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Review Article

# Impact of personalized medicine on pharmacological treatment outcomes

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## Abstract

Personalised medicine aids in the identification and development of medications with better rates of success by concentrating on particular molecular targets or patient populations that are more likely to respond to treatment. Prescribe more effective drugs. avoid prescribing drugs with predictable side effects. Reduce the time, cost, and failure rate of pharmaceutical clinical trials. eliminate trial-and-error inefficiencies that inflate health care costs and undermine patient care.

**Keywords**: Artificial Intelligence, Personalized Medicine, Healthcare, Data Analysis, Ethical Considerations, Interdisciplinary Collaboration

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## 1. Introduction

Pharmacogenetics assesses the impact of genetic differences on medication reactions. Genetic testing is now more sophisticated, more reasonably priced, and its integration is backed by more solid clinical data. Genotype-based prescribing is made easier by guidelines like those from the Clinical Pharmacogenetics Implementation Consortium and tools like PharmGKB; the FDA and other organisations encourage genetic testing before to starting specific medications.[1-3]

In the medical and healthcare sectors, personalised medicine (PM) is a particularly innovative and fascinating subject at the moment. By offering efficient, personalised treatment plans based on a person's unique genetic, epigenomic, and proteomic profiles while also taking into account their unique circumstances, this idea has the potential to revolutionise medical operations. The effectiveness of PM is found in both prevention and treatment. Medical practitioners will have solid data to base treatment plans for specific patients on if they make greater use of molecular stratification of patients, such as looking for mutations that result in resistance to particular medications. This will eliminate the reliance on the unfavourable results of trial-and-error prescribing techniques.[4-5] At the moment,The patient may switch to an alternative drug if the prescribed one is not working. Patients had worse outcomes from this trial-and-error method in terms of negative side effects, drug interactions, possible illness progression, delayed effective treatment, and patient discontent.[6]

### *1.1. Benefits*

Through the approval of novel therapeutic strategies and the modification of the medical community's perception of medicine, PM has the potential to improve medication selection and targeted therapy, decrease side effects, boost patient compliance, change the focus of medicine from reaction to prevention, improve cost effectiveness, and boost patient confidence after marketing.[7]

1. Better medical care for the patients.
2. Bringing benefits to society and healthcare systems.
3. Developing innovative medicines more efficiently[8]

### *1.2. Strategy*

It is imperative that pharmaceutical corporations invest in these new technologies and demonstrate a readiness to collaborate with academic research teams in order to

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facilitate the development and rapid acceptance of PM. To guide a proactive approach to PM, more stringent biomarkers must be identified. One instance is the new technology known as liquid biopsies, which allows for the detection of DNA flowing in the blood. Compared to standard biopsy, this sort of biopsy is non-invasive, significantly reduced risk, and has been utilized to diagnose disease at a very early stage. A test for Down syndrome in expectant moms was one of the earliest applications of liquid biopsy.[9] These days, research like TRACERx uses circulating tumour DNA, or ctDNA, to analyze and forecast how lung cancer tumors will evolve.[10] Such strategies would enable physicians to use PM more proactively by anticipating the trajectory of tumor growth and transferring patients to alternative treatments as soon as indications of medication resistance are found. This could be able to postpone the development of resistance. Pharmaceutical businesses need to educate themselves in order to profitably use the new diagnostic and treatment approaches at significantly lower numbers over the long run. The cost of developing new treatments is unaffordable, and pharmaceutical companies are becoming more eager to reuse their current products. PM makes it possible to optimize treatment plans, which raises the usefulness of currently available products.

Every pharmaceutical company has a different approach to implement PM, but these are the general guidelines: i) Switching from conventional drug techniques to PM is a requirement, not an option. Recognize that every molecule in the pipeline is not intended for the mainstream market, but rather for specific patient populations. ii) PM is a cutting-edge strategy that lowers total healthcare expenses while providing better healthcare. This will be accomplished by the implementation of digital healthcare, enhancement of the healthcare IT system, and utilization of cutting edge technologies, like the creation of single-cell omics, which enables high throughput analysis of various cells[11] iii) Adding PM expertise to the current healthcare infrastructure. Utilizing scientific advancements to enhance patient care is the main objective of the large group of stakeholders involved in PM implementation.[12-13]iv) Biomarkers, which are indicators of a biological state, are helping to fund research and R&D in the fields of healthcare. Improving R&D means accelerating time to market and reducing trial sizes. Help less popular but more likely to succeed therapeutic drugs. v) Create alliances to gain access to new capabilities. One such alliance would be between companies that create assays and various sectors and the best diagnostics in the world.vi) Astute sales representatives equipped with the newest knowledge. In addition to diagnostic and treatment procedures, sales teams will need to be familiar with patient histories. Molecular analysis and disease pathways are other topics that sales teams need to be knowledgeable on. vii) Post-marketing surveillance is especially crucial in PM to enable more targeted clinical studies of pharmaceuticals.[14]

