Research protocol

Project Title:

Influence of social deprivation on benzodiazepines and antidepressants drugs dispensing among children and adolescents: a large cross-sectional population-based study in France.

Principal Investigators

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## General information

### Project Information

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<th>Project Title</th>
<th>Influence of social deprivation on psychotropic drugs dispensing adequacy pattern among children and adolescents: a large cross-sectional population-based study in France.</th>
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### Document Information

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<td>Project Role</td>
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List of abbreviations

ALD: Affection de longue durée (recognition of a medico-administrative chronic disease status)
CMHD: Common Mental Health Disorders
CMU-C: Couverture Maladie Universelle complémentaire (Universal Supplemental Health Coverage)
EDI: European Deprivation Index
ENCePP: European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
Eu2P: European programme in Pharmacovigilance and Pharmacoepidemiology
FDA: Food and Drug Administration
HP: Healthcare Provision
GP: General Practitioner
GPP: Guidelines for Good Pharmacoepidemiology Practices
INSERM: Institut national de la santé et de la recherche médicale (National Institute of Health and Medical Research)
IRIS: Ilots Regroupés pour l’Information Statistique (IRIS are specific codes and data related to more than 50,000 districts, built by the National Institute of Statistics and Economic Studies)
MSA: Mutualité Sociale Agricole (Agricultural Regime)
PLA: potential localised accessibility
RG: Régime General (General Regime)
RSI: Régime Social des Indépendants (Social Regime of Independents)
SEP: Socioeconomic Position
STROBE: STrengthening the Reporting of OBservational studies in Epidemiology
I. About this Research Protocol development

A. Guidance

This Research Protocol was drafted as one of the first steps in the research project, and has been / will be amended or updated as needed throughout the course of the study development.

As recommended by the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) Guide on Methodological Standards in Pharmacoepidemiology\(^1\), the content and format of this Research Protocol was developed through guidance provided by the International Society for Pharmacoepidemiology (ISPE) Guidelines for Good Pharmacoepidemiology Practice (GPP) fourth version (June 2015)\(^2\).

When applicable to this research project, the Food and Drug Administration (FDA) 2013 guidance\(^3\), the (Strengthening the Reporting of Observational Studies in Epidemiology) STROBE reporting framework\(^4\), and the ENCePP checklists for protocols\(^5\) also provided general guidance to this Research Protocol.

B. Dated amendments and updates – Version identifier

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\(^2\) [https://www.pharmacoepi.org/resources/policies/guidelines-08027/](https://www.pharmacoepi.org/resources/policies/guidelines-08027/)  
\(^3\) [https://www.fda.gov/downloads/drugs/guidances/ucm243537.pdf](https://www.fda.gov/downloads/drugs/guidances/ucm243537.pdf)  
\(^4\) [https://www.strobe-statement.org/](https://www.strobe-statement.org/)  
## II. Responsible parties

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<tr>
<td>Name</td>
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III. Synopsis and timeline

A. Synopsis of the Research Protocol

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<td>Title</td>
<td>Influence of social deprivation and healthcare provision on psychotropic drugs dispensing adequacy pattern among children and adolescents: a large cross-sectional population-based study in France.</td>
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<tr>
<td>Justification/context</td>
<td>Worldwide prevalence among children and adolescent of anxiety and mood disorder is close to 7 and 3% (1). In France and in North America, 5% of children and adolescent suffer from a mood disorder (2–4) and the demands for care continues to increase (5). Currently, French and international guidelines tend to recommend non pharmacological treatment for anxiety disorder (6) as pharmacotherapy has limited evidence, especially benzodiazepine (7). For mood disorder, benzodiazepines should not be prescribed in this population (8,9) and the treatment with antidepressant drugs should be decided by psychiatrists in case of mild to severe depression, (8,9). Yet, Anxiolytics and hypnotic drugs are also largely prescribed in this population, and general practitioners (GPs) are mainly involved (10,11). If trends of antidepressant drugs’ use remain stable in the last decades, off-label use of these drugs is frequent, and GPs remain the first prescribers in this population (12): the limited healthcare provision in specialized cares is one of the main barrier to optimal management (5,13).</td>
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Some social deprivation factors are associated with a greatest need for mental health care among children and disparities in care provision (13,14). As a result, children living among family with a lower socio-economic position (SEP) are more prone to be prescribed antidepressants (12). This is also true for the prescription of antipsychotic drugs (15).

