Data Resource Profile

Data Resource Profile: Results Analysis Base of Navarre (BARDENA)

Gorricho J,1,2 Leache L,2,3 Tamayo I,2,4,5 Sánchez-Sáez F,5, 6 Almirantearena M,2 San Román E,7 Ballaz J,7 Turumbay J,8 Librero J,2,4,5\*

1 Servicio de Evaluación y Difusión de Resultados en Salud, Servicio Navarro de Salud-Osasunbidea, Pamplona, Spain

2 Instituto de Investigación Sanitaria de Navarra (IdiSNA)

3 Sección de Innovación y Organización, Servicio Navarro de Salud-Osasunbidea, Pamplona, Spain

4 Unidad de Metodología-Navarrabiomed, Hospital Universitario de Navarra (HUN), Universidad Pública de Navarra (UPNA), Pamplona, Spain

5 Red de Investigación en Servicios de Salud en Enfermedades Crónicas (REDISSEC)

6 Unidad de Investigación en Servicios de Salud y Farmacoepidemiología, Fundación para el Fomento de la Investigación Sanitaria y Biomédica de la Comunitat Valenciana (FISABIO), Valencia, Spain

7 Servicio de Tecnologías de la Salud, Dirección General de Telecomunicaciones y Digitalización, Pamplona, Spain

8 Subdirección de Sistemas de Información, Servicio Navarro de Salud-Osasunbidea, Pamplona, Spain

\*Corresponding author

**Key features**

* The Results Analysis Base of Navarre (BARDENA) is a population data warehouse of the Navarre Health Department (Spain), which includes weekly updated information since 2012.

BARDENA integrates individual-level information generated at any level of health care of approximately 97% of the Navarre population, totaling more than 660,000 people.

* formal request after corresponding ethical and legal evaluation (mediante solicitud formal a SSCC).
* BARDENA is a useful tool for improving quality of healthcare, decision-making and for research purposes.
* BARDENA interoperates with national and international databases, and has been used in multiple research projects and studies

**Abstract:**

The Results Analysis Base of Navarre (BARDENA) is the health information system of the Navarre, a region with more than 660,000 inhabitants in the north of Spain. It was created as was created to improve quality of healthcare, to help health policymaking, and for data reuse in clinical research. BARDENA is an integrated set of population-wide electronic databases that works as a data warehouse continuously gathering the information generated as part of routine clinical care provided by the the Navarre Health Service along the last 15 years. It covers administrative, socio-demographic, economic, lifestyle, clinical and pharmaceutical data, as well as healthcare information from hospitals, emergency services, specialized care centers (including mental and obstetrics care, among others)and primary care centers. It includes information on hospital admissions, medical consultations, diagnoses, medical procedures, pharmacological treatments, vaccination, microbiological and laboratory data, among others. The database BARDENA interoperates with national and international databases,

BARDENA is in compliance with the National and European legal framework (GDPR) and interoperates with other national and international databases and networks.

**Keywords**

Results analysis, database, healthcare, BARDENA

**1Data resource basics**

*Spanish National Health System*

Spain has a decentralized health system that operates as a network of 17 regional health services. It is publicly funded (mainly from taxes), and provides universal, free of charge, needs-based care coverage to the resident population of Spain. The Ministry of Health is responsible for the national health planning, coordination and regulation, but other competences such as the primary jurisdiction over operational planning, resource acquisition, allocation, and provision are devolved to the regional health authorities. 1In practice,the regional health services, such as the Navarre health service, are organized into Health Departments (each one grouping several primary healthcare districts each of one with an influence over 5000-25000 people) and are responsible for providing global health access to their population of influence in primary, hospital and specialized outpatient care.

However, it worth noting that while the health assistance is free of charge, medicines and medical devices (including orthoprosthetics such as wheelchairs, hearing aids, etc.) are subject to a co-payment 1, which is established on the basis of the economic income and employment status of each individual.

*The Spanish region of Navarre*

Navarre is a region in the north of Spain with more than 660,000 inhabitants, representing 1.4% of the Spanish population, and approximately 1.5 per thousand of the European population. The mean age of the Navarre population is 43,8 years, slightly lower than the overall mean age in Spanish (44,1 years). The age distribution in Navarre is the following: ≤19 years 20%; 20-39 years: 22%; 40-59 years: 31%; 60-79 years: 20%; and ≥80 years: 6%. The annual birth rate is around 7 per 1000 inhabitants (4765 births in 2022)2.

