REPORT
CCM-BRIDGE Project

"Creation and development of the Italian network supporting the European BRIDGE-Health project aimed at structuring and providing sustainability to European activities in the field of Health Information (HI)"

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Index

Abstract

The aim of the project was to verify and improve the availability of health information to organize and develop an integrated, sustainable and standardized National Health Information System (HI) to serve both as the Italian hub for a future European infrastructure and as a source of data, tools and methods for health research.

The main activities of the project were carried out by four working groups and involved: **a)** the establishment of a network of HI experts ; **b)** the verification of health data sources; **c)** the updating of ECHI short list indicators for Italy; **d)** the identification of information gaps due to problems in transmitting and communicating Italian data to international organizations; **e)** the identification of regulatory and ethical constraints on ethics and privacy, related to access, use and integration of health data through a proposal aimed at a sustainable organization and governance of the system, **f)** the implementation of a pilot project to interconnect and integrate current health and administrative data with data from longitudinal epidemiological studies carried out at the Istituto Superiore di Sanità (National Health Institute).

Keywords: Health Information; Public Health; Record linkage;

Introduction

The Italian project "Creation and development of the Italian network supporting the European BRIDGE-Health project aimed at structuring and providing sustainability to European activities in the field of Health Information (HI)", developed by the Centre for Disease Control of the Ministry of Health, was approved with the aim of supporting the activities envisaged under the European BRIDGE Health project, for the development of a national HI infrastructure.

The European BRIDGE Health project - BRidging Information and Data Generation for Evidence-Based Health Policy and Research, approved by the European Commission to establish a consortium aimed at providing long-term structuring and sustainability to European activities in Health Information, aims at improving the availability of health information, which is still fragmentary and not timely, through the building of a sustainable and integrated information system at European level. The objective is therefore to support research and health policy decisions through standardized tools, methodologies and procedures for collecting, harmonizing, processing and transferring data at European level. The project was launched in May 2015 and includes 31 partners from 16 Countries. The activities of BRIDGE Health see the participation of the networks of previous European projects that over the years have contributed to the definition of indicators, the collection of data and the implementation of tools to assess population health, trends in pathologies and clinical performance (Health Examination Survey, population records, environmental risk surveys, use of administrative data, data integration with specific surveys, assessment of health systems). The project is divided into 12 Work Packages (WPs), including three packages typical of European projects (coordination, dissemination and evaluation of activities), four packages on specific surveys (WP4-European Core Health Indicators Monitoring, WP5-Harmonized Population Based Health Examination Survey, WP6- Impacts of Environmental Chemicals on Health, WP7-Reproductive, Maternal, Newborn, Child and Adolescent Health), four packages on the integration of administrative data to assess population health and Health Care System (WP8-Platform for Population Based Registries, WP9-Platform for Injury Surveillance, WP10-Building a Platform for Administrative Data on Health Care, WP11-Integration of Approaches into a Comprehensive EU Information System for Health and Health Care Monitoring and Reporting), and one on the evaluation of Health Care System (WP-12 Evaluation of Health Care System). The project foresees the achievement of the objectives, the preparation of technical reports and manuals (blueprints), the development of guidelines for the training of healthcare professionals, and finally the drafting of a concept paper, which should summarise the debate developed in the networks about the creation of a potential organizational infrastructure capable of taking on the tasks deriving from the need to strengthen the EU health information system. To this end, one of the most appropriate forms of organization is the European Research Infrastructure Consortium (ERIC), a specific legal form to facilitate the establishment and operation of research infrastructures with European interest. The main task of the ERIC is to establish and manage new or existing non-economic research facilities to carry out research programmes and projects through the transfer of knowledge and/or researchers and the dissemination and enhancement of results. An ERIC is a legal entity with full powers of action, recognized in all Member States and composed of at least three Member States. Member States, associated countries, non-member countries, non-associated countries and intergovernmental organizations may participate, and together they shall contribute to the achievement of the objectives of the ERIC, in particular the establishment and management of a research infrastructure of European importance. Member States, associated countries, third countries other than associated countries and intergovernmental organizations may also play the role of non-voting observers.

An ERIC on the Health Information System (ERIC-HI-System) would therefore facilitate research activities and the exchange of evidence-based health policy information between Member States, and it would strengthen the health monitoring of EU citizens and services provided by EU healthcare systems.

Objectives

The general objective of the Italian CCM-Bridge project is to enhance the activities envisaged by the European BRIDGE-Health project and can be summarized as follows:

- To create an Italian network made up of HI experts;
- To collect useful data for health policies through standardized and validated indicators for the monitoring of population health and the performance of health systems;
- To ensure national transferability of disease frequency and healthcare performance indicators through common and standardized procedures for the creation of complex indicators;
- To improve quality and use of this tool at all stages, from collection to treatment and elaboration of estimates on the general population;

- To ensure quality improvement through the validation of health indicators;
- To set priorities and deal with ethical and legal issues arising from the collection and use of health data following the recommendations and developments of the EU BRIDGE-Health project;
- To develop a sustainable, integrated and standardized HI system as a national infrastructure proposal, by identifying common methodologies among the Member States;
- To assess the ethical and legal problems associated with collecting and using health data at Member State level;
- To facilitate the exchange of expertise with other Work Packages (WPs) and participation in the Horizontal Activities (HA) of the BRIDGE-Health project.

Kick-off meeting

The kick-off meeting of the CCM-Bridge project took place in Rome on May 9, 2016 at the Bovet Hall of the Istituto Superiore di Sanità (ISS – National Health Institute). The workshop was attended by representatives of the Ministry of Health, the ISS, the National Institute of Statistics (Istat) and other Italian research organizations. During the meeting, the European BRIDGE-Health project was illustrated and some examples of European integrated data reading initiatives developed by leading international organizations (WHO, OECD, European Commission) were described. The main outcome of the workshop was the creation and development of an Italian Network of Experts, which led to the creation of four Working Groups aimed at structuring and providing sustainability to European activities in the field of HI.

Working Groups (WGs)

The four WGs identified during the kick-off meeting were:

WG 1: ECHI indicators

The aim of this group was to develop the following topics:

- Analysis of the availability of Italian ECHI indicators within the ECHI tool;
- Analysis of the differences between the indicators in the ECHI tool at European level and those calculated at national level;
- Identification of the data source for the required information, calculation methodology and procedures underlying the calculation of the ECHI indicator;
- Data quality assessment;
- Discussion of possible alternative solutions;
- Up-to-date inventory of ECHI indicators available in Italy;
- Critical issues and enabling factors, advantages and disadvantages of indicator availability/accessibility.

WG 2: Data communication, transmission and dissemination

The aim of this group was to develop the following topics:

- Obstacles to data accessibility/availability at local/regional/national level;
- Approach and methodology of access, query, data analysis according to its use, including rules for data availability/accessibility to public and private facilities;
- "Good practice" rules for the production of data/indicators/quality methodologies.

WG 3: Governance

The aim of this group was to develop the following topics:

- Organization of an Italian HI system;
- Building a reference network for the production of the indicators required at international level;
- Creating the necessary structures for the management and coordination of the HI system;
- Identifying actions and tools needed to ensure the sustainability of the HI system.

WG 4: Data Interconnection

The aim of this group was to develop the following topics:

- Methods for data interconnection, analysis and usage from current administrative flows and surveys or registers;
- Availability and accessibility of data;
- Data processing and ethical and privacy issues;
- Ability to produce quality evidence.

The four working groups contributed to the drafting of this report which consists of different topics.

National Institutions and stakeholders involved

In Italy, the main players involved in setting up a monitoring system based on the ECHI short list indicators are:

- National Institute of Statistics;
- Ministry of Health
- Istituto Superiore di Sanità/National Health Institute
- Italian National Tumour Association
- The Italian focal points for data transmission to international organizations (EUROSTAT/OECD/WHO/EMCDDA)

To facilitate collaborations between Italian research bodies and international institutions, each Country has identified some technical-scientific subjects to behave as points of contact with international organizations; these subjects are called 'Focal points', and their task is to facilitate the transmission of Italian data to international organizations such as Eurostat, OECD and WHO.

The network of experts

The creation of a network of experts belonging to the main Italian research organizations that have expressed an interest and have actively participated in the various phases of the project was the first specific objective achieved by the CCM-Bridge project; the creation and consolidation of the working groups is crucial to the development of a sustainable national HI infrastructure.

Table 1. Network of CCM-Bridge Project Experts

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The members of the expert network, divided into four working groups, met three times during the year at the Ministry of Health, and a fourth and fifth time in joint session, according to the following calendar:

	1st meeting	*2nd meeting*	*3rd meeting*	*4th meeting*	*5th meeting*
WG 1	11/06/2016 10:00am - 1:00pm	22/09/2016 10:00am - 1:00pm	29/11/2016 10:00am - 1:00pm	01/02/2017 10:00am – 5:00pm	15/03/2017 10:00am – 5:00pm
WG 2	11/06/2016 2:30pm - 5:30pm	05/10/2016 2:30pm - 5:30pm	12/12/2016 10:00am - 1:00pm		
WG 3	12/06/2016 10:00am - 1:00pm	22/09/2016 10:00am - 1:00pm	02/12/2016 10:00am - 1:00pm		
WG 4	12/06/2016 2:30pm - 5:30pm	06/10/2016 2:30pm - 5:30pm	12/12/2016 3:00pm - 5:00pm		

Right from the first meetings, a need emerged to have a clear understanding of the procedures and rules to access data and not just to know whether data existed. In particular, the different working groups stressed the need to distinguish between data "access" and data "availability". In this regard, it was decided to develop a glossary containing the terminology used in the HI application, and an inventory of existing national data sources.

Glossary

The glossary of the main terms used for data procedures and access rules was developed by WG 2 in order to clarify concepts and reduce terminology confusion in this area through the harmonization of the adopted terminology. The terms selection and their definitions here below have been discussed by the WG and validated by the network of project experts. When available, English definitions (in italics) have also been reported.

TERM	DEFINITION/DESCRIPTION	BIBLIOGRAPHY
Access	Operation that allows anyone to view and copy electronic documents	Dpcm_13_11_2014_allegato_1_glossario_definizioni-1
On-line Access	In the case of public administrations, on-line access means the possibility to access data and documents published by the administrations, in any form and without any explicit license and intended as open data.	Legislative Decree 7 March 2005, no. 82 (Digital Administration Code) as amended (updated to Legislative Decree 26 August 2016, no. 179)
Data processing	Data processing refers to the operation performed on data in order to derive new information according to a given set of rules. Data processing may involve various processes, including data validation, summarization, aggregation, analysis and reporting.	Eurostat glossary. Available at : http://ec.europa.eu/eurostat/statistics-explained/index.php/Category:Statistical_concept. Viewed on 27/03/2017
Local Healthcare Unit (ASL)	Territorially competent authority entrusted with health protection functions. It is a body with public legal personality and with full autonomy as concerns organisation, administration, financial, accounting, management and technical Istituto Superiore di Sanitàues. It ensures common levels of assistance.	Istat Glossary. Available at: http://www3.istat.it/dati/catalogo/20101119_00/PDF/glossario.pdf Viewed on 06/12/2016
Hospital of Reference (AO)	Highly specialized Hospital of national importance. These hospital are university hospitals, but also those hospitals that meet the following characteristics: - presence of at least three highly specialized units; - Consolidated structure bringing together all departments and services that make up a highly specialized structure. The Hospital of Reference (AO acronym in Italian) has public legal personality and full autonomy as concerns organisation, administration, financial, accounting, management and technical Istituto Superiore di Sanitàues. It has the same agencies as the local healthcare unit and has an administrative director, a medical director and a health council. The management of these hospitals is guided by the principle of economic and financial autonomy as well as autonomy in actual and estimated costs for each cost centre, based on services provided.	Istat Glossary. Available at: http://www3.istat.it/dati/catalogo/20101119_00/PDF/glossario.pdf Viewed on 06/12/2016
Database	(1) Compilation of files, data, or other independent materials systematically or methodically arranged and individually accessible through electronic means or otherwise	Directive of the European Parliament and Council, dated 11 March 1996 (96/9/CE), published in the Official Journal of the European Union

		no. 77 of 27 March 1996. – Legislative Decree of 6 May 1999, no. 169
	(2) Any organized set of personal data, divided into one or more units located in one or more sites.	Legislative Decree 196/2003, as amended "Personal Data Protection Code" (updated to Legislative Decree 14 September 2015, No. 151) (English version: http://194.242.234.211/documents/10160/2012405/Personal+Data+Protection+Code+-+Legislation + Decree + no.196 + of + 30 + June + 2003.pdf)
	(3) Databases are web interfaces for browsing and downloading of data produced. Each database has meta-information (methodologies, classifications, definitions) related to the subject being discussed.	Istat. Available at: http://www.istat.it/it/prodotti/banche-dati Viewed on 16/01/2017
Database of national interest	(1) Collection of registered and interconnected data	(Decree of the President of the Council of Ministers, 3 December 2013. Technical rules for the IT Protocol pursuant to articles 40-bis, 41, 47, 57-bis and 71 of the Digital Administration Code as per Legislative Decree no. 82 of 2005)
	The collection of information digitally gathered and managed by public administrations, homogeneous by type and content, and whose knowledge is relevant to the performance of the institutional functions of other public administrations, even for statistical purposes only, in accordance with the competences and regulations in force. Without prejudice to the competencies of each public administration, these databases of national interest constitute, for each type of data, a unitary information system that takes into account the different institutional and territorial levels and ensures homogeneous information and access to the same by the public administrations concerned. These information systems have minimum security, accessibility and interoperability characteristics and are made and updated according to technical rules and in compliance with the rules of the National Statistical System. At first application, the following national data bases are identified: (a) national directory of territorial data; (b) national population register; (c) a national database of public contracts referred to in Article 62-bis; D) criminal records; E) business register; F) automated immigration and asylum archives	Legislative Decree 7 March 2005, n. 82 (Digital Administration Code) as amended (updated to Legislative Decree 26 August 2016, no. 179)

	referred to in Article 2, paragraph 2, of Presidential Decree no. 242 of 27 July 2004 F-bis) National Healthcare Register (ANA). (Art. 60. Legislative Decree 82/2005 as amended)	
Benchmark	Points of reference or a standard against which measurements can be compared. In the context of indicators and public health, a benchmark is an accurate data point, which is used as a reference for future comparisons (similar to a baseline). Sometimes it also refers to as "best practices" in a particular field.	Tyler Norris, et al. The Community Indicators Handbook: Measuring Progress toward Healthy and Sustainable Communities. San Francisco: Redefining Progress, 1997.
Disclosure of personal data	The disclosure of personal data to one or more persons other than the person concerned, the data representative/owner in the territory of the State (the natural person, the legal person, the public administration and any other body, association or entity which, also in connection with some other data owner, are entitled to take decisions on the purposes, the manner and the instruments used for the processing of personal data, including security issues, the person responsible (the natural person, the legal person, the public administration and any other body, association or entity authorized by the owner of data to process personal data) and those persons (natural persons authorized to carry out processing operations by the data owner or the person in charge) who are entitled to know data, in any form, including by making data available or allowing data consultation.	Legislative Decree 196/2003 as amended, "Code on the protection of personal data" (updated to Legislative Decree 14 September 2015, no. 151) (English version: http://194.242.234.211/documents/10160/2012405/Personal+Data+Protection+Code+-+Legislat.+Decree+no.196+of+30+June+2003.pdf)
Data	(1) Statistical data. It is the result of the operation of statistical data processing aimed at gathering of statistical data and producing the input object data of a statistical survey.	Istat. Available at: http://www.istat.it/it/prodotti/banche-dati Viewed on 16/01/2017
	(2) Data refer to characteristics or information, usually numerical, that are collected through observation. Data are typically the results of measurements and can be visualized using graphs or images	Eurostat glossary. Available at: http://ec.europa.eu/eurostat/statistics-explained/index.php/Category:Statistical_concept Viewed on 27/03/2017
	(3) Open Data. Open-type data has the following characteristics: 1. it is available under the terms of a license allowing its use, including commercial use, in a disaggregated format, by legal entities; 2. it is accessible through information and communication technologies, including public and private telematic networks, in open formats as referred to in (a); it is suitable for automatic use by computer programmes and provided with the relevant metadata;	Legislative Decree 7 March 2005, no. 82 (Digital Administration Code) as amended (updated to Legislative Decree 26 August 2016, no. 179)