In European studies, association between socio-economic indicators of precariousness and benzodiazepines misuse (16–18), or antidepressants (19–23) has been found, but these studies targeted more specifically the adults. Some French studies dealing with mental health management of children were not specifically assessing the link between SEP and psychotropic drugs use and/or adequacy as a primary objective (12,13), or SEP was not measured with an indicator specific to a particular cultural and social policy context and at an individual level (24,25).

We assume that lower SEP is associated with an inadequacy to the recommendation of psychotropic drugs use among children and adolescent, regarding recommendations. Lower SEP should be associated with a greater number of benzodiazepines and antidepressants dispensing, at an individual level.

### Objectives

**Primary objective:** To assess correlation between the number of benzodiazepines dispensing (anxiolytic and hypnotic drugs) and the European Deprivation Index (EDI).

**Secondary objectives:** To assess correlation between the number of antidepressant dispensing and EDI, and study this association in both subgroups of children below 12 and adolescent above 12, where antidepressant can be recommended.

### Study Design

Cross-sectional population-based study, based on secondary data collection, from the joint use of the Health Insurance information system and a social deprivation index in the large French region of Midi-Pyrenees during the year 2012.

### Inclusion criteria

Persons, aged below 18, with the right to access, as of 31 December 2012, one of the three main health insurance schemes (General Regime from March 2012 to February 2013, Mutualité Sociale Agricole and the
<table>
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<tr>
<th>Exclusion criteria</th>
<th>Social Regime of Independents for the year 2012) in the Midi-Pyrénées region of France.</th>
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<td>- Some populations have been excluded due to the differences in the management of the beneficiaries: the local mutual sections for the RG, the grouping of the health insurers of the operators for the MSA and self-employed professions for the RSI</td>
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<td>- People who died during the period of interest</td>
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<td>- Beneficiaries to whom no IRIS could be allocated (specific codes and data related to more than 50,000 districts, built by the National Institute of Statistics and Economic Studies)</td>
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<th>Outcomes</th>
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<td>Outcomes</td>
<td>Number of distinct benzodiazepine drugs dispensing (ATC: N05) by subject, distinctly for each class of psychotropic drugs:</td>
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<td>➢ Number of hypnotic drugs (ATC: N05BA)</td>
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<td>➢ Number of anxiolytic drugs (ATC: N05CD and N05CF)</td>
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<td>Secondary outcomes:</td>
<td>Number of distinct antidepressants drugs dispensing (ATC: N05 and N06) by subject, distinctly for each class of psychotropic drugs:</td>
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<td>➢ Number of antidepressant (ATC: N06A)</td>
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<td>Adequacy with guidelines regarding antidepressants drug dispensing patterns: Six or more distinct dispensing dates of antidepressant drugs (ATC: N06A) (considered equivalent to at least 6-month dispensing, the minimum recommended treatment duration), if any antidepressant drugs dispensing.</td>
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| Main data of interest | - European Deprivation Index (EDI): a validated ecological deprivation index that approaches SEP |
|                      | - Healthcare Provision (HP): measured by potential localized accessibility (PLA) to a general practitioner |
|                      | - Number of distinct anxiolytic, hypnotic (N05) and antidepressant (N06A) drugs dispensing. |
### Other data collected / Covariates

- Demographic data: gender, age
- Number of consultations or visits with a GP
- Time of access to a GP office
- Attending physician stated
- Available chronic comorbidities
- Number of consultations or visits with a psychiatrist
- CMU-C status (universal health coverage for deprived patients)
- ALD status (recognition of a medico-administrative chronic disease status)