Health care for the population of Navarre is provided through the publicly financed Navarre health service, which includes three Health Departments and 56 Primary Healthcare Districts. The organization of the Health Service of Navarre is represented in Figure 1.

*The Results Analysis Base of Navarre (BARDENA)*

Each regional health system holds the health information of its reference population, and therefore develops and operates its own information systems. Navarre is no exception and here is where the Results Analysis Base of Navarre (BARDENA) comes into play by driving the integration of Navarres health information systems in Navarre.

BARDENA is a publicly funded data warehouse, property of the Department of Health of the Government of Navarre based in Pamplona. It is managed by administrators of the Navarre health service, who are responsible not only for its operation but also for the validity and quality of the information. It was created in 2015 in order to audit processes, evaluate health results, generate reports for the different health decision-makers, and to promote health research.

As such, BARDENA sequentially includes health related information generated by the Navarre health service for the population of the region, regardless of the area or setting from which the care has been provided. At this moment, BARDENA includes health records of more than 600,000 people, approximately 97% of the Navarre population.

The data warehouse includes exhaustive longitudinal patient level information, providing a wide follow-up of the population, which increases over time. This is done through the integration of all the information generated from each person´s first contact with the system (usually from birth) till death, and without any time limit.

During the process of data gathering, transformation and integration, quality reports are automatically generated. These reports are revised and managed by the administrators of the database in order to detect and correct inconsistencies before entering data in BARDENA.

**Data collected**

As stated before, BARDENA is continuously supplied from different data sources, which together constitute the BARDENA Core, which is the backbone of the data warehouse. RECUPERAR ESTE PÁRRAFO. Cambiar patient person. Main por administrative. Cambiar unity por care unit

BARDENA contains individual level information. The Population Information System (LAKORA) is the source of the exclusive and permanent pseudonymized identifier associated with each individual. This identifier is shared between the different modules of information that supply BARDENA, allowing data linkage across the multiple databases, and ensuring the traceability of the individuals through the Navarre health service.

*Data included in BARDENA*

BARDENA incorporates the following type of information: administrative data, socio-demographic data, economic data, lifestyle data, clinical data, pharmaceutical data, healthcare though hospitals, emergency services, specialized care centers (including mental and obstetrics care, among others), primary care centers, and other services provided by the Navarre health service. Table 1 summarizes data available in BARDENA.

**Table 1.** Data included in BARDENA (Rehacer las tablas. Añadir una columna con las 5 dimensiones a la izquierda y volverlo a poner en el texto).

|  |  |
| --- | --- |
| **Data category** | **Data available** |
| Administrative data | Health insurance, date of birth, date of the first contact with the Navarre health service, date of death |
| Healthcare unit | Primary care center and physician of reference |
| Geographic location | Geolocation of the residence and the primary care center of reference |
| Socio-demographic data | Gender, country of birth, nationality, employment status, risk of social exclusion, address. |
| Economic data (analytical accountability) | Pharmaceutical co-payment each individual according to income level.  Unit cost of the humana and material resources (drugs, medical devices, etc.) employed and of the surgical and non-surgical interventions carried out in the Navarre Health Service |
| Lifestyle data | Smoking, alcohol intake, physical activity classified by the GP. |
| Diagnostic procedures | Biochemical/laboratory data, microbiological, anatomic pathology, radiological data |
| Medical diagnoses | Medical diagnoses registered at any level of care. |
| Preventive procedures | Vaccination (type of vaccine, manufacturer, batch number, number of doses, administration date and location, adverse reactions related to vaccines, rejected vaccinations and, if applicable, risk groups). |
| Medical interventions | Surgical and non-surgical medical procedures. |
| Nursing interventions and measurements | Blood pressure, pulse, heart rate, respiratory rate, oxygen saturation, weight, height, body mass index. |
| Social assistance | Interventions conducted by social workers (e.g. providing support to patients and caregivers, assisting patients in health care transitions, managing social health centers, processing the applications for financial and social assistance, building community connections, and patients´ functional capacity assessment).  The type of intervention done, the result of the intervention, and of the beginning and end of the intervention are registered. |
| Pharmaceutical data | Drug prescription (date of prescription, treatment duration, drug prescribed, dose, prescriber, etc.) both in the inpatient and in the outpatient setting.  Drug dispensing to outpatients (number of packages dispensed, date of dispensation, etc.). |
| Contact with health services | Contact with hospitals, emergency services, specialized care centers (including mental and obstetrics care, among others), primary care centers, and other services provided by the Navarre health service, such as palliative care and home hospitalization units, and public social care centers.  Both visits and admissions (including the date of admission and discharge) are registered. |

aThe cost of the human resources is estimated through salaries.