	3. it is made available free of charge through information and communication technologies, including public and private telematic networks, or made available at the marginal costs incurred for its reproduction and dissemination. The Agency for Digital Italy must establish, with its own resolution, the exceptional cases, identified according objective, transparent and verifiable criteria , in which data can be made available at fees far above marginal costs. (Art. 68 Legislative Decree 82/2005 as amended)	
	(4) Personal Data. Any information concerning specific natural persons or persons that can also be identified by means of other information, for example, by a number or an identification code. For example, personal data can be the name, family name or denomination of a person, his/her address, or tax code; But also an image, voice recording, fingerprint, health data, bank data, and so on.	Glossary of the Data Protection Authority. Available at: http://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/docweb/1663787 (Viewed on 16/01/2017)
	(5) Sensitive data: data that may reveal racial or ethnic origin, religious or other beliefs, political opinions, party membership, trade union or association membership, the state of health and sexual life of persons.	Glossary of the Data Protection Authority. Available at: http://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/docweb/1663787 (Viewed on 16/01/2017)
Dataset	The term refers to any organised collection of data. The data set lists values for each of the variables and for each member of the dataset. Each value is known as a datum.	Eurostat glossary. Available at: http://ec.europa.eu/eurostat/statistics-explained/index.php/Category:Statistical_concept Viewed on 27/03/2017
Data disclosure/ Dissemination	Dissemination is the release to users of information obtained through a statistical activity and consists of distributing or transmitting statistical data to users. Various release media are possible; for example: electronic format including the internet, CD-ROM, paper publications, files available to authorised users or for public use; fax response to a special request, public speeches, press releases.	OECD Glossary of statistical terms. Available at: https://stats.oecd.org/glossary/detail.asp?ID=3004 Viewed on 27/03/2017
	Dissemination is any process by which information is transmitted (made available or accessible) to intended audiences or target groups.	WHO. A glossary of terms for community health care and services for older persons. Available at: http://www.who.int/kobe_centre/ageing/ahp_vol5_glossary.pdf Viewed on 27/03/2017
	Disclosure of personal data: Disclosure of personal data to the public or, in any case, to an indefinite number of subjects (for example, publication of personal data on a newspaper or on a web page).	Glossary of the Data Protection Authority. Available at: http://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-

		display/docweb/1663787 (Viewed on 16/01/2017)
	Dissemination of personal data: process by which personal data is made known to unknown individuals, in any form, including by making data available or accessible.	Legislative Decree 196/2003 as amended. “Personal Data Protection Code” (updated to Legislative Decree 14 September 2015, no. 151) (English version: http://194.242.234.211/documents/10160/2012405/Personal+Data+Protection+Code+-+Legislat.+Decree+no.196+of+30+June+2003.pdf)
Availability	The possibility for a public administration to make any given data accessible and usable to other administrations in accordance with the legislation on the protection of personal data, when the use of the given data is necessary for the performance of institutional tasks.	Legislative Decree 7 March 2005, no. 82 (Digital Administration Code) as amended (updated to Legislative Decree 26 August 2016, no. 179)
Research institution (1)/ Research organizations (2)	Public or private non-university scientific institutions entrusted with the task of promoting or carrying out activities to further enhance knowledge.	Legal Encyclopaedia. Available at: http://www.enciclopedia-juridica.biz14.com/it/d/enti-di-ricerca/enti-di-ricerca.htm (Viewed on 06/12/2016)
	Non-profit entity, such as a university or research institute. It is an entity established according to private or public law, irrespective of its sources of funding, whose main purpose is to carry out basic research, industrial research and experimental research, and to disseminate the results through teaching, publication or technology transfer. Profits are reinvested in research activities, the dissemination of research results, or teaching; the undertakings that can influence such an entity, for example as shareholders or members, do not enjoy any preferential access to the research capabilities of the entity or to the results obtained (Ref 2006/C323/01).	Glossary of the National Research Programme (Programma Nazionale della Ricerca) – MIUR. Available at: http://www.miur.it/UserFiles/3248.pdf , Viewed on 16/01/2017
Ethics	The moral principles adopted and observed by an organization.	Quality Glossary. Sapienza – University of Rome. Available at: www.uniroma1.it/sites/default/files/allegati/Glossario-Sito.pdf viewed on 16/01/2017
	The science of conduct which, if viewed from the point of view of the intent of a person and of his inner disposition, assumes, the name of morality, according to what asserted by G.W.F. Hegel, whereas if it is considered from the point of view of the values actually realized in history, it takes the name of ethics	Galimberti, U. (1999). Dizionario di Psicologia. Torino: UTET (p. 374)
Ethics (of care)	The basic evaluative principles which (should) guide	A glossary of terms for

	"good" care. Principles typically refer to respect for, and the dignity of, human beings.	community health care and services for older persons. WHO Centre for Health Development - Ageing and Health Technical Report: www.who.int/kobe_centre/ageing/ahp_vol5_glossary.pdf. Viewed on 27/03/2017
Administrative source	*The administrative source is the register of units and data associated with an administrative regulation (or group of regulations), viewed as a source of statistical data.*	Eurostat glossary. Available at: http://ec.europa.eu/eurostat/statistics-explained/index.php/Category:Statistical_concept. Viewed on 27/03/2017
Data usability	In order to facilitate the dissemination of data of general interest available at the national, regional and local public administrations, a National Directory of Territorial Data is set up at the AgID (Digital Agency for Italy), as a reference agency for the provision of local data search services and related services, and as national access point for the implementation of Directive 2007/2/EC (INSPIRE Directive) with regard to metadata.(Art. 59 Legislative Decree 82/2005 as amended).	Legislative Decree 7 March 2005, n. 82 (Digital Administration Code) as amended (updated to Legislative Decree 26 August 2016, no. 179)
Data Protection Authority	The Protection Authority has the task of ensuring the protection of fundamental rights and freedoms in the processing of personal data and respect for the dignity of the person. It is a collegiate body composed of four members elected by the Parliament; It is based in Rome, 121, Piazza di Montecitorio. It has an office with a staff of 125 units. The Authority examines the complaints and reports of citizens and ensures the respect for the rules that protect people's privacy. It rules on the actions brought by citizens and prohibits, also automatically, illicit or incorrect data treatment. It performs inspections, imposes administrative sanctions and issues opinions in the cases provided by the Code. It advices Parliament and Government on the opportunity for regulatory actions on personal data protection. The Data Protection Authority is an independent administrative body established by the Privacy Act (Law 675 of 31 December 1996, now incorporated into the Code). The establishment of similar authorities is envisaged in all other EU Member States (Article 8 of the Charter of Fundamental Rights of the European Union).	Glossary of the Data Protection Authority. Available at: http://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/docweb/1663787 Viewed on 16/01/2017
Survey	A survey is an investigation about the characteristics of a given population by means of collecting data from a sample of that population and estimating their characteristics through the systematic use of statistical methodology.	OECD Glossary of statistical terms. https://stats.oecd.org/glossary/detail.asp?ID=3004 Eurostat glossary. Available at: http://ec.europa.eu/eurostat/statistics-

		explained/index.php/Category:Statistical_concept. Viewed on 27/03/2017
	An investigation in which information is systematically collected but in which the experimental method is not used.	John M. Last. A Dictionary of Epidemiology. Fourth Edition. Oxford University Press: Oxford 2001
Indicator	Quantitative or qualitative factor or variable that provides a simple and reliable means to measure achievement, to reflect the changes connected to an intervention, or to help assess the performance of a development actor.	Glossary of the main terms used in results based management. Available at: www.oecd.org/development/peer-reviews/17484948.pdf https://www.oecd.org/dac/evaluation/dcdndep/39249691.pdf Viewed on 27/03/2017
	Indicators are a measure that can be used to help describe a situation that exists and to measure changes or trends over a period of time. Most health indicators are quantitative in nature but some are more qualitative.	Vaughan, J.P., Morrow, R.H. Manual of Epidemiology for District Health Management, WHO 1989
	In statistics, a variable taking only one of two possible values, one (usually 1), indicating the presence of a condition, and the other (usually zero) indicating absence of the condition. Used mainly in Regression Analysis.	John M. Last. A Dictionary of Epidemiology. Fourth Edition. Oxford University Press: Oxford 2001
Statistical indicator	Data element that represents statistical data for a specified time, place, and other characteristics, and is corrected for at least one dimension (usually size) to allow for meaningful comparisons.	Available at: https://sdmx.org/wp-content/uploads/SDMX_Glossary_Version_1_0_February_2016.docx Viewed on 27/03/2017
Health indicator	"A health indicator is a characteristic of an individual, population, or environment which is subject to measurement (directly or indirectly) and can be used to describe one or more aspects of the health of an individual or population (quality, quantity and time)."	The WHO Health Promotion Glossary. Available at: http://www.who.int/healthpromotion/about/HPG/en/. Viewed on 27/03/2017
Metadata	Metadata is structured information that describes, explains, locates, or otherwise makes it easier to retrieve, use, or manage an information resource. Metadata is often called data about data or information about information. There are three main types of metadata: • Descriptive metadata describes a resource for purposes such as discovery and identification. It can include elements such as title, abstract, author, and keywords. • Structural metadata indicates how compound objects are put together, for example, how pages are ordered to form chapters. • Administrative metadata provides information to help manage a resource, such as when and how it was created, file type and other technical	National Information Standards Organization. Understanding Metadata. Available at: http://www.niso.org/publications/press/UnderstandingMetadata.pdf Viewed on 16/01/2017

	information, and who can access it.	
	Data set associated with a computer document, computer file, or set of computer documents used to identify the document and describe its context, content and structure as well as to allow its management in the data retaining system over time	(Decree of the President of the Council of Ministers 3 December 2013. Technical rules for the IT protocol pursuant to Articles 40-bis, 41, 47, 57-bis and 71 of the Digital Administration Code as per Legislative Decree no. 82 of 2005.
	It can be defined as information that is needed to be able to use and interpret statistics. Metadata describe data by giving definitions of populations, objects, variables, the methodology and quality. A distinction is generally made between structural and reference metadata. Structural metadata are used to identify, formally describe or retrieve statistical data, such as dimension names, variable names, dictionaries, dataset technical descriptions, dataset locations, keywords for finding data etc. For example, structural metadata refer to the titles of the variables and dimensions of statistical datasets, as well as the units employed, code lists (e.g. for territorial coding), data formats, potential value ranges, time dimensions, value ranges of flags, classifications used, etc. Reference metadata sometimes called explanatory metadata) describe the contents and the quality of the statistical data from a semantic point of view. They include explanatory texts on the context of the statistical data, methodologies for data collection and data aggregation as well as quality and dissemination characteristics.	Available at: http://ec.europa.eu/eurostat/statistics-explained/index.php/Category:Statistical_concept Viewed on 27/03/2017
Microdata	Microdata are the units of data that aggregate statistics are compiled from. Microdata consist of sets of records containing information on individual respondents or business entities. To protect the anonymity of respondents (persons, organizations), the access to microdata is restricted.	Available at: http://ec.europa.eu/eurostat/statistics-explained/index.php/Category:Statistical_concept Viewed on 27/03/2017
Monitoring	Checking the evolution of a phenomenon, through repeated and/or continuous measurements and the use of indicators.	Glossary of the Ministry of Health. Available at: http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=314&area=qualita&menu=sicurezza&tab=11. Viewed on 27/03/2017
	Continuous process of observing and checking.	WHO. A glossary of terms for community health care and services for older persons. http://www.who.int/kobe_centre/ageing/ahp_vol5_glossary.pdf. Viewed on 27/03/2017