### Data source

Health Insurance information system; data from the AAPRISS ARS 2012 database

### Sample size

540,295 individuals are below 18 in the exhaustive regional database that included 2,574,310 individuals (after excluding 92,542 beneficiaries who died during the period of interest and 41,349 beneficiaries to whom no IRIS could be allocated)

### Duration of the study

December 2019 to March 2020
### Statistical analysis

- Descriptive analyses
- Comparative analyses between groups (depending on EDI assessment, psychotropic drug or mental healthcare use levels) with Chi2 (or exact Fisher tests if not applicable) for categorical variables, and Student’s T test (or non-parametrical test if not applicable) or variances analyses (ANOVA for continuous variables, when relevant).
- p-value <0.05 will be considered as statistically significant
- Univariate analyses (linear regression) of the association between the number of drugs dispensed, for each class of drugs (antidepressants, anxiolytics and hypnotics) and the EDI, the HP, and other covariates, will be performed.
- Then, a multivariate analysis (linear regression), will be performed. Covariates known to be associated with psychotropic drug misuse in the literature, and those associated in the univariate analysis (p-value < 0.20) will be selected for inclusion in the multivariate model, and secondarily excluded by a backward stepwise procedure, retaining variables associated with a p-value <0.05 Adjusted Odds Ratios (OR) and their 95% confidence interval will be provided. In case of significant interaction between covariates, a stratification on these covariates will be performed. A multivariate analysis will also be performed on secondary outcomes (antidepressants) and the subgroups of children below and above 12.
- Sensitivity analyses, regarding association between EDI or HP and levels or number of psychotropic drugs dispensing by classes of drugs, will be performed.

### Expected results

We expect to find an association between a higher social deprivation index and number of benzodiazepines and antidepressants dispensed at an individual level.
B. Milestones and proposed study timeline

Literature review and context and objectives definition: 2019

Start of data extraction: in the case of this secondary use of data, data extraction (from pre-existing data; AAPRISS ARS 2012 study) will start on the 15th of January 2020.

End of data collection: Expected end of February 2020

Progress/Interim report: Expected March 2020

Registration in the EU PAS Register®: 21st of December 2019

Final report of study results: Expected April 2020. The research results will be published in the EU PAS Register over the course of 2020.
IV. Context

A. Background and rationale

Worldwide prevalence among children and adolescent of anxiety and mood disorder is close to 7 and 3% (1). In France and in North America, 5% of children and adolescent suffer from a mood disorder (2–4) and the demands for care continues to increase (5). Currently, French and international guidelines tend to recommend non pharmacological treatment for anxiety disorder (6) as pharmacotherapy has limited evidence, especially benzodiazepine (7). For mood disorder, the diagnosis by a psychiatrist, after a screening by the GP, is recommended and benzodiazepines should not be prescribed in this population (8,9). The treatment by antidepressant should be decided by the psychiatrists in case of mild to severe depression, and non-pharmacological treatment (psychotherapy, social support) should be proposed for all degrees of depression’s severity (8,9). Yet, Anxiolytics and hypnotic drug are also largely prescribed in this population, and GPs are mainly involved (10,11). If trends of antidepressants use remain stable in the last decades, off-label use of these drugs is frequent, and General Practitioners (GPs) remain the first prescribers in this population (12): the limited healthcare provision in specialized cares is one of the main barrier to optimal management (5,13).

Some social deprivation factors are associated with a greatest need for mental health care among children and disparities in care provision (13,14). As a result, children living among family with a lower socio-economic status are more prone to be prescribed antidepressants (12). This is also true for the prescription of antipsychotic drugs (15).

In European studies, association between socio-economic indicators of precariousness and benzodiazepines misuse (16–18), or antidepressants (19–23) has been found, but these studies targeted more specifically the adults. Some French studies dealing with mental health management of children were not specifically assessing the link between SEP and psychotropic drugs use and/or adequacy as a primary objective (12,13), or SEP was not measured with an indicator specific to a particular cultural and social policy context and at an individual level (24,25).