*Sources of data*

The different sources of information from which BARDENA draws are shown in figure 2 and described below.

The Population Information System (LAKORA) is the module that provides administrative, socio-demographic, and economic data. LAKORA is the source of the personal identifier.

The module of primary care information (ATENEA), implemented in 2003, includes the electronic medical records of primary care, reaching a 95% coverage of the population in 2008. ATENEA includes information on both pediatric and adult primary care, as well as any related social assistance and nursing care. Diagnoses are coded in ATENEA vía the 2nd Edition of the International Classification of Primary Care (ICPC-2) 3.

The pharmaceutical data is registered in two modules according to the dispensation setting: LAMIA and FARHO. LAMIA includes drugs prescriptions and dispensations in outpatients (drug prescription in primary care), and FARHO includes drugs prescription in inpatients and in ambulatory patients (drugs prescription in the hospital or other specialized care setting). Both of them use of the Anatomical Therapeutic Chemical (ATC) classification system 4 and the (Spanish) National Pharmaceutical Catalog for drug prescription, allowing the identification of the exact content of each drug prescription and dispensation. LAMIA includes a comprehensive e-prescription system connected to all community pharmacies in Spain. This system links each drug prescription to the corresponding dispensation by the community pharmacy through a specific prescription identification number.

The Hospital Medical Records module was created in 2001 and provides comprehensive information covering all areas of specialized care. Includes data on hospital admissions (both convention and home hospitalization), specialized care consultations (including mental health care and prenatal care, among others), emergencies, diagnostic procedures, medical and nursing procedures, surgeries, prevention and safety measures, and interventions by social workers in inpatients.

Information on medical diagnoses and procedures included in the Hospital Medical Records module is obtained from the Minimum Basic Data Set at Hospital Discharge (MBDS). This is a synopsis of clinical and administrative information on all hospital admissions and major ambulatory surgery that all hospitals from the whole national health system are mandatorily required to complete. Since its implementation in 1987, information from public partnership hospitals and private hospitals has been progressively incorporated. To date, MBDS is the largest administrative and clinical database available in the Spanish health system.5

MBDS includes information on age, sex, geographical area and hospital, hospital admission and discharge dates, principal and secondary diagnoses at hospital discharge, diagnostic and therapeutics procedures conducted during the hospital stay, complications, in-hospital mortality, and destination at discharge. In each hospital, the MBDS database is completed by trained coding staff based on the medical discharge report and other information available in the clinical records.5Medical diagnoses and procedures are coded in MBDS through the ICD.6 The 9th version of the ICD (ICD-9) was used until December 2015 and the 10th version (ICD-10) was adopted thereafter.

All the data related to laboratory analyses are recorded in the SILNA module. There is also a specific module that includes blood management related information (blood transfusions, donations, etc.).

The Vaccine Information System (INMUNIS) module stores all the information on vaccination in Navarre since 2000. Available data includes the type of vaccine, manufacturer, batch number, number of doses, administration date and location, adverse reactions related to vaccines, rejected vaccinations and, if applicable, risk groups. Besides, COVID-19 vaccine data is included.

In addition, BARDENA also includes information from specific databases and registries, such as thediabetes registry. (Añadir esta referencia ORDEN FORAL 37/2014, de 16 de abril, de la Consejera de Salud, por la que se crea y regula el Registro Poblacional de Diabetes tipo 1 de Navarra y se crea el fichero de datos de carácter personal correspondiente. Link: <https://bon.navarra.es/es/anuncio/-/texto/2014/88/10/>) con el título).This registry was aproved by the gobernment of navare and the personal data information management audited by good practice and quality program of the national health system. “Buenas prácticas en al sistema nacional de salud: Creación de un registro para analizar la diabetes tipo 1 y su morbilidad” Link: https://www.sanidad.gob.es/organizacion/sns/planCalidadSNS/pdf/BBPP\_2014/Anexo\_I\_Def\_BBPP\_Diabetes\_A6\_NAVARRA\_2014.pdf

*Data integration, traceability, validation*

BARDENA data collection started in 2012, but gathered all historical data from the existing information systems in Navarre Health Service (hospitalizations and clinical diagnosis since 1996).

