

CHARACTERISING INDIVIDUALS WITH NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER USING ROUTINE LINKED HEALTH DATASETS: A FEASIBILITY STUDY

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Objectives

Non-metastatic castration-resistant prostate cancer (nmCRPC)[1] is a disease state in which cancer is localized but resistant to testosterone suppression therapy (Androgen Deprivation Therapy (ADT) or bilateral orchidectomy). There is relatively little real world data focusing on this disease state either for characterising patients or describing their treatment pathways. This study set out to assess the feasibility of using linked routine health datasets to identify individuals with nmCRPC and to estimate their nmCRPC progression date.

Methods

The study datasets were routine health data for Wales hosted by the SAIL Databank, Swansea University, Wales. Records of patients diagnosed with prostate cancer between 2000 and 2015 were identified by clinical coding (ICD-10 and Read). An algorithm was designed to specify the features of nmCRPC based on presence of codes for testosterone suppression therapy, Prostate Specific Antigen (PSA) test results and codes indicating absence of metastatic disease. Only records that contained at least 3 PSA test results (used to determine a rise during treatment, indicating progression to castration resistance) were included (see figure for details). The algorithm was tested with three different criteria for PSA test levels and intervals, and two thresholds of stringency for determining cases [2-6].

Results

The datasets produced a cohort of 38,021 individuals diagnosed with prostate cancer. Of these 14,860 received ADT while non-metastatic and 6,101 had at least three recorded PSA test results during ADT. The number of nmCRPC cases identified was between 1,281 and 1,534 (non-stringent criteria) and between 439 and 509 (stringent criteria).

Two cohorts were selected for further work were based on the simplest PCWG2 [7] specification providing 1,432 cases without a metastatic diagnosis and 471 with a positive non-metastatic code after inclusion.

Conclusions

Case identification is dependent on accurate, complete coding. The results of this study suggest that it is feasible to use linked routine health datasets to create cohorts of individuals with nmCRPC, including an estimation of date of progression to nmCRPC. Various processes were investigated to improve data quality, particularly in the identification of metastases, resulting in cohorts of sufficient size to enable statistical analysis.

