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Short Communication

Personalized Evidence-Based Medicine in Need of High-Quality Data

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1. Short Communication

The truth in medicine does not exist, since 3500 publications are added every day to the knowledge base of medicine[1]. Each day the truth changes a little.

Today, evidence-based medicine with its key methodology of systematic reviews of randomized controlled trials attempts to sift out the valuable 'true' information[2]. Systematic reviews are the building blocks of guidelines, currently the corner-stone of medical practice. Clinical practice guidelines made by experts tell which treatments are true and of sufficient benefit in comparison to harm to be prescribed to patients.

Guideline recommendations are based on averages in groups of patients; but many patients do not fit the average. The recommendations are also dependent on the publications chosen and their interpretation and extrapolation by the committee of experts; guideline recommendations can vary considerably between countries. In addition, the process of conception, validation and authorization of guidelines takes several years and often valuable new information is not incorporated.

There is a clear need for personalized evidence-based medicine[3].

True knowledge of treatment benefits such as cure, remission, improved quality of life or survival is then translated to the individual patient; ideally also the risk of harms such as adverse effects and costs is tailored to the individual patient. Such a system will allow the user (physician and patient) to view personalized information on efficacy, adverse effects and costs for all licensed treatments. It will be an invaluable tool to select the treatment option that fits the patient best from all the available evidence.

Is such a system of personalized evidence-based medicine practically applicable, independent of experts, up-to-date and accessible?

We have developed a prototype for individual based treatment decision making in hepatitis C, which uses data of 66,000 patients from 176 publications of clinical trial and prospective real-life studies. The data are linked to 132 patient profiles and 35 therapy combinations. Modern app technology allows personalization of data by entering 4 patient characteristics on aetiology, disease stage, therapy status and comorbidity. Outcome of patient profile-therapy combinations can be viewed by physicians and patients to support treatment decision making[4].

This proof-of-principle holds the potential to be used across a wide range of diseases and could innovate clinical medicine. To develop generic methods applicable to many diseases, further fundamental and applied research in the field of biomedical data science is needed.

What is needed first of all? High-quality individual patient data. In this respect the big-data revolution is of major interest. Unfortunately, most data bases are inadequate or incomplete. Electronic health record databases usually lack outcome data and have too many missing values and faulty data points [5], probably related to the time pressures of ordinary clinical practice. Databases coupled to disease registries have the specific purpose of clinical research and more dedicated data collectors. Disease registries use observational methods to collect uniform data on a population defined by a particular disease and that is followed over time[6]. Registry data bases are increasingly being developed and could play an important role in satisfying the need for individual patient data in the future. Yet universal criteria for quality need to be developed in addition to methods to cope with an often considerable percentage of 'lost to follow-up'. In theory it is desirable that registry databases for personalized evidence-based medicine contain data from Europe, America, Asia, Australia and Africa.

The core of medical knowledge, publications, has been the basis of the hepatitis C prototype. Its database uses exclusively data of phase 2 and 3 clinical trials and prospective real-life studies. However, not only pivotal studies published in major journals are included, but all publications fulfilling the high-quality criteria are being used thereby minimizing the selection bias.

Individual patient data or patient profile-therapy regimen specific data are being requested from the first author. In a considerable percentage these data have been obtained.

Individual patient data are becoming more accessible since major journals now require authors of publications to include a data sharing statement for anonymized IPD to be made available on reasonable request [7].

For many decades editorial decisions of many biomedical journals have been taken with focus on originality. In addition to original findings of robust clinical research, controversial topics published on behalf of the public interest are being selected for publication since they increase the number of readers, citations and the impact score. Unfortunately, the latter type of articles actually can do considerable damage [8]

Now, in this time of big data, quality and accessibility of data are more important than originality.

It does not matter whether the publication is first in its kind and what the impact factor of the journal is; all high-quality data can contribute to databases of individual patients for single diseases and add to the reliability of personalized medicine. It is desirable to have high-quality data from Europe, America, Australia, Africa and Asia. The new Japanese Journal of Gastroenterology and Hepatology may fit well in that prospect.

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