

From One-Size-Fits-All to Tailored Therapies: The Rise of Personalized Medicine

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ABSTRACT

Personalized medicine is revolutionizing healthcare by tailoring treatments to individual genetic, proteomic, and metabolic profiles. This review explores the integration of omics technologies—genomics, proteomics, and metabolomics—in advancing personalized approaches, particularly in cancer and psychiatry. Genomic data enables targeted cancer therapies, while proteomics and metabolomics offer insights into complex psychiatric disorders, paving the way for more effective, individualized treatments. However, the implementation of personalized medicine faces economic challenges, including the high costs of data collection, analysis, and therapy development. This article discusses the potential of personalized medicine to transform healthcare outcomes and emphasizes the need for cost-effective strategies to make these advancements accessible and sustainable on a global scale.

KEYWORDS: *Personalized Medicine, Genomics, Proteomics, Metabolomics, Cancer Treatment, Psychiatry, Omics Technologies, Targeted Therapy, Precision Medicine, Healthcare, Data Collection, Tailored Therapies, Individualized Treatment, Pharmacomicrobiomics*

INTRODUCTION

Millions of people take prescription drugs every day that do not provide any relief. Due to the prejudice against white Western subjects in traditional clinical studies, some medications are even detrimental to specific ethnic groups. Precision medicine is gaining a lot of attention due to the realization that doctors must account for patient individual variability.[1] Pharmacogenetics, or personalized medicine, uses a person's genetic information to enhance the safety and effectiveness of drugs, with the potential to completely transform healthcare. Drug prescription and dosage will no longer be "one-size-fits-all" under a personalized medicine program; instead, they will be precisely customized to each patient's unique genetic variations.[2] Through early detection, prevention, accurate risk assessment, and effective treatment delivery, personalized medicine promises to improve patient outcomes, improve clinical practice

quality, and provide tailored care pathways. It also promises to reduce total health care expenditures. The goal of personalized medicine is to greatly reduce the cost of ineffective therapies incurred by the current trial-and-error clinical paradigm by using cutting-edge genomic technologies, rich medical record data, tissue and blood banks, and clinical knowledge to enable clinicians and payers to customize treatment to individuals.[3]

PERSONALIZED MEDICINE

Personalized medicine refers to the practice of prescribing individualized treatments that are most appropriate for each patient. Pharmacogenetic, pharmacogenomic, and pharmacoproteomic data are typically the basis for it, however additional patient individual differences are also taken into account.[4] Certain experts acknowledge that the use of genomic markers should be employed to generate

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more homogeneous and smaller patient groupings for targeted therapy, rather than treating each individual patient as an individual.[5] Hippocrates provided each patient with a personalized diagnosis and course of treatment, such as cold meals for a phlegmatic patient. This idea of personalizing medicine has long been popular.[6] The term "personalized medicine" lacks a defined definition and is used to refer to a wide range of practices, the definitions of which frequently conflict. The European Parliamentary Research Services (EPRS 2015) defines it as a new and developing medical paradigm that guides decisions about disease diagnosis, treatment, prevention, and prediction by drawing on scientific understanding of the genetic and molecular underpinnings of health and disease resulting from the sequencing of the human genome. Similarly, using unique data on each patient's genes, proteins, and environment, the National Cancer Institute highlighted the three primary goals of personalized medicine: disease prevention, diagnosis, and treatment. Furthermore, according to our September 2008 report from the President's Council of Advisors on Science and Technology at the Executive Office of the President of the United States, personalized medicine refers to the ability to identify patients into subpopulations that differ in how susceptible they are to a given disease or how they respond to a particular treatment, rather than the actual production of drugs or medical devices tailored to each individual patient.[7] It is not unexpected that medicine is fully establishing itself in this market given the rise in the personalization of almost everything, including mugs, stationery, t-shirts, and phone covers. Since the 1960s, personalized medicine has been gradually gaining momentum in the medical community. It was first mentioned in a 1998 monograph and then published on the Medline Interface in 1999. The foundation and driving force behind personalized medicine has been the advancement of genetic technologies, particularly single-nucleotide polymorphism, genotyping, and microarrays/biochips.[8] Serious drug toxicities cost between \$30 to \$100 billion USD a year and result in over 100,000 fatalities in the USA. Therefore, figuring out how to gauge a patient's likely response to a medication, boost therapeutic efficacy, and lower the chance of adverse drug reactions is essential. According to current estimates, genetic variables may account for 20% to 95% of the variation in how different medications affect a patient.[9]

