure may be associated with factors that may also be related to the outcome of interest, such as indication for prescribing. Compliance, publicity and the natural course of the disease are other factors to take into account. Though, ability to control adequately for "indication for prescribing" (e.g., adopting strict, standardized and measurable criteria for prescribing drugs) and to obtain an accurate estimative of the relationship between drug exposure and health status, have to be considered[8].

Drug utilization research was defined by the WHO in 1977 as "the marketing, distribution, prescription, and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences"[6]. Drug utilization studies can increase our knowledge on how drugs are being used on society: estimate prevalence or incidence of drug use; extend of the use at a specific moment in time and/or in a specific area (country, region, hospital or community, specially if integrated on an evaluation system); estimate to what extend

drugs are properly being used to treat particular conditions; and application of quality indicators to patterns of drug utilization like drug utilization 90% (DU90%)[6;9].

The main goal of drug utilization research is to assist the rationale use of drugs in populations. With the knowledge on how drugs are being prescribed and used, a discussion on rational drugs use and suggestions on measures to improve prescribing habits should be more efficiently. Descriptive studies are part of drug utilization research and their main target is to describe variations and trends in the extend, costs and quality of drug use among individuals and populations. They also play an essential role in identifying relevant questions and problematic areas for an appropriate base for intervention be setted[6].

Most national and international guidelines on hypertension treatment recommend diuretics as first-line agents in hypertension treatment. Compared to other countries, Portugal uses the highest percentage of Angiotensin-converting enzyme inhibitors and is the lowest user of both diuretics and beta-blockers[10]. Since antihypertensive drugs are the mostly costly therapeutic subgroup the chosen drug class has also implications on health system expenditures. As a consequence, policies of rationalization of drug expenditures should take into account the epidemiological pattern of drug use.

However, it should be mentioned that it is not the purpose of drug utilization studies to assess the quality in prescribing, but rather the prescribing patterns in the light of the available evidence. Treatment should take into account not only clinical drug profile (e.g. main indication) but also contraindications, comorbidities, costs, accessibility, etc[3].

Descriptive studies are needed to understand which drugs are being used and by whom, when and how they are used. The knowledge and the understanding of the context of drug use situation are crucial to develop and evaluate the impact of further interventions.

Medication practices vary not only by country, but by area within a country, so that descriptive studies of local prescribing patterns are essential do determine the precise nature of the problem in any given locality[11]. Geographical differences and changes in drug use over time may have medical, social and economic implications both for individuals and the society, and should be identified, explained and, if necessary, corrected[6]. The importance of doing research on local drug use practices before embarking on an intervention study has already been stressed[12;13].

On 2004, the International Narcotics Control Board report advised Portugal to analyse the procedures on prescription and utilization of benzodiazepines as it was one of the leading European countries on the consumption of these drugs. From 1999 to 2003 there was a decrease of 1.2% on benzodiazepine's utilization[14] with an increase of anxiolytic benzodiazepines (3.8%) and a decrease in hypnotic benzodiazepine's (-21.9%). As already seen in other Portuguese studies[10;15-18], national asymmetries also exits. Although potentially positive, this decrease might have occurred by a shift to other therapeutic classes with indication for anxiety-related disorders treatment, and not in a true change in overprescribing

habits. Antidepressive drugs could have been an alternative to benzodiazepines, as these medicines have also indication for anxious states that usually follow depressive conditions.