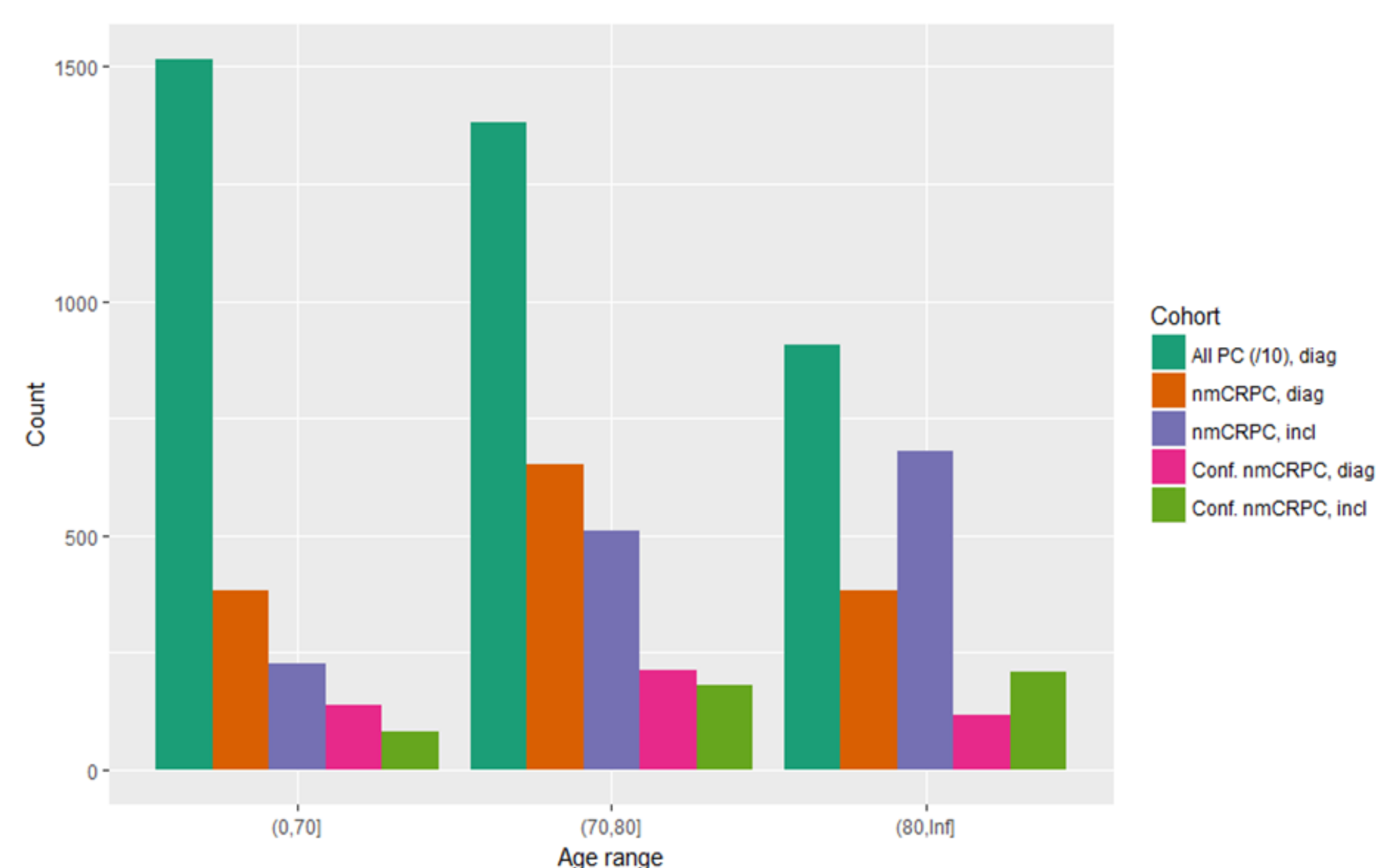
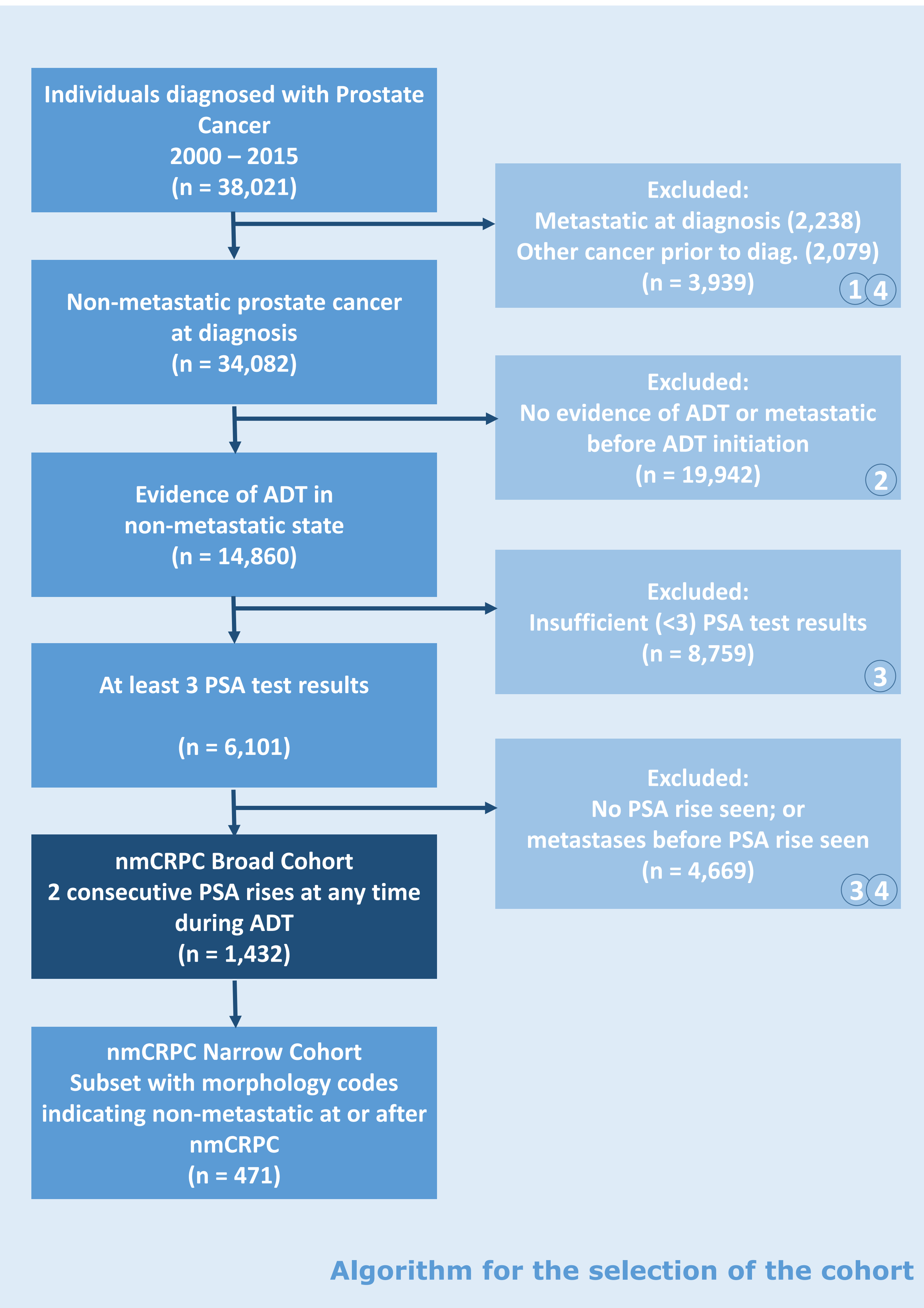
References