B. Hypothesis

We assume that lower SEP are associated with an inadequacy to the recommendation of psychotropic drugs use among children. Lower SEP and lower HP should be associated with a greater number of benzodiazepines and antidepressants dispensing, at an individual level.
C. Justification of the methodological approach adopted

We will carry out a retrospective cross-sectional population-based study. Based on the joint use of French healthcare insurance population-based data of reimbursement of out-of-hospital care during the year 2012, which included 2,574,310 individuals, of any age, and an ecological indicator of social deprivation (the European Deprivation Index (EDI)) (26,27) and an indicator of potential spatial accessibility of HP in the Midi-Pyrénées region (25,28). This study will focus on the population below 18 years old.

A modelisation will be performed through a linear regression model evaluating of the association between the number of individual dispensing of benzodiazepines (anxiolytic and hypnotic drugs) and EDI

We will study, as secondary objective, the association between the number of individual dispensing of antidepressant and EDI. We will stratify the analysis in 2 groups:

- Below 12, where no antidepressant is recommended.
- Above 12, where fluoxetine has marketing authorization above 8 but is recommended above 12.

This is necessary to assess the antidepressants dispensed in both subgroups since recommendations on antidepressants use are different in both groups.

Since this cohort is a prevalent cohort, no data is available on the psychotropic drug dispensing before or after the year of 2012. Thus, assessing the exact adequacy to the recommendations of psychotropic drugs dispensing patterns could not be accurate. The number of each drugs dispensed may be a good proxy to assess the adequacy to the recommendations of the psychotropic drugs dispensing patterns.

We plan to use an insurance reimbursement database, which seems more relevant to use than prescription database, since prescriptions data might not be representative of real drug exposure, particularly in case of undelivered prescriptions. Besides, the consistency between drug reimbursement data and chronically consumed drug self-report was shown (29,30).
D. Expected results

We expect to find an association between a higher social deprivation index and number of benzodiazepines and antidepressants dispensed at an individual level among children and adolescent, regarding recommendations.
V. Aim and objectives

**Primary objective:**
To assess correlation between the number of benzodiazepines dispensing (anxiolytic and hypnotic drugs) and EDI.

**Secondary objectives:**
To assess correlation between the number of antidepressant dispensing and EDI, and study this association in both subgroup of children below 12 and adolescent above 12, where antidepressant can be recommended.
VI. Methods

A. Study Design

This cross-sectional population-based study is based on secondary data collection, from the joint use of the Health Insurance information system and a social deprivation index and an indicator of potential geographical accessibility of healthcare provision in the French region of Midi-Pyrenees during the year 2012.

B. Data source

The population sample was built from the French National Healthcare Insurance records in the French region of Midi-Pyrenees. Several healthcare and demographic data were recorded on one year (2012). National Healthcare insurance automatically register prospectively reimbursement data of out-of-hospital care. However, health services use data were merged with SEP and healthcare provision data and analyzed retrospectively. This data registration was performed prospectively in 2012. It included reimbursement data of beneficiaries from National Healthcare Insurance persons with the right to access, in one of the three main health insurance schemes (General Regime (RG), Mutualité Sociale Agricole (MSA) and the Social Regime of Independents (RSI)). There were approximately 2.9 million inhabitants in the region (about 5% of the whole French population); the database registered included 2,574,310 individuals, about 87% of the total population of the region, among which, 540,295 individuals are below 18 (31–33).

Data are provided by the French Public Regional Health Agency for the Occitanie region, which is funded by the French State. A CNIL Authorization (no. 1634837) was obtained for the record of these data in order to perform epidemiological studies. Some epidemiological studies have already been performed on these data. Data on psychotropic drug and psychiatric consultation reimbursement have not yet been studied.
C. Study population

Target population and enrolment criteria are described in the initial study detailing the source of the data (31).

