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Complete List of Authors:	Gorricho, Javier; Servicio Navarro de Salud - Osasunbidea, Servicio de Evaluación y Difusión de resultados en Salud; Instituto de Investigación Sanitaria de Navarra Leache, Leire; Instituto de Investigación Sanitaria de Navarra; Servicio Navarro de Salud - Osasunbidea, Servicio de Evaluación y Difusión de resultados en Salud Tamayo, Ibai; Navarrabiomed, Methodology; Instituto de Investigación Sanitaria de Navarra; RICAPPS Sánchez-Sáez, Francisco; FISABIO, Unidad de Investigación en Servicios de Salud y Farmacoepidemiología Almirantearena, Maite; IdiSNA San Román, Edurne; Servicio de Tecnologías de la Salud Ballaz, Jerónimo; Servicio de Tecnologías de la Salud Turumbay, Javier; Servicio Navarro de Salud - Osasunbidea, Subdirección de Sistemas de Información Librero, Julián; Navarrabiomed, Methodology; IdiSNA; RICAPPS	
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# Data Resource Profile

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Gorricho  $J_{\nu}^{1,2}$  Leache  $L_{\nu}^{2,3}$  Tamayo  $I_{\nu}^{2,4,5}$  Sánchez-Sáez  $F_{\nu}^{6}$  Almirantearena  $M_{\nu}^{2}$  San Román  $E_{\nu}^{7}$  Ballaz  $J_{\nu}^{7}$  Turumbay  $J_{\nu}^{8}$  Librero  $J_{\nu}^{2,4,5}$ 

- 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

#### **Key features**

- The Results Analysis Base of Navarre (BARDENA) is a population data warehouse of the Navarre Health Department (Spain)
- BARDENA includes individual-level data of approximately 97% of the Navarre population, totaling more than 660,000 people
- BARDENA integrates all the health information generated at any level of care, including administrative, socio-demographic, economic, lifestyle, diagnostic, medical and pharmaceutical data.
- 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

# Keywords

Results analysis, database, healthcare, BARDENA

#### 1 Data resource basics

# 1.1 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

<sup>\*</sup>Corresponding author

are devolved to the regional health authorities. <sup>1</sup> In 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 <sup>1</sup>, which is established on the basis of the economic income and employment status of each individual.

## 1.2 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.

# 1.3 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 is continuously monitored and updated. It 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.

#### 2. Data collected

As stated before, BARDENA is continuously supplied from different data sources, which together constitute the BARDENA Core. "BARDENA Core" is the backbone of the data warehouse, where the different sources are stored in the backend and then linked all together in a star schema design. It is made up of main five dimensions common for all the fact tables: patient (the main data of all the people who have received assistance by the Navarre health service or who lived in Navarre), location (geolocation of patients and the reference healthcare centre), diagnosis (medical diagnosis coded through the International Statistical Classification of Diseases-ICD, and procedures), unity (healthcare center and provider), and professional (main characteristics of the professional profile).

BARDENA includes an Analytic Countability Component (ACC) with costs from the health care perspective.

#### 2.1 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

Data category	Data available	
Administrative data	Health insurance, date of birth, date of the first contact with the Navarre health	
	service, date of death, referring primary care physician.	
Socio-demographic data	gender, Country of birth, nationality, employment status, risk of social exclusion, address.	
Economic data	Pharmaceutical co-payment according to income level.  Unit cost of all interventions carried out in the Navarre health service	
Lifestyle data	Smoking, alcohol intake, physical activity	
Diagnostic procedures	Analytical, biochemical, microbiological, anatomic pathology , radiological results.	
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, rejecte	
	vaccinations and, if applicable, risk groups).	
Medical interventions	Surgical and non-surgical medical procedures.	
Nursing interventions	Vital signs, weight, height, body mass index.	
Social assistance	Interventions of social workers.	
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	
	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.	
	Both visits and admissions (including the date of admission and discharge) are	
	registered.	

# 2.2 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 exclusive and permanent pseudonymized identifier associated with each individual. This identifier is shared between the different sources of information that supply BARDENA, allowing data linkage across the multiple databases, and ensuring the traceability of the individuals through the Navarre health service.

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 2<sup>nd</sup> Edition of the International Classification of Primary Care (ICPC-2) <sup>3</sup>.

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 <sup>4</sup> 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.<sup>5</sup>

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. Medical diagnoses and procedures are coded in MBDS through the ICD. 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 acute stroke or diabetes registries.

#### 2.3 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.

Since BARDENA complies with the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CM),<sup>7</sup> it is possible for other organizations to analyze or consult our data warehouse, using Observational Health Data Sciences and Informations (OHDSI) tools as ATLAS.<sup>8</sup>

#### 2.3 Access to BARDENA information, data visualization, and data mining

The information stored in BARDENA Core can be accessed by health decision-makers and researchers via Tableau server<sup>9</sup>. 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 the tool, 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.

#### 3. Ethical clearance

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, unless informed consent is obtained from patients allowing access to their data. In addition, ethical approval by an accredited ethical research committee is required when data from BARDENA are used for research purposes.

#### 4. Data resource use

# 4.1 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	Reference
Infectious diseases	COVID-19	10–19
Mental health	Incidence of Attention Deficit Hyperactivity Disorder (ADHD)	20
Cardiovascular diseases	Diabetes	21–26
Cancer	Breast cancer	27
Other Chronic conditions		28
Obesity		29
Safety	Adverse events during hospitalization	30

BARDENA also contributes to Spanish national networks, such as the Atlas of Variations in Medical Practice Variation in the National Health Service.<sup>31–37</sup>

# 4.2 BARDENA interoperability with national and international databases

At this moment BARDENA information from the hospital setting is integrated with that of other regions in the MBDS, which is piloted at national level.<sup>5</sup> Also, 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.<sup>38</sup> Work is also underway to integrate information from BARDENA into the Spanish Data lake that will be created soon.<sup>39</sup>

Moreover, at this moment BARDENA is in the process of being integrated into the European European Health Data & Evidence Network (EHDEN), a European network of data sources. 40

#### 5. 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, <sup>28</sup> polymedicated people, people with cancer, <sup>22,41</sup> 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.

## 6. Data resource 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). 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.

#### 7. Ethical approval

Not applicable

#### 8. 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

All authors have agreed to the submitted version of the manuscript.

#### 9. Supplementary data

Not applicable

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Not applicable

# 11. Acknowledgements

None

#### 12. Conflicts of interest

None declared

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# Figures:

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

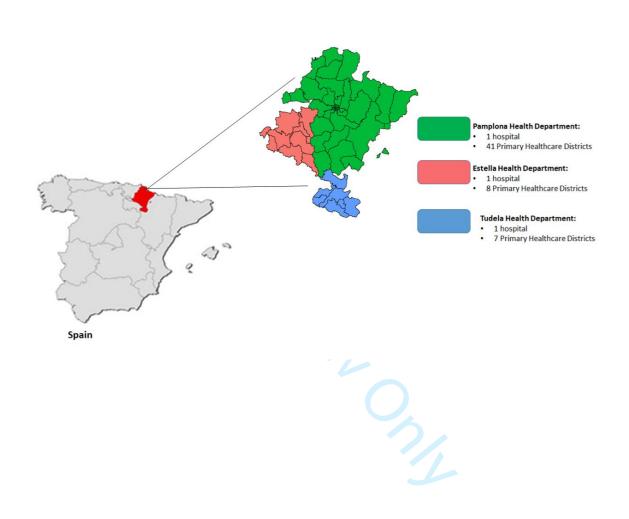


Figure 2: The BARDENA Core data sources