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Data Sources

Prostate cancer diagnosis was determined from the Patient Episode Database for Wales (PEDW) and the Welsh Cancer Intelligence and Surveillance Unit (WCISU) using ICD-10 diagnosis codes and from GP data using Read codes. The GP data also provided prescription data for Androgen Deprivation Therapy and results of Prostate Serum Antigen testing.

Code-list concepts were created for each of these categories and were used to create flags in a DB2 database with an SQL script. The resulting cohort was imported into an R environment and processed using bespoke code and SAIL's reproducible research library for R.



Cohort size at diagnosis of prostate cancer and inclusion as non-metastatic, castration-resistant by age at diagnosis and inclusion respectively.

1

Code-lists were managed with the SAIL Concept Library

2

ADT continuous treatment period
A continuous period of treatment (t_{cont}) was defined as the time from the first prescription date until the date the last prescription had been completed and that there was at least a 6 month interval before the next prescription.

3

nmCRPC diagnosis by PSA results
A patient is defined as castration-resistant when, whilst on androgen deprivation therapy, his PSA levels show two consecutive rises (over a period of at least one week each) such that the final PSA level is ≥ 2 ng/ml.

Scher et al (PCWG2), J CLIN ONCOL 26;7 1148-59
Pound et al, 1999 JAMA 281;17 1591-7

4

Cancer morphology codes were available in PEDW and WCISU.

TNM codes were used in the exclusion of metastases at diagnoses (none, M0 or MX codes only permitted). These codes are only available after 2011.

PEDW (ICD10) morphology codes have the form Mddd/d, for example, M8010/3. The final digit is a behaviour digit where 6 and 9 indicate possible metastases and 0-3 indicate non-metastatic.

For the nmCRPC cohort, the absence of a 6 or 9 final digit is taken as indicating non-metastatic.

For the confirmed nmCRPC cohort, the presence of a 0-3 behaviour digit was required.

Gleason scores are also available but were not used in the cohort creation algorithm due to the apparently poor coverage. However, approximately 2/3 of the nmCRPC cohort have a Gleason score and this may be useful in the analysis.

Morphology codes in the data