Inclusion criteria: every beneficiary, ages below 18, from the National Healthcare Insurance with the right to access, in one of the three main health insurance schemes (General Regime (RG), Mutualité Sociale Agricole (MSA) and the Social Regime of Independents (RSI)) from the Midi-Pyrénées region of France were included, regardless of the age or gender. These 3 main schemes include 87% of the total region's population.

Exclusion criteria:
- Some populations have been excluded due to the differences in the management of the beneficiaries: the local mutual sections for the RG, the grouping of the health insurers of the operators for the MSA and self-employed professions for the RSI
- People who died during the period of interest
- Beneficiaries to whom no IRIS could be allocated (specific codes and data related to more than 50,000 districts, built by the National Institute of Statistics and Economic Studies)

D. Data collection, management and verification

Data collection, management and verification are described in the initial study detailing the source of the data (31).

Data on beneficiaries and concerning the year 2012 were collected by the health insurance schemes in their information systems. These are the Regional Health Insurance Information System "SIAM-ERASME" for the General Scheme, the Infocentre "Base Santé" for the Agricultural Social Mutuality and the "Observatoire des caisses d’assurance maladie des professions indépendants" (OCAPI) for the Social Scheme for the Self-employed.
E. Outcomes

**Primary outcome:**
Number of distinct benzodiazepines drugs dispensing (ATC: N05) by subject, distinctly for each class of psychotropic drugs:

- Number of hypnotic drugs (ATC: N05BA)
- Number of anxiolytic drugs (ATC: N05CD and N05CF)

**Secondary outcomes:**
Number of distinct antidepressants drugs dispensing (ATC: N06) by subject, distinctly for each class of psychotropic drugs:

- Number of antidepressant (ATC: N06A)

Adequacy with guidelines regarding antidepressants drug dispensing patterns: Six or more distinct dispensing dates of antidepressant drugs (ATC: N06A) (considered equivalent to at least 6-month dispensing, the minimum recommended treatment duration), if any antidepressant drugs dispensing.
F. Data of interest and covariates

- European Deprivation Index (EDI): a validated ecological deprivation index that approaches SEP. This index is constructed from the patients' residential address. The approach is to consider geographical measures as truly environmental measures and to set itself the task of separating influences attributable to the environment from those attributable to individual economic characteristics. In 2012, the Inserm Cancers and Prevention team (UMR1086) and the Inserm Equity team (UMR1027) proposed a new methodology to develop an index adapted to France but also to temporal and transnational comparisons: the European Deprivation Index (EDI), a score that combines the following variables: Overcrowded housing; Low level of education; No car; Foreign nationality; Housing without shower or bathtub; Non-owner; Unemployed; Person whose socio-professional category is different from "intermediate professions or executive/manager"; Single-parent families; Households with at least 6 people (26–28,32).

- Healthcare Provision (HP): measured by potential localised accessibility (PLA) to a general practitioner, an indicator developed in France by the “Direction de la recherche, des études, de l’évaluation et des statistiques” (Drees, Directorate for Research, Studies, Evaluation and Statistics), integrating proximity and availability of GPs. This indicator of potential accessibility to a health professional takes into account the level of activity of this professional to measure supply (notion of full-time equivalent) and the rate of use, differentiated by age of the inhabitants, to measure demand. It was calculated at the commune level by the Drees: IRIS (Ilots Regroupés pour l’Information Statistique), a local indicator, calculated at the level of each geographical area considered, but which takes into account the supply of doctors and the demand in the surrounding areas (34,35). The indicator is then interpreted as a density. The unit of measurement is a number of full-time equivalents per 100,000 population. The LPA for liberal general practitioners used here is calculated as of January 1, 2013. The calculation of the "LPA general practitioner" indicator required the geocoding of the addresses of the main and secondary practices of liberal and mixed general practitioners according to the same methods as for the beneficiaries of the three main health insurance schemes. Physicians working on 1 January 2013 are taken into account. The indicator has been divided into quintiles based on the number of IRIS in the Midi-Pyrénées region.
- Gender
- Age
- Number of consultations or visits with a GP
- Time of access to a GP office
- Attending physician stated
- Available chronic comorbidities
- Number of consultations or visits with a psychiatrist
- CMU-C status
- ALD status