SYNONYMOUS TERMS

1. Individualized Medicine: Cell-based therapies for diseases for which there is no effective medication treatment available. For instance,

cancer vaccinations and stem cell treatments. [10]

- 2. Precision Medicine:** Creating a more precise molecular taxonomy of diseases to improve diagnosis, treatment, and disease management by fusing clinical data from individual patients with molecular research. [11]
- 3. Stratified Medicine:** Using clinical biomarkers, medicines are matched to certain patient group features. [12]
- 4. P4 Medicine:** The clinical application of systems biology and medicine tools and techniques to measure wellbeing and demystify illness for an individual's well-being. [13]
- 5. Personalized medicine:** the use of genomic and molecular data to help identify a patient's propensity for a specific disease or condition, speed up the development and clinical testing of novel medicines, and better target the delivery of healthcare. [14]
- 6. Personalized Healthcare:** Adjusting medical supervision and patient treatment to each patient's unique needs. [15]

Boguski et al. coined the phrase "precision medicine" in 2009. Trusheim et al. (2007) first used the phrase "Stratified Medicine." Leroy Hood coined the phrase "P4 Medicine" in 2008. Hood and Flores hypothesized that in the future, organ-specific blood proteins will be examined throughout life, everyone's genome will be sequenced and yearly reviewed for new actionable variants, and the system's approach to the immune system will make it possible to predict potential future occurrences of disease-perturbed networks, making medicine as a whole more preventive. In a 1971 study, Gibson used the term "personalized medicine" for the first time in written literature. Personalized medicine appears to have become the most popular term, serving as a catch-all for the entire idea.[16]

HUMAN GENOME PROJECT AND SNP

The human genome sequencing project is a huge milestone that is necessary for the development of customized medicine. From 1992 to 2003, the Human Genome Project took 13 years to finish. The International Human Genome Sequencing Consortium, which includes more than 200 partner labs from 19 countries, undertook this significant project. It was found that the human genome consists of about 20,500 genes, and that 99.99% of the genomes belong to each individual, meaning that just 0.01% of the genomes include genetic variations. Moreover, the genome has been found to contain

extensive repetitive sequences, and variations in a single nucleotide may serve as distinct markers of disease.[17]

The era of genomics is almost upon us. Genetic information will be available to clinicians and patients to personalize medical care. Whole genome sequencing will soon be available for less than \$1000.[18] After the human genome was fully sequenced in 2000, the US Department of Energy and the National Institutes of Health finished the Human Genome Project in 2003, having identified between 22,000 and 23,000 genes. The entire genetic makeup of humans, made up of roughly 3 billion nucleotides, is known as the genome. Each person's unique genome contains important information about varied development and progression as well as treatment response. SNPs, insertions and deletions, structural variations, and copy number variation of the human

genome can all result in variations in the human genome.[8] Long stretches of DNA and entire chromosomes are studied in chromosomal testing. Protein quantity and activity are investigated using biochemical testing. Furthermore, the application of whole exome sequencing—which is less expensive than whole genome sequencing—is utilized to detect common and rare genetic diseases by identifying rare coding variants that are found through carefully analyzing coding areas.[7] Single nucleotide polymorphisms, or SNPs, are already an important tool for mapping complicated genetic features and are now understood to be the primary cause of human genetic variability. Numerous DNA variations linked to various features and diseases have been found. Personalized medicine will customize treatments to the patient's unique genotype by fusing these genetic connections with phenotypes and drug response.[18]