Drug use and illness do not often follow the same pattern. Drug utilization studies can show how far actually practice deviates from the conditions under which drugs were originally developed. They add also an important input into the way on which the natural history of diseases is sought, providing more hard data and fewer hypotheses. Information on patterns of drug usage has increasingly become an indicator of why a drug is chosen and taken which is a process that very often is not related with the patient's needs[3]. Other factors that not just the basic needs are influencing drug consumption and the quality of use (overuse, underuse and misuse - discrepancies between actual use and national or international prescription guidelines and formularies[6]). They can be inherent to the countries scientific knowledge, sociodemographic state and culture or inherent to individual's beliefs and expectations[3;13]. Drug utilization research not only can profile the discrepancy that exists between true need and therapeutic practice but also a tool to correct it. If it is unquestionable the importance of promoting compliance on prescribed medicines, it is not of less importance, to avoid unnecessary or overuse of drugs, which may be responsible for an increase in adverse events, iatrogenic diseases and unnecessary costs. Since drug utilization studies are designed only to provide the existing distribution of variables, without any regard for causality, external validity of such studies is limited[19], and what is an apparent inappropriate or irrational drug utilization in one scenario, can be quite rational on others[11].

Drug utilization data can be used to estimate drug utilization in population by age, sex, social class, morbidity, and other characteristics, and to identify areas of possible over- or underutilization. They can monitor the utilization of specific therapeutic categories and, on chronic therapies, they can be used as markers for very crude estimates of drug prevalence[9;19].

Commonly drug use studies are based on physician's prescriptions or drug sales. Temporal and regional trends based on sales, may reflect a variation on disease frequency or in the proportion of subjects that are on treatment. However, sales are indicators only of the quality of medicines; as no information exists on (prescription) indication, no inferences on prescription's quality can be made[19]. By turn, studies based on a consumer approach, using self-administered questionnaires on representative samples, allow gathering information on the real use of medicines by the population under investigation[3]. Recall accuracy of self-reported medications exposures may occur and is influenced by the type of medication, drug use patterns, the design of the data collection materials, and respondent characteristics. Similarly, the ability to remember disease conditions varies by disease with best reporting seen for conditions that have clear diagnostic criteria and are easily communicated to the patient, as diabetes, hypertension and asthma. Cancer and symptom-based conditions such as sinusitis, arthritis and low back pain that are often not immediately followed by a physician, are more difficult to recall[20;21]. Besides collecting information on drugs use and information on prescription

drugs, health surveys also collect information on non-prescriptions medications, health status, health risk factors and sociodemographic variables[22].

Although with few limitations some countries have managed to develop healthcare databases that have provided healthcare information for epidemiological studies to be done. The General Practice Research Database (GPRD)[23] in the UK (lacks information on adherence), and Medicaid[24;25] and Kaiser Permanent[26] in the US (containing both drug and morbidity data)[9], are only a few examples.

The above mentioned databases have proved to be essentials for risk and benefits evaluation of medicines. These particular fields of science have a relevant public and politic impact as it is directly related with the protection of population health.

**Objectives**

This study aims to identify factors that contribute to the knowledge of how medicines are being used by individuals, with a specially emphasis on diabetes disorder therapeutic management. These should be accomplished by means of the following manuscripts:

- Prevalence of drug use in a Portuguese urban population (2001-2004)
- Prevalence of diabetes in a Portuguese urban population (2001-2004): self-reported drug use and comparison with guidelines

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**Prevalence of drug use in**
**a Portuguese urban population**
**(2001-2004)**

**Prevalence of diabetes in a Portuguese urban population (2001-2004): Self-reported drug use and comparison with guidelines**

# General Discussion

It is already known that medicines are increasable consumed both in developed and developing countries with major implications for countries health costs. However, their use is not absent from harm. Understanding how a drug is being used provides insight into the magnitude of exposure and vulnerabilities of the population being treated.

The patterns of physician prescribing and patient drug usage are necessary to ascertain the cost implications of drug use, both at an individual and society level. Drug beneficial effects can be measured by the reduction in the need for medical care, resulting in larger health costs savings. An example is diabetes treatment, where special emphasis has to be made on its therapeutic comorbidities management. However, the gap between the practice of health care delivery and the knowledge base that should guide that practice is huge as it was shown in both manuscripts.