All the information coming from different sources and belonging to the same individual are coded with the same identifier, which is the aforementioned LAKORA personal pseudonymized identification code. This allows a holistic view of the individual and guarantees the confidentiality of the information.

The information generated as the routine clinical care is weekly collected. Accordingly, datasets are updated daily and hence, data are generally available in BARDENA from the same day they are extracted. In the case of MBDS, data are subject to a consolidation, quality check and validation processes before data become available in BARDENA, so in this case data from the last quarter before the data extraction may be missing or non-consolidated in BARDENA. In case of any inconsistency or incorrect value detected during the validation processes, they are flagged and returned to the module of origin for revision, not being transformed in BARDENA.

In relation to the processes of data hosting, extraction, and analysis, BARDENA is hosted on local servers using SQL Server 2016. It makes use of the SQL Server Integration Service for the Extract, Transform, Load (ETL) processes, to make up BARDENA data wareHouse.

**Ethical clearance**

Ethical approval of the study protocol by an accredited ethical research committee is required when data from BARDENA are used for research purposes. The Health Department of the Government of Navarre ensures the pseudonymization of the data extracted from BARDENA by providing to the recipients (health decision-makers or researchers) de-identified datasets The Navarre Health Service serves as the data custodian for BARDENA, ensuring the proper management, safeguarding, and responsible use of the collected data. It is committed to upholding privacy, security, and ethical standards in handling the data.

**Data resource use**

*Experience with the use of BARDENA in research projects and studies*

Information in BARDENA has been used as a basis for multiple research projects and studies on various clinical and epidemiological issues, both nationally and internationally. Table 2 includes mention of these studies.

**Table 2.** Studies conducted with information from BARDENA

|  |  |  |  |
| --- | --- | --- | --- |
| **Thematic area** | **Specific topic** | **Research question and main findings (buscar keywords de los artículos)** | **Reference** |
| Infectious diseases | COVID-19 |  | 7–16 |
| Mental health | Incidence of Attention Deficit Hyperactivity Disorder (ADHD) |  | 17 |
| Cardiovascular diseases | Diabetes |  | 18–23 |
| Cancer | Breast cancer |  | 24 |
| Other Chronic conditions |  |  | 25 |
| Obesity |  |  | 26 |
| Safety | Adverse events during hospitalization |  | 27 |

BARDENA also contributes with information of the hospital admissions , regarding demographic, diagnoses, procedures, dates and types of admission and discharge to Spanish national networks, such as the Atlas of Variations in Medical Practice Variation in the National Health Service.28–34, an initiative aimed at describing systematic and unwarranted variations in medical practice at geographic level, that results in the graphical representation of communitie differences in surgical procedures, hospitalizations for cardiovascular problems or rates of avoidable complications of diabetes.

*BARDENA interoperability with national and international databases*

Individual patient data corresponding to hospital health care (demographics, medical diagnoses, procedures, in-hospital mortality, etc.) included in BARDENA is transmitted to the Ministry of Health at the national level. This information is integrated with the data of the rest of the Spanish regions in the MBDS database, which is the database of reference of the Spanish national health system.5 This allows for interoperability of information and analysis of variability between the Spanish hospitals.

In addition, BARDENA information is integrated in the Spanish database for pharmacoepidemiological research in the public sector (BIFAP), managed by the Spanish Agency for Drugs and Medical Devices. This database was created in 2001 and at this moment includes more than 20 million medical records.35 Work is also underway to integrate information from BARDENA into the Spanish Data lake that will be created soon.36

Moreover, at this moment BARDENA is in the process of being integrated into the European European Health Data & Evidence Network (EHDEN), a European consortium of data sources from 12 countries funded by the European Union´s Horizon 2020.37 EHDEN was launched in 2018 and aimed at building a standardized large-scale network to reduce the time needed to provide answers in real world health research. This involves transforming data into the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM),38 an open community data standard designed to standardize the structure of the data from the different sources. This allows to other organizations to analyze and consult our data warehouse through the Observational Health Data Sciences and Informatics (OHDSI) program.39

ATLAS.40

**Strengths and weaknesses**

BARDENA has several strengths and some differential features with regard to other information resources. First, it links population-wide individual healthcare data including administrative, sociodemographic, and clinical information. This allows the study of the impact of social determinants of health (including age, sex, ethnicity, income level) in access and use of health resources and in clinical outcomes at an individual level in the Navarre population.