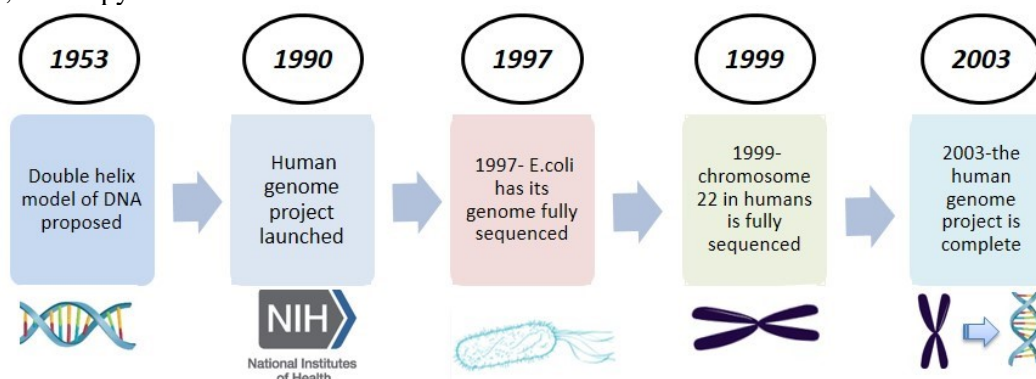


Fig 1 The Road to Human Genome Project

HUMAN PROTEOME PROJECT

Proteomic data is added to genomic data to further support tailored therapy. A profile of every protein and peptide found in a clinically healthy individual was established as part of the Human Proteome Project, and it was compared to the protein and peptide profile of a cancer patient. The Human Proteome Project has produced a map of the protein-based molecular architecture of the human body and is now a resource to help clarify biological and molecular activities, improve illness detection and treatment, and characterize all 21,000 genes in the known genome. Protein interactions underpin the primary pathways involved in the development of cancer, including the EGFR, tyrosine kinase, Notch, mTOR, MAP kinase, receptor kinase, and apoptosis pathways.[19]

THE ERA OF OMICS

Biology has changed dramatically as a result of the availability of massive omics (genomics, transcriptomics, proteomics, epigenomics, metagenomics, metabolomics, neutriomics, etc.) data. Systems biology has emerged as a means of better comprehending biological mechanisms.[20]

METABOLOMICS:

In a recent assessment of the most recent developments in blood transcriptomics and metabolomics, Shuzhao Li et al. emphasized how these novel omics technologies may hold the key to bridging the gap between phenotypes and genetics. They emphasized the importance of metabolomics, a rapidly developing field of study that looks for illness markers in endogenous metabolites as well as environmental exposures. Metabolomics is unique in that it can match data from other omics technologies, making it possible to identify and measure certain metabolites. A single blood and urine sample submitted for a metabolomic screen can quickly and simultaneously monitor a multitude of genetic anomalies, as demonstrated by studies by S. Li et al., K. Beebe, and A. D. Kennedy. These findings suggest that metabolomics may be a viable alternative to clinical blood tests. Furthermore, they noted that the application of metabolomics technology may potentially measure more than 1,000 compounds in less than ten minutes, thereby revolutionizing clinical practice and all diagnostic processes.[7] In the context of personalized medicine, metabolomic data may

provide information on a person's particular physiologic response to a medication. Currently, by discovering biomarkers for disease states, metabolomic investigations of biofluid and tissues have aided in the development of personalized medicine approaches and may help physicians diagnose and treat patients earlier. Nuclear magnetic resonance spectroscopy (NMR) was frequently employed in the early days of metabolomic investigations to identify metabolites. However, in the last ten years, there has been a significant movement toward MS since it provides superior resolution and sensitivity to smaller concentrations.[17]

PHARMACOMICROBIOMICS :

Research on how a person's genetic background affects drug response variability or toxicity has been at the forefront of pharmacogenomics, and more recently, the gut microbiome—also referred to as the second genome—has been identified as a significant factor in this regard. The study of the relationship between medication response and disposition and microbiome variation is known as micromicrobiomics, and it is a rapidly developing area. Thousands of distinct bacterial species and other microbes make up the intricate ecology found in the human gut. There are significant interindividual differences in the gut microbiome's makeup, which can be attributed to a variety of host and exogenous variables. Comprehending the function of the gut microbiota in drug response could facilitate the creation of microbiome-focused strategies that augment treatment effectiveness. Modulating the gut microbiota has the potential to become a very appealing strategy for regulating therapeutic efficiency and safety on an individual basis. It is evident that the gut microbiome is becoming a crucial component in the development of personalized medicine. Drugs have the potential to modify the microbial community's makeup and function via affecting the intestinal milieu, microbial metabolism, or bacterial proliferation. The most researched effects of antibiotics are on the gut microbiome, where antibiotic-induced dysbiosis can worsen immune system balance, alter metabolism, and lead to obesity and increased susceptibility to infection. In addition, it is a major contributor to the development of *Clostridium difficile* infection, a serious intestinal inflammation brought on by the overgrowth of this bacterium that affects over 1,24, 000 individuals yearly and results in 3,700 fatalities in Europe.[9]

PHARMACOGENOMICS :

Pharmacogenomics is the study of how an individual's genes affect their reaction to a medicine. Today, curators at the Pharmacogenomics Knowledge