Privacy	English word with several and sometimes different meanings, but close to the concepts of "confidentiality" and "privacy." In today's world, privacy does not simply mean the right to be left alone or to protect one's private sphere, but it means above all the right to control the use and dissemination of personal data that constitutes a primary asset in today's Information-based society.	Glossary of the Data Protection Authority. Available at: http://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/docweb/1663787. Viewed on 16/01/2017
	Privacy is the ability of an individual to be left alone, out of public view, and in control of information about oneself. One can distinguish the ability to prevent intrusion in one's physical space ("physical privacy", for example with regard to the protection of the private home) and the ability to control the collection and sharing of information about oneself ("informational privacy"). The concept of privacy therefore overlaps, but does not coincide, with the concept of data protection. The right to privacy is enshrined in the Universal Declaration of Human Rights (Article 12) as well as in the European Convention of Human Rights (Article 8).	European Data Protection Supervisor Glossary Available at: https://secure.edps.europa.eu/EDPSWEB/edps/site/mySite/pid/84#privacy. Viewed on 27/03/2017
Administrative data collection	Administrative data collection refers to the set of activities involved in the collection, processing, storage and dissemination of statistical data from one or more administrative sources. It is comparable to a survey but with the source of data being administrative records rather than direct contact with respondents.	Eurostat glossary. Available at: http://ec.europa.eu/eurostat/statistics-explained/index.php/Category:Statistical_concept. Viewed on 27/03/2017
Region	At political and administrative level, and according to Constitutional and ordinary laws, each of the territorial entities in which a regional state may be divided has a more or less extensive administrative autonomy and also a legislative power, albeit limited.	Treccani online dictionary. Region. Available at: http://www.treccani.it/vocabolario/regione/ (Viewed on 06/12/2016)
Type of hospitalisation	Specific type of healthcare delivery services. Healthcare services can be delivered as "inpatient" or "outpatient" services. Inpatient services: patients are admitted as inpatients in the hospital and hospitalised overnight (at least for one night). Outpatient services: patients do not stay overnight in the hospital but visit the hospital during the day to receive medical or surgical care. This hospital care is provided by hospital departments or units that supply diagnostic and/or healthcare and/or rehabilitation services and has all the following functional features: it is a planned single admission or planned multiple admissions; it does not foresee the presence of the patient in the hospital for the entire day but it is limited to part of the day; it provides multi-professional and/or multi-specialist	Glossary - Lazio Region. Available at: http://www.regione.lazio.it/statistica/dettaglio_glossario/azienda_sanitaria_locale_asl/21/0/0/a-320/0/ . Viewed on 27/03/2017

	services that exceed the time normally needed for ambulatory care.	
Register	In epidemiology the term register is applied to the file of data concerning all cases of a particular disease or other health-relevant condition in a defined population such that the cases can be related to a population base. The register is the actual document, and the register is the system of ongoing registration.	John M. Last. A Dictionary of Epidemiology. Fourth Edition. Oxford University Press: Oxford 2001
	The term “register” refers to a collection of data on all cases of a particular disease or other relevant health condition in a defined population, so that cases can be related to a specific population and, if cases are regularly followed, information can be obtained on healing, recurrence, survival and prevalence	Porta M (Ed.). A dictionary of epidemiology, fifth edition. New York. NY: Oxford University Press; 2008.
Hospital Discharge Summary	The Hospital Discharge Summary is the tool that collects information on every patient discharged from a public or private hospital throughout the country. In this way, and in compliance with privacy regulations, information is collected on hospital activities essential to healthcare professional and citizens. Discharge Summaries are compiled by the doctors who treated the patient in the hospital; this encoded information is transmitted to the Regions and to the Ministry of Health.	Glossary – Ministry of Health – Available at: http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=3669&area=ricoveriOspedalieri&menu=vuoto (Viewed on 12/01/2017)
National Healthcare System (NHS)	This system is made up of the functions, structures, services and activities for the promotion, maintenance and recovery of physical and mental health of all the population, without distinction of individual or social conditions, and in ways that ensure the equal access of all groups of society to health services.	Istat Glossary. Available at: http://www3.istat.it/dati/catalogo/20101119_00/PDF/glossario.pdf (Viewed on 06/12/2016)
Surveillance	Surveillance means the systematic ongoing collection, collation and analysis of data for public health purposes and the timely dissemination of public health information for assessment and public health response as necessary.	World Health Organization - Fifty-eight World Health Assembly. Revision of the International Health Regulations. Geneva: WHO; 2005. (Document WHA58.3). Available at: http://apps.who.int/gb/ebwha/pdf_files/WHA58-REC1/english/Resolutions.pdf Viewed on 27/03/2017
Stakeholder	Holders of various interests, people who influence in some way the process or system being considered. In healthcare, these stakeholders are, among others: service users, citizen organizations, volunteer associations, community, healthcare employees and their organizations, public administrators, suppliers and insurers.	Glossary – Ministry of Health Available at: http://www.salute.gov.it/portale/temi/p2_6.jsp?id=314&area=qualita&menu=sicurezza. Viewed on 27/03/2017
	It is any individual or entity impacted, addressed or otherwise concerned by an EU intervention.	European CommIstituto Superiore di Sanitàion

		Glossary Available at: http://ec.europa.eu/smart-regulation/guidelines/ug_chap8_en.htm. Viewed on 27/03/2017
	A stakeholder is any group or individual who can affect, or is affected by, the achievement of an organization's objective.	Freedman R. Strategic Management: A Stakeholder Approach. 1984
Electronic transmission of documents	The electronic transmIstituto Superiore di Sanitàion of documents is the way to send documents by any telematic means or IT technology, which is able to ascertain the source from where the document originates.	References to the legislation: Art. 45 Legislation Decree n. 82/2005
Data processing	Any operation or set of operations carried out also without the use of electronic means, relating to the collection, registration, organization, storage, consultation, processing, modification, selection, extraction, comparison, use, interconnection, restriction, communication, dissemination, deletion and destruction of data, even if not recorded in a database.	Legislative Decree 196/2003 as amended. "Personal Data Protection Code" (updated to Legislative Decree 14 September 2015, no. 151) English version: http://194.242.234.211/documents/10160/2012405/Personal+Data+Protection+Code+-+Legislat.+Decree+no.196+of+30+June+2003.pdf
Use of personal data	Personal data is collected and stored for specific, explicit and legitimate purposes, and used in other data processing operations in ways compatible with those purposes. Data processing operations can be performed only by those working under the direct authority of the owner or the person in charge, and only following the instructions given for this processing.	Legislative Decree 30/06/2003 no. 196, art. 11 and art. 30
Data validation	Validation is the process of testing the degree to which a model is useful for making forecasts. The sample data are often split into two segments, one being used to estimate the parameters of the model, and the other being used as a holdout set to test the forecasts made by the model. There are many variations on this process of validation.	Eurostat glossary. Available at: http://ec.europa.eu/eurostat/statistics-explained/index.php/Category: Viewed on 27/03/2017

Italian data sources

The main sources of statistical-epidemiological data necessary for the development of an integrated and sustainable HI system are grouped into the following subsets:

Current health data sources.

These are systematic data collection systems, updated with a predefined frequency and related to a sector of activity involving a specific population group. These sources are characterized by a regular, continuous or periodic data collection; they use standard definitions for all the population groups involved; they are compelled to collect data in a complete and regular manner and according to national, regional or local relevance, depending on the representativeness of the population groups involved.

Here below there are some examples, albeit not exhaustive, of national or regional flows:

Resident population data

- Data resulting from municipal registries (http://demo.istat.it/) Istat provides the most recent official data on the population resident in the Italian municipalities, as per the investigations carried out at Registry Offices:
- Resident population by sex, age and marital status at 1 January;
- Demographic situation by sex (monthly and yearly data);
- Foreign citizens: resident foreign population according to age and sex at 1 January; Resident foreign population according to gender and citizenship at 31 December.
- Population census (http://dati-censimentopopolazione.istat.it/Index.aspx): It is one of the main national statistical surveys carried out by ISTAT on a ten-year basis; it provides information regarding population size, population distribution by gender and age, as well as socio-economic information. The 2011 census closed the era of general censuses, which, at ten-yearly intervals, provided a detailed picture of the country, in line with the development policies dictated at European level and in line with the modernization programme defined by Istat. In 2012 (Article 3 of Legislative Decree 179/2012, converted with amendments to Law 221/2012), the Italian law established the permanent Census of Population and Housing, which provides for the creation of statistical registers based on integrated administrative data sources and the carrying out of statistical surveys to support these registers.

Population Health and Healthcare Data

- Certificato di assistenza al parto (CeDAP – Birth Assistance certificate): CeDAP flow ensures systematic birth control for health and demographic Istituto Superiore di Sanitàues. The midwife, the physician who has supervised the birth, or by the physician responsible for the operating unit where the birth occurred shall fill in the specific form provided for this certificate. This document shall be sent by the health department of the hospital (public or private) where the child has been born to the competent Local Health Unit that, after verifying its correct compilation, shall send it to the Ministry of Health, and this in turn shall forward it to Istat. Since January 1, 1999, ISTAT activated the individual reporting of registered people according to birth data, as this allows to know, at municipal level (and by population section), births classified according to the following variables: birth sex date of birth, place of birth, citizenship (of the child), age of the mother (year of birth) and cohort, age of the father (year of birth) and cohort, mother's marital status, father's marital status, mother's citizenship, father's citizenship.

- Reporting of deaths and causes of death : the "Reporting of Death Causes" is a comprehensive investigation that provides health and demo-social information for all deaths occurring in Italy. The Local Health Unit and the Regional Authorities that collect the Death Certificates made by the physicians are responsible for this reporting; they also certify the deaths through the mortality registers (see section "Surveillance systems and health records") and transmit this information to Istat. This reporting is made through different forms, depending on whether the death occurred in the first year of life or after it. Mortality statistics by cause of death refer to the "root cause" of this sequence, that is, to the disease or traumatic event that led to death, through possible complications or intermediate morbid conditions. To select the root cause, the rules set by the International Classification of Diseases and Related Health Problems (ICD-10) are followed and this allows for comparisons in space and time. An essential tool for the correct application of these rules is the ACME decision tables (2009), developed and updated by the National Centre for Health Statistics (USAID), and currently used by ISTAT for manual and automatic coding of the root cause of death. Demographic and social information is subsequently recorded by the civil registrar of the municipality where the person died (http://www.istat.it/en/archivio/4216) .
- Hospital Discharge Summary Card (Italian acronym: SDO): this form contains all information concerning each patient dismIstituto Superiore di Sanitàed by public and private hospital throughout the country. Hospitals must send this information to the region or autonomous province where the patient is resident, including information on healthy infants. The hospitals and the regions must then verify, through surveys carried out on medical records, the completeness, consistency and accuracy of the information collected through the Discharge Summary and send this information to the Ministry of Health on a monthly basis, as established by the Health information system.
- Reporting of voluntary terminations of pregnancy (Italian acronym: IVG): this reporting was launched in 1979, following the entry into force of law 194/78.The survey is conducted by ISTAT in agreement with the Regions, the Ministry of Health and the National Health Institute. According to Art. 16, the Minister of Health must submit to Parliament a report on the implementation of the law itself and its effects, including reference to prevention. Moreover, according to art. 15, update training is foreseen for healthcare staff on the use of the most modern techniques, more respectful of the physical and psychic integrity of women and less risky for the termination of pregnancy. The survey is a key tool for knowledge and prevention of voluntary terminations of pregnancy; therefore, socio-demographic information on women and technical information about the termination surgery are required. Istat is the owner of this data collection and takes care of its methodological aspects and contents, prepares the collection forms and controls and processes the data, in collaboration with the Ministry of Health and the National Health Institute (http://www.istat.it/it/archivio/9025).

- Discharge from hospitals or clinics after miscarriage: This survey was started in 1979, in conjunction with the survey on voluntary termination of pregnancy. The Italian law defines miscarriage as "an involuntary termination of pregnancy caused by pathological causes, in particular, any expulsion or death of the foetus or embryo occurring within 180 days of pregnancy (25 weeks and 5 days) "; after 180 days, the term used is “stillborn”. The survey is conducted by ISTAT, which is the owner of the survey, and takes care of its methodology and contents, prepares the survey forms, and controls and processes the data. The survey is a fundamental tool to get knowledge on the phenomenon; socio-demographic information about the woman as well as information on the miscarriage is collected. The survey only identifies cases of miscarriages for which hospitalization has been necessary in both public and private care institutions. Miscarriages without hospitalization, such as those that did not require the intervention of a physician or required only outpatient care, are not detected. The survey is conducted annually and collects information related to each individual event. In addition to the annual survey, Istat also carries out a monthly-based investigation on women discharged from hospitals/clinics after miscarriage. For the latter, the healthcare institutes report the cases of miscarriage occurred in the reference month. The information collected helps quantify the phenomenon faster than the annual survey and serves as consolidated data for the final data collected at the individual level (http://www.istat.it/en/archivio/197015) .
- Residential health and social care facilities: The survey, envisaged by the current National Statistical Programme (IST 00243), since 2010 has expanded its information content, adapting it to the need-to-know of the socio-sanitary integration process, i.e. that set of personal assistance services aimed at meeting both social needs (linked to discomfort and marginalization) and social needs with health relevance (linked to aging of the population and disability).The survey was redesigned with the collaboration of experts from the Ministry of Health, the Ministry of Labour and Social Policies and the Cisis - Working Group on Social Policies. The survey identifies the offer of residential health and social care facilities and the types of users assisted during the reference year. The new survey extends the field of observation and increases the detail of the collected information, thus providing better detailed information on both users and resources involved in this form of territorial assistance. In particular, this new annual survey identifies all the structures that fall within the definition of residential health and social care facilities. Such establishments provide services for people in need because of different reasons: elderly people or people with health problems, people with disabilities, minors without protection, young women in distress, foreigners or Italian citizens with economic problems and people in a condition of social and/or personal marginalization. Starting from the 2014 survey, the data collection is carried out exclusively via the web at the following address: https://indata.istat.it/presa. (Http://www.istat.it/en/archivio/7786).
- Health Insurance Card Flow: The Health Insurance Card is an important tool to monitor the healthcare expenditure in Italy, and know and manage healthcare resources through a better use of public money. The Health Card contains the personal data of the person and shows the person’s Tax Code; it also shows the expiry date, valid only for the purpose of healthcare services; it has some free space for any regional health data, plus three "Braille" characters for the blind; the Tax Code reported in a bar-code

format and a magnetic stripe. The flow records data on specialist outpatient care, i.e. outpatient specialist services provided upon prescription Istituto Superiore di Sanitàued by GPs and their economic value, as well as data relating to pharmaceuticals sold under agreements with the State, namely the pharmaceuticals sold upon presentation of an NHS prescription and their economic value (http://sistemats1.sanita.finanze.it/wps/portal/portalets/cittadinots/ts) .

