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Editorial

# Administrative database, observational research and the Tower of Babel

Annamaria Iorio [a,b], Gianfranco Sinagra [a], Andrea Di Lenarda [a,*]

[a] Cardiovascular Center, University Hospital and Health Services, Trieste, Italy
[b] Cardiology Department, Papa Giovanni XXIII Hospital, Bergamo, Italy

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Over the last decades, a number of methodological approaches have been used for depicting the epidemiology and natural history of diseases. Several strategies need to be utilized to obtain a large and comprehensive knowledge of a disease from the real-world perspective. This may be especially relevant when it comes to heart failure (HF), for which intensive effort is necessary to meet research challenges and plan effective disease management programs, quality improvement initiatives, and future clinical trial interventions.

Administrative data have been acquiring an increasingly important role by providing useful information about patient's characteristics, pattern of care and pathways [1]. Actually, their representativeness of routine clinical care on large number of patients makes it possible to study real-world effectiveness, while their availability at a relatively low cost makes them accessible and efficient. Furthermore, these data sets may have the advantage of producing absolute incidence rates and assessing several disease outcomes [1,2].

In the current observational scenario, Niedziela and co-workers [3] should be commended for conducting the first large study based on administrative data in the Silesian Province of Southern Poland (SILCARD database). The study aimed at describing secular trends in incidence and case fatality among HF patients. The attention was focused on HF patients with first diagnosis of HF assessing in-hospital mortality and clinical outcomes at 12 month follow-up. The main findings indicated a marked increase of HF incidence with an unadjusted constant trend across analyzed period along with high rates of in-hospital fatality.

Worthy of note, the decreasing duration of hospital stay along with significant improvement in both in-hospital and long-term survival were observed. In sharp contrast, the rates of hospital HF readmissions increased. These epidemiological trends may be of concern. However, the reported findings present shortcomings inherent to administrative database. Generally, incomplete or inadequate coding of routinely collected data exacerbates the challenges about their validity. This analytical issue is not easily resolved, and most studies have chosen to view each diagnostic code separately, assigning to diagnosis a different weight in their analyses. Recognizing this analytical shortcoming, Niedziela and co-workers [3] focused their attention only on patients with first HF diagnosis.

Further, without population-level data on most important variables, we can only speculate on possible interacting explanations for the reported trends. In SILICARD database the lack of key clinical variables such as left ventricular ejection fraction, and some comorbidities may be felt as a serious limitation to the interpretation of HF epidemiological trends.

To overcome the aforementioned gaps, it would be necessary to link healthcare administrative systems with clinical information derived from other sources.

In this regard, Trieste Observatory of Cardiovascular Diseases established an example of population-based databases in which administrative data and clinical information are integrated within observational networks [4,5]. The collection of data from each E-chart is linked with clinical and instrumental information drawn from clinical consultations, instrumental procedures, laboratory analyses and prescribed treatments (Fig. 1 Panel A). Within such an epidemiological network, a stepwise approach is performed to define diagnosis of disease. Each of these steps can identify a disease diagnosis by merging of discharge codes with diagnostic codes of chart review, as well as instrumental, laboratory and pharmaceutical data defining chronic disease (Fig. 1 Panel B).

By using this approach, some of the most common pitfalls may be avoided and the risk of underestimation and misclassification may be minimized. Furthermore, the integrity and continuity of patients' health information can be maintained since each patient's E-Chart is collected in a Data Warehouse (Fig. 1 Panel A). This integrated observational system is especially relevant in a HF setting to improve evidence based-practice and to enhance our understanding of seamless transitional care, embracing primary hospital and community care [6].

Notably, this healthcare system is also able to systematically integrate new clinical information to establish an ongoing learning-and-improvement process.

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* Corresponding author at: Centro Cardiovascolare ASUITS, Via Slataper, 9-34125 Trieste, Italy.
*E-mail addresses:* gianfranco.sinagra@asuits.sanita.fvg.it (G. Sinagra), dilenar@units.it (A. Di Lenarda).