The need for PM will also rise in the ensuing decades as consumers get greater awareness of this innovative method of treatment. This will facilitate the transition from the existing medical module to the cutting-edge techniques for diagnosis and treatment. Furthermore, clinical studies now take a long time and a large number of personnel; nevertheless, with the aid of regulatory permission, the concept of clinical trials will evolve and become easier to accommodate PM in the future. The creation of a PM R&D map through enhanced public/private sector involvement. Develop an easy-to-use system for classifying and ranking the illness, one that might profit from the use of cutting-edge technology. Furthermore, collaborative venture programs are being developed to validate study designs and standardize biomarkers.[15]

## 2. Materials and Methods

Researchers frequently conduct studies known as "genome-wide association studies" (GWAS) to determine whether a mutation is linked to a particular disease. This information is useful for doctors to know. The goal of the AGWAS study is to identify common mutations in the genomes of numerous patients who share a same disease by sequencing their genomes. When a GWAS study finds a mutation linked to an illness, the same mutation can be utilized to diagnose that disease in subsequent patients by analyzing their genome sequence. In the initial GWAS, which took place in 2005, patients with age-related macular degeneration (ARMD) were examined. It discovered two distinct mutations that were linked to ARMD, each of which included only a single nucleotide variation (also known as a single nucleotide polymorphism, or SNP). Such GWAS studies have been extremely effective in locating common genetic variants linked to illnesses. More than 1,300 GWAS investigations have been finished as of early 2014.[17-20]

## 3. Key Components of Personalized Medicine and their Impact on Different Medical Specialties

### *3.1. Genomics and pharmacogenomics*

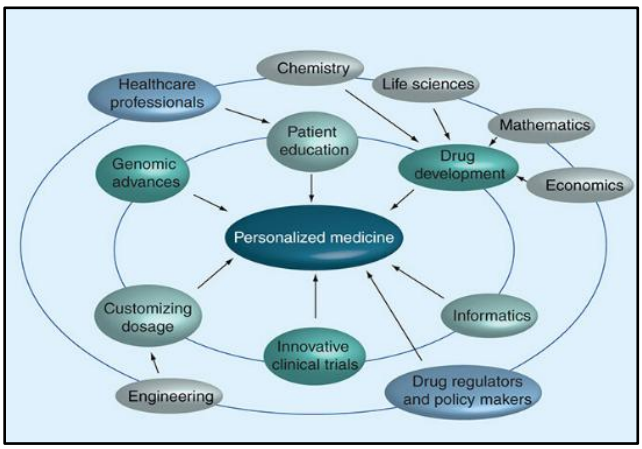
Genomics is the study of a person's genetic composition, encompassing variations, trends, and DNA sequences. The identification of genetic variables that influence therapy response and illness susceptibility is a critical function of genomics in personalized medicine. The association between a person's genetic variants and how they react to medications is the special focus of pharmacogenomics.[16] Pharmacogenomics provides physicians with the ability to customize medicine selection and dose in order to maximize treatment success and decrease side effects by examining genetic markers. In oncology, where genetic profiling of malignancies aids in guiding targeted medicines and predicting therapy response, the influence of genomics and pharmacogenomics is especially noticeable.

*3.2. Particularized treatments*

The application of medications that precisely target molecules or pathways implicated in the onset and progression of diseases is known as targeted therapy. Certain molecular targets, including proteins or receptors, that are essential for the development or maintenance of disease are the focus of these treatments. Many medical fields have seen substantial changes as a result of the introduction of targeted medicines. For instance, by blocking particular signaling pathways that promote tumor growth, targeted medicines have completely changed the way cancer is treated. These medicines have demonstrated better treatment efficacy and fewer side effects than traditional chemotherapy by focusing on the underlying molecular abnormalities in a patient's cancer cells.