Second, BARDENA includes information from almost all the Navarre population, being therefore representative. This makes it possible to carry out observational studies in specific subpopulations excluded from clinical trials, such as the people from ethnic minorities, elderly, people with multiple chronic diseases,25 polymedicated people, people with cancer,19,24 pediatric population, and pregnant women, among others, with a high precision.

Third, information in BARDENA is constantly updated, which means that information is available in almost real time. This facilitates decision-making in situations that require an agile response, such as in COVID-19 pandemic, and also makes it possible to make forecasts about the material and human resources that will be needed in the near future.

Forth, BARDENA allows the construction and follow-up of large cohorts of patients over time and the development of longitudinal studies, enabling monitoring of health outcomes in the long-term.

Fifth, data quality in most of the information modules is distinctively high, such as in LAKORA, MBDS or the vaccines registry, providing insight into a population of more than 600,000 inhabitants. Sixth, the availability of unit cost data per patient and activity allows economic evaluation studies with high specificity and granularity.

Seventh, as a source of population health records, it can contribute to pragmatic studies by providing a sample of patients undergoing routine practice This reduces the cost and the timing of access to the data compared to studies with experimental designs, such clinical trials.

Eighth, BARDENA is an ultimate tool for pharmacoepidemiology, since it integrates linked information on clinical conditions, drug prescriptions and dispensation at the individual level. This can be used for conducting accurate drug utilization and adherence studies.

Ninth, BARDENA Core can interact with other integrated tools and information systems besides health, such as education, open government and transparency, and social information systems.

Tenth, the information stored in the BARDENA Core can be easily visualized by health decision-makers and researchers via the Tableau server, which provides statistics of aggregated data, tables and figures.

Eleventh, BARDENA allows data mining, which can be used for discovering clinical processes that permit the application of improved protocols, checking the performance of current processes, detecting, and removing bottlenecks, accelerating clinical processes, and simulating how the introduction of changes in the processes affect the system.

Twelfth, BARDENA interoperates with national and European databases, promoting the development of knowledge and population research at a macro level. Finally, the verification and quality processes to which BARDENA is subjected, guarantee the validity of the information. In this regard, a high effort is being made to integrate and audit information, resulting in high quality data that strengthens data exploitation capabilities.

BARDENA also has some limitations. Some of the information modules that comprise BARDENA Core are subject to the inherent limitations of the routine clinical practice electronic databases. In some specific processes, there may be an information bias due to absent registration (data incompleteness), delay in the registration in the database (e.g., in cases of acute stroke or cardiorespiratory arrest) or due to differing data recording practices (data inaccuracies, misclassification, and heterogeneity), although this is an intrinsic problem of any repository using data from routine clinical practice. In addition, different information modules were created at different moments, and therefore cover different time periods. Moreover, there is a lack of data on specific mortality causes and on drug prescriptions in patients from private nursing-homes. However, pharmacologic information from private nursing-homes is being progressively integrated and is expected to be completely integrated in BARDENA in the forthcoming years. Finally, BARDENA does not include information on people who do not receive assistance from the Navarre health service, that is, who are attended exclusively through private centers. However, this is an unusual situation in Navarre, estimated at approximately 3% of the population.

**Data resource access**

*Ownership and application for access*

BARDENA is owned by the Health Department of the Government of Navarre and operated by managers from the Navarre health service. BARDENA information can be used for improving quality of healthcare, decision-making and for research purposes. Data are currently available for health decision-makers and researchers (internal and external to the Navarre Health Service). Industry funded studies are not accepted. Access to data is free of charge.

In the research field, access to BARDENA information requires a formal application to access to BARDENA information accompanied by: (i) a complete study protocol that details the planned purpose of the use of data, (ii) the approval of the project by an accredited ethics committee, iii) informed consent of patients or a waiver granted by an ethics committee, and (iii) in some cases the classification of the study by the Spanish Agency of Medicines and Medical Devices.

BARDENA has a committee (BARDENA Data committee) that revises the applications, approves, or refuses access to BARDENA information, and establishes priorities. The applications to access to BARDENA information under these requirements should be submitted electronically to the Management Office of the BARDENA Data Commission ([salsedrs@navarra.es](mailto:salsedrs@navarra.es)). Following authorization, researchers must sign a document in which they commit to keep the data in a secure environment, not attempt to re-identify patients or to cross data with other databases, not using the data for purposes or projects other than those specified in the project protocol (including commercial purposes) (although a new application may be presented for these purposes), and not transferring the data to third parties. These latter commitments limit the possibility of storing data in open data repositories or including individual level data as supplementary material in published articles.