Base have annotated the evidence for more than 2,000 genes implicated in medication response. An interesting case study in cardiovascular medicine shows how germline genetic information can be used to tailor a patient's treatment plan: warfarin, an anticoagulant medication. Because the therapeutic window is narrow, it is crucial to determine the appropriate dose of warfarin for each patient, as it varies by a factor of more than ten. Variations in three genes' genetic codes, Patient variability in response to warfarin is largely influenced by cytochrome P450, family 2, subfamily C, polypeptide 9, CYP2C9, vitamin K epoxide reductase complex subunit 1, VKORC1, and cytochrome P450, family 4, subfamily F, polypeptide 2, CYP4F2. According to a recent study, the risk of hospitalization for outpatients starting warfarin was lowered by about one-third when warfarin dosage was determined using patient genotype data. When choosing between several treatment alternatives, pharmacogenetic information may have clinical relevance in maximizing therapy benefit and minimizing side effect risk.[21]

PROTEOMICS :

Protein-protein interactions, protein production and degradation rates, protein structure, concentration, and cellular localization are all revealed by proteomic analyses. Information on protein abundance in a tissue or post-transcriptional modification may be crucial for illness diagnosis, progression, and treatment in the context of personalized medicine. The bottom-up approach, commonly referred to as shotgun proteomics, employed mass spectrometry to examine sizable mixed protein samples and ascertain their makeup. Although it is imprecise for a number of reasons, the bottom-up approach is generally helpful for studying an unknown mixture of proteins. When a protein is broken apart, information about that specific protein may be lost. Only proteins with high concentrations in the mixture show up on the MS output, therefore MS data is easily misconstrued. Nevertheless, the shotgun technique helps create a distinct proteome fingerprint for every patient, which is helpful in individualized therapy. The top-down strategy is a more recent method that starts with whole protein MS analysis and goes on to extract, fragment, and study specific proteins of interest. One essential method for researching protein post-translational modification is top-down proteomics. Recently, a hybrid approach known as "middle-down proteomics" has surfaced in an effort to maximize the benefits of both methodologies.[17]

OMICS DATA :

With omics data, minimizing sources of error is crucial since it can be difficult to discern between

genuine interaction signals and random error. Errors in omics studies might also include faulty data entry and sample swapping. Competing private sector companies, such as Anaxomics and LifeMap, are actively developing software that integrates and interprets omics data, potentially leading to rapid advancements in the field in the near future.[20]

Although the potential of omics data to comprehend disease is enormous, acquiring them also poses a significant challenge: storage. The Cancer Genome Atlas from the National Cancer Institute has 2.5 petabytes of data—more than 5,30,000 DVDs—in it. An omics test is defined as the combination of an omics assay and a particular computational model. Omic tests exist in two varieties: prognostic tests, which forecast clinical outcomes as measurements, and therapy directing tests, which pinpoint a subset of patients who respond differently to a specific treatment.[17] Over the past ten years, there has been a noticeable slowdown in our capacity to produce, as opposed to integrating and interpreting, omics data. The omics revolution of the early 21st century was driven by biotechnology businesses and new technologies and information resulting from the Human Genome Project. Cloud computing is one promising solution to bridge the gap between the generation and handling of omics data. It is an adaptive computing and storage service that uses the Internet to fully utilize numerous computers as a single virtual resource. Examples include the Embassy Clouds as part of the ELIXIR project, in cooperation with several European nations such the UK, Sweden, Switzerland, Swiss Republic, Estonia, Norway, Netherlands, and Denmark, and the EasyGenomics Cloud at the Beijing Genomics Institute. GPUs have been suggested for general-purpose computing in cloud environments more recently. Creating secure and error-free applications is a difficult but vital endeavor that requires a lot of work. In the shift to personalized medicine, a great deal of programming work is still required for the integration and interpretation of omics data.[20]