## 4. Expanding Access to Personalized Medicine

The potential of AI in customized medicine to democratize access to individualized treatment solutions is among its most exciting opportunities. The scalability of customized medicine may significantly improve if AI technologies become more widely used and reasonably priced. Wearable technology and mobile health apps are examples of AI-driven technologies that are become more and more accessible. These products have the potential to be platforms for directly providing customers with individualized health data, independent of their socioeconomic status or location. By lowering the costs and technological obstacles involved in genomic sequencing and data processing, cloud-based AI technologies may make it possible to analyze genetic data and medical records on a huge scale. This change would enable more people to get customized treatment plans, advancing personalized medicine outside of specialist hospitals and into primary care environments. Healthcare systems can increase efficiency and save costs while increasing access to individualized care by using AI to expedite the creation and delivery of customized therapies.[28-36]




*4.1. Biomarkers*

Biomarkers are quantifiable indications, such proteins, genetic variants, or imaging features, that can provide details about a patient's health, the course of their condition, or how well their treatment is working. Personalized medicine relies heavily on biomarkers to help identify patients who may be more susceptible to adverse effects or who are more likely to benefit from a particular treatment. Biomarkers are useful for monitoring the course of a disease, determining how well a treatment is working, and making treatment decisions. For example, in cardiology, particular biomarkers—like troponin levels—are used to diagnose and grade the severity of heart diseases as well as to inform therapy decisions.

## 5. Data Analytics and Artificial Intelligence

By making it possible to analyze huge, complicated datasets and derive actionable insights, the combination of artificial intelligence (AI) and data analytics has revolutionized personalized medicine. AI is able to recognize trends, forecast treatment results, and assist in clinical decision-making through the use of predictive modeling and machine learning algorithms. Numerous medical specializations can benefit from the use of data analytics and AI, including primary care, radiological image interpretation, and treatment regimen optimization. Through the utilization of these technologies, personalized medicine may effectively leverage data to offer customized treatment recommendations and enhance patient outcomes (Kohane IS).

## 6. Data Combination and Cross-Disciplinary Cooperation

Integration of data from multiple sources, such as genetics, imaging, clinical, and lifestyle aspects, is necessary for personalized therapy. This integration enables a thorough grasp of every patient's distinct qualities and aids in adjusting treatment strategies accordingly. The successful application of personalized medicine requires cooperation between several medical professions, including pharmacologists, geneticists, bioinformaticians, and clinicians. Together, these experts can evaluate intricate datasets, create individualized treatment programs that take into account all aspects of a patient's health, and interpret findings.

## 7. OMICS in Advancing Clinical Decision-Making Advances

Precision medicine has been revolutionized by advances in omics technology since the DNA structure was discovered, providing hitherto unseen insights into the intricate molecular processes underlying human health and illness. The term "omics" refers to a group of biological fields that analyze the roles, relationships, and actions of different molecules in an organism's cells. The suffix "omes" comes from "chromosome." Omics is an umbrella term that encompasses these fields and greatly improves clinical decision-making by offering comprehensive insights into patient-specific molecular profiles and creating new opportunities for more accurate prevention, diagnosis, and treatment[40-42] Omics is based on high-throughput analytical methods and has a track

record of success, whereas typical approaches to examine molecular mechanisms are time-consuming and have been shown to be inefficient. more effectively.[43] Precision medicine, which takes into account data pertaining to the remaining population in addition to individual level genomic traits, aims to treat patients based on their present understanding.44 [44]. Its main goal is to target the most appropriate therapeutic approach and foundational framework for precision medicine in a variety of populations by fusing aggregate data with individual data from patient-specific multi-omics.[45] Accurately forecasting medication responses can be complicated by factors other than genetic makeup, such as lifestyle choices and environmental variables.

