The Italian Hub of Population Biobanks as a Potential Tool for Improving Public Health Stewardship

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In Italy, a country that is experiencing the decentralization of health services from central to regional level of government, the Minister of Health is proposing stewardship as a model of governance for the public health system. Stewardship favors efficiency in the policy decision-making process, based on reciprocal trust, and tends to be more ethical. The embryonic proposal to test stewardship in the field of population-based research was advanced during the launching conference *Challenges and Opportunities of the Italian Hub of Population Biobanks (HIBP)* held in 2012 in Rome. Resources collected by population biobanks (i.e., blood and its derivatives, and/or DNA isolated from any type of biological samples and relative associated data) have, in fact, a recognized scientific value for the investigation of links between genetics, health and life style, and epidemiological outcomes through population biobank-based studies, and are essential to planning effective and qualified interventions for public health. The current economic crisis requires a strong push to rationalize investment in health policies. In particular, population biobank-based studies require financial commitment, often of long duration, for the realization of their goals. Thus, innovative solutions to allow fast integration of scientific knowledge into political health strategy are required. During the conference in Rome, it was proposed to test the stewardship model by its application to the inter-relationship between population biobank-based studies and disease prevention. Stewardship minimizes barriers to innovation and uses information more effectively to better develop new strategies for prevention and/or treatment. In the months following the conference, the proposal was defined more clearly, and the HIBP network became a potential tool for testing and implementing this model in the Italian Public Health prevention system.

Introduction

POPULATION BIOBANK-BASED RESEARCH aims at identifying genetic traits affecting human chronic diseases, longevity, aging, health, thus allowing the investigation of the relationships between disease risks and environmental elements. In each country, population biobanks, because of their informational and biological patrimony, represent recognized valuable resources that potentially provide the ability to compete strongly at the international level for available projects aimed at investigating links between genetics, health, and life style. Additionally, population biobanks are a powerful tool in the hands of policy makers who need to address relevant questions of preventive medicine more closely related to national inhabitants. The outcomes of these studies are fundamental for planning effective and qualified interventions for public health priorities. Subsequently, the epidemiological evidence derived from these studies can play a crucial role in designing national health strategy and planning preventive medicine interventions by decision makers. However, the integration of population-based scientific findings into operative national health plans

may be a slow process, which is, sometimes, characterized by low efficacy.

Furthermore, the present economic crisis results in difficulties for implementing new biobank-based studies, which require strong and long-lasting investments. In this scenario, there is an increased need for new solutions to exploit existing population biobank work in order to increase efficiency and rapid translation of population-based research findings in the national health plan for the benefit of the general population. It is worth noting that devolution, which has decentralized health services from the central to regional level of government, increases the urgency of finding well-established innovative governance solutions that rationalize integration of knowledge into prevention programs. In fact, the mandatory governance model, which translates tasks in a pyramidal sequence, is not applicable in a decentralized system where all stakeholders (national and regional) have the same weight.

These important issues were partially addressed during the conference “Challenges and Opportunities of the Italian Hub of Population Biobanks (HIBP)”¹ held in Rome on March 9, 2012, which was also dedicated to illustration of the HIBP activity and to discuss the population biobanks issues

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in the national and international context.² The conference was structured in two main sessions. The first one presented the contribution of Italian biobanks, both founder and associated HIBP partners, to the activities of this network. The second session focused on population biobanks in the context of the international scenario, and on the main European epidemiological projects, with the aim of facilitating and stimulating collaborative research between different studies and major international networks of population biobanks. The final roundtable of the meeting aimed to disseminate HIBP work to facilitate participation in intra-regional, national, European, and international collaborations, and to align the goals of predictive and preventive medicine with the strategic objectives of BBMRI (European infrastructure Biobanking and Biomolecular Resources Research Infrastructure), the European infrastructure dedicated to the biobank activity. In particular, this part of the conference focused not only on the role of population biobanks and their activities in the context of BBMRI, but also on developing a closer inter-connection with other related Life Science European infrastructure, such as Translational Medicine (EATRIS) and Clinical Studies (ECRIN). Furthermore, the meeting addressed the important role of population biobanks in defining innovative relationships between scientific results stemming from biologic samples and health policy management.

Stewardship: A Proposal for a New Model of Governance

The conference was opened by the coordinator of the joint project between Istituto Superiore di Sanità (ISS) and the National Centre for Disease Prevention and Control (Ccm)³ for the construction of HIBP, Filippo Belardelli, who welcomed all participants and introduced Antonio Federici, delegate of the Italian Ministry of Health and of the Ccm. Federici outlined the potential role of population biobanks in the scenario of health regional governments. As an effect of the devolution in the health system recently introduced in Italy, a new model of stewardship governance has been proposed in the management of health national plans. During the conference, it became clear that the model would fit particularly well with those including surveillance and prevention.⁴ The choice of this model implies the application of its principles in the complex relationships between institutions directly involved in health care decision processes.

In 2000, WHO⁵ suggested that if policy-makers have to act on measures of performance, they need a clear understanding of the key functions that health systems have to undertake. The WHO report defines stewardship—setting and enforcing the rules of the game and providing strategic direction for all the different actors involved—as one of the most critically important.