- Electronic health records (EHR): it is the set of digital data and documents relating to health and social care generated by past and present clinical events regarding the patient; it is set up by the regions and autonomous provinces, in accordance with local regulations on personal data protection, for the purposes of (a) prevention, Diagnosis, care and rehabilitation; b) study and scientific research in medical, biomedical and epidemiological sectors; C) health planning, quality of care and health care assessment (Article 12, paragraph 1 of Legislative Decree No 179 of 18 October 2012, entitled "Further Urgent Measures for Country Growth ", as amended by Law No 221 of 17 December 2012, and its subsequent amendments). The EHR contains a minimum set of data and documents, as well as other supplementary data and documents.
- INAIL accident and occupational disease database: it lists all occupational illnesses and work-related accidents with a recovery exceeding three days occurred to hired and self-employed workers, and reported, determined and duly compensated. Claims for work-related accidents or illnesses, accompanied by a medical certificate, must be filed using the forms provided by INAIL, which contain the information necessary to the analysis of the work-related accident and illness for social security purposes.

Survey

It is an investigation on the characteristics of a given population, carried out through the collection of data from a sample of that population, to evaluate the characteristics of this population through the systematic use of statistical methodology.

Examples of national sample surveys conducted in Italy are:

- Multiscope Survey on Families "Aspects of Daily Life". This sample survey is part of an integrated social survey system and captures basic information about the daily lives of individuals and families. The survey is carried out annually since 1993, and the collected information allows to know citizens' habits and their daily problems (school, work, family life and relationships, home and neighbourhood, free time, political and social participation, health, lifestyle and their relationship with services).This survey is part of the National Statistical Programme, which collects all statistical data necessary to the country (http://www.istat.it/it/archivio/91926).
- Survey on Health Conditions and Use of Health Services. The survey, which is part of an integrated system of social surveys (Multiscope Surveillance System on Families) is a sample survey to know citizens' needs on health and quality of life, and provides a wide range of information on the spread of chronic diseases, perceived health, conditions of disability, lifestyles and prevention, and the use of health services. The main topics investigated are acute and chronic diseases, some types of disability, disability, lifestyles (overweight and obesity, physical inactivity, habitual smoking), prevention, overall health condition assessment, participation in social life, citizens' relationship

with health services (medical examinations, diagnostic examinations, hospitalizations, rehabilitation services, etc.) and the use of unconventional drugs and therapies. The survey also includes some aspects related to childbirth (pregnancy, childbirth and breastfeeding). The survey is part of the National Statistical Programme (codes: IST 02067 and IST 02153) (http://www.istat.it/en/archivio/7740).

- Household Expenditure Survey. The household expenditure survey detects the spending behaviours and tourist habits of families living on the Italian territory. It is carried out in agreement with Eurostat, on the basis of a harmonized classification of expenditure items (Classification of Individual Consumption by Purpose (Coicop)) in order to allow comparison between countries. The purpose of the survey is to cover all expenses incurred by resident households for the purchase of goods and services for household use: food, utilities, furniture, household appliances, clothing and footwear, medicines and other health services, transport, communications, entertainment, etc. The survey, which also represents the official basis for the official estimates of relative and absolute poverty in Italy, is one of those included in the National Statistical Programme, which collects all statistics data necessary to the country. Between 1997 and 2013, expenditure data was collected through the Household Consumption Survey, later replaced by this survey (http://www.istat.it/en/archivio/71980).

Examples of European surveys are:

- European Union Statistics on Income and Living Conditions (EU-SILC). It is an instrument aiming at collecting timely and comparable cross-sectional and longitudinal multidimensional microdata on income, poverty, social exclusion and living conditions. Social exclusion and housing condition information is collected mainly at household level while labour, education and health information is obtained for persons aged 16 and over. The core of the instrument, income at very detailed component level, is mainly collected at personal level. The EU-SILC survey started in 2004 (http://www.istat.it/en/archive/5663).
- European Health Interview Survey (EHIS). The survey is conducted in all EU states with the aim of comparing the situation in the various countries with regard to the main aspects of the health conditions of the population and the use of health services. The results of this type of sample survey are of great social significance, as they allow monitoring key health indicators useful for health planning in the country, and helping define European policies to meet the needs of citizens. The survey is provided for by the European CommIstituto Superiore di Sanitàion Regulation (EU) No 141/2013 of 19 February 2013 implementing Regulation (EC) No 1338/2008 of the European Parliament and Council on Community statistics on public health and health and safety at work based on the European Health Survey - EHIS). The survey was conducted in 2015 and falls within the scope of the National Statistical Programme (code IST 02565), which collects all statistical information necessary to the country (http://www.istat.it/en/archivio/167485).
- European Health Examination Survey (EHES). It is an initiative to set up a system of standardized, representative health examination surveys of the adult population of the European countries. Health examination surveys include questionnaire(s) as well as physical measurements, such as blood pressure, and collection of biological samples

such as blood or urine. The EHES pilot project (2009-2012) was financed by European CommIstituto Superiore di Sanitàion/DG SANTE. During the pilot phase, manuals and training materials were prepared, and training seminars were organized. A pilot survey was conducted in 12 countries (Czech Republic, Finland, Germany, Greece, Italy, Malta, Norway, the Netherlands, Poland, Portugal, Slovakia, United Kingdom / England) between July 2010 and May 2011. The EHES Reference Centre (RC) is the co-ordination centre for European health surveys and is hosted by the National Institute for Health and Welfare (THL) of Finland. The 1st edition of the manual with procedures for the core measurements was published in 2013. The 2nd edition of the EHES Manual was published on 30 December 2016. In Italy, the EHES reference centre for the survey is the National Health Institute, which, in collaboration with the National Association of Medical Cardiologists (Anmco) conducted two surveys on the health of the general population, carried out at 10 year intervals (Oec 1998-2002 and Oec/Hes 2008-2012) and also collecting preserved biological samples stored in the Biobank of the National Health Institute (www.cuore.Istituto Superiore di Sanità.it).

Health surveillance systems and health records.

Surveillance surveys collect health data about individuals in a general or sample population, but this information differs from that contained in registers as it is more explicitly aimed at prevention purposes, such as the identification and management of epidemics. The term "surveillance" was used until the second half of the 20th century in the context of infectious diseases with control objectives; only after its incorporation into the smallpox eradication programme in 1967, has the range of monitored items expanded, and the term has also been used in other public health settings. The historical evolution of the term is to be sought in the transition from the concept of controlling infectious disease to that of monitoring the health of a population or community. Public health surveillance means the systematic collection, filing, analysis and interpretation of data related to health-related events, followed by the dIstituto Superiore di Sanitàemination of information to all persons who provided it and to those who must plan, implement and evaluate public health interventions. The ultimate objective of surveillance is the use of data for disease prevention and control, and for the monitoring and evaluation of the relationship between interventions and changes.

In the field of public health, registers are tools for gathering data on all cases of a particular disease or other health condition considered relevant in a defined population. A comprehensive data collection allows cases to be correlated with a specific population and track this population over time, in order to collect information on healing, recurrence, survival and prevalence of diseases. Disease registries therefore allow the collection of information regarding the progress of the disease and are essential to health planning, policies for disease prevention and control, intervention assessment, and the need to provide correct and exhaustive information and directions to citizens, as no Italian public or private hospital has the obligation to keep an archive containing the data relating to the Diagnosis and treatment of some specific pathologies. Most Italian registries are made up of population registries that collect data on diseases found in a resident population of a given territory. Specialized registers, on the contrary, collect information on a specific feature of a disease (e.g. a particular type of cancer) or on specific age groups.

Article 12, paragraph 11 of Legislative Decree 18 October 2012, no. 179, as amended by Law no. 221, states that "Surveillance systems and registers [...] are established by a decree of the President of the Council of Ministers, upon a proposal by the Minister of Health, upon agreement by the Permanent Conference on Relations between the State, Regions and the autonomous provinces of Trento and Bolzano and once obtained the opinion of the Data Protection Authority. The lists of surveillance systems and registers [...] are updated periodically through the same procedure. "

The Decree of the President of the Council of Ministers (DPCM) on Surveillance Systems and Registries received the opinion of the Data Protection Authority on 23 July, 2015. Subsequently, on August 2, 2016, it was sent to the State-Regions Conference for its preliminary agreement. This agreement was reached on 24 November 2016. The decree was then signed by the Presidency of the Council of Ministers on 8 March 2017. The DPCM is made up of 10 articles and three annexes, listing respectively national and regional surveillance systems and disease registers, and registers already covered by the National legislation and, finally, other registries and surveillance systems of regional importance only.

Below are some examples of surveillance systems and disease registers contained in the above-mentioned DPCM, divided into two in two subgroups, depending on whether or not they are governed by existing national and/or regional legislation.

<u>National and Regional Disease Registers</u>: these are registers regulated by regional or national legislation and established by the Decree of the President of the Council of Ministers of the Italian Republic (DPCM); some registries are managed by the Ministry of Health, others by the National Health Institute. The following registers are included in this category:

- *Cancer Register*. It is set up at the Ministry of Health and collects information about cancer patients resident in a given territory. At present, there are 43 operative registers: 38 are population registries and 5 of them are specialized registries; in all, they cover approximately 28 million Italians, representing 47% of the total resident population. Register coverage is quite uneven on the national territory. All Italian Cancer Registries are part of the Italian Association of Cancer Registries (AIRTUM), which provides technical assistance, promote the use of harmonised and comparable registration and classification systems and assess the quality and completeness of Register data (Accreditation Procedure). Cancer Registries are general registries and collect information on all oncology pathologies, whereas Specialized Registries only collect information for specific tumours or specific age groups.

- *Coronary and cerebrovascular register*. The National Register is a system for monitoring coronary and cerebrovascular diseases, fatal and non-fatal, and covers the population aged 35 to 74 years; it is coordinated by the National Health Institute. The Register was established in 1998 with the aim of assessing the feasibility of a registration system to estimate the frequency of acute coronary and cerebrovascular events in geographically strategic and representative areas of the country; it collects all data gathered on the territory.

- *Register of prosthetic implants*. It is a data collection system on prosthetic implants and allows the clinical evaluation of device efficacy and safety after its placing on the market, as well as a timely tracing of patients in case of specific follow-up or any removal of the prosthesis (DPCM, Article 2, paragraph 1, letter p. Updated in September 2016).

- *National Register of Congenital Hypothyroidism*. This epidemiological registry realizes the continuous and complete collection, registration, retention and processing of data related to children with congenital hypothyroidism all over the country.
- *National Register of Congenital Coagulopathies*. The register, established at the National Health Institute, collects data on the prevalence of various coagulopathies, on complications of therapies (in particular infections and the appearance of blocking antibodies), as well as on drugs and their amounts required to cover the treatment.

Registers already governed by national legislation: the following registers are included in this category:

- *Nationally Register of Medically Assisted Procreation (PMA)*. The National Register is funded by the Ministry of Health and data is collected by the National Health Institute under Law 40 of 19 February 2004.The main purpose of this Register is to evaluate the most effective and safe assisted reproduction techniques offering the best results to couples.
- *Death Register*. This register was established by DPR 285 of 10 September 1990. The primary data source is the death card prepared by the National Institute of Statistics (Istat), which must be filled in by the treating physician or by the physician who has assisted the deceased patient. This card, in accordance with the Police Mortuary Code (DPR 285/90), is drawn up in duplicate and must be sent to Istat and to the Local Health Unit by the Municipality where the death occurred. Along with the ISTAT mortality database, regional databases and regional mortality registers have been established and are managed by Health Units and Regions. These databases and registers foresee that every local health unit should establish and maintain a register for each municipality included in its territory of competence. These registers/database shall contain the list of people deceased in a specific year and the cause of death.
- *Organ transplantation register*. The Organ Transplantation Information System (SIT) was established within the Health Information System by Law 91 of April 1, 1999, which has among its main objectives the digitalisation of the activities of the national transplantation network, to ensure the traceability and transparency of the whole "donation-removal-transplantation" process. The SIT performs the following activities: it registers and collects citizens' declarations of consent for organ and tissue donation; it collects the lists of patients waiting for transplantation, prepared at regional level; it manages the National Paediatric Programme and the list of urgencies at national level; it registers the data flow on organs and tissue donation and removals, organ transplantation and tissue distribution to certified banks; it manages the register of transplants from living donors; it collects follow-up data of transplanted patients, even in a more specific way than what foreseen by the various safety protocols. The SIT is implementing a cooperation programme, already operative to a large extent, with regional information systems to optimize and expand the acquisition of processed data. The SIT geographical network connects Regional and Interregional Centres with the National Organ Transplantation Centre (CNT) through an intranet network of the

Public Administration specially dedicated to transplants. Local Health Unit operators connect to this network through the public Internet to register citizens' declarations of consent, whereas organ transplantation centres use this network to send follow-up data, and tissue banks connect to get the single code required by European Directives EC 23/2004.

- *National Register of Rare Diseases*. The Register is established at the National Health Institute in implementation of Article 3, Ministerial Decree 279 of 18 May 2001.The purpose of the Register is to monitor rare diseases and support intervention planning at national and regional level for patients with rare diseases.
- *National and regional blood and plasma register*. The Register was established in Italy by Ministerial Decree of June 18, 1991, and is a permanent information system to know data on the collection and distribution of human blood and the general activities carried out by national transfusion services and centres. The data collection questionnaire is compiled by the head of each transfusion centre or service and sent to the Regions, which in turn send it to the Ministry of Health and the National Health Institute.

National and Regional Surveillance Systems: they are governed by regional or national legislation and established through the Decree of the President of the Italian Council of Ministers (DPCM), currently in the signing procedure by the President.

- *Legionnaires' disease National Register*. The Legionnaires' disease is included among the infectious and contagious diseases subject to mandatory reporting. Reporting cards, containing patient data, clinical data and possible sources of exposure to infection should be sent to the National Health Institute by the Health Departments of the hospitals where the diagnosis is made or by the Regional Public Health Services.
- *The national health surveillance system "0Kkio alla Salute".* This surveillance system is promoted and funded by the Ministry of Health/CCM (National Centre for Disease Prevention and Control), coordinated by the National Centre for Epidemiology, Surveillance and Health Promotion of the National Health Institute and conducted in collaboration with all Italian Regions and the Ministry of Education, University and Research; since 2007, it is a sound source of epidemiological data on lifestyles of primary school children and represents the Italian institutional response to get knowledge on the issue of overweight and obesity in the infant population.
- *Surveillance System on Voluntary Termination of Pregnancy (IVG) :* The system is established at the National Health Institute and collects, analyzes and publishes data on IVG in Italy. The law stipulates that every year the Minister of Health shall present to Parliament a report on the IVG in Italy, which shall also contain aspects related to prevention.
- *Integrated Epidemiological System of Acute Viral Hepatitis (Italian acronym, SEIEVA).* This system is set up at the National Health Institute and is based on the collaboration with a network of Local Health Units, distributed throughout the country, that participate on a voluntary basis. All cases of acute hepatitis are included in the surveillance; the relevant Local Health Unit is the SEIEVA referent for each of them and collects demographic information and the main risk factors through the administration of a standardized questionnaire.