Because biomarkers can function as markers of a disease or a particular physiological condition, they are typically the basis for decision-making in precision medicine. Indeed, a contemporary trend in biomarker research and development is pharmaceutical sectors. For instance, the proteomics analysis of cancer can provide important insights into the tumor's progression and spread, which can help identify biomarkers and potential treatment targets.[46] The goal of the omics-based personalized medicine approach is to identify biomarkers that aid in decision-making by offering extremely precise information on the pathophysiology of the disease.[47]

In light of the aforementioned, physicians ought to be proficient in interpreting genetic information and biomarker findings and applying them to modern patient care. In order to assist physicians in this process, computer-based decision support (CBDDS) tools are necessary since they can provide support by enumerating the most recent research and guidelines.[48] But not all healthcare institutions or medical professionals are prepared for like this. To promote precision medicine, a commitment to staff training and systemic changes in the healthcare system should be made.

In fact, the scientific community holds great hopes for precision medicine and its promise to increase therapy effectiveness and tolerance. However, these studies usually go through a complicated procedure called multi-omics before being used in clinical practice. In metabolic diseases, for instance, a multi-omics study typically proceeds as follows: (1) genomics, which determines a person's entire genome and creates biomarkers; (2) pharmacogenomics, which forecasts treatment efficacy by examining genetic variants; (3) transcriptomics, which studies outside factors that impact gene expression and affect the patient's phenotype; (4) epigenomics, which investigates mechanisms that regulate gene expression; (5) proteomics, The field of pharmacology comprises several subfields: (6) pharmacoproteomics, which applies proteomics to pharmacology; (7) metabolomics, which identifies metabolism variants; (8) pharmacometabolomics, which applies metabolomics to pharmacology to support the development of personalized medicine by measuring drug metabolism and metabolic phenotypes; and (9) integrating multi-omics, which involves the integration and interpretation of diverse omics, a complex exercise to apply in clinical routine.

### *7.1. Theranostics*

Using comparable molecules for both imaging (diagnostic) and therapy, theranostics is a personalized approach to cancer treatment. A combination of the words "therapeutics" and "diagnostics" yields the word "theranostics". Nowadays, the most widespread use is in nuclear medicine, where radioactive compounds are affixed to beta, alpha, or Auger electrons for therapeutic purposes, or to gamma or positron emitters for SPECT or PET imaging. The treatment of thyroid cancer patients with radioactive iodine is among the first instances. Additional instances include the use of radiolabelled anti-CD20 antibodies (such as Bexxar) to treat lymphoma, the use of Radium-223 to treat bone metastases, the use of Lutetium-177 DOTATATE to treat neuroendocrine tumors, and the use of Lutetium-177 PSMA to treat prostate cancer. Fluorodeoxyglucose, which uses the isotope fluorine-18, is the most often used reagent

### *7.2. Radiotheranostics*

A branch of theranostics called "radiotheranostics" uses comparable medications for radiation therapy as well as imaging. With the radionuclide being interchangeable and the therapeutic radiopharmaceutical frequently being a beta or alpha emitter, the pharmaceutical or mechanism of localization/action stays the same. The phrases "theragnostics" and "theranostics" are synonymous and have the same meanings. Additionally, the terms radiotheranostics and radiotheragnostics are equivalent. The words originate from two Greek words: "gnostic" from Greek "gnos" meaning knowledge and to know, e.g. diagnostic, and "thera" from "therapeia" meaning healing or to heal, e.g. therapy. Dosimetry is frequently used to direct medical professionals in determining a customized, precise therapeutic dose for each patient.

### *7.3. Respiratory proteomics*

Globally, respiratory disorders impact people, with lung cancer and chronic lung diseases (such as asthma, chronic obstructive pulmonary disease, and idiopathic pulmonary fibrosis) leading to significant morbidity and mortality. Due to their extreme heterogeneity, many illnesses need to be diagnosed quickly. The clinical diagnosis is typically made later than expected, and the initial symptoms are unclear. In recent years, personalized medicine has become a well-known medical care strategy that employs cutting-edge technology with the goal of tailoring therapies to the specific medical needs of each patient. Proteomics is specifically utilized to examine several protein expressions rather than just one biomarker. Proteomics aids in early detection since proteins regulate many bodily functions, including health and illness. Proteomics examines a number of biological samples

in the case of respiratory illness. Includes blood cells, serum, sputum, nasal lavage fluids (NLF), bronchoalveolar lavage fluids (BAL), and so forth. Mass spectrometry and sophisticated analytical techniques are used to identify and quantify the full expression of proteins from these biological samples. In recent years, respiratory proteomics has significantly advanced the field of customized medicine to enhance healthcare. For instance, the proteomics-based technique significantly improved the identification of several lung cancer biomarkers in a 2012 study by Lazzari et al., which can be used to customize therapy for specific patients. The value of proteomics in delivering tailored treatments for respiratory disorders has been shown in an increasing number of studies.