Stewardship, already endorsed by 52 member states of WHO European Regions,⁶ is the model proposed to be adopted for the relationship between regions and national government in Italy, and it is in the main plan of countries that are experiencing devolution, as Italy. Stewards should be able to formulate a strategic framework and put into practice a model that includes international comparison and cultural growth. In comparison to traditional “mandatory models,” which are defined by a hierarchical relationship, stewardship involves a co-planar net, where each actor, independently of individual decisional power, is inter-

connected with the other partners.⁷ The steward acts to promote community; his/her main functions are:

1. Formulating strategic policy framework
2. Ensuring tools for implementation
3. Building coalitions/building partnerships
4. Ensuring a fit between policy objectives and organizational structure and culture
5. Ensuring accountability
6. Generation of intelligence

The model of stewardship⁷ creates suitable synergies to “Generate intelligence” that contribute to more informed decisions, and thus to better health system outcomes. The goal is to ensure that all health system stakeholders, not just stewards, have access to the information needed for making their contribution to health system outcomes. National health must be accessible and affordable, not only because it is socially fair, but also because it will help each country to achieve a system that is effective and efficient. *Intelligence* is broader than information, as it implies identifying and interpreting essential knowledge for making decisions from a range of sources. However, so far, there is little experiential evidence about its implementation, and the model has not been tested in the field of population biobanks and their impact on preventive medicine.

In this context, the HIBP project is intended to be a tool for providing information derived from population-based studies so that it may contribute to the process in the public health prevention field. With regard to this point, Elena Bravo’s presentation underlined that the promotion of integration of population biobanks in the Italian biomedical research scenario and the encouragement of synergistic activities between private and public stakeholders, including Regions and Ministers, are the main objectives of the HIBP project.

The Role of Harmonization in the “Sharing Model”

In Italy, the potential capability of population biobank collections to contribute to preventive and predictive medicine has been hampered by the lack of a common platform of epidemiological biobanks. Many collections and population biobanks with their great patrimony are already part of European and International projects and are listed in the catalogue of Public Population Projects in Genomics (p3g).⁸ However, incomplete availability of information on each collection, lack of national interaction, and low reciprocal knowledge between population biobanks activities strongly reduces valuable synergies and the potential impact of their outcomes for public health. HIBP aims to increase scientific knowledge of population biobanks in the whole scientific community as well as promoting collaboration between epidemiologists and experts in omics and novel technologies for biomarker evaluation. This strategy will establish an informative tool for national stewardship for the prevention and treatment of human diseases, and thus lead to the recognition by policy makers of the great value of population-based studies in improving public health and reducing health care spending, and ultimately to the adoption of a stewardship model to translate science into health policy. This is of particular importance in a scenario in which decreased public resources and the medium to long-term economical investment required for prospective population-based studies make

it more difficult to implement prospective biobank-based studies.

In the stewardship model, the main health objectives (called “central” actions), that the Ministry of Health is responsible for, support the specific regional goals and the regional preventive programs. HIBP reflects an attempt to synergize at the national level different population biobank-based studies, which are often regional-based. Synergy between different epidemiological population studies is closely related to the harmonization tools. As specifically addressed by Dany Doiron in the conference, the future perspective is to perform population biobank studies that have common international harmonized standards for sample collection, storage, analysis, and database infrastructure realized on a common ethical and legal platform (*prospective harmonization*). However, there is no doubt that the present global challenge is *retrospective harmonization* through methodologies that favor data integration by harmonization and e-tools, allowing the use of existing data. In this regard, the p3g network has developed dedicated software⁹ to identify variables targeted for harmonization and evaluation of potential integration among different existing studies. The process of harmonization made up through a web-based service makes the process faster, cheaper, more transparent, and reproducible with outputs that could be accessible for future projects.

Perspective Actions

Based on the vision of synergizing information by harmonization and to test the HIBP network as a potential tool for implementing the stewardship model in Italian disease prevention, a pilot project has been launched. Starting from the different studies carried out by HIBP¹ founding partners, which were often based in different Italian regions, the pilot project aims to achieve «proof of concept» for sharing already existing data by providing supplementary epidemiological information,¹⁰ which may also be useful for public and private health stakeholders. Starting with the data already collected by the different HIBP studies participating in the pilot project, the specific objective is to evaluate the correlation between the lipidemic profile and regional geographical provenance of single subjects. Currently, of interest from the methodological point of view, an attempt is being made to include some demographics data, as well as physical parameters (i.e., body weight, height) and laboratory lipid parameters. The idea is that harmonization and well-planned population-based research represent determinant tools for preventive and predictive medicine. In this context, the HIBP pilot project may be a practical model to further test and corroborate the stewardship theory for the national health system. Currently, the pilot, which was planned before the conference, is turning more and more towards stewardship. According to the modalities defined by an agreed and signed data transfer agreement (DTA), participating biobanks have uploaded 5071 total records in a common database, using a dedicated informatics infrastructure. It should be noted that in the DTA, it was agreed by the project's partners to share about 4000 records. However, the gradual and empirical adoption of stewardship principles is leading to increasing trust between the network partners, with the result that the number of available records for the pilot project was higher than expected.

So far, the final data that originated from the harmonization process of the collected variables includes 3882 people.

This file is now under statistical analysis. In perspective, the proposed model of stewardship applied to biomedical population-based biobanks research aims to minimize barriers to innovation and to use information more effectively to understand disease better and to develop new strategies for prevention and/or treatment. A new attitude and strategy for sharing data and promoting cooperation in the field of population biobanks may not only have a great impact on public health programs, but also play a role in the development of new biomarkers and drugs, and thus act as economic and social driver in the development of our society in the coming years.

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