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## Personalized medicine: Definitions, history, and implications for the OT profession

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## Personalized medicine: Definitions, history, and implications for the OT profession

### Keywords

individualized medicine, personalized medicine, precision medicine, stratified medicine, paradigm shifts

### Credentials Display

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That dreaded phone call comes from your physician in the middle of the day informing you of the results of your biopsy that was ordered following an abnormal mammogram. The diagnosis is stage 3 breast cancer. After the shock, you begin to explore treatment options. An optional prescription is Herceptin, which has been touted as an effective medicine for patients with breast cancer whose tumors have the targeted growth receptor protein resulting from gene amplification, as identified through genetic testing. If given the option, do you chose the treatment that works for the average person, or do you chose a treatment that is tailored to you based on your genetic profile?

In this Letter from the Editor, I will explore the impact that biomedical advancements are having on the medical professions and define the various terms that are used to label this paradigm. The history of the concept of personalized medicine will connect to the occupational therapy (OT) philosophical assumptions and lead to implications for the OT profession.

According to Topol (2014), biomedical advancements in the ability to sequence a human genome have ushered in a new era of medical treatments with the potential to impact preconception counseling; fetal and neonatal care; identification of rare diseases; and treatment of infectious diseases, cancer, and chronic illnesses. This new paradigm in drug discovery and development, called pharmacogenomics, is being used to produce new personalized medicines based on information about individuals' genotypes (Tutton, 2012; Tutton & Jamie, 2013). Personalized medicines are now being developed for the

treatment of leukemia, cystic fibrosis, liver cancer (Kaiser, 2015), lung cancer (Eisenstein, 2014), amyotrophic lateral sclerosis (Cashman & Ospri, 2013), prostate cancer, and human immunodeficiency virus (Burke, Trinidad, & Press, 2014). Much of the pharmacogenomics research focuses on the translation of basic scientific findings into future products and drugs that might accrue significant financial gain and benefit future patients (Tutton, 2012). Adding to the excitement about the potential of these scientific advancements, a new journal, *Personalized Medicine*, was launched in 2007, and Barack Obama just announced a \$215 million dollar initiative to fund the development of these personalized medicines (Kaiser, 2015).

Although these personalized medicines have ultimately turned out to be more accurately labeled as stratified medicines because they are aimed at the treatment of subgroups who are classified according to genetic markers, they have ushered in renewed focus on the paradigm of personalized medical care. According to Tutton (2012), "the term 'personalized medicine' (in the singular now) has become a powerful language in which to imagine significant change in medicine from a 'one size fits all' model to one that tailors prediction, diagnosis and treatment to the individual" (p. 1721).

Many terms have been used to label this paradigm, including individualized medicine, precision medicine, stratified medicine, and personalized medicine (Topol, 2014). These terms have not yet been universally defined, and authors have varying opinions about the distinctions among the varied labels. In the strictest sense of the

meaning, individualized medicine refers to medical products or devices, such as prostheses or implants, that are custom designed and fitted to an individual. In the broadest sense, however, the term refers to a turning away from a focus on treatments developed for entire populations and centering treatment on the individual person.

Individualized medicine is commonly defined as research that identifies, validates, and integrates biomarkers and determines the outcomes or unwanted effects for certain groups of patients. It is also defined as preventive, therapeutic, or rehabilitative health care practices that are characterized by the fact that they use biomarkers for systematic prediction of risks or courses of diseases (Fischer, Langanke, Marschall, & Michl, 2015). Because most models of individualized medicine, such as pharmacogenomics, also known as pharmacogenetics, categorize individuals into groups, this use of the term individualized medicine more accurately refers to stratified medicine (Flessa & Marschall, 2015).

There often is no distinction drawn in the literature between the terms individualized medicine and personalized medicine; consequentially, they are used synonymously. Sociologically, however, distinctions are made, with “individual” referring to systemic and unique aspects and “person” referring to the roles the individual has to fill (Flessa & Marschall, 2015). Because of the narrow focus of individualized medicine on pharmacogenomics and the use of biomarkers, some authors use the term personalized medicine to indicate a broader spectrum of health

care that is of interest to professions other than pharmacogenomics (Tutton & Jamie, 2013).

Pharmacogenomics does not equal personalized medicine, as there are other elements of individualized care that need to be considered, such as patients’ values and preferences. Because most diseases involve a complex and multi-factoral dynamic with multiple biological and social determinants, pharmacogenomics need to be used in this larger context of health promotion and disease prevention (Burke et al., 2014; Pöder & Assel, 2015; Tutton & Jamie, 2013). The concept of individualization based exclusively on the human genome fails to account for many other important elements of patient care, such as the person’s needs and preferences (Burke et al., 2014).