*7.4. Cancer genomics*

High-throughput sequencing methods are used to characterize genes associated with cancer in order to better understand disease pathology and improve drug development. This process is known as "Personalized Onco-genomics," and it is the application of personalized medicine to Cancer Genomics, or "oncogenomics." Among other prospects, these discoveries raise the possibility of finding that drugs that have not given good results applied to a general population of cases may still be successful for a proportion of cases with particular genetic profiles. its consequences for medication therapy. Examples of these include:

1. Trastuzumab, a monoclonal antibody medication that interacts with the HER2/neu receptor (trade names Herclon, Herceptin). Treating some breast tumors is its primary application. This medication is only administered when it is determined that the patient's malignancy overexpresses the HER2/neu receptor. To determine whether patients will benefit from receiving Herceptin, two tissue-typing tests are employed. The tissue testing methods include fluorescence in situ hybridization (FISH) and immunohistochemistry (IHC). The use of Herceptin therapy (trastuzumab) will only be extended to Her2+ individuals.

2. To treat chronic myeloid leukemia (CML), tyrosine kinase medicines like imatinib (marketed as Gleevec) have been developed. In CML, >95% of patients contain the BCR-ABL fusion gene, which is the result of a reciprocal translocation between chromosome 9 and chromosome.[22] of instances and results in hyperactive protein signaling driven by abl. Being a prime example of "rational drug design" based on understanding of disease pathophysiology, these drugs specifically inhibit the Ableson tyrosine kinase (ABL) protein.
   The FoundationOne CDx report, created by Foundation Medicine, analyses gene profiles from tumor biopsies of individual patients and suggests particular medications

3. Certain patterns of mutations have been linked to prior exposure to cytotoxic cancer drugs, and a high mutation burden is suggestive of an immunotherapy response.[17-21]

## 8. Innovations in Personalized Medicine

Animal models are being developed and evaluated by the FDA in order to determine the safety and efficacy of bacteriophage mixtures in treating antibacterially resistant bacterial illnesses.[21] Other breakthroughs are pharmacogenetic testing and the research and application of gene treatments. Clinicians can learn more about how a patient's genetic composition affects how well they respond to specific therapies by ordering pharmacogenetic testing.[21] Additionally, researchers at the FDA are working on critical regulatory science questions pertaining to medication approval concerning the use of immunotherapy drugs and other innovative compounds that can be used to treat different types of cancer. Additionally, they are investigating the role that genetics plays in the development of immune-related side effects and the therapeutic response to these drugs.As the field of customized medicine continues to grow, the FDA stated in January 2021 what it was doing to alert doctors about new treatment developments. For individualized antisense oligonucleotide (ASO) treatments designed to treat a severely disabling or life-threatening genetic illness, the FDA released draft guidelines on submissions for novel medications under investigation. In order to provide sponsors creating ASO products with guidelines on how to communicate with the FDA and submit regulatory applications, the guidance was created. The following points are covered in the guidance: the process for getting a response from the FDA using a predetermined communication strategy; the guidelines and process for preparing regulatory submissions to the FDA; and suggestions on the prerequisite for the procedures' assessment by the Institutional assessment Board. within as well as how to obtain informed permission.

## 9. Continued Research Projects

Research on the benefits of individualized medicine is still ongoing. A group of translational scientists with experience in clinical pharmacology, human genetics, epidemiology, and molecular biology work with the FDA in the Division of Translational and Precision Medicine (DTPM).[24] Its general objectives include verifying that precision medicine techniques and clinical pharmacology concepts are appropriately applied throughout the medication development process to maximize patient benefit and minimize risk.[24] According to the DTPM, advancing the development and accessibility of safe and efficient targeted medicines is one of precision medicine's main objectives. Another is to support scientific research efforts to incorporate omics-based techniques, technologies, and biomarkers into drug development.[24] The DTPM is centered on the development of genomics integration, They carry out these

applications through their core operational duties, which include the following tailored therapeutics and support of biomarker qualification across therapeutic domains.