- *Influenza Surveillance System (FluNet).* The national epidemiological and virological surveillance system of influenza is coordinated by the Ministry of Health; it is established at the National Health Institute and utilises the collaboration of the Interuniversity Research Centre on Influenza (CIRI), general practitioners and freely chosen paediatricians, the network of peripheral laboratories investigating influenza and Regional Health Departments. The surveillance aims at estimating the weekly incidence of influenza during the winter season to detect the duration and intensity of the epidemic, monitor the spread of the different types and subtypes of influenza viruses in the different geographic areas and in the different periods of the epidemic season and evaluate the antigenic homology between epidemic strains and vaccine strains. Data collected and processed at national level is made available to the International Reference Organisations (WHO, ECDC) .
- *Alcohol-related monitoring system (Sisma).* This monitoring system was established at the National Health Institute with the aim of carrying out an analysis of the alcohol-related impact in Italy, to verify and assess the achievement of prevention objectives and actions (at national and European level) to counteract the harmful and hazardous consumption of alcohol in the population.

National and Regional Surveillance Systems already regulated by current legislation; the following registers fall within this category:

- *National Register of the Creutzfeldt-Jakob Disease and related syndromes.* In Italy, surveillance activities began in January 1993 as part of a European project aimed at identifying possible changes in incidence and clinical or neuropathic manifestations of Creutzfeldt-Jakob disease in Europe following the epidemic of bovine spongiform encephalopathy in the United Kingdom. The register, established by Ministerial Decree on December 21, 2001, detects CJD deaths and related syndromes with probable or definitive DiagnosIstituto Superiore di Sanità and is established at the National Health Institute.
- *Surveillance system of new HIV infection diagnoses*. The system was established by Ministerial Decree on March 31, 2008; it collects data on AIDS cases and new HIV diagnoses, and carries out periodical analysis of data collected. Data is disseminated annually and published in the National Health Institute Newsletter.
- *Infectious Disease Surveillance System (Simi)*. The surveillance of infectious diseases is entrusted to the Infectious Disease Information System, based on mandatory notifications by medical practitioners who diagnose the disease. The system includes immediate reporting to alert public health practitioners, and monthly summaries of all notified infectious diseases, compiled by each Local Health Unit. The Simi was redefined in the Ministerial Decree of 15 December 1990, as amended for tuberculosis and mycobacteriosis (Ministerial Decree 29 July 1998).

Epidemiological studies and ad hoc databases.

Here are three types of epidemiological studies that differ from one another as for their time structure: cross-section or prevalence studies, prospective or cohort studies ("follow-up" or incidence studies) and retrospective or case-control studies. Examples of prospective epidemiological studies conducted in Italy are:

ILSA (Italian Longitudinal Study on Aging). It is a longitudinal epidemiological study of 5632 subjects selected from registry lists of 8 Italian cities. Over the years, three trials (1992, 1995, 2000) have been conducted, and a follow-up on overall mortality and its causes has been carried out 20 years later. The study was designed to analyze the major age-related risk factors of the most common pathologies and functional disorders, such as cardiovascular diseases, diabetes, peripheral arterial disease, thyroid disease, dementia, depression , Parkinson disease, stroke and peripheral neuropathy.

- IPREA (Italian Project Epidemiology Alzheimer's disease). It is a longitudinal epidemiological study of 4785 subjects selected from the registry lists of 12 Italian cities. Over the years, two surveys (2003 and 2004) were conducted and a follow-up on overall mortality and its causes was carried out10 years later. The study aimed at estimating prevalence, incidence and risk factors of dementia in the pre-clinical phase, analysing the transition to dementia, and establishing the predicting value of an extensive range of neuropsychological diseases, as well as identifying biological and instrumental markers .
- OEC (Cardiovascular Epidemiological Observatory)/HES (Health Examination Survey). The OEC is an observatory resulting from the collaboration between the National Health Institute (Istituto Superiore di Sanità) and the National Association of Hospital Cardiologists (Anmco) and is made up of a network of public hospitals (divisions, services or rehabilitation centres), and prevention departments, homogeneously distributed on the Italian territory. All regions are involved. Between 1998 and 2002, the first survey was conducted on an adult sample (35-74 years), divided by age and gender, examined for direct measurement of risk factors, lifestyles and presence of major chronic and degenerative pathologies. 4908 men and 4804 women were examined. A second survey (Oec/Hes 2008-2012) was conducted between 2008 and 2012 using the same data collection procedures and methodologies of the first survey, but also specifying the different types of data collected and including a further age group (75-79 years); altogether, 4371 men and 4339 women aged between 35 and 79 were examined. In the 2nd Survey, a sample of the 25-35 years age group was examined to be included in the European Health Examination Survey (Ehes) pilot study.
- NCD Risk Factor Collaboration (NCD-RisC). It is a network of researchers who provide data on the risk factors of chronic degenerative diseases collected through standardized procedures and methodologies in 189 countries. The group works closely with the WHO, through the WHO Collaborating Centre on NCD Surveillance and Epidemiology at London Imperial College, led by Professor Majid Ezzati. NCD-RisC has put together aggregate data on the general adult populations using advanced statistical methods for chronic-degenerative disease risk factors. NCD-RiskC uses data that comes from over 2000 population surveys collected since 1957, with about 25 million participants on which risk factors were detected.

Italy participates in these activities with 46 population surveys conducted for a variety of reasons over the last forty years; some of them are community surveys, others are sub national or national surveys; all measured weight and height by applying standardized methodologies. Among the most important, there are MONICA surveys (monitoring trends and determinants in cardiovascular disease) and EPIC surveys (European Prospective Investigation into Cancer and Nutrition), as well as those of the CUORE Project

(Cardiovascular Epidemiological Observatory/HES, MATISS, FINE). A complete list is reported in the annexes to the two articles.

Data accessibility and availability

The availability of collected data must be ensured in compliance with personal data protection rules. Data sources can be consulted through different procedures, depending on the information to be obtained and, in particular: the type of data (personal data, sensitive data, judicial data ...), the desired data territorial detail and data on privacy compliance from the requesting organisation (public, private), as well as the reason why access to data is requested.

Microdata files are elementary data collections that can be made available (e.g. by the Ministry of Health, ISTAT and Eurostat) in different formats. Below are some mapping examples of the main data sources used in the healthcare sectors:

SDO Database (Hospital Discharge Summary cards)

Organisation: Ministry of Health

Website: www.salute.gov.it

Short description	The SDO (Hospital Discharge Cards) database contains information on all hospital admissions provided in public and private facilities on the national territory.
Minimum statistical unit	Every hospital admissions
Territorial scope	National
Accessibility	Data is available for scientific research purposes and not for commercial purposes. The application must include the applicant's references and the reference of the Research Institute, a brief description of the research project for which the SDO data is to be used, the methods of use of the data and the results to be obtained, as well as a brief description of the ways of publication and/or dissemination of the results.
Availability	• Analytical data (each line refers to a single hospital admission) • Aggregate Data (each row in the aggregate table refers to multiple episodes of admission, all with the same characteristics A list of available variables is provided
Format	Text format (ASCII) with tab separated areas
Data disaggregating/ breakdown	The SDO shows the region, province and the municipality of residence but the representative of the organisation or the contact person of the project that has applied for it receives data in an anonymous form and without any elements that could allow personal identification, in compliance with what specified in the project regarding the use of the data
Dissemination	The application form for data requesting is available on the Ministry

	of Health website.
Use restrictions	• The SDO data provided by the Ministry of Health is anonymous and free of any element allowing personal identification • The SDO data provided by the Ministry of Health is owned by the Ministry of Health - Directorate General of Health Planning - and can in no case be transferred and/or provided to third parties; • The SDO data provided by the Ministry of Health can in no way be used for purposes other than those agreed with the Ministry of Health; • Subject to prior authorization by the General Directorate for Health Planning, the applicant entity may publish the results of the data processing provided that the source is quoted on the publication and it is specified that the work was done thanks to the collaboration with the Ministry of Health; • The Requesting Authority is required to comply with all the rules to protect the correct use of the information contained in the database and all applicable privacy protection regulations.

Multiscope Survey on Families - Aspects of Daily Life

Organisation: National Institute of Statistics (Istat)

Website: www.istat.it

Short description	The Sample Survey "Aspects of Daily Life" is part of an integrated social survey system - the Multiscope Surveys on Families - and collects basic information about the daily lives of individuals and families. The information collected allows knowing the habits of citizens and the problems they face each day. The survey is among those included in the National Statistical Programme, which collects all statistical data necessary to the country.
Minimum statistical unit	Reporting unit: Households drawn from Municipal population register Analysis Unit: Individuals
Territorial scope	National
Accessibility	The types of files available are as follows: • Open files, directly downloadable from this website • Search files (MFR), available to university researchers or research entities following the submission of a research project; • File for Sistan, which can only be released to the statistical offices of the national statistical system.
Availability	• Analytical data (each line refers to each individual interviewed) • Aggregated Data (Each row in the aggregate table refers to multiple individuals with the same characteristics).
Format	Text format (ASCII) with tab separated areas
Data disaggregating/ breakdown	The sample design is built to provide estimates at regional level. The use of data to produce estimates at the municipal or provincial level is under the full responsibility of the applicant, who will have to

	adequately report this circumstance in any publications.
Dissemination	List of on-line data (Istat or non-Istat databases and datasets) where data can be accessed: • Historical series • Datawarehouse I.Stat (http://dati.istat.it/?lang=it) the Istat data warehouse • Culture in figures : a site for cultural statistics • Report statistics: they have as topic: "Citizens' opinions," Health and Healthcare, "Culture, Communication, Leisure ", "Social Participation". • General Volumes (Annual Report, Italian Statistical Yearbook, Noi Italia (We Italy), Italy in Figures)
Use restrictions	Non-SISTAN Users. The Institute has developed differentiated ways to use microdata, to meet different types of requests. • Standard Files and Search Files: these two typologies contain individual data, without any reference allowing a direct knowledge of the person's identity and appropriately processed to reduce the risk of identification. • Public use files: developed from search files, to which confidentiality techniques are applied that involve a reduction in information content greater than that provided for search files SISTAN users. According to the Code of Ethics, Istat can communicate individual data to Sistan users without any particular limitations (or even identifying data, if this is indispensable to the achievement of the project's objectives, and sensitive and judicial data, if this is foreseen in the National Statistical Programme).

European Union Statistics on Income and Living Conditions (EU-SILC)

Organisation: Eurostat

Website: http://ec.europa.eu/eurostat/web/microdata/european-union-statistics-on-income-and-living-conditions

http://www.istat.it/adele/ListaRilevazioni

Short description	The European Union Statistics on Income and Living Conditions (EU-SILC) is an instrument aiming at collecting timely and comparable cross-sectional and longitudinal multidimensional microdata on income, poverty, social exclusion and living conditions.
Minimum statistical unit	Reporting unit: Households Drawn from Municipal population register analysis unit: Persons aged 16 and over
Territorial scope	National
Accessibility	The access to microdata is possible only for scientific purposes. Only research entity like a university, research institution or research department in public administration, bank, statistical institute etc, can apply for access to Eurostat 's microdata.
Availability	Two different types of access to data are possible: Access to principal researcher files containing partially anonymised data (scientific-use files) on electronic devices (CD-Rom, DVD, etc.) Authorization to access non-anonymised data (secure-use files) in Eurostat's "Safe centre" in Luxembourg.
Format	GESIS provides a list of tools for EU-SILC including transfer routines from .csv to Stata and SPSS. In January 2016, GESIS launched a new resource (Excel format) for identifying EU-SILC variables by type of data, reference period, unit of observation and mode of collection.
Data disaggregating/ breakdown	The planning of the sampling design has been guided by requirements set by Eurostat on different aspects of the survey, e.g.: type of parameters to be produced, periodicity and reference of the questions, and the precision of some cross-sectional and longitudinal estimates. In addition to Eurostat requirements, specific sub-national geographical domains of Istat interest have been considered. For the sake of estimates' precision comparability, Eurostat requires a minimum sample size under the hypothesis of two-stage simple random sample where the first stage is represented by the municipalities and the elementary units are the resident households.
Dissemination	List of on-line data (Istat or non-Istat data bases and tables). • I.Stat: the Istat data warehouse • Istat tables: Income and living conditions. Years 2006-2007
Use restrictions	Access to microdata is only valid for the period specified in the research proposal. At the end of that period, it's necessary to destroy any original scientific-use files sent by Eurostat and any confidential data derived from the files, and it's necessary to send to Eurostat the research results

Examples of Available Data Accessibility (Istat):

- *Open files* are collections of elementary data that can be downloaded freely and free of charge from the sites of the Institutions that hold the data. Usually, this type of database uses additional privacy protection techniques that necessarily imply a reduction in information content, or data is elementary data that, according to regulations, may be disseminated in a disaggregated form. The acceptance of the rules regarding data use developed by the Institution holding the data is requested also for the dissemination of these data files.

- *Standard files* are microdata files that can be released upon a motivated request for study or research purposes. Standard files refer to some surveys of individuals and families (such as the Istat files of Multiscope surveys), but do not contain elements that can direct identify the interviewee and are however treated in ways that do not allow connection with the respondents. The data protection applied to these files partially limits their information content in comparison to the information contained in the source file. In the request made to the data holder, it is necessary to specify the purposes of the research project, but also the place where the file shall be stored and maintained, and the commitment not to provide to third parties the elementary data it contains.