PERSONALIZED MEDICINE IN THE WORLD OF CANCER

Personalized medicine is already widely used in many clinical settings. Trastuzumab and Imatinib are two examples of chemotherapy drugs that specifically target tumors. For medications like warfarin, a tailored pharmacogenetic dosing algorithm is employed, and for medications like abacavir, carbamazepine, and clozapine, adverse event incidence is decreased by examining sensitive genotypes.[18] With the development of early detection markers and diagnostic technologies,

several cancer forms can now be identified before clinical symptoms appear. Biochemical, epigenetic, genetic, imaging, metabolomic, and proteomic indicators are among them. Even though various cancerous tumors may have the same DNA, each form of tumor expresses genes differently. In order to differentiate a cancer-associated gene expression profile from a typical profiling, technologies like gene expression microarray enable us to look at the gene expression profile of hundreds of genes at once. A genetic disease is cancer. It is becoming increasingly clear that every tumor has a unique set of genetic alterations as more information about particular tumor types is discovered.[19] The National Institutes of Health also financed a 15-year study in 2005 to investigate the genetic underpinnings of breast cancer, stroke, and coronary heart disease in relation to postmenopausal hormone therapy in 808 women aged 50 to 79. Perlegen Sciences Inc. and the Women's Health Initiative are working together on this project, which is based on a high-density whole-genome scan of SNPs. The path toward customized treatment is being paved by these attempts to comprehend diseases through their genetic makeup.[18] Different trial designs have been created to take patient variability into better consideration. Basket trials, mostly applied to cancer, include the assignment of 1,000 patients with various late-stage cancer types to therapy 'baskets' based on genetic markers found in tumors. About thirty patients, all of whom have specific genetic abnormalities, will be included in each basket. Each person will receive one of about twenty-five medications. As the trial progresses, the efficacy of the various treatment matches to genetics will be compared. Researchers assess the efficacy of several medications in a single illness study through umbrella studies.[1] The BRCA1 and 2 and PARP genes in breast cancer tumors, the ERBB2 receptor in breast adenocarcinoma, the BCR/ABL infusion gene in chronic myelogenous leukemia, and the BRAF (V600E) gene in melanoma, colorectal, and thyroid cancer are just a few examples of the many cancers for which there is now a well-established genetic association. Personalized medicine in oncology is made possible by the ability to use modern technology to hunt for actionable drug-able alterations within each tumor.[7] Standard cancer treatment consists of four key components: immunotherapy, chemotherapy, radiation therapy, and surgery. Immunotherapy, which uses a patient's own immune system to combat cancer, is another type of cancer treatment that has opened the door to more focused and efficient therapies. The use of immunotherapy has sparked a movement in the field

of cancer treatment toward customized and precision medicine, which involves selecting therapies based on a patient's unique needs. The fact that no two patients' malignancies are exactly the same and may therefore respond differently to genetic treatments like radiation and chemotherapy has become more and more evident over the past ten years. Since 1998, when the FDA approved the drug trastuzumab for the treatment of HER2 receptor-positive breast cancer, the agency has supported personalized medicine by approving various technologies.[17] Because the various histologic subtypes of non-small-cell lung cancer appeared to have similar causes, clinical traits, and treatment outcomes, the illness was once thought to be a single entity. When Lynch et al. and Paez et al. discovered activating mutations in the EGFR tyrosine kinase domain in patients who responded dramatically to the EGFR tyrosine kinase inhibitor gefitinib in 2004, it was the first significant step toward customized treatment. Since then, lung cancer patients can now receive individualized treatment.[22] Currently under development are CAR T cells, MABs, and cancer vaccines as examples of personalized medicine therapy.[17] The significance of customized medicine in patient treatment is demonstrated by the impact of CYP2D6 genotyping on Tamoxifen treatment for breast cancer. Prior to treatment, CYP2D6 genotyping may be used to predict treatment response. Ethical concerns need to be resolved beforehand because pharmacogenomics-based techniques rely on CYP2D6 genotyping to determine the phenotype of the individual metabolizer. Treatment strategies should be clearly understood by patients and those who are caring for them.[19]

PERSONALIZED MEDICINE IN THE WORLD OF PSYCHIATRY

Predictive, preventative, personalized, and participatory medicine, or P4 medicine, will assist in finding the appropriate medication for the right patient at the right time, preventing the prescription of expensive and ineffective medications as well as any potentially dangerous side effects. While tailored cancer treatment is receiving a lot of attention and excitement, it is important to keep in mind that other ailments, such as psychiatric disorders, are just as burdensome on society and are still not well enough understood to be of use.[3] With a 50–80% hereditary risk, schizophrenia is one of the diseases most influenced by genetics. Major depressive illness has a hereditary risk estimated to be between 40 and 70 percent, and bipolar disorder has a highly heritable risk estimated to be between 60 and 85 percent based on genetic characteristics. Bragazzi developed a novel method for diagnosing psychiatric diseases, which

