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# Healthcare utilization database and real world evidence are we able to grasp an extraordinary challenge?

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Healthcare decision-makers are increasingly developing policies that seek information on "real-world" data to provide "evidence" to support and monitor changes in clinical practice or policy decisions. Due to the current focus on information and computer technology to provide safer and more efficient healthcare delivery, the amount of electronic medical records and other electronic healthcare data is increasing exponentially, and these 'real world data' can be used for evidence generation. Among electronic healthcare data, those denoted Healthcare Utilization Databases (HUDs) initially created for administering payments to providers in nationally funded public or private healthcare delivery systems, are receiving increasing interest as evidence generators. The main appeal of HUDs is related to the possibility of retracing the care pathways (i.e., all preventive, diagnostic, therapeutic or rehabilitation services received) of all the beneficiary of the National Health Service (NHS), and analysing their relationships with health outcomes and economic sustainability. This way, we can monitor the real-life impact of treatments delivered on public health and NHS resource use, which accounts for the growing interest on the part of decision-makers and public health researchers.

The position paper of the Italian Society of Medical Statistics and Clinical Epidemiology (SISMEC) entitled "Towards the rational use of Healthcare Utilization Databases for generating real world evidence: new challenges and proposals" and published in this issue of EBPH, focuses on HUDs, describes their strengths and weaknesses, and puts forward some proposals to regulate their use.

Here, we shall focus on a few inter-related points contained in the SISMEC position paper. First, the use of HUDs as a secondary data source should be considered within the framework of clinical research and its effects on public health care, rather than market access of a single product.

Second, clinical research in this context must necessarily make use of emerging, often unconventional methods, algorithms and designs, capable of overcoming or at least rationally taking into account, the pitfalls of observational research, especially if based on HUDs. This implies that, rather than technological, the real challenge in the correct use of HUDs is related to the appropriate use of scientific method, robust observation plans and adequate analytical algorithms able to take into account the complexity of phenomena and generate credible evidence. However, while expertise on the methodological aspects of experimental research is relatively widespread, the area we are dealing with is still unexplored for a large part of clinical researchers.

Third, the good practice rules of clinical research, universally accepted and strictly regulated in drug and medical device testing, should be adapted to this context. However, we are witnessing a certain degree of regulatory relaxation that allows for mere notification of the Ethics Committee to initiate this kind of study.

The above considerations underlie the proposals contained in the SISMEC position paper. Among them, suggestions aimed to

- regulate the access to HUDs by public bodies external to the regional administration,
- set up Regional Evaluation Committees (RECs) to assess the methodological soundness of the observational research projects using secondary data promoted by research centres accredited by the Region, and thus relieve the Ethics Committees from duties that are too cumbersome and fragmentary to be credibly sustained,
- establish a national coordination of the RECs aimed at harmonizing the rules of good practice of observational research using secondary data, as well as supporting the single Regions by supplying adequate expertise and infrastructures,
- promote training courses on observational research using secondary data to embark on a "virtuous" pathway of research quality improvement in our country,
- valorise cooperation initiatives between the National Health Service, Universities and enterprises,

have extraordinary strategic power. Implementing these proposals should be seen as an investment looking not only to use the HUDs as good governance tools, but also to optimize scientific competitiveness in a sector in which we no doubt excel in terms of the huge wealth of information available but which, as is often the case, we find difficult to valorise.

The SISMEC proposals, if implemented, would allow us to attract resources, access European Community research funds and promote employment in a specialist, but strategically important sector. For these reasons, we hope that the SISMEC position paper will spark a debate that from the pages of EBPH may extend to institutional meetings.

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