*Data visualization and data mining*

The information stored in BARDENA Core can be accessed by health decision-makers and researchers via Tableau server41. This is the BARDENA diffusion product that allows producing analysis tables and visuals of the key information of the BARDENA Core.

BARDENA Milenia is the tool that BARDENA Suite could perform data mining of its data through thetool, which permits BARDENA Suite to perform data mining at the same time as the data are generated in clinical practice. These data analyses can be carried out using platforms such as R, Python platforms, and ProM, providing BARDENA with advanced functionality.

**Ethical approval**

Not applicable

**Author contributions**

J.G: proyect administration, supervision, design, writing, reviewing, and editing of the draft

L.L: design, writing, reviewing, and editing of the draft

I.T: design, writing, reviewing, and editing of the draft

F.S: design, writing, reviewing, and editing of the draft

M.A: Writing, reviewing, and editing of the draft

E.S.R: Reviewing and editing of the draft

J.B: Reviewing and editing of the draft

J.T: proyect administration and reviewing of the draft

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**Conflicts of interest**

None declared

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**Figures:**

Figure 1. Geographical context and administrative organization of the Navarre health service

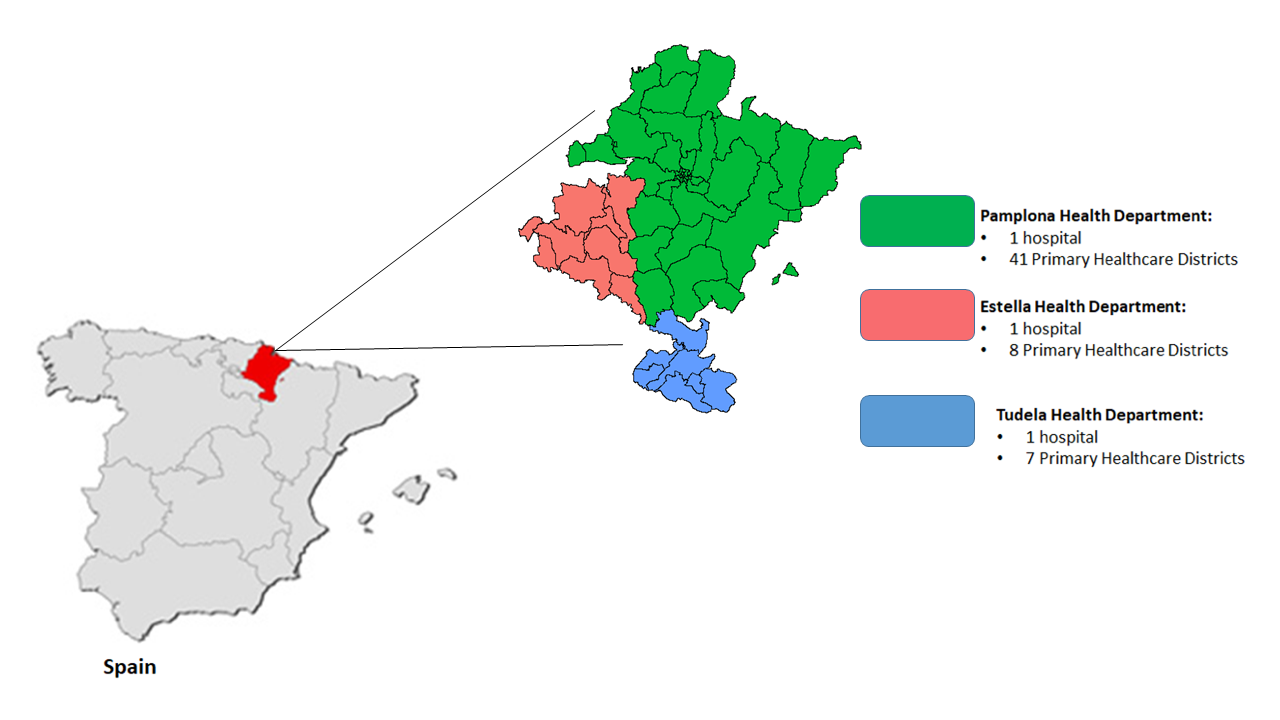


Figure 2: The BARDENA Core data sources