Since we aimed to evaluate drug use in a chronic continuous way and recall bias should have been of minor importance, it is always present and should be taken into account. Potential bias could have been limited by asking patients to bring their medication or enumerate them, by the time the interview was done. Memory aids could also have been helpful. Also, as no temporal question about drug exposure was made, patterns of drug use were not possible to assess. The data that we have worked was not specifically collected to address drug use. Nevertheless, there was an undutiful cost-opportunity that could not be missed. Besides, although we are in mind that the knowledge gathered is not sufficient to change practice, it is a necessary first step.

Pharmacoepidemiology is changing the way medicines are regulated and pharmacoepidemiology data are now routinely used for regulatory decisions. Risk/balance of some drugs can only be acceptable with active management of their use, to maximize their efficacy and/or minimize their risk. As a consequence, risk management programs are being required by regulatory agencies as a means of improving drugs benefit/risk balance. That can only be accomplished by increasing the benefit and/or decreasing the risk associated with a specific drug or, alternatively, by limiting the use of the drug to those most likely to need it.

To meet the needs for pharmacoepidemiology, the ideal database should include records from inpatient and outpatient care, emergency care, mental health care, laboratory and radiological data, and all prescription and non-prescription medicines. In Portugal no such databases exists.

Although a recorded-linkage system is the ideal situation, databases as the one that we have used for these studies, can and should be improved. This can be accomplished by joining these databases with information specific collected by field studies (e.g. adherence and persistence to drug use). Databases and field studies should be used together in order to assemble information that minimize drug risks and maximize their benefits. Only then we can design drug policies based on rational drug use.

Methodological advances are expected to continue in order to support pharmacoepidemiology studies as well as newer approaches, such as risk management programs and molecular pharmacoepidemiology. Challenges faced by pharmacoepidemiology include limited funding opportunities, regulatory restrictions and privacy concerns surrounding human research, limited training opportunities, and inadequate personal resources.

*All drugs have adverse effects. Pharmacoepidemiology will never succeed in preventing them. It can only detect them, hopefully early, and thereby educate healthcare providers and the public, which will lead to better education use (Strom 2007).*

## Summary

**Prevalence of drug use in a Portuguese urban population: an emphasis of diabetes**

We are assisting to an increasing medicines use all over our societies. This has major implications for both individuals and populations and for efficient health resources utilization, as much of that use may be unnecessary, inappropriate or irrational. Descriptive studies are needed to understand which drugs are being used and by whom, when and how they are used. Discrepancies between actual use and national or international prescription guidelines exist. The knowledge and the understanding of the context of drug use situation are crucial to develop and evaluate the impact of further interventions.

**Objectives**

This study aims to identify factors that contribute to the knowledge of how medicines are being used by individuals, with a specially emphasis on diabetes disorder therapeutic management. These should be accomplished by means of the following specific objectives:

- To determine the prevalence of drug use in a Portuguese urban population, identify its determinants and the main therapeutic groups involved – Manuscript 1

- To determine de prevalence of reported diabetes and self-reported drug use, and to compare it with existent guidelines – Manuscript 2

**Manuscript 1** – Prevalence of drug use in a Portuguese urban population (2001-2004)

Data on the prevalence of drug use was obtained as part of a cross-sectional health and nutrition survey of adults living in Porto, Portugal, during 2001-2004. One thousand, two-hundred and forty (1,240) subjects were inquired about drug use in a chronic continuous way for in the last 12-months.

Drug use was reported by 65.2% of the subjects interviewed. The prevalence was higher in females (71.3%), subjects older than 66 years (93.1%) and in those with less than 4 years of complete education. However, after adjustments were made, no significant association remained for educational level. Drug use was also higher for those in retirement or handicapped (90.1%) and in those who reported suffering for more than one disease. Each additional reported disease increased by 84% the probability in consuming medicines.