involved integrating omics science into psychiatry. This method, which takes into account the biological roots and environmental exposures of psychiatric diseases, may enable P4 medicine to advance by incorporating the psychocognitive domain. Thus, it might adopt the new P5 medical system, which views mental health as a crucial component of overall wellbeing.[7] Further research on the relationship between genetics and psychotherapy, including light therapy, deep brain stimulation, electroconvulsive therapy, cognitive behavioral therapy, dialectical behavioral therapy, and transcranial magnetic stimulation, will help to improve and optimize mental health services. Personalized medicine in psychiatry is expected to be significantly impacted by the rapidly developing field of neuroimaging, and more particularly, neuroimaging genetics. In a nutshell, imaging measures are used as quantitative biological phenotypes in imaging genetics. In order to connect genetic diversity with protein function, brain anatomy, connectivity, and psychopathology, it aims to integrate genetics, psychiatry, and neuroscience. Verification of the effects of specific genetic changes and identification of imaging alterations in a population with a well-defined genetically determined illness are two major approaches in neuroimaging genetics.[23]

FINANCIAL VIEWPOINT

According to Dzau et al., if personalized medicine emphasizes prevention over therapy, health care costs will go down. But given that personalized medicine is focused, particular, and customized by nature, it is inevitable that these therapies will cost far more than the widely used, historically effective preventive measures. Costs for medications are influenced by the size of the intended market. The cost of the medicine increases with population size. Personalized medicine medications are intended for a limited and specific target population.[24] Customizing a patient's course of care is expensive. For instance, patients can pay Foundation Medicine in Cambridge, Massachusetts between US \$5,000 and \$7,500 for the business to sequence their tumors and use the data to recommend a course of treatment. Furthermore, there is still a great deal of work to be done on data analysis techniques, study designs, monitoring tools, and biomarkers.[1] Long-term cost savings from tailored treatment may be substantial, but who will pay for it in the short term is an unknown. There are currently very few examples of government payers or private insurance firms covering the costs of wide-ranging genetic testing and analysis. To decide what they will cover, insurers and payers rely on massive amounts of outcome-based data. In the absence of strong proof that novel, unproven treatments will work, payers are

reluctant to cover them. Since personalized medicine is a relatively young and developing discipline, payers do not believe that there is enough data or evidence to warrant the widespread coverage of these treatments.[17] The economic worth of tests for customized medicine and other technologies cannot and should not be decided by a single institution. Benefits and costs must be balanced, and this requires cooperation from payers, industry, patients, professional associations, and guideline groups.[25] Most payers have been hesitant to engage in individualized healthcare, despite the fact that it has the potential to significantly lower costs. There are several causes, some of which are listed here. It is challenging to determine whether diagnostic procedures, related assays, data, tools, and operational systems will actually result in cost savings. Even while a diagnostic tester or system alone might not cost much, the total cost could be shockingly significant. The protection of private information, especially during the stages of research and development, makes data security an extremely difficult assignment. It has never been easy to establish standards in the healthcare industry, and there are currently no mechanisms in place that let payers evaluate the financial benefits of prognostic and preventive diagnostic tests.[3]

CONCLUSION

A revolutionary approach to healthcare, personalized medicine replaces the conventional "one size fits all" model with therapies catered to the unique genetic profiles, lifestyles, and environmental conditions of each patient. Personalized medicine has already made great strides in the field of cancer treatment, enabling focused medications that are less harmful and more successful. Personalized methods to psychiatry have the potential to improve patient outcomes by taking into account unique drug reactions and genetic predispositions, which can help more accurately address the complex nature of mental health illnesses.

Personalized treatment is not without its difficulties, though, especially when it comes to costs.

The incorporation of modern technologies into normal care, the development of targeted therapeutics, and the high expense of genetic testing can put a strain on healthcare systems and worsen gaps in access to state-of-the-art treatments. The development of solutions that render these advances both economically feasible and accessible to a wider population is imperative in order to fully realize the potential of customized medicine. For personalized medicines to be widely adopted and remain cost-effective, healthcare providers, legislators, and industry stakeholders must work together to ensure

that the benefits of this ground-breaking approach can be realized on a worldwide basis. In summary, customized medicine has the potential to completely transform healthcare in the future, with the fields of psychiatry and cancer leading the way. We can guarantee that this exciting field reaches its full potential by tackling the financial obstacles, which will ultimately result in more efficient, individualized, and fair healthcare solutions for everybody.

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