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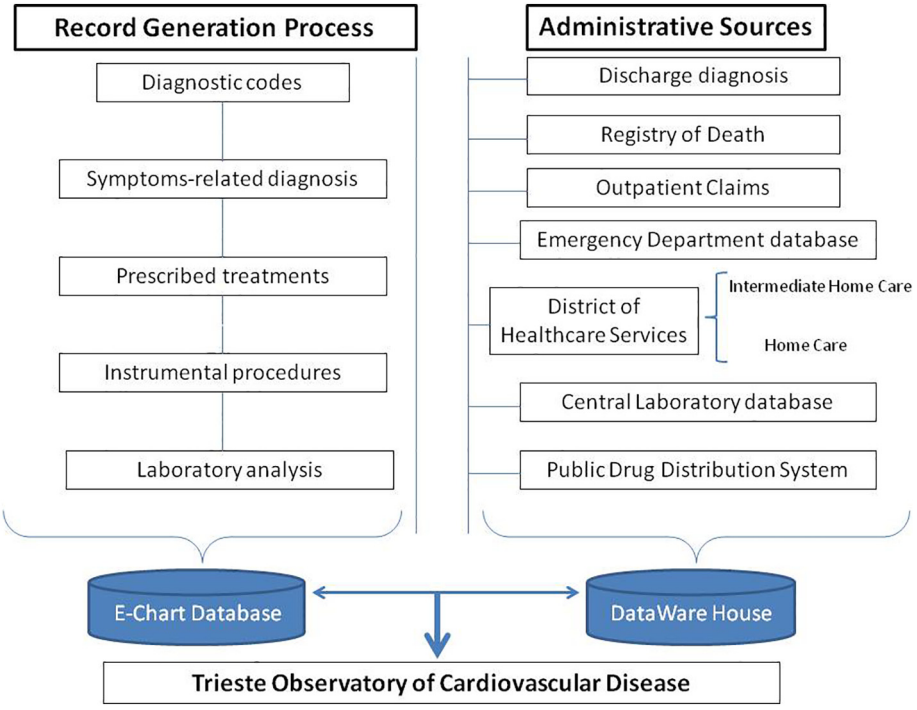


**Fig. 1.** Trieste Observatory of Cardiovascular Diseases is an example of population-based databases in which administrative data and clinical information are integrated within observational networks.

However, the workflow of Trieste Observatory covers only one region from north-eastern Italy. By contrast, Northern Europe (i.e. Denmark, Sweden) and North America are examples of public healthcare systems providing systematic collection of integrated health data which cover the entire population and country [7].

An important issue may clarify the differences between patients from Poland as compared to patients from other regions. However, in order to compare epidemiological data across different regions, it would be crucial to have same analytic platform and standardized reporting.

This heterogeneity in performing observational network is partially related to significant within- and across-country variations in the financing, organization, access, delivery, quality, and effectiveness of cardiac care [7].

It is worth reflecting on the role of scientific medical societies given their independence from the business world and their relationships with health authorities and health care administrators. Moreover, scientific societies should plan several research goals to be pursued within their implemented networks. Most clinical data exchange should occur between organizations at national and international levels.

Over the past few decades, the Italian Association of Hospital Cardiologists (ANMCO) has adopted a scientific program based on several objectives carried out along a number of different directions. Studies were undertaken on clinical epidemiology; surveys and observational studies focused on specific clinical settings through centralized databases; assessments were conducted regarding the effectiveness of new therapies brought into clinical practice, and observational studies aimed at encouraging their implementation [8]. Now, the time has come to take a step forward and start integrating "Big Data" with some limited but critical amount of clinical information. In our view, the reported findings of SILICARD's database offer the opportunity for a reflection about the evidence derived from observational methods' research. It is important to acknowledge that there is room for improvement and that no major changes will be achieved until observational research finds ways to best manage our integrated system's network. Hence, our international scientific community should ideally work with institutions, payers and providers to support a rigorous observational research methodology aimed at answering relevant research questions in a manner that will be useful for decision-makers and effective in comparing worldwide epidemiological data.

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