G. Statistical analysis

- Descriptive analyses, with mean and standard deviation for quantitative variables, and percentages and absolute numbers for quantitative variables.
- Comparative analyses between groups (depending on EDI assessment, psychotropic drug use levels) with Chi2 (or exact Fisher tests if not applicable) for categorical variables, and Student’s T test (or non-parametrical test if not applicable) or variances analyses (ANOVA) for continuous variables, when relevant.
- A comparison between both subgroups of children above and below 12 will be performed.
- p-value <0.05 will be considered as statistically significant.
- Univariate analyses (linear regression) of the association between the number of drugs dispensed, for each class of drugs (antidepressants, anxiolytics and hypnotics) and the EDI, the HP, and other covariates, will be performed.
- Then, a multivariate analysis (linear regression), will be performed. Covariates known to be associated with psychotropic drug misuse in the literature, and those associated in the univariate analysis (p-value < 0.20) will be selected for inclusion in the multivariate model, and secondarily excluded by a backward stepwise procedure, retaining variables associated with a p-value <0.05 Adjusted Odds Ratios (OR) and their 95% confidence interval will be provided. In case of significant interaction between covariates, a stratification on these covariates will be performed. A multivariate analysis will also be performed on secondary outcomes (antidepressants) and the subgroups of children below and above 12.
- Sensitivity analyses, regarding association between EDI and levels or number of psychotropic drugs dispensing by classes of drugs, will be performed. Adjustment and groups analysis regarding gender, age, CMU-C status, ALD status will be done.

H. Limitations or strengths of the study design, data sources, and analytic methods

The main strength of our work will be the number of patients included in the study. Even if it was a regional population-based study, it concerns more than 540,000 children and adolescent, from a cohort of 2 million people, which represented 87% of the total region’s population, among which. Follow-up bias or attrition bias is very limited in studies on national healthcare insurance database since data are recorded from the reimbursement, thus, unless a beneficiary leave the country, there are almost no lost to follow-up, even if the beneficiaries move to another region.

Even though the sample included 87% of the region population, some insurance schemes are not represented, such as civil servants (they were not available in the data source used). Classification and measurement bias may occur with studies on national healthcare insurance database: reimbursement data may not reflect the real drug consumption. The data extracted will allow an approximation of the correct use of psychotropic drugs, but might not be an accurate reflection of its use. Nonetheless, good concordance between self-declared consumption and reimbursement data was shown for chronic drug exposure (29).

The database does not provide the exact dispensed amount of drug, only distinct dates of dispensing. We can only approximate the time frame of drug exposure based on the total number of pills available in the drugs packaging (usually 28 days for antidepressants, 28 days for anxiolytics and 14 days for hypnotics). In France psychotropic drugs are dispensed in community pharmacies by periods of 28 days at most, whatever the prescription duration is. The beneficiary will always have to come back every month to get another dispensing; thus, the monitoring of drug dispensing is a good estimate of the total duration of exposure to a drug, using reimbursement databases.

Attrition bias is very limited in this reimbursement database, since any included beneficiary data is automatically recorded at each reimbursement on the whole French territory.
The data extracted are representative of the dispensing of drugs over the given period of time (prevalent data), and the potential continuation or cessation of dispensation beyond the limits of the period studied will lead to information bias. The same is true for drugs dispensed before the study period, preventing from studying the accurate dispensing pattern and their adequacy with the recommendations (more than 6 month of antidepressants, less than 3 months for anxiolytic and one month for hypnotics). These data only reflect health insurance reimbursement data. Moreover, they do not provide any indicator of time continuity in dispensing. They only allow an approximation of the adequacy with the recommended treatment times. Thus, considering the number of drugs dispensed, and not the adequacy of the delivery to the recommendations, is more accurate.
VII. Plans for protecting human subjects; ethical and regulatory considerations

No subject will be placed at risk as a result of the study. In accordance with the data charter regarding the initial AAPRISS study, provisions are made to preserve the confidentiality of information on study subjects. Investigators ensure that personal identifiers will be removed from any study files that could be accessible to non-study personnel in accordance with applicable laws and regulations. Whenever feasible, study files will be coded and stripped of personal identifiers, and code keys stored separate from study files. All personnel with access to data containing personal identifiers have signed a pledge to maintain the confidentiality of study subjects.