- *Search Files (MFR*). These are microdata files available to university researchers or research institutions following the submission of a research project; these source surveys concern individuals, families and businesses and are designed to meet scientific research needs. These files are subject to special statistical treatments that limit the identity of the respondent, while maintaining a high level of detail information. These files may only be requested by subjects belonging to universities or research institutes implementing the "Code of practice for statistical data processing carried out outside Sistan"; they can also be requested by other subjects in possession of the necessary requirements set up by Eurostat for the provision of microdata files and provided for in Regulation (EC) No. 557/2013. To request this type of file, it is necessary to submit a research project that documents that data is processed for statistical or scientific purposes and the scientific coordinator of the project as well as any other organizations participating in the research project must be clearly stated.

- *Files for Sistan*. These files can only be released to the National Statistics Offices as provided by Directive n. 9 of the Comstat, "Criteria and Modalities for the Communication of Personal Data within the National Statistical System". The purposes for which they may be requested must relate to the implementation of the National Statistical Programme, or the fulfilment of institutional activities, or activities concerning the territorial scope of the applicant. This type of files is also intended to provide personal data with personal identification details, but limited to cases of absolute and strict necessity (impossibility to reach the target set without the personal data) and the applicant must assume full responsibility for the compliance with the Law on personal data protection.

- *Eurostat microdata files*. Micro data files can be obtained from Eurostat for scientific purposes only. The request can be made only by organizations recognized as research entities (universities, research institutes or research departments of public administration, banks, statistical institutes, etc.). The applicant be accredited to

Eurostat and submit the research project. Data may be requested in anonymous form or otherwise, depending on research purposes, but in the case of access to personal data, this is only possible at the Eurostat safe centre in Luxembourg.

Criteria to assess the identification risk

The assessment of the identification risk of the subjects to which the data relates must take into account the following criteria:

- Combinations of modes to which a frequency not below a predetermined threshold is associated, or an intensity given by the sum of the values assumed by a number of statistical units equal to the above threshold, are considered as aggregate data. The minimum value attributable to the threshold is three;
- When assessing the threshold value, account must be taken of the level of information confidentiality;
- The statistical results relating to only public variables are not subject to the threshold rule;
- The threshold rule may not be observed if the statistical result does not reasonably permit the identification of statistical units, given the type of detection and nature of associated variables;
- The statistical results pertaining to the same population can be disseminated so that links between them or other known sources of information are not possible, and no identification can be made;
- It is assumed that confidentiality is adequately protected if all the statistical units of a population have the same variable mode.

Privacy and ethics

In Italy, the right to privacy and the confidentiality of personal data is guaranteed by the Personal Data Protection Code (Legislative Decree 30 June 2003, No.196. Personal Data Protection Code. Official Journal - Ordinary Supplement No.174 of 29 July 2003). In May 2018, the 2016/679 European Parliament and Council Regulations 2016/679 of 2016 on the protection of individuals with regard to personal data processing and the free circulation of such data will enter into force, repealing Directive 95/46/EC and will be transposed, at national level, by some of the provisions of Legislative Decree 196/2003, where these guarantee an inalienable "greater protection" than the standard proposed by the EU Regulation; There are also codes of ethics and good conduct on personal data processing for statistical purposes and scientific research carried out within the National Statistical System (SISTAN) (Guarantor's Order No. 13, July 31, 2002, Official Journal no. 230 of 1 October 2002) (Guarantor Order No 2 of 16 June 2004, Official Journal No.190 of 14 August 2004) and a series of Authorization of the Data Protection Authority (reiterated annually or every two years) that regulate the handling of sensitive and genetic data in medical, biomedical and epidemiological research. In short, the abovementioned provisions state that the possibility of interconnecting administrative flows of current data, surveys and registers is permitted when there is a rule of law specifying in its provisions the detailed type of data to be handled (in this case, data connection) or, in the case of data collected in ad hoc surveys, widely used in biomedical and epidemiological domains, when the interested party has provided explicitly informed consent for this purpose. The procedures to be adopted must therefore be analyzed and taken in relation to the specific type of data collection and its purposes.

Routine data.

In the case of data produced for example at a Local Health Unit or Region level, access to administrative sources is normally governed by an administrative decree, which is granted only after being screened by the Data Protection Authority after receiving a detailed information on the purposes of the collection and a list of people/organisations that have access to the data. It is not possible to process routine data if the number of "records" produced (at the level of municipal aggregation) is equal to or less than three units, as there is a risk of "potential identification", a risk safeguarded by the privacy law by adopting the principle of maximum precaution. The information resulting from such processing can therefore be published as long as it does not violate the constraint on personal identification. In this case, the total number of people falling under a certain (sensitive) condition is not less than three, and their aggregate value will be indicated as "equal to or less than 3 units". The dissemination of sensitive data is forbidden in any case.

Data from specific studies.

In the case of data obtained through surveys, longitudinal studies, population registers, or ad hoc studies, access to data is reserved to scientific partners, as described in the study protocols and according to what is provided by the opinions of ethics committees in compliance with the privacy regulations, informed consent, etc. In this case, data can be used for scientific and research purposes (publications, reports, congresses, seminars, etc.) and can be strictly published in aggregate form. The availability of this type of data to other applicants, even in anonymized form (also encoded with double encoding), should be regulated through research protocols and approved by the relevant ethical committees, in compliance with legal requirements.

Interconnection of data flows is therefore only possible if flows (register or surveillance flows) are defined in the decree establishing routine and administrative collections and associated with a unique identifier (Univocal Patient Identification Number) valid for all regions, which will be used to display the data, but only for the purposes defined by the decree."

Computerized healthcare systems regulated by decree

General purpose and use of databases interconnection

The interconnection of healthcare databases has the main aim of providing healthcare professionals and accredited researchers a platform with anonymous individual data, to be used whenever one main risk factors and lifestyles are to be investigated in relationship to the individual's state of health, the burden of illness, the diagnostic, therapeutic and assistance pathways experienced by patients with a disease and treated by the National Healthcare System. A platform with interconnected data from multiple information flows is crucial to analyze the safety, efficacy and cost-effectiveness of healthcare services in order to produce useful evidence to guide future choices and policies aimed at continuous improvement of quality performance, care, intervention and services.

Interconnection of current national flows: purpose and use

The information flows sent by the Regions to the Ministry of Health cover the areas of emergency care (118 and Emergency services), home care, residential and semi-residential care, mental health, addictions and assistance provided in hospices and specialist outpatient care structure, as well as pharmaceuticals sold under agreements with the state. The development of indicators to evaluate the time trends of care and services received by individuals at hospital and territorial level is made possible by the analysis of the flows related to the healthcare system; their analysis allows to verify the achievement of the objectives set in the regional planning, and to compare the level of healthcare services provided by the various regions.

To improve healthcare information and statistical systems monitoring the organization of the levels of healthcare services, the Ministry of Health has established some anonymization procedures for personal data present in the information flows in order to protect the identity of the person in the data processing. Anonymised data can thus be used to improve the monitoring and evaluation of the quality and effectiveness of care pathways through the use of interdisciplinary, hospital and specialist pharmacy archives. Information systems in the healthcare sector are analyzed taking into account the dual function they play, as, on the one hand, they are a support tool for the management of the national healthcare system and, on the other hand, they are a supportive tool in patient care. In Italy, after a long period of discussion with the Personal Data Protection Authority, a specific implementation decree was adopted for the interconnection of Healthcare Information Systems, based on the use of the tax code in the Discharge Summary Cards, and the National Univocal Patient Identification Number (CUNA) to detect also services supplied to every individual patient (specialist outpatient and pharmaceutical services) that the Ministry of Economy and Finance needs to monitor healthcare expenditures. The implementing decree received a positive opinion by the State Council and is awaiting approval by the Minister; according to this decree, the Ministry of Health shall establish the anonymizing rules to handle personal data contained in the information flows acquired on the basis of the person’s tax code; the tax code shall therefore be transformed for all interconnection processing. This procedure must be structured in such a way as not to allow the person to be directly identified during the processing of personal data.

Interconnection procedures of the current national flows of the National Healthcare System

The publication of Decree 7 December 2016, no. 262 "Regulations and procedures to interconnect the individual-based information systems of the National Healthcare Service at national level, even when these are administered by different state administrations" in the Official Journal, has now provided the possibility to retrace the pathway of care provided to the patient by the various healthcare structures. This decree, in fact, sets out the procedures that the various state administrations must apply to provide all NHS patients with a unique national code to be used in information systems reporting health events on an individual basis. The Decree entered into force on February 23, 2017, and will offer an integrated key to interpret the data of the New Information System (NSIS). Patients' information flows belonging to the New Health Information System (NSIS) are regulated by a Ministerial decrees issued in collaboration with Regions, State-Regions Conference and the Ministry of Health, and are adopted in accordance with the opinion of the Personal Data Protection Authority. These flows are summarized in the table below.

Information Flow		**Information collected**		
Typology	**Legal framework**	**Supplier**	**Services**	**Patient**
Hospital admission	Ministerial Decree 26.07.1983	Data from hospital; Discharge Unit	Diagnosis; DRG; Surgery	Personal data; Type and reason of admission; cost of hospital stay; Hospital discharge
Emergency care	Ministerial Decree 17.12.2008	Data from hospital; Hospital Unit; Referral Institution	Health evaluation; Diagnosis; Services provided; Treatment outcome	Personal data; service provision scheme; situation of NHS beneficiary ticket; exemptions
Emergency Medical Service 118	Ministerial Decree 17.12.2008	Data from operation centre; Data from hospital Unit	Health evaluation; Detected pathology; Services provided; Treatment outcome	Personal data
Pharmaceuticals sold under agreements with the State	Art. 50 L.326/2003	Data from unit	Type of drug, quantity and cost	Personal data; exemptions
Outpatient specialist services	Art. 50 L.326/2003	Data from care facility Unit	Diagnosis; Medical specialist care; Services provided; Quantity and cost	Personal data; exemptions
Home care	Ministerial Decree 17.12.2008	Local Health Unit	Health evaluation; Pathology; Type of treatment	Personal data; household
Residential/ semi-residential care	Ministerial Decree 17.12.2008	Care Facility	Health evaluation; Specialised care; Type of service provided	Personal data; household
Addictions*	DM 11.06.2010	Care Facility (SerT)	Pathology; Services provided; Drugs	Personal data
Metal Health*	DM 15.10.2010	Care Facility; DSM	Diagnosis; Services provided	Personal data
Birth assistance certificate	Ministerial Decree 16.07.2001 n.349	Care Facility	Childbirth event; newborn characteristics; Congenital malformations; Stillborn data	Personal and socio-demographic data of parents
Hospice	Ministerial Decree 06.06.2012	Care Facility	Pathology; macro-services	Personal data

* In relation to the peculiarity of handled data, Art. 7 of the Ministerial Decree specifies that the univocal code assigned to each patient must be different from the code used for data transmission from other information systems, and this not to allow interconnection with other databases.

The interconnection of the various databases is made possible by the national CUNA generation procedure, in which the tax code is replaced for all data processing in the interconnection system. This procedure must be structured so as not to allow the person to be directly identified during the processing of personal data and it is used to interconnect the various individual-based information systems.

Proposal of a Pilot Project to create a Hub to access and process Italian Data on Cardiovascular Diseases as a prototype to establish a National Health Information System

The pilot project has been launched to find an operative and practical solution for some needs coming from research environments, but also from the regional system that manages the NHS, and in particular:

a) Why the interconnection? To produce what? Where is it useful / necessary?

b) Interconnection between what and at what level (for what types of sources is interconnection important and what level can be reached (national, regional, local)?

c) How to get interconnection? Which models to use?

d) d) What are the ethical and privacy requirements raised by the first three points above, on the basis of the existing legislative and regulatory framework and the applicability of the rules that provide the framework in which the Ministry of Health and the other healthcare institutions can operate (see the following paragraph)?

The project aims to create a web-based system to make available, elaborate, integrate and disseminate data from National Health Institute population studies (e.g. longitudinal cohorts of the CUORE Project) and the current flows provided by the National Health Service of the Lombardy, Marche and Sicily Regions in order to produce scientific evidence, monitoring tools and healthcare services assessments.

Cardiovascular diseases (CV) are the leading cause of death worldwide and global spending on cardiovascular diseases is higher than that on any other disease.

In Italy, cardiovascular diseases are, still today, one of the most important public health problems: they are among the main causes of morbidity, disability and mortality. This group includes the most common atherosclerotic disorders, in particular ischemic heart disease (acute myocardial infarction and angina pectoris) and cerebrovascular disease (ischemic stroke and haemorrhagic stroke). It should be remembered that those who survive an acute form become chronic patients with significant repercussions on their quality of life and the consequent economic and social costs borne by society. Moreover cardiovascular diseases are among the major determinants of aging-related disease, producing physical disabilities and cognitive impairment.

Population data surveys (longitudinal cohorts, health examination survey/health interview survey, population registers) actively collect health information through direct screening of representative samples of the adult population and use standardized procedures and methods for the collection of risk factors and lifestyles, high risk behaviours and frequency of disease through standardized diagnostic criteria (longitudinal cohorts or health examination surveys) or self-reported information. They consider self-assessed health (health interview survey), for which it is essential to maintain an up-to-date follow-up on hospital admissions and deaths, on emerging pathologies, adherence to treatments, diagnostic and therapeutic pathways. There are also databases that include routinely collected current health data to be used by the NHS for administrative purposes (Health Care Utilization-HCU), or store patient data concerning demographic aspects, healthcare procedures, and services which represent a cost to the health authorities. However, that data lacks all information about risk factors and lifestyles, needed to have a complete overview of the health status of both each single individual and the entire population. The integration of these data sources would help to bridge the inadequacy of individual sources and use and exploit the information collected in different areas and with different purposes to produce scientific evidence, create monitoring tools and evaluate healthcare services. This would ultimately be used to improve the health of the population and would also help to fulfil the moral commitment that the researcher has towards the people who participated in the studies by providing biological samples and material, and for which they gave their informed consent with the ultimate purpose of improving the health status of future generations.

The main objectives of the pilot project are: 1) the feasibility of system to interconnect and process health and epidemiological data from population studies and current health data from regional systems; 2) the evaluation of different ways for research institutes, local health systems and other stakeholders to access, obtain availability and use of the system interconnecting and processing health and epidemiological data; 3) the identification and evaluation of issue related to privacy and ethics inherent in the system operation and its accessibility under current legislation, and the identification of possible solutions; 4) the verification of system operability through a pilot study on the evolution of certain risk conditions of greater interest for public health (hypertension, diabetes, obesity), and the consequent assessment of their development, adherence to drug treatments and lifestyles in healthy people and people at risk (hypercholesterolemia, diabetes, obesity) enrolled in the cross-sectional studies of the National Health Institute (OEC/HES 1998-02 and 2008-12 surveys) in Lombardy, Marche and Sicily.