Group C (33.5%), group A (33%) and group N (25.9%) were the most frequently reported ATC groups. Females were the higher users of both group A and group N, with no major difference being found for cardiovascular system drugs (63.4% *vs* 36.6%, p=0.324). Psycholeptics were the most frequently subgroup with prevalence being higher in those with less education (56.1%), retired or handicap (73.2%) and in the elderly (68.3%). Hypertension and dyslipidemia were the most frequently reported disorders, accounting for 26% and 33.3% of the cases, with no major differences being found between sexes. Drugs acting on the rennin-angiotensin system were the most frequent reported (15.6%) followed by diuretics (7.0%) and beta-blocking agents (6.0%). This may account for an increase in healthcare national expenditures on medicines. Depression was more prevalent among women (84.6% *vs* 15.4%, p<0.001) and in those in the middle age group. No significant difference was found regarding socio-economic status.

For neoplasm and for circulatory and nutrition, endocrine or metabolic diseases no major differences seems to exist between reported disease and drug use, while for musculoskeletal, respiratory and mental disorders the difference is clear. Twenty-four percent (24.3%) of study participants reported having any disease of the musculoskeletal or connective tissue but only 8.2% were in treatment; 23.1% reported having a respiratory disease whereas 4% are under treatment. For those using drugs for the nervous system (25.9%), only 11.5% reported having any mental disorder.

Drug use was found to be directly correlated with older ages, female sex and not being currently employed. A gap between self-reported disease and respective treatment may also exist.

**Manuscript 2** – Prevalence of diabetes in a Portuguese urban population (2001-2004): self-reported drug use and comparison with guidelines

Diabetes prevalence has been increasingly so fast that it was already been considered the 21st century epidemics. If no urgent measure takes place, it is estimated that by the end of 2025, more than 300 million of adults will be suffering from diabetes.

Much of the morbidity and mortality of diabetes results from its microvascular and macrovascular complications. As disease progresses the risk of complications increases in more than two-fold. Cardiovascular diseases are responsible for more than 65% of deaths in people with diabetes but an adequate blood pressure control may reduce in almost 50% the risk of macrovascular and microvascular outcomes. Intensive drug regimens may prevent microvascular complications.

Data on the prevalence of diabetes was obtained as part of a cross-sectional health and nutrition survey of adults living in Porto during 2001-2004. A prevalence of 5.6% was found among the 1.240 subjects interviewed, with 88.6% having type 2 diabetes. A significant difference in employment status was found between diabetics and non-diabetics, with diabetics being more on retirement or being handicapped (60%*vs* 25.8%) and less on current employment status (25.7% *vs* 53.8%). Diabetics were twice as likely to have hypertension (61.4% *vs* 31.6%) or dyslipidemia (52.9% *vs* 24.4%) with the risk of hypertension being almost three times higher in females (70.3% *vs* 29.7%). Eighty-percent (80%) of diabetics were taking antidiabetic drugs. Drug for cardiovascular system were reported by 67.1% of the patients, with agents acting on the rennin-angiotensin system being the most frequently used (45.7%) followed by diuretics and calcium channel blockers (18.6%). Thirty two-percent (32.9%) of diabetics were using lipid modifying drugs and almost 16% were on psycholeptic drugs.

Fifty-percent (50%) of diabetics were currently on oral drugs, 7.1% on insulin and 4.3% on an association of oral and insulin therapy. Diet was mentioned in 28.6% of the cases.

Our study found that hypertension was present in more than 50% of diabetics while hypertension was present in 20% of the non-diabetic population. Despite the evidence that diabetic patients with cardiovascular diseases are at increased risk for cardiovascular events, of the 60% who mentioned dyslipidemia, only 35% were on treatment. Although guidelines mention diet and physical activity as the first approaches to diabetic treatment, only a minority of patients have mentioned it. Since only 4% of diabetics have mentioned using oral and insulin therapy, barriers in starting insulin or a more intensive treatment may exist.

