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New steps to individualize patients care

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In the current issue of *Psychotherapy and Psychosomatic* Dr. Ralph Horwitz and colleagues outline new methodologies, in addition to the well-known randomized controlled trials, to gather information that may lead to individualized patient care.

The individualized care of patients has always been the focus of physicians in the practice of medicine. The commitment of physicians to the care of sick patients has remained steadfast despite the urgings of health policy experts who often prefer an emphasis on population medicine or of health system leaders who emphasize system-level efficiency and economic performance.

The ideal information base for a clinician choosing treatment for a particular patient is an archive of clinical histories closely matched to the patient in question, where some individuals have received the contemplated treatment and others have not.

Most of the data currently available about the results of using alternative treatments derive from RCTs. Unfortunately, the populations enrolled in such trials are far more heterogeneous than are required for a set of close matches to the patient being seen by the physician. Although these average treatment effects from heterogeneous RCTs may be acceptable for regulators licensing drugs, they are rarely sufficient for the clinician focusing on a single patient. Likewise, psychosocial features of patients at the individual level also directly affect clinical outcomes.

Dr. Horwitz and colleagues argue that rather than relying solely on the

average results of groups of patients drawn exclusively from randomized trials, we can use information from biology, behavior, and psychosocial influences to describe distinct profiles of individual patients. Patient profiles would then be formed by integrating information across all of these domains, biology, behavior, and psychosocial.

To accomplish this objective requires improved taxonomic systems and improved measurement tools. Clinical medicine is fast developing new ways to profile patients. Current devices are capable of "digitizing" a person with wearable sensors that quantify physiological metrics such as vital signs, provide high-definition images of a persons' anatomy, and characterize the microbiome. What remains missing, however, is a comprehensive approach that seeks to understand how the interactions among genetics, mind, body, behavior, and the environment affect both the risk for disease and the response to treatment.

The new era of individualized patient care will require new ways of thinking, new types of data that describe clinical, social, and behavioral features of individuals, and new methods of analysis. What will no longer suffice is the sole reliance on the average results from randomized controlled trials to guide treatment decisions.

The first step in new ways of thinking is to acknowledge that the primary focus of the research and evidence generation must be at the individual level, rather than the group or population. Individual level data will emphasize detailed and repeated measures over time of each subject across multiple domains including deep biology, clinical physiology, social and behavioral features, and the associated environment. It will then be necessary to create individual-based "profiles" that integrate the data across these domains and to assemble large archives of these profiles to enable the identification of approximate matches for each subject. Next, it is essential that we expand the customary data beyond the usual information collected in RCTs to include genomic and other

"-omics" data, the microbiome, and the newly available data made possible through new digital technologies. These capabilities already exist. What does not yet exist are analytical methods that create patient profiles with a full integration of multiple domains and with repeated measures over time.

The strategy of analysis will not proceed from large populations to smaller subgroups. Instead, it starts with the individual patient, and uses his/her characteristics to define populations relevant to guide patient management - i.e. the approximate matches to the individual patient. Personalized medicine, so constituted, will require a new kind of evidence base containing the multidimensional patient histories associated with a large number of common chronic disorders.

More information: Ralph I. Horwitz et al. Biology, Social Environment, and Personalized Medicine, *Psychotherapy and Psychosomatics* (2017). DOI: 10.1159/000452134

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