*9.1. Disease risk management*

Many common and complex diseases are influenced by the combined effects of multiple genes. Based on one or more genes, personalized medicine can also be used to forecast an individual's risk for a certain disease. Using the same sequencing technique, this method focuses on assessing the patient's risk for sickness, enabling the doctor to start preventive treatment before the illness manifests in the patient. For instance, if it is discovered that a person has a higher risk of Type 2 Diabetes due to a DNA mutation, this person can start making lifestyle adjustments to lower their risk of getting the disease later in life. The development of personalized medicine will result in a more cohesive approach to therapy that is tailored to each patient's unique genetic makeup. Better diagnosis with early intervention and more effective medication development could be possible with personalized medicine.

*9.2. The role of the pharmacist*

Pharmacists must be informed about new developments in customized medicine's potentially promising roles in the diagnosis, treatment, and prevention of certain diseases, as well as about ongoing research and recent approvals, as the integration of personalized medicine into clinical practice continues to grow. According to published research, pharmacists' knowledge of pharmacokinetics and pharmacodynamics makes them valuable contributors to the advancement of pharmacogenomics and customized medicine.[25] Pharmacogenomic testing, for instance, has been shown by the American Society of Health-System Pharmacists (ASHP) to enhance medication-related outcomes throughout the continuum of care in all practice areas within the health system.[26] Benefits, according to AHSP, may include a drop in less than ideal clinical outcomes, a reduction in treatment costs, improved medication adherence, a more appropriate choice of therapeutic agents, a reduction in treatment length, and an improvement in patient safety through involvement of a pharmacist. Twenty Furthermore, because of their training and experience, pharmacists may play a significant role in collaborating with physicians by guaranteeing the best possible drug selection and dosage based on pharmacogenomic test results.[26]

## 10. Application of Personalized Medicine

1. Making earlier diagnoses with excellent surveillance to enable for more effective therapies or treatment options when a disease is diagnosed.
2. Preventing drug-related difficulties and adverse effects that can be avoided by following a "one size fits all" approach when administering generic medications.
3. Through ensuring that the right medication is utilized and that any genetic variations increase the therapeutic efficacy that may alter the drug's metabolism are taken into account in the dosing schedule.
4. In the event that an individual possesses a heightened susceptibility to illness, advocacy and assistance with adhering to accessible preventive measures should ensue.[27]

## 11. Advantages of Personalized Medicine

1. Lower medical expenses.
2. The likelihood of achieving the intended results will increase as a result of more effective targeted therapies.
3. Pay more attention to illness prediction and prevention than to treatment.
4. The likelihood of unfavorable side effects can be decreased.
5. Compared to the past, disease intervention will occur sooner.[9]

*11.1. Healthcare*

Benefits of Personalized Medicine

1. -Better treatments for patients.
2. -Delivering benefits to healthcare systems and society.
3. -More effectively developing novel medicines.

*11.2. Better treatments for patients*

Decreased adverse events: PM could be directed towards patients who are less likely to experience an adverse reaction, reducing safety concerns

1. Improvements in overall survival.
2. Improved efficacy: patient more likely to receive a medication delivering a clinical benefit, and treatment targeted at patients who will respond 2.

Delivering benefits to healthcare systems and society 3 PM has the potential to change the way health care providers and systems determine and manage health issues.

This could start with better diagnoses and coverings because of higher matching of patients.[7]

## 12. What Are Some Possible Definitions of Personalized Medicine?

Personalized medicine is connected to the three previously described dimensions: technological types, clinical questions, and medical judgments. Treating breast cancer with trastuzumab in accordance with the results of a HER2/neu test is a popular application of personalized medicine. It is safe to conclude, then, that companion diagnostic tests—which aim to forecast treatment outcomes prior to treatment initiation—undoubtedly fall under the purview of personalized medicine. The degree of