This study complies with guidelines on Data Privacy, Medical Record Confidentiality, and Research in the Interest of Public Health. The current study is categorized as exempt from Institutional Review Board/Independent Ethics Committee review, and meets other legal and regulatory requirements for the protection of human subjects. A CNIL Authorization (no. 1634837) was obtained for the initial record of extracted data in order to perform epidemiological studies. More information regarding ethical and regulatory considerations on the database used can be found in the initial study detailing the source of the data (31).

Study results will be independently reviewed by an academic advisor from an educational and training organization.

VIII. Amendments and deviation

If an amendment or deviation to this protocol were to prove necessary, the authors will document it in the EU PAS Register database and mention it in the final report of the study.
IX. Plans for disseminating and communicating study results

Authors are aware that there is an ethical obligation to disseminate findings of potential scientific or public health importance. Authorship should follow guidelines established by the International Committee of Medical Journal Editors (http://www.icmje.org/).

The completed study will be summarized in a final report that accurately presents the study objectives, methods, results, strengths and limitations of the study, and interpretation of the findings.

The final report will include at minimum:

1. A descriptive title;
2. An abstract;
3. Purpose (objectives) of the research, as stated in the protocol;
4. The names, titles, degrees, addresses and affiliations of the principal investigator and all co-investigators;
5. Name and address of each potential sponsor;
6. Dates on which the study was initiated and completed;
7. Introduction with background, purpose, and specific aims of the study;
8. A description of the research methods, including:
   a. source population and selection of study subjects;
   b. data collection methods and, if questionnaires or surveys are involved, complete copies (including skip patterns);
   c. transformations, calculations, or operations on the data;
   d. statistical methods used in data analyses.
9. A description of circumstances that may have affected the quality or integrity of the data; Describe the limitations of study approach and the methods used to address them (e.g., response
Influence of social deprivation on psychotropic drugs use/dispensing – Research Protocol
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rates, missing or incomplete data). All sensitivity analyses conducted to assess the impact of critical assumptions should be listed.

10. Analysis of the data; Include sufficient tables, graphs, and illustrations to present the pertinent data and to reflect the analyses performed. Epidemiologic parameters (e.g., risks, rates, risk or rate differences, risk or rate ratios) are the most typical epidemiologic measures to report. Both unadjusted and adjusted results should be presented. Effect measures should not be described as “significant” or “not significant.” Precision of estimates should be quantified using confidence intervals. Confidence intervals communicate both the strength of the relationship and the precision of the measure and are therefore more informative than point estimates accompanied by p-values.

11. A discussion of strengths, limitations and possible bias of the study, including direction and magnitude of bias, if known.

12. A statement of the conclusions drawn from the analyses of the data;

13. A discussion of the implication of study results; Cite prior research in support of and in contrast to present findings. Discuss possible biases and limitations in present research. Inferences about causal effects should be based on a variety of factors that should be explored in the discussion section. These factors include strength of relationship, temporal relationship, biological mechanism, plausibility of alternative theories, biases, confounding, precision, and others.