These goals will be achieved by using and integrating several data sources:

1. Data of the National Health Institute collected through cross Surveys of the CUORE Project (general population samples, men and women aged between 35 and 79 years and resident in all 20 Italian regions examined during the years 1998-2002 (n=9,712) and 2008-2012 (n= 9,111)). Data includes information collected and retained for each enrolled person, regarding systolic and diastolic blood pressure, lipid profile and blood glucose levels, anthropometric measurements, lifestyles (smoking, physical activity, diet), history of disease, electrocardiogram coded according to the Minnesota Code, for the diagnosis of some cardiovascular diseases;
2. Data on the use of healthcare services (Lombardy, Marche and Sicily regions) obtained from automated routine collection systems, directly managed by regional authorities, which include databases common to all Italian regions obtained from the register of resident population enrolled with the National Health Service, which includes demographic and administrative data, the database on hospital discharge diagnosis, outpatient prescriptions of drugs reimbursed by the NHS or drugs directly administered in outpatient and day-hospital services, outpatient services, regional

emergency services, the register of exemptions for selected chronic diseases, including diabetes, hypertension, family hypercholesterolemia and coronary heart disease, the costs for the NHS, calculated through the sums paid by regional healthcare authorities to healthcare providers who provide the service. For each beneficiary of the NHS within a single Region, the above-mentioned databases can be linked through a single identification code.

To achieve the project's objectives, various statistical analyses on studies of the National Health Institute on population data and regional health data will be made available for use on the web, once linked to specific objectives. The availability of these data will allow investigations on a broad spectrum of objectives in the general population, under baseline risk conditions (hypercholesterolemia, obesity) and in patients with specific diseases (e.g. type I diabetes, chronic kidney disease, chronic respiratory disease, CV disease). It will also be possible to: (i) describe the heterogeneity of patient pathways in primary prevention of cardiovascular disease including adherence and persistence with evidence-based guidelines, (ii) describe the heterogeneity of patient pathways (iii) identify the components of the various pathways by explaining the probability of occurrence of the selected outcomes, (iv) assess the economic profile of these health pathways, and (v) develop a co-morbidity score. In addition, further studies will be performed on selected databases to evaluate the validity of codes used to identify outcomes in health resource databases and quality of life. For each of these objectives, specific study protocols will be produced.

A platform will be created to generate evidence based on real-world data according to research protocols that will allow integrating data from cohort studies with data on HCU available in Lombardy, Marche and Sicily, regions involved in the project.

Web-based system for data integration and interconnection

The update, modification and integration of the “Beaver” software already used by the Bicocca University of Milan under the FRAME Project of the Ministry of Health have been proposed to create the web-based interconnection and data processing system. The 'Beaver' software allows the “in situ” integration and processing of current data per each region through a dedicated server. The new system will extend this integration and processing to data from different sources, NHI population surveys and possibly health data from multiple regions.

Record linkage and data processing procedures

The record linkage procedure is of crucial importance for the proposed analyses. It shall be carried out, on a case-by-case basis, according to the analyses chosen and the data selected in a protected environment, avoiding processing of data that would allow an uncoded reading of data. The procedure chosen as a possible solution for both the interconnection of NHI epidemiological data with health data from each region and data processing through the system upgraded and developed for the NHI starting from the Beaver system used by the Milan Bicocca University, foresees:

- The creation, at the regional health data manager, of a dedicated and protected storage area accessible only to the NHI;
- the sending of population data chosen for the pilot study on interconnection, to the dedicated area created by the regional health data manager;

- The algorithm used to pseudo-anonymize regional health data shall be used also for data from the National Health Institute and, based on the identification codes obtained, linkage will be implemented to current health data from regional sources;
- The implementation of analyzes that can only be carried out by the National Health Institute via the web and whose results, in aggregate form, can be viewed by the NHI.

The hypothesis of developing an Italian HIS

The main objective of the Health Information System (HIS) is to create an infrastructure providing common access to data, tools and methods for health research, with the purpose of conducting research activities as well as public health and healthcare services monitoring. The system shall be accessible to all researchers after a legal and ethical assessment of the access request. In the development of an Italian healthcare system, it is necessary to create an infrastructure with a well-defined legal, economic and political framework that could support the following activities:

1. To provide technical and scientific support for the development of comparable, standardized and accessible indicators to monitor health services determinants and population health. This activity involves the updating of existing indicators, the development of new indicators and the improvement of existing ones based on European ECHI indicators; indicators produced must therefore ensure quality information and be standardized at regional, national and European level.
2. To facilitate and support the development and hosting of database platforms, metadata documentation, data collection protocols, tools and methods of harmonization, quality assessment, analysis and reporting, and tools useful to facilitate access to and use of data for research.
3. To develop and/or strengthen the network of researchers in order to connect the scientific community, national infrastructures and international organizations and develop new and more efficient methods and tools for data collection, quality assessment, use of information, analysis and reporting;
4. To provide a sustainable structure for the exchange of best practices at regional, national and European level, to support political decision-makers and also to disseminate to all members the activities carried out by individual researchers.

Within the activities of the European Bridge-Health project, various possible solutions have been explored to create an organizational structure that could strengthen the health information system of EU countries, taking into account the feasibility of establishing such a structure from a legal, economic and political point of view. The first hypothesis of such a structure analysed the inclusion of the new health information system into an already existing one or the setting up a totally new information system.

The different structures identified at European level through the BRIDGE-HEALTH project and the national ones identified through the CCM-Bridge project are presented in the table below.

STRENGTHENING THE EXISTING STRUCTURE		CREATING NEW STRUCTURES	
European Level	**National Level**	**European Level**	**National Level**
Widening Eurostat tasks	Widening the tasks of Istat or Ministry of Health	New independent European Agency	
Widening the scope of the European Centre for Disease Prevention and Control (ECDC)	Widening the scope of CCM-National Centre for Disease Prevention and Control	European Research Infrastructure Consortium (ERIC)	Establishment of a national consortium National reference HUB to ERIC
Reorganisation of DG SANTE			
Widening the scope of the Joint Research Centre (JRC)	Widening the scope of the National Health Institute.	European superstructure (e.g. Codex Alimentarius Commission)	
Other Institutions: WHO AND OECD			

Development of the governance system of a possible HIS

The future HIS governance structure must be organized on three levels: a decision-making level, represented by the interinstitutional committee and the scientific committee; an executive level, represented by the executive central office; and an operational level represented by the operative network. Strategic decisions shall be taken by the Interinstitutional Committee with the support of the Scientific Committee. Executive activities shall be carried out by the Central Management Office, which includes a general manager and the operative network. Operational activities shall be carried out by the Technical Committee.

The Interinstitutional Committee

The Inter-Institutional Committee is the HIS governing body and is composed of representatives from Istat, the Ministry of Health and the National Health Institute. The Interinstitutional Committee shall have full decision powers and each participating entity shall appoint its official representative and alternates. The Interinstitutional Committee shall appoint the Director General, who will be responsible for the reporting to the Interinstitutional Committee of the activities carried out by the Executive Office. The envisaged activities include discussion, modification and adoption of the governance structure, changes to the strategic plan, annual or multi-year work plans, the approval of the annual and multi-year financial statements, the adoption of the annual budget proposed by the Director-General, the evaluation of the Managing Director's general plan and the translation of the management plan into a strategic plan and operational objectives, the approval of new members, the adoption of implementing rules and the approval of internal regulations.

The Scientific Committee

The Scientific Committee is composed of a group of experts recognized at national and international level in the field of health research; it offers its advice at the request of the interinstitutional committee and can be consulted on all questions related to research programmes, scientific strategies, ethical issues and annual work programme. The Scientific Committee has also the task of periodically assessing HIS activities and products (strategic and operational objectives). The Scientific Committee must also include a representative of the Data Protection Authority in order to know beforehand all legal issues related to privacy issues, and directly address and solve them.

The Executive Central Office

The central office is the permanent body composed of the general manager and his staff; it is responsible for HIS management, operational and budget decisions.

Organization of the national information system

The Central Management Office implements the decisions taken by the Shareholders' Meeting. The Director-General shall be appointed by the Interinstitutional Committee. The staff is responsible for HIS coordination and legal support and coordinates the dissemination of health information. The executive office is also responsible for day-to-day operations (such as meeting organization), assesses the priorities to be set and defines the goals to be achieved.

The operative network

The operative network consists of representatives from national and regional health information authorities. It is responsible for all national and regional scientific activities relating to health information and collaboration among member institutions. The operative network acts under the responsibility of the executive central office and subgroups of experts can be created within it, to help achieve the objectives proposed by the network itself or by the Director General.

Survey of the ECHI short-list indicators

In the past, several projects (ECHI-1, ECHI-2, ECHIM-1, ECHIM-JA) have been funded by the EU, leading to the establishment of a list of 88 health indicators (ECHI-Shortlist).

For each indicator in the ECHI shortlist, a documentation sheet was developed by European project experts in close collaboration with Eurostat, DG SANTE, WHO and OECD. For each indicator, documentation sheets show the definition and source data that experts determined to be as the best possible choice in terms o methodology, data availability, usage in the Member States, and political relevance of the indicator's topic.

For more than 50 of these indicators (implementation section), data is available in international databases and/or international data collections such as the European Health Survey (EHIS), or European Union Statistics on Income And living conditions (EU-SILC); however, over the years, changes in the calculation method of some indicators or in data collections required modifications and updates in the shortlist indicator definitions. In addition to the Implementation section of the shortlist, there are two additional sections that include indicators: the "Work-in-progress" section, i.e. the section containing indicators that are technically (almost) ready to be incorporated into periodic data collections of international organisation but still present critical issues, and the "Development" section, i.e. the section containing indicators for which the documentation provided by the European Expert Group is not yet fully formalized and which need to be further developed and/or implemented during the BRIDGE-HEALTH project.

Starting from the Excel file provided by the WP4 of the BRIDGE-Health Project, Italy has carried out the monitoring and assessment of 94 indicators (88 indicators + 6 coming from the register) of the ECHI short list (Implementation, Work In Progress, Development), as well as the assessment of their availability in the ECHI Indicators Tool of the Implementation section, (ECHI_indicators_Italian_data_july_2016_revBMI.xlsx).

This analysis led to a classification of indicators according to their availability (see Figure 1):

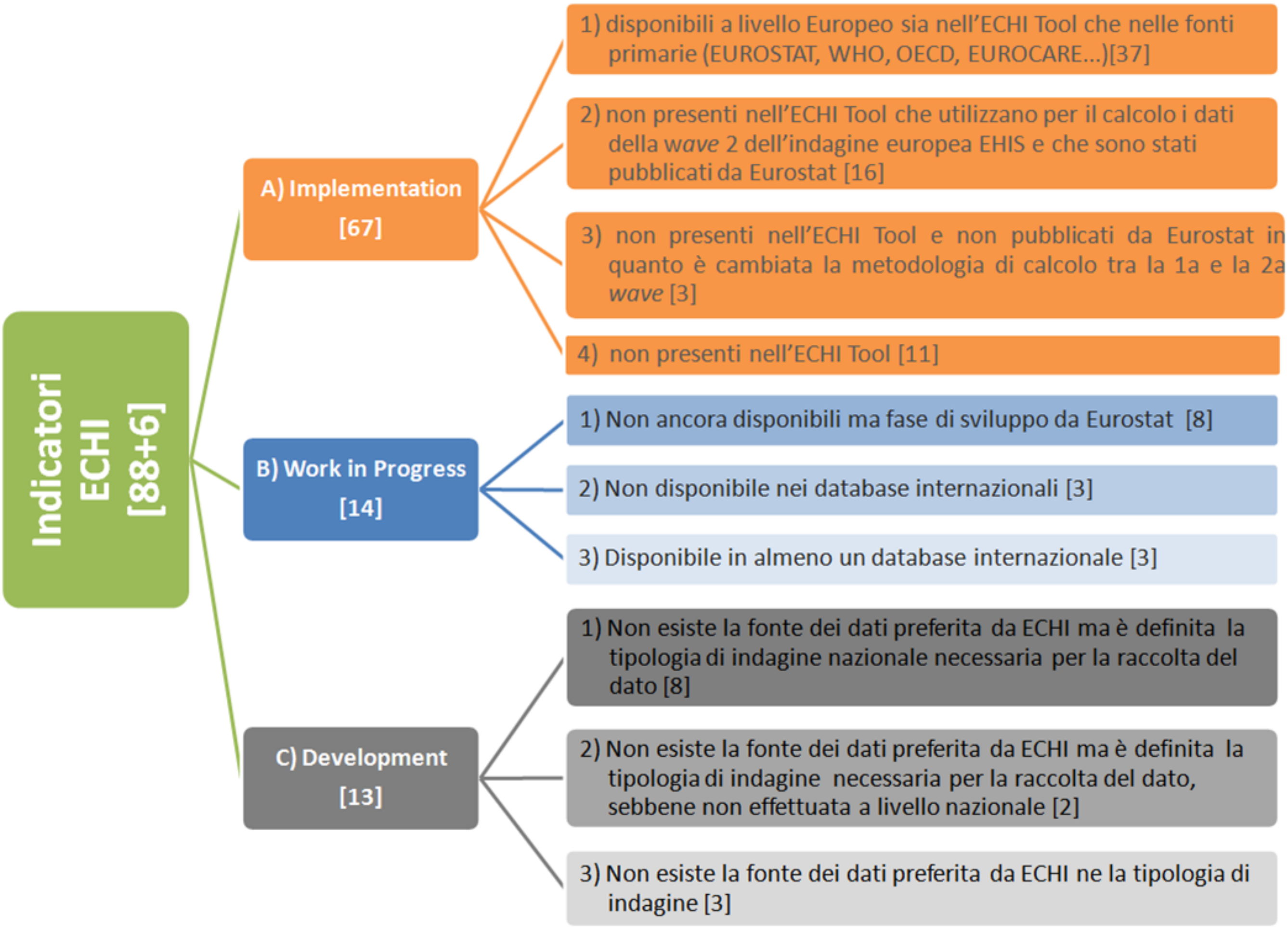
Group A. Indicators of the Implementation section