**Sumário**

**Prevalência da utilização de fármacos numa população urbana Portuguesa: enfoque na diabetes**

O consumo de fármacos está a aumentar cada vez mais em todas as sociedades. Este facto tem implicações importantes quer a nível individual quer a nível das populações, bem como para uma eficiente gestão de recursos de saúde, nomeadamente se tivermos em atenção que muitas das vezes a utilização de fármacos é desnecessária, inadequada ou irracional. Os estudos descritivos são necessários para perceber de que forma os fármacos estão a ser utilizados, por quem e em que circunstâncias está a ocorrer a sua utilização. Sabe-se que existem discrepâncias entre o uso de fármacos na prática clínica usual e as recomendações nacionais ou internacionais. Conhecer e compreender o contexto da utilização de fármacos é essencial para o desenvolvimento de intervenções e avaliação do seu impacto.

**Objectivo**

Este estudo pretende identificar os principais factores que contribuem para o consumo de fármacos, com especial atenção para a gestão terapêutica da diabetes.
Para concretizar estes objectivos será necessário:

- Determinar a prevalência da utilização de medicamentos numa população urbana Portuguesa, identificar os determinantes para o seu uso e enumerar os principais grupos terapêuticos envolvidos (Manuscrito 1)

- Determinar a prevalência da diabetes auto-declarada pelo participante e a correspondente utilização de fármacos e comparar os resultados encontrados com as orientações existentes (Manuscrito 2)

**Manuscrito 1** – Prevalência da utilização de fármacos numa população urbana Portuguesa (2001-2004)

A informação sobre a utilização de fármacos foi obtida no decorrer de um estudo transversal realizado no período de 2001 a 2004 no Porto. Neste estudo os participantes foram inquiridos sobre a sua saúde e respectivos hábitos alimentares. Foram entrevistados 1240 indivíduos aos quais se questionou sobre a utilização crónica e contínua de medicamentos no decorrer dos últimos 12 meses.

A utilização de medicamentos foi referida por 65.2% da população inquirida. A prevalência da utilização de fármacos foi maior para as mulheres (71.3%), para indivíduos com mais de 66 anos (93.1%) e para indivíduos com menos de 4 anos de escolaridade completos. No entanto, após ajustar para os outros factores, o nível de escolaridade perdeu a sua significância estatística. A utilização de medicamentos foi ainda superior para os reformados ou inválidos (90.1%) e para aqueles que referiram sofrer mais de uma doença. Para cada doença adicional referida encontrámos um aumento de 84% na probabilidade de consumir medicamentos.

Os fármacos pertencentes aos grupos C (33.5%), A (33%) e N (25.9%) da classificação ATC, foram os mais frequentemente referidos pelos participantes. As mulheres foram as que mais utilizaram medicamentos do grupo N e grupo A, não se tendo verificado diferenças significativas entre sexos para os medicamentos para o sistema cardiovascular (63.4% *vs* 36.6%, p=0.324).

Os psicotrópicos foram os fármacos mais utilizados, nomeadamente nas mulheres, para aqueles com níveis de escolaridade inferiores (56.1%), para os reformados ou inválidos (73.2%) e nos mais idosos (68.3%). As doenças mais frequentemente reportadas foram a hipertensão e a dislipidemia, sendo referidas por 26% e 33.3% dos casos. Não foram encontradas diferenças significativas entre sexos. Os inibidores da enzima de conversão da angiotensina foram a classe mais referida (15.6%), seguindo-se os diuréticos (7%) e os bloqueadores beta (6%). Dado que as classes mais utilizadas são as mais caras, isto trás importâncias consequências para as despesas nacionais de saúde. A depressão foi mais frequente nas mulheres (84.6% *vs* 15.4%, p<0.001) e nos indivíduos de meia idade (35-65 anos). Não se verificou diferença significativa para o nível socio-económico.