effectiveness, the likelihood of significant side effects, the ideal dosage (to maximize effectiveness and safety), and the best medication to employ with a patient can all be predicted using these tests, as was previously mentioned. When individuals discuss instances of personalized treatment in the literature, companion diagnostic tests are so frequently mentioned that we may even use them as the foundation for a definition of personalized medicine. This definition could be expressed as follows: the application of accumulated information about an individual, whether genetic or not, to forecast treatment response and subsequently enhance that individual's health. **Table 1** displays this initial definition. When asked to give examples of individualized treatment, some point to predictive tests like Mammaprint or Oncotype Dx.[11] A group of genetic tests known as Oncotype Dx are used to determine the prognosis of breast cancer patients in women. Adjuvant chemotherapy may not be helpful for a woman whose risk of recurrence is low. If prognostic tests of this kind are to be regarded as a component of customized therapy, then the term has to be clarified. This definition could be expressed as follows: the application of accumulated information about an individual, whether genetic or not, to forecast the likelihood of a disease or the effectiveness of a therapy, ultimately leading to the improvement of that individual's health. Lastly, when discussing customized medicine, some also mention disease susceptibility tests like BRCA testing. For instance, the US National Cancer Institute defines personalized medicine as referring to disease prevention, which can only be accomplished by looking at disease susceptibility, whereas the President's Council defines the term specifically including disease susceptibility.[37-40] In the event that the concept of personalized medicine should also include this kind of test, it might look something like this: the application of a person's entire body of information—genetic or not—to forecast their likelihood of contracting an illness, its prognosis, or how well they will respond to therapy, all of which can lead to better health. the application of a person's entire body of information—genetic or not—to forecast their likelihood of contracting an illness, its prognosis, or how well they will respond to therapy, all of which can lead to better health.

**Table 1:** Drug development and usage

| Type of test | Disease | Test | Function | Implications for treatment |
|---|---|---|---|---|
| Disease susceptibility test | Breast cancer | BRCA1 | Individuals with a deleterious BRCA1 or BRCA2 mutation are at increased risk of breast and ovarian cancer. | Surveillance, risk modification, chemoprevention, prophylactic surgery |
| Prognostic test | Breast cancer | Mammaprint | Test predicts the risks of cancer recurrence within 5–10 y after the initial event. | Adjuvant chemotherapy (yes or no) |
| Companion diagnostic — effectiveness-oriented | Breast cancer | HER2 | Trastuzumab (Herceptin) is beneficial only for tumors with an HER2 overexpression. | Trastuzumab (yes or no) |
| Companion diagnostic — safety-oriented | Epilepsy and other indications for carbamazepine | HLA-B*1502 | Patients with HLA-B*1502 are more likely to have dangerous skin reactions following carbamazepine therapy than other patients. | Carbamazepine (yes or no) |
| Companion diagnostic | Atrial fibrillation and other indications for warfarin and other coumarin derivatives | CYP2C9, VKORC1 | Optimal maintenance dose for coumarin therapy is partly dependent on CYP2C9 and VKORC1 genotypes. | Warfarin dosage |
| Treatment response monitoring test | Hepatitis C | HCV RNA test | The test measures viral RNA levels after starting treatment with pegylated interferon alfa and ribavirin. | Length of treatment |

HCV, hepatitis C virus.

The availability of a person's genomic information can be very helpful in the drug development process while it waits for FDA approval for public use. A thorough description of a person's genetic composition can be very helpful in determining whether a patient can be selected for inclusion or exclusion in the last stages of a clinical trial. The ability to identify patients who will benefit most from a clinical trial will also increase patient safety from unfavorable outcomes caused by the product in testing, allow for smaller, faster trials, which will reduce overall costs, and allow drugs that are deemed ineffective for the general public to be approved by the FDA by using personal genomes to qualify the effectiveness and even though a small portion of

the population may require that particular medication or therapy.

Doctors frequently employ a trial-and-error approach to discover the treatment plan that works best for their patient.These medicines can be more precisely customized thanks to personalized medicine, which uses a patient's genome to anticipate how their body will react to a given treatment and if it will be effective. According to one summary, this involves "therapy with the right drug at the right dose in the right patient." This method would also be more accurate and economical. For example, tamoxifen was once often prescribed to women with ER+ breast cancer; nevertheless, 65% of these women eventually developed resistance to the medication. Following investigation Researchers like David Flockhart found that women who had a specific mutation in the CYP2D6 gene, which codes for the metabolizing enzyme, were unable to effectively break down tamoxifen, rendering the medication ineffective for them. In order to determine the best course of action, women are now genotyped for these particular mutations. High-throughput screening and phenotypic screening are the methods used to search for these mutations. These tools are currently being used by a number of pharmaceutical and drug development businesses to further genetic research as well as the field of personalized medicine. In addition to the conventional "forward" transfection library screening method, other multