University of Exeter

MSc Health Data Science

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Project Report

Project title:

Predicting individual-level stroke risk associated with risperidone use in dementia using cardiovascular disease history

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Summary

Clinically, dementia is characterised by the decline of brain functioning. Progressive memory loss is a major symptom of dementia. Other symptoms are agitation, aggression, hallucinations, hearing voices, or false beliefs that others harm them. Risperidone is one of the medicines to reduce these symptoms for some patients, on the other hand, it has major side effects on patients' cardiovascular biological pathways and can cause stroke. Risperidone is the only licenced drug in the UK for these dementia symptoms. Despite the major side effects prescribing risperidone is very common.

The average figures for strokes associated with risperidone were published, however, the individual risk was not known. The official guidance underlines that it is not known what will happen to patients when risperidone is given to them. The main target of this master's project is to help doctors with their decision to make risperidone safer. This master's project's outputs will be the inputs of 13 months NIHR funded prediction of a stroke risk project started following this one.

Two cohorts were generated:

Cohort 1: People with dementia who have been prescribed risperidone aged>=65.

Cohort 2: People with dementia who have never been prescribed risperidone aged>=65.

Abstract

Background

Risperidone is an antipsychotic drug and is frequently prescribed to dementia patients to reduce their behavioural and psychological symptoms such as agitation, aggression, and psychosis. However, despite its benefits according to some studies, risperidone has major side effects such as stroke. The average stroke risk of risperidone in dementia patients had been declared but the individual-based stroke risk of risperidone had not been calculated.

Methods

The Exeter diabetes teams' precision medicine coding infrastructure was used to be able to predict excess stroke risk for the prospective risperidone treatment. Primary care electronic health records data from the Clinical Practice Research Datalink (CPRD) Aurum database[38] was selected to create risperidone and control cohorts. Propensity scores were estimated with logistic regression by using the matchit package of R. SQL scripts were developed to test the R codes on MySQL database.

Results

N=1935 risperidone patients were found and N=19350 matched control patients. Cox proportional hazard models weighted by propensity score to adjust for cofounders had been planned to be fitted to predict the stroke risk on individual cardiovascular disease (CVD) data on the CPRD Aurum database. There were not any stroke patients who were prescribed risperidone before or after the first risperidone prescription.

Conclusion

49 mio patients on the CPRD Aurum database were reduced to final analytic cohorts after data cleaning and wrangling steps. There were no stroke patients in the risperidone cohort.

Introduction

Research question: Can a person with dementia's individual clinical history be used to estimate stroke risk if prescribed risperidone?

Half of dementia patients suffer from agitation, aggression, and psychosis. According to some studies, these symptoms decrease their life quality more than cognitive problems[1,2.] Risperidone is an atypical antipsychotic drug and is frequently prescribed to dementia patients to reduce their behavioural and psychological symptoms such as agitation, aggression, and psychosis. However, despite its benefits according to some studies, risperidone has major side effects such as stroke. Ma, H. et al. study presented that 27 in 1,000 dementia patients had stroke after risperidone usage[5]. Some studies have found that risperidone is prescribed to 2% (>8500) of dementia patients every year [8-11] and 5.5% of dementia patients in care homes use risperidone annually[12]. Scientists underline that risperidone has a more negative effect on cardiovascular diseases (CVD) because of biological weakness. In the past decade, increasing death numbers related to risperidone, especially in the elderly population have been reported. Risperidone is permitted to treat dementia in the United Kingdom, Canada, Australia, and New Zealand but it is not approved in the USA [43]. Risperidone is the only licenced drug in the UK for agitation, aggression, and psychotic symptoms. Despite the major side effects prescribing risperidone (licensed and off-label) is very common.

Exeter University has already created a precision medicine methodology for tailored type 2 diabetes treatments. It was intended to use this approach to evaluate the potential stroke risk of each patient against risperidone via clinical features associated with CVD in the Clinical Practice Research Datalink (CPRD) database. This study aimed to provide a major improvement in supplying sensible prescribing and preventing mortality in dementia patients.

The main tasks of this master's project were data cleaning, data wrangling and coding a significant amount of data.

Methods

Study Design and Data Sources

This project was designed as a comparative cohort study and its purpose is to investigate the correlation between risperidone and stroke and then evaluate possible statistical models to calculate the individual risk. Primary care electronic health records data from the Clinical Practice Research Datalink (CPRD) Aurum database[38] and CPRD Aurum dictionary files were the primary data resources.

Risperidone and other antipsychotics' brand and generic names were collected from the internet and required clinicians' confirmation. Required program scripts were developed by R and SQL was used for testing purposes on the MySQL database on the Linux server. This project used the Exeter diabetes team's object-oriented coding infrastructure.

Definition of Study Population

People with a formal diagnosis of dementia aged ≥65.

Data Cleaning and Wrangling

The observation table includes 1232 dementia patients whose observation dates are null or less than the year of birth of patients. These values were excluded. Most of the patients' month of birth value is missing so "01" is assigned to them. Since CPRD Aurum database does not include patients' day of birth, all patients' day of birth was accepted "01" for the age calculation of cohorts.

Code list generation

Code lists contain primary care electronic health records products and medical codes, codes which are used in hospitals were not included.

Risperidone code lists:

Risperidone brand and generic names were collected from the internet. Risperidone, Risperdal and Okedi are used in the UK, however, project clinicians Prof Nefyn Williams and Dr Christophe Mueller informed that only Risperidone was prescribed in the UK for dementia patients in primary care. Okedi is only for hospital use and Risperdal is for schizophrenia or other psychotic disorders. Risperidone production codes were extracted from CPRDAurum Product Dictionary [38] and inserted into the

codesets table on the CPRD Aurum database by developing an R script. R script (Risperidone_Product_Codes.R) and its output file(risperidone_prod_codes.txt) including production code lists have been uploaded to the Github Exeter-Prediction-of-Stroke-Risk repository[40].

Dementia code lists:

At Exeter University Medical School, the diabetes team has been developing codeslists for diagnostic categories such as dementia and cardiovascular diseases. To define dementia medical codes, the Exeter diabetes team's read and snomed codes were combined with the read codes of the study Donegan, K. *et al*[23.] Dementia codes due to neurodegenerative disease were selected related to the project concept. Dementia codes due to other significant reasons such as alcohol, HIV, head trauma, and prion disease were eliminated. Read and snomed codes joined with CPRDAurum Medical Dictionary[38] to define the med codes of dementia. Dementia medical codes were uploaded to the GitHub repository in the dementia folder [40].

Stroke code lists:

Exeter diabetes team supplied stroke medical codes for stroke, haemorrhagic stroke, and ischaemic stroke. Dementia medical codes can be accessed via exeter_medcodlist_stroke file under the GitHub Exeter-Prediction-of-Stroke-Risk repository in the stroke folder[40].

Hypertension code lists:

The Exeter diabetes team provided hypertension med code lists to test the prediction of the stroke-risk cohorts. Medical codes can be viewed under the GitHub Exeter-Prediction-of-Stroke-Risk repository in the hypertension folder[40].

Other Antipsychotics:

Risperdal and other antipsychotics' brand and generic names were collected from the internet and finalised the document according to clinicians' additions and reviewing. 30 brand names and 205 generic names can be accessed from the GitHub Exeter-Prediction-of-Stroke-Risk repository in the other antipsychotics folder[40]. Other antipsychotics' will be used to eliminate dementia patients who have major mental illnesses like schizophrenia in the second phase of the project.

Initial Data Extraction

Exeter diabetes precision medicine R coding infrastructure on the CPRD Aurum database was used to evaluate the individual-based prediction of stroke. The study period was between 01/01/2000 and 01/06/2021. The first risperidone prescription date was assigned as the index date. The end date was defined as the earliest date of gp end of registration (deregistration date), date of death (emis date), last collection date or end of the study period ("01/06/2021").

Cohort Generation

Risperidone Cohort

Firstly, all dementia patients were identified by merging dementia code lists and the observation table. Next, the earliest observation date of each patient was selected from the observation table, and they are joined with acceptable patient data from the patient table. Then, the earliest date of risperidone (minimum issue date) was identified from the drug issue table as an index date of the risperidone group. The patients whose earliest dementia observation date was after the date of the earliest risperidone prescription date were excluded since the risperidone usage can be related to any other mental illnesses. In addition, any patient whose date of risperidone prescription was before age 65 was excluded since this project's content is limited to neurodegenerative factors for dementia. Rejected dementia codes can be accessed from codelists folder and R scripts can be accessed from the R_codes folder on the Github Exeter-Prediction-of-Stroke-Risk repository. The Risperidone cohort includes 1935 unique dementia patients prescribed risperidone after the observation of dementia associated with neurodegenerative reasons at the age of 64 or before the age of 65.

Control Cohort

Firstly, all dementia patients were identified by merging dementia code lists and observation table and then the earliest observation date of each patient was selected from the observation table. After that observation data and acceptable patients were joined. All patients who reached age 65 at any date during the study period (Jan 2000-June 2021) or before, at the death date or before or at the registration end date or before were selected. Lastly, any patient who had been prescribed risperidone was excluded.

Creating a main analysis table

The index date was assigned as the first risperidone prescription date for the risperidone cohort. Age was defined at the end of the study period (01/06/2021) for all patients. Sex was extracted from the

patient table and added to the main analysis table. A case-control variable was defined that is 1 for the risperidone patients and 0 for the control patients. Risperidone and control cohorts' data were combined into the main analysis table.

Matching

The risperidone cohort had 1935 patients meanwhile the control cohort had 291, 647 so the control group's patient number should have been reduced. Matchit[42] *R package was installed to decrease the control group and match them with the risperidone group. 10:1 The nearest neighbour method was selected to make matching on covariates age and sex between cohorts. Propensity scores were estimated with logistic regression. In the end, there were 1935*10 = 19350 risperidone and control cohort altogether.*

Results

According to Figure 1: Including/Excluding Criteria – Flow Chart, CPRD Aurum database observation table stored over 15,718,230 patient's observation information. After excluding patients' observation data (n=15,400,042) which include of other illnesses except dementia at any time point there were 318,818 dementia patients.

Before creating risperidone cohort, data was cleaned. Firstly, zero acceptable codes were excluded, and then null observation dates were excluded after that if the observation date smaller than year of birth of the patients were excluded. Only first observation dates were kept. (n=15820 rows were excluded).

Creating risperidone cohort: After inner joining dementia and risperidone cohorts, patients whose earliest dementia codes is after the date of earliest risperidone prescription and patients whose date of risperidone prescription is before age 65 were excluded (n=300,433). Risperidone cohort had 1935 patients.

Patients who reach age 65 at any time after the study period, patients whose observation date is null and observation date < year of birth were excluded (n=23960)

WHO reach age 65 at any date during the study period or before ('2000-01-01'-'2021-06-01')(n = 294,228)

Creating the control cohort: patients whose follow-up ends before they reach 65 and patients who are prescribed risperidone at any time were excluded (n=2581). The control group had n=291,647.

Since there is a huge between risperidone and control cohorts, *10:1 The nearest neighbour method was selected to make matching on covariates age and sex between cohorts. Propensity scores were estimated with logistic regression. In the end, there were 1935*10 = 19350 risperidone and control cohort altogether.*

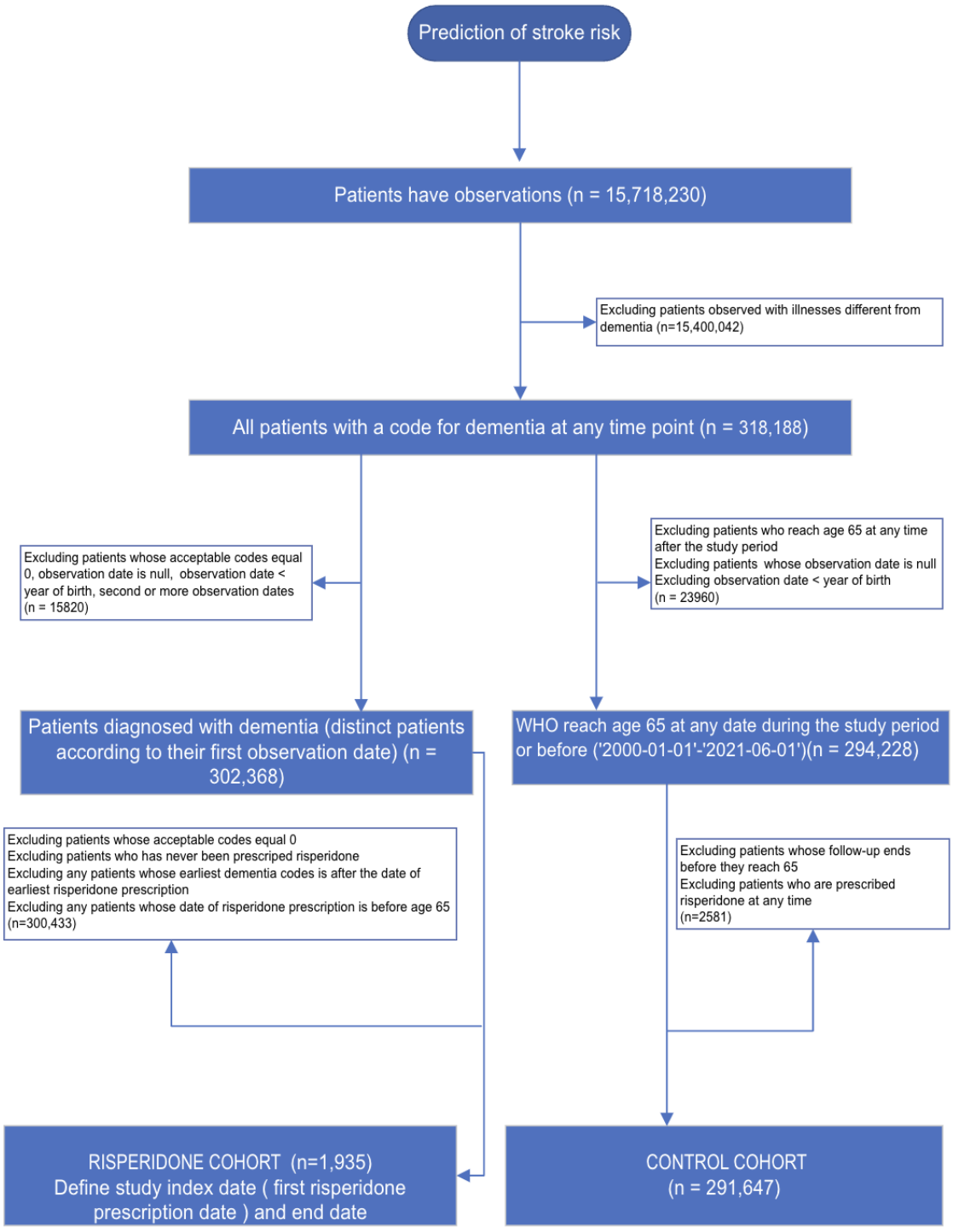

Figure 1: Including/Excluding Criteria – Flow Chart

Outputs	Risperidone Case	Matched Control
Number of Patients	1933	17,077
Age (Mean and SD)	Mean = 90.1 SD = 9.13	Mean = 90.5 SD = 9.11
Number of females Female (%)	1169 60.48%	10391 60.85%
Stroke Before first risperidone prescription Number of Patients (%)	0 0%	1531 8.97%
Stroke in 12 months after first risperidone prescription Number of Patients (%)	0 0%	302 1.77%
Stroke any time after first risperidone prescription Number of Patients (%)	0 0%	1455 8.52%

Figure 2: Final baseline table

According to Figure 2 Final baseline table, the risperidone cohort included 1933 patients and the matched control cohort included 17,077 after excluding patients whose end date was smaller than the index date because of the data quality problem. The average age was 90.1 and the standard deviation(sd) was 91.3 for the risperidone cohort and 90.5 and 9.11 for the matched control. Over 60 per cent of the patients were female for both groups (60.48%, 60.85% respectively). I investigated the risperidone and stroke correlation. There were not any stroke patients before or after the risperidone prescription. Meanwhile, there were 1531 patients who had a stroke before the risperidone prescription, 302 patients who had a stroke within the first year of the risperidone prescription and 1455 patients who had a stroke any time after the first risperidone prescription. (8.97%, 1.77%, 8.52% respectively)

Relevance and Impact

This study will help future studies investigating risperidone's stroke effect in dementia. It will help to provide better communication between clinicians and patients. It will help doctors' decisions about whom they can prescribe risperidone safely.

Discussion

This is a highly technical study including 49 million patients and over 13 billion massive observation data. Since it is a master's project investigating, coding and documentation time is limited. This is an intensive health data science project requiring more human resources to design, analyse, develop, and test the project properly. Missing or wrong data were another significantly time-consuming problems of electronic health care data.