14. Acknowledgements

15. References.

The final report will also follow the Eu2P master research project guideline 2018-2019, which indicates confidentiality issues and intellectual property rights guidance, and which is available on the Eu2P website.
X. References


XI. Appendix

- Checklist of the ENCePP Code of Conduct
  *submitted to the EU PAS Register*

- ENCePP Checklist for Study Protocols (Revision 4)
  *submitted to the EU PAS Register*

- Declaration of compliance with the ENCePP Code of Conduct
  *submitted to the EU PAS Register*

- Declaration of Interests of the contributing investigators and researchers
  *submitted to the EU PAS Register*
Abstract of the initial study detailing the source of the data: *Use of medical and administrative databases to measure social health inequalities* (31)


**[Use of medical and administrative databases to measure social health inequalities].**

[Article in French]

Ducros D¹, Nicoules V, Chehoud H, Bayle A, Souche A, Tanguy M, Valière JP, Cayla F, Grosclaude P.
Abstract

OBJECTIVE: The ability to measure social health inequalities is a prerequisite to the implementation of local policies designed to reduce such inequalities. The absence of individual socioeconomic data in medical and administrative databases does not allow direct evaluation of those inequalities. The objective of this study is to propose a method of measurement of social health inequalities from national health insurance databases and a validated deprivation index.

METHODS: 27 health care and prevention indicators were constructed to identify social health inequalities. Medical and administrative databases were cross-matched with the European Deprivation Index, completed by a potential spatial accessibility indicator in order to take into account the spatial distribution health care services.

RESULTS: The study population comprised data derived from the three main health insurance schemes, and represents 89% of the population of the Midi-Pyrenees region. 98% were able to be geographically coded. The 27 indicators were therefore calculated on a total of 2,574,310 individuals, i.e. 87% of the regional population.

CONCLUSION: This study illustrates the value of using medical and administrative data to create databases allowing measurement of social health inequalities and their variations within a region. The proposed indicators could be used as decision-making tools for the selection of zones of intervention and to assess the impact of public policies designed to reduce social health inequalities.

PMID: 26414140
   [Indexed for MEDLINE]


- Dictionary of relevant database variables
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<td>psy_c</td>
<td>Nombre de consultations chez un psychiatre</td>
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### Code Régime (Reg2)
- 1 Régime Général
- 2N MSA Nord
- 2S MSA Sud
- 3 RSI

### Sexe (sexe3)
- 1 Hommes
- 2 Femmes

### Tranches d'âge de 10 ans (TR_AGE)
- 1 Moins de 10 ans
- 2 Entre 10 et 19 ans
- 3 Entre 20 et 29 ans
- 4 Entre 30 et 39 ans
- 5 Entre 40 et 49 ans
- 6 Entre 50 et 59 ans
- 7 Entre 60 et 69 ans
- 8 Entre 70 et 79 ans
- 9 Entre 80 et 89 ans
- 10 90 ans et plus

### Tranches d'âge de 5 ans (TR_AGE2)
- 1 Moins de 5 ans
- 2 Entre 5 et 9 ans
- 3 Entre 10 et 14 ans
- 4 Entre 15 et 19 ans
- 5 Entre 20 et 24 ans
- 6 Entre 25 et 29 ans
- 7 Entre 30 et 34 ans
- 8 Entre 35 et 39 ans
Entre 40 et 44 ans
Entre 45 et 49 ans
Entre 50 et 54 ans
Entre 55 et 59 ans
Entre 60 et 64 ans
Entre 65 et 69 ans
Entre 70 et 74 ans
Entre 75 et 79 ans
Entre 80 et 84 ans
Entre 85 et 89 ans
Entre 90 et 94 ans
Plus de 95 ans

**Catégorie de la commune dans le zonage en aires urbaines 2010 (ZAU)**

111 : Commune appartenant à un grand pôle (10 000 emplois ou plus)
112 : Commune appartenant à la couronne d’un grand pôle
120 : Commune multipolarisée des grandes aires urbaines
211 : Commune appartenant à un moyen pôle (5 000 à moins de 10 000 emplois)
212 : Commune appartenant à la couronne d’un moyen pôle
221 : Commune appartenant à un petit pôle (de 1 500 à moins de 5 000 emplois)
222 : Commune appartenant à la couronne d’un petit pôle
300 : Autre commune multipolarisée
400 : Commune isolée hors influence des pôles