The term personalized medicine, therefore, seems to fit better with the OT scope of practice. According to Burke, Trinidad, and Press (2014), “personalized medicine is best understood as a comprehensive process to determine the best health care options for a particular patient, deriving from a partnership between patient and clinician. This approach offers the opportunity to weigh personal values and preferences as well as clinical findings” (p. 196). In addition, Topol (2014) defines personalized medicine as the tailoring of medical treatments to the individual characteristics of each patient with a focus on the individual as the source of medical data and as the driver of health care, which fits with the OT focus on client-centered care.

Individualized Medicine	Personalized Medicine
*Customized medical products and devices	*Focus on roles of the individual
*Focus on genetic variances	*Consider person's values and preferences
*Integrated use of biomarkers	*Partnership between client and provider
*Predict individual risk or course of disease	*Individual as source of medical data
*Stratified pharmacogenetics	*Incorporates the art of clinical judgment
*Disease-focused intervention	*Psychosocial and environmental factors
*Treatment based on laboratory medicine	*Fits with OT body of knowledge

Figure 1. Summary of major points of individualized versus personalized medicine

### History of Personalized Medicine

While the current focus on personalized medicine has been ushered in by the development of genomics and publicized by the industry, governments, academia, patient advocates, and clinical practitioners, the concept of personalized medicine is not new (Tutton, 2012). Historically, it has been used to describe patient-centered care in which clinicians “elicit, understand and respond to patients’ perspectives and practice the ‘art’ of clinical judgement” (p. 1721). To these clinicians, personalized medicine is not a new concept ushered in by the development of genomics, but a practice that is endangered by the continued reductionism of biomedicine that focuses on the universality of disease processes and not on the individual with the illness (Tutton, 2012). There have been various movements throughout the practice of modern medicine that have pushed for either a focus on universal care or personalized care.

In the 1800s, there was controversy surrounding medical practice when physicians aligned themselves with laboratory science based on

its promise to transform medical practice.

Laboratory-based medical practice replaced biographical medicine, which up until that time had consisted of a bedside visit during which the physician considered the entire body and mind of the person in relation to the surrounding environment. According to Tutton:

As opposed to working with a ‘norm’ with which to re-align patients, physicians understood that each patient had their own unique equilibrium and drew on their detailed understanding of the biography of the individual—their gender, their age, their family background, and occupation—in order to customize their treatment of their disease. (2012, p. 1723).

Before the advent of laboratory-based medicine, “Doctors could not assume that a therapeutic intervention to alleviate one person’s suffering in a particular place and time could be used again in different circumstances with a different individual. Therefore, treatment was very much directed at the person and not the disease” (Tutton, 2012, p. 1723).

With the development of pharmaceuticals, however, laboratory-based medicine viewed disease as a condition whose causes and symptoms were similar in all individuals. During this movement, the interest in the unique qualities of the individual and treatment of the whole person evaporated and was replaced by universal guidelines for treatment developed by the laboratory sciences (Tutton, 2012).

In the early 1900s, the laboratory science paradigm was challenged by the patient-as-a-person paradigm. The patient-as-a-person movement

emphasized the unique nature of the doctor-patient relationship and the understanding of the whole person, which had been devalued by the reliance on pharmaceuticals and a preference for the use of numerical data and statistics as a means of diagnosing patients. The patient-as-a-person movement acknowledged the universality of scientific knowledge to assist with the diagnosis and treatment of diseases and embraced the status of medicine as a science-based profession, but pushed for a balance with an understanding of the unique nature of the individual. Disease was conceptualized as a scientific construct that could be defined by its biological processes, but illness included the psychological and emotional reactions of the individual in the specific social and physical environment (Tutton, 2012). The profession of OT developed during this patient-as-a-person paradigm shift (Gordon, 2009).

After WWII and into the 1950s, an era of science-based practice was introduced by the emergence of new pharmaceutical drugs, such as antibiotics. Attempts were made to find a universal, cure-all approach to medicine. Issues related to individual variance, however, once again thwarted this movement (Tutton, 2012).

Recently, individualized medicine was ushered in with the advent of pharmacogenomics, the development of drugs specific to stratified groups of individuals based on genetic variations. The development of drugs based on genetic variations was seen as a departure from therapeutic universalism or a one-size-fits-all approach to treatment. Historically, the technological advances,

laboratory measures, were seen as a means to standardize care, not individualize it. In this way, the latest paradigm shift is different (Burke et al., 2014). Individualized medicine in this conceptualization, however, is not the same as the version promoted by the patient-as-a-person movement of the early 1900s. In this paradigm, scientific evidence matched to genetic subpopulations can replace the art of practice used to assess and treat individual differences.