Group B. Indicators of the Work In Progress section

Group C. Indicators of the Development section

Group D. New proposal of indicators (not yet in the shortlist)

Figure 1 - Mapping of ECHI shortlist indicators after assessing their availability for Italy



Mapping of ECHI shortlist indicators available for Italy

GROUP A- *Implementation* section

The indicators of the *Implementation* section are those for which a metadata sheet is defined at European level. The indicators of this group were analyzed for Italy taking into account their availability in ECHI DataTool, at European and national level. Below you will find the indicators of the *Implementation* section according to their availability in the ECI DataTool:

1. List of **37** indicators for which Italian data are available at European level both in the ECHI Data Tool and in the primary sources (EUROSTAT, WHO, OECD, EUROCARE ...):

   1. Population by sex/age
   2. Birth rate, crude

3. Mother’s age distribution*
4. Total fertility rate
5. Population projections
6. Population by education
8. Total unemployment
9. Population below poverty line and income inequality
10. Life expectancy
11. Infant mortality
12. Perinatal mortality
13. Disease-specific mortality; Eurostat, 86 causes
14. Drug-related deaths
18. Selected communicable diseases*
19. HIV/AIDS
28. (Low) birth weight
31. Injuries: workplace
33. Self-perceived health
34. Self-reported chronic morbidity
35. Long-term activity limitations
40. Health expectancy: Healthy Life Years (HLY)
46. Total alcohol consumption
48. Use of illicit drugs
55. PM10 (particulate matter) exposure
56. Vaccination coverage in children
62. Hospital beds
63. Practicing physicians
66. Medical technologies: MRI units and CT scans
67. Hospital in-patient discharges, limited diagnoses
68. Hospital daycases, limited diagnoses selected DiagnosIstituto Superiore di Sanità
69. Hospital day-cases as percentage of total patient population (in-patients & day-cases), selected diagnoses
70. Average length of stay (ALOS), limited diagnoses
73. Surgeries: PTCA, hip, cataract
76. Insurance coverage*
78. Survival rates cancer
79. 30-day in-hospital case-fatality AMI and stroke
80. Equity of access to health care services

* Some subcategories are not present

2. List of 16 indicators for which there are no Italian data in the ECHI Data Tool, which use data from EHIS Wave 2 for their calculation and were recently published by Eurostat:

21. (A) Diabetes, self-reported prevalence

23. (A) Depression, self-reported prevalence

26. (A) Asthma, self-reported prevalence

27. (A) COPD, self-reported prevalence
29. (A) Injuries: home/leisure, violence, self-reported incidence*
30. (A) Injuries: road traffic, self-reported incidence*
42. Body mass index
43. Blood pressure
44. Regular smoker
49. Consumption of fruit
50. Consumption of vegetables
52. Physical activity
57. Influenza vaccination rate in elderly
58. Breast cancer screening
59. Cervical cancer screening
60. Colon cancer screening

* Some subcategories are not present

3. List of 3 indicators for which there are no Italian data in the ECHI Data Tool and data has not yet been published by Eurostat as the method of calculation changed from Wave 1 to Wave 2:

36. Physical and sensory functional limitations
72. Selected outpatient visits
74. Medicine use, selected groups

4. List of the **11** indicators that are not present in the ECHI Tool:

7. Population by occupation
20. Cancer incidence
29. (B) Injuries: home/leisure, violence, register-based incidence
30. (B) Injuries: road traffic, register-based incidence
47. Hazardous alcohol consumption
53. Work-related health risks
54. Social support
64. Practicing nurses
71. General practitioner (GP) utilization
77. Expenditures on health
85. Policies on ETS exposure (Environmental Tobacco Smoke)

GROUP B- *Work In Progress section*

The Indicators of the *Work In Progress* section; these indicators are technically (almost) ready to be incorporated into periodic data collections of international organizations but still have critical issues. For this group of indicators an analysis has been made that produced the following three subgroups:

1. List of 8 indicators whose definition has not yet been completed but which are being developed at European level by the European Commission - DG Eurostat:

   21. (B) Diabetes, register-based prevalence

   22. Dementia

   23. (B) Depression, register-based prevalence

   24. AMI

   25. Stroke

   26. (B) Asthma, register-based prevalence

   27. (B) COPD, register-based prevalence

   75. Patient mobility

2. List of **3** indicators for which data is not collected in any international source:

   45. Pregnant women smoking

   51. Breastfeeding

   61. Timing of first antenatal visits among pregnant women

3. List of **3** indicators available in some international databases although not harmonized at European level:

   15. Smoking-related deaths

   16. Alcohol-related deaths

   41. Health expectancy, others

GROUP C- *Development section*

The Indicators of the *Development* section, for which the documentation provided by the European Expert Group is not yet fully formalized and are therefore not yet ready to be included in an international data collection due to significant methodological problems and/or data availability. The analysis of these indicators falls within the WP4 activities of the European BRIDGE-Health project. The Italian network analysed this class of indicators by dividing them into three subgroups:

1. List of **8** indicators, available in Italy, for which ECHI has not identified a harmonized source of data to be used, whose survey/study to collect the data needed to calculate the indicator (HIS Survey, Population or disease registers, etc.) is already available.

37. General musculoskeletal pain

38. Psychological distress

39. Psychological well-being

81. Waiting times for elective surgeries

82. Surgical wound infections

86. Policies on healthy nutrition

87. Policies and practices on healthy lifestyles

88. Integrated programmes in settings, including workplace, schools, hospital

2. List of **2** indicators for which ECHI has not identified a harmonized data source to be used; for these indicators, a survey/study to collect the data needed to calculate the indicator (HIS Survey, Population or disease registers etc.) is already available and they are NOT available in Italy.

83. Cancer treatment delay

84. Diabetes control

3. List of 3 indicators for which ECHI has not identified a harmonized data source and a data collection survey/study is not available.

17. Excess mortality by extreme temperatures (formerly 'by heat waves')

32. Suicide attempt

65. Mobility of professionals.

GROUP D- *Proposal for new indicators*

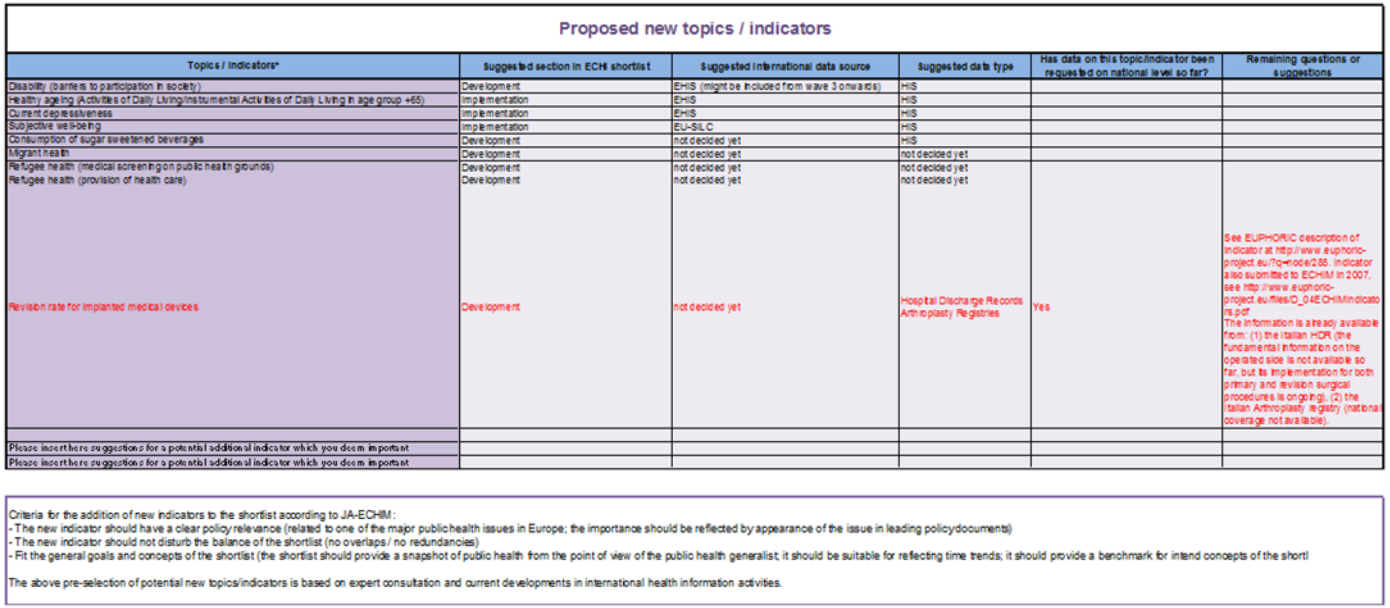
The inclusion of the *Revision Rate for Implanted Medical Devices* has been proposed; this is a new indicator to be submitted to Work Group 4 of the European BRIDGE Health project.

The term *revision* refers to the removal (and usually replacement) of one or more components of the implanted device, regardless of the cause of the revision. For example, in the case of orthopaedic prosthetic surgery, the term *revision* indicates the intervention with which an articular prosthesis is totally or partially replaced due to failure (e.g. aseptic mobilization, device breakdown, infection, ... https: // www.nice.org.uk/guidance/ta304/resources/total-hip-replacement-and-resurfacing-arthroplasty-for-endstage-arthritis-of-the-hip-review-of-technology-appraisal-guidance-2- And-44-82602365977285).

The *Revision Rate* is defined as the proportion of patients undergoing a revision surgery within a defined follow-up period (e.g. 10 years, in the case of joint prosthesis surgery) compared to the population who underwent primary replacement surgery. Starting from the *revision rate*, it is possible to calculate the survival rate (1- revision rate) that measures the performance of the implanted medical device and is generally represented by a Kaplan-Meier cumulative incidence curve. This indicator monitors the time period between primary surgery and revision surgery, and allows early detection of medical devices that perform below the standards; the indicator supports any decision to withdraw these devices from the market, improve the quality of life of patients and reduce public health expenditure for revisions.

The main data source to be used for the calculation of the Revision rate is Hospital Discharge Summary Cards (if the interventions concern a specific side, only if this information is available for the primary and the revision surgery) and the secondary data source from medical device implant records (for example, in orthopaedics, arthroplasty registers).

Figure 2 - Proposal for the new indicator ”Revision Rate”



Proposed new topics / indicators

Topics / Indicators*	Suggested section in ECHI shortlist	Suggested international data source	Suggested data type	Has data on this topic/indicator been requested on national level so far?	Remaining questions or suggestions
Disability (barriers to participation in society)	Development	EHIS (might be included from wave 3 onwards)	HIS		
Healthy ageing (Activities of Daily Living/Instrumental Activities of Daily Living in age group +65)	Implementation	EHIS	HIS		
Current depressiveness	Implementation	EHIS	HIS		
Subjective well-being	Implementation	EU-SILC	HIS		
Consumption of sugar sweetened beverages	Development	not decided yet	HIS		
Migrant health	Development	not decided yet	not decided yet		
Refugee health (medical screening on public health grounds)	Development	not decided yet	not decided yet		
Refugee health (provision of health care)	Development	not decided yet	not decided yet		
Revision rate for implanted medical devices	Development	not decided yet	Hospital Discharge Records Arthroplasty Registries	Yes	See EUPHORIC description of indicator at http://www.euphoric-project.eu/?q=node/285. Indicator also submitted to ECHIM in 2007, see http://www.euphoric-project.eu/files/D_04ECHIMindicators.pdf The information is already available from: (1) the Italian HDR (the fundamental information on the operated side is not available so far, but its implementation for both primary and revision surgical procedures is ongoing), (2) the Italian Arthroplasty registry (national coverage not available).
Please insert here suggestions for a potential additional indicator which you deem important					
Please insert here suggestions for a potential additional indicator which you deem important					

Criteria for the addition of new indicators to the shortlist according to JA-ECHIM:
- The new indicator should have a clear policy relevance (related to one of the major public health issues in Europe; the importance should be reflected by appearance of the issue in leading policydocuments)
- The new indicator should not disturb the balance of the shortlist (no overlaps / no redundancies)
- Fit the general goals and concepts of the shortlist (the shortlist should provide a snapshot of public health from the point of view of the public health generalist; it should be suitable for reflecting time trends; it should provide a benchmark for intend concepts of the shortl

The above pre-selection of potential new topics/indicators is based on expert consultation and current developments in international health information activities.

Conclusions

The aim of the project was to verify and improve the availability of health information to organize and develop an integrated, sustainable and standardized National Health Information System (HI) to serve both as the Italian hub for a future European infrastructure and as a source of data, tools and methods for health research.

During the year of activity, HI experts were invited and involved in the project, including Ministry officials who had participated in the preparatory work of ERIC (European Research Infrastructure Consortium), responsible for the coordination of population registers, numerous in ISS, researchers of the ISTAT that collaborate in the European context to the collection and processing of health data with EUROSTAT and DG-Santè, experts from Universities, Public Health Units, and Medical Associations.

An Italian network of experts on HI was created with them and various integrated activities were carried out through the establishment of four working groups ('ECHI indicators', 'Communication, transmission, data dissemination', 'Governance', 'Data interconnection') that worked in parallel, but in connection to each other, for **a)** the establishment of a network of HI experts ; **b)** the verification of health data sources; **c)** the updating of ECHI short list indicators for Italy; **d)** the identification of information gaps due to problems in transmitting and communicating Italian data to international organizations; **e)** the identification of regulatory and ethical constraints on ethics and privacy, related to access, use and integration of health data through a proposal aimed at a sustainable organization and governance of the system, **f)** the implementation of a pilot project to interconnect and integrate current health and administrative data with data from longitudinal epidemiological studies carried out at the Istituto Superiore di Sanità (National Health Institute).

Some results of the project are described in the Report, but the main added value of the project lies in having put at the same table, with a common goal, some of the main institutions that collect, manage and provide health data, such as the Ministry of Health, the National Institute of Health, the National Institute of Statistics, the Universities. Certainly other institutions and associations will have to be involved, but this experience represents a first step towards the establishment of a national hub, in the form of an integrated network, that can be part of the future ERIC on Health Information (HIREP-ERIC).