Verificámos uma elevada discrepância entre o consumo de fármacos e a presença de doença, nomeadamente no que se refere às doenças do foro musculo-esquelético, respiratório e mental. Dos 24.3% de indivíduos que referiram ter qualquer doença muscular apenas 8.2% referiram tomar medicamentos para essas doenças e dos 23.4% com doenças respiratórias, apenas 4% estão em tratamento. No que se refere ao sistema nervoso a situação inverte-se: dos 25.9% que referiram utilizar psicotrópicos, apenas 11.5% referiram padecer de doença mental.

Assim sendo, os nossos resultados apontam para um consumo preferencial de fármacos nas mulheres, em indivíduos com idades mais avançadas e para aqueles que não estão actualmente empregados. Dada a discrepância verificada entre algumas doenças e o seu tratamento podemos pensar que alguma inadequação no diagnóstico auto-declarado ou na referência ao consumo de fármacos.

**Manuscrito 2** – Prevalência da diabetes numa população urbana Portuguesa (2001-2004): consumo de fármacos auto-declarado e diferenças face às recomendações

A diabetes é considerada como a epidemia do século 21 devido ao aumento assustador no número de casos da doença. Caso não sejam adoptadas medidas urgentes, estima-se que até ao final do ano 2025, mais de 300 milhões de adultos sofram da doença.

A morbilidade e mortalidade associada à diabetes devem às complicações que ocorrem a nível micro e macrovascular. Sabe-se que à medida que a doença progride, o risco de desenvolver estas complicações aumenta para mais do dobro. As doenças cardiovasculares são responsáveis por mais de 65% das mortes devidas à diabetes, mas sabe-se que um controlo adequado dos valores da pressão arterial podem reduzir praticamente em 50% o risco de complicações vasculares.

A informação sobre a diabetes foi recolhida enquanto parte de um estudo transversal sobre a saúde e hábitos alimentares realizado no período de 2001 a 2004 em 1240 adultos residentes no Porto. A prevalência da diabetes foi de 5.6% sendo que 88.8% dos casos eram diabéticos do tipo 2. Os diabéticos encontraram-se mais frequentemente reformados ou inválidos (60% *vs* 25.8%) e menos vezes empregados (25.7% *vs* 53.8%*)* que a correspondente população não diabética. A hipertensão (61.4% vs 31.6%) e a dislipidemia (52.9% *vs* 24.4%) são mais frequentes na população diabética. O risco de hipertensão é cerca de três vezes superior nas mulheres que nos homens (70.3% *vs* 29.7%). A utilização de antidiabéticos ocorreu em 80% dos casos. Sessenta e sete (67%) dos diabéticos estavam a fazer terapêutica cardiovascular, sendo os inibidores da enzima de conversão da angiotensina, os fármacos mais frequentemente utilizados, seguindo-se os diuréticos e bloqueadores dos canais de cálcio (18.6%). A utilização de fármacos para a dislipidemia ocorreu em 32.9% dos casos e cerca de 16% dos doentes estavam a tomar psicotrópicos.

Cinquenta por cento (50%) dos diabéticos fazem presentemente terapêuticas orais, 7.1% terapêutica com insulina e 4.3% terapêutica combinada (insulina e antidiabéticos orais). Cerca de 30% dos fármacos (28.6%) referiram fazer dieta.

O nosso estudo demonstrou que cerca de 50% dos doentes diabetes sofre de hipertensão enquanto que na população não-diabética este número é de 20%. Apesar de existir evidência científica que os doentes diabéticos com patologia cardíaca estão em risco aumentado para eventos cardiovasculares, apenas 35% dos doentes que referiram dislipidemia (60%) estão em tratamento.

As orientações nacionais e internacionais referem que a dieta e o exercício físico devem ser a primeira estratégia para a gestão da doença. No entanto, apenas uma minoria dos doentes referiu estar em dieta ou fazer exercício físico.

Dado que apenas 4% dos casos estavam a fazer terapêutica combinada de insulina e antidiabéticos orais, alguma resistência à introdução de insulina na intensificação dos regimes terapêuticos pode existir.