Although this current paradigm represents a shift from universal disease diagnosis and treatment, the person as a whole, with potential variable “non-genetic determinants of disease and drug response, tend to be marginalized” (Tutton, 2012, p. 1726). This new conceptualization of individualized medicine does not consider the psychological, socio-economic, and environmental factors (Tutton, 2012). Therefore, as stated previously, many authors will use the term personalized medicine to represent a more holistic conceptualization of health care that considers the many possible individual variables. According to Tutton (2012), “The challenge today is to re-imagine a vision of ‘personalized medicine’ that better captures the myriad factors that shape the health and wellbeing of us all” (p. 1726).

### **Implications for the Profession of OT**

The fact that the profession of OT was formed during the patient-as-a-person initiative of the early 1900s is evident in our philosophical assumptions. These philosophical assumptions include eight statements distilled from the OT literature to summarize the profession’s basic beliefs about the nature of the individual and the

environment, the relationship between the individual and the environment, and the purpose of the OT profession in meeting the needs of the individual and society (Mosey, 1996). Of the eight philosophical statements listed, six begin with the phrase “each individual.” These six statements summarize the OT philosophy as focusing on the rights and preferences of individuals relative to his or her biological and social environment. The seventh statement discusses functional interdependence, and the eighth statement concludes that the focus of the OT intervention depends on the individual’s needs (Mosey, 1996).

In addition to the philosophical assumptions that summarize the profession’s basic beliefs, the patient-as-a-person movement is reflected in OT practice. OT practitioners consistently use guidelines for practice, such as the Rehabilitation Frame of Reference and the Motor Skills Acquisition Frame of Reference, that are based on Dynamic Systems Theory and models, such as the Person/Environment/Occupation Model, that emphasize the importance of considering all aspects of an individual’s well-being, including the person, task, and environmental factors that contribute to a person’s occupational performance.

Personalized medicine is also part of the OT profession’s research body of knowledge. *The Open Journal of Occupational Therapy* consistently publishes articles that address issues related to personalized medicine. Holmes, Lutz, Ravenek, Rudman, and Johnson (2013) discussed the need to consider the knowledge, experiences, values, and self-identified health issues of people with Parkinson’s disease (PD). “As PD remains a chronic

and progressive disorder, with highly variable impairment of motor and non-motor function, it is crucial that treatment interventions be individualized, client-centered, and focused on improving day-to-day QOL (*sic*-quality of life) via enabling occupational participation” (Holmes et al., 2013, p. 6). Sood, LaVesser, and Schranz (2014) found that individual variations in parenting stress, the availability of learning materials, and parent responsiveness toward the child influences participation patterns in home activities of children with autism spectrum disorders. Cirone and McEwen (2014) found that self-generated relax strategies that were individualized according to the needs of the person with stroke increased performance impaired by fatigue or tension. Darawsheh, Chard, and Eklund (2015) investigated how occupational therapists adapt treatments to meet the needs of individuals from various cultures and developed a model to guide this process. Morrison, Spaulding, Holmes, and Jenkins (2015) developed a cognitive cueing approach to gait training for people with PD using personalized gait training videos with specific cues for each person. Each of these contributions to the OT body of knowledge exemplifies the profession’s philosophy.

The question posed in the opening scenario is, of course, easy to answer. If given the option, you would choose the treatment that is tailored to you based on your genetic profile. It is evident from the focus on individual variance in the OT body of knowledge that occupational therapists are acutely aware that there is no standard or universal patient and therefore place an emphasis on personalized care. As paradigm shifts push the

OT profession toward various ideas, the adherence to our basic beliefs remains. New ideas may briefly sway the profession, but the ability to adapt and integrate the new concepts with the body of knowledge that forms the core of the OT profession recurs. With the renewed focus on the paradigm of personalized medicine, whether defined as using genetic information or as the tailoring of treatment to the individual, the profession of OT can incorporate these ideas into our narrative and continue to grow as a profession. As stated by Burke et al. (2014):

Personalized medicine will remain what it has always been: a therapeutic alliance between clinician and patient, focused on choosing from among the full range of therapeutic options those that are best suited to the particular needs and preferences of that patient. Genetics does not offer a paradigm shift, rather, it demonstrates how effective personalized care must incorporate new tests and technologies on an ongoing basis, as they are proven effective. (p. 195)

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