This project was developed with R and R codes are well designed, analysed and tested. They are reusable and highly readable codes. It makes the testing the code with other codelist easy such as diabetes or hypertension instead of stroke. This individual based coding structure and statistical methodologies can be converted new data science solutions for other antipsychotics, other drugs or other illnesses such as schizophrenia, Alzheimer's, cardiovascular diseases. This is the strongest part of the project.

The mean of the age is 90.1 for the risperidone cohort and 90.5 for the control cohort. These numbers look higher than expected the data should be reviewed if there is any data quality problem on CPRD Aurum Patient table.

I could not find any stroke occurrence for the risperidone cohort. It can be a genuine finding. I strongly recommend checking the CPRD data in the related tables to see whether any missing data has affected the results or not. Obtaining the updated codelists and CPRD Aurum dictionaries would be useful. Our codelists are open source. Dementia read codes from Donegan, K. *et al belong between 2005 to 2015. 15 read and snomed codes from Exeter codelists were not in the CPRD Aurum medical dictionary. From the beginning, every step and codelist should be double-checked and codelist should be updated parallel to the study period.*

I used age and sex as covariates since the master's project time is limited but ethnicity, blood pressure, cholesterol, BMI, QRisk Score, blood tests, length of dementia, frailty, and other cardiovascular diseases can be added to the coding structure easily and effectively.

Conclusion

This study is a significant milestone for dementia and antipsychotic drugs since it represents an individual structure established on CPRD Aurum database including 49 million patients' electronic health care data. Its outputs will be an enormously important part of the main NIHR-funded project

and new projects. The output main table is ready for mathematical modelling and statistical analysis. Only the statistical part is missing due to the zero result of stroke occurrence for the risperidone cohort. It can be a true result, or a missing data issue related to the CPRD Aurum database.

Future Studies

Investigating missing data on CPRD Aurum database, possible biases and confounding, conducting mathematical modelling and conducting statistical analysis, distributed the programs to doctors and testing the risk predictor tool and reporting the results and tools efficiency will be the main milestones of the future studies.

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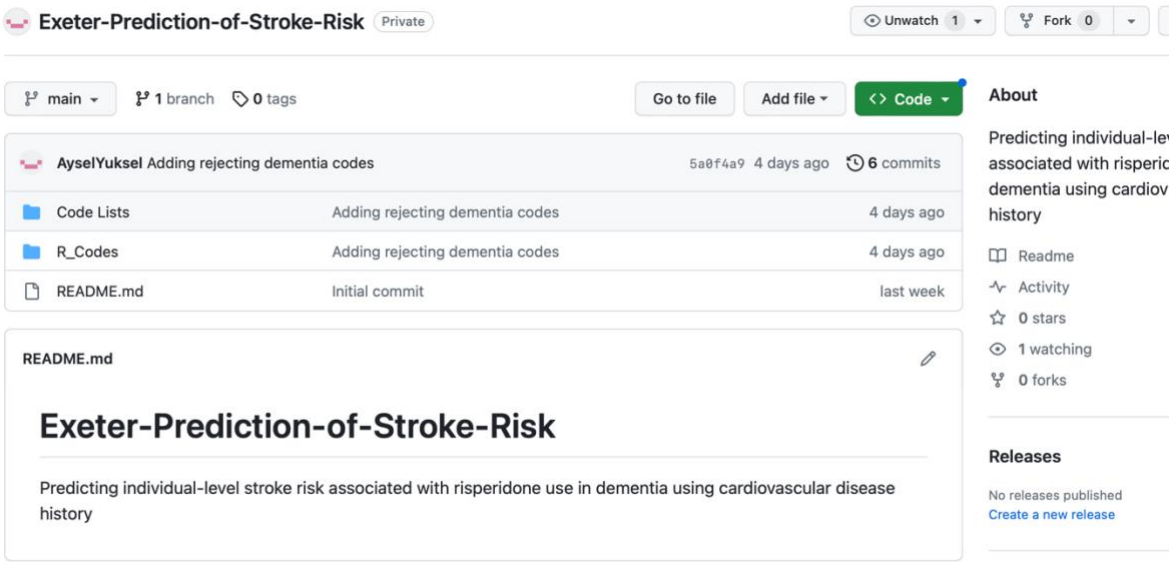
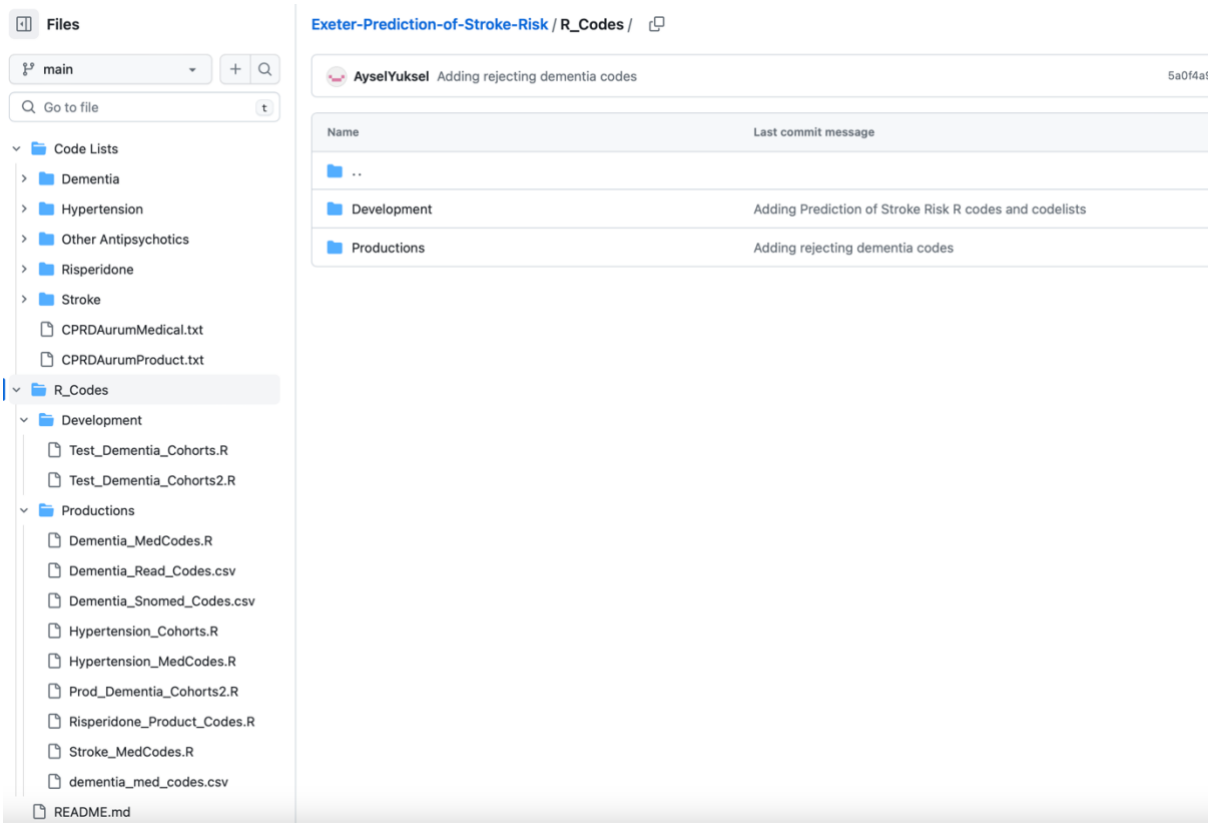
44. Prediction of the Stroke Risk Application document. https://cprd.com/guidance-completion-cprd-research-data-governance-rdg-application

Appendix:

All project works are uploaded to Github repository can be accessed via below link. Exeter predicition of stroke risk. https://github.com/AyselYuksel/Exeter-Prediction-of-Stroke-Risk Code list folder including all the risperidone, dementia, and stroke codelists and CPRD dictionaries.R_Codes folder contains Development and Production codes. There are test codes in development folder. Production folder includes R scripts for generating codelist and Prod_Dementia_Codes2.R for generating main source codes to generate the cohorts. Hpyertendion _Cohorts.R is written for test purposes.

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Exeter-Prediction-of-Stroke-Risk / R_Codes /
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Development
Adding Prediction of Stroke Risk R codes and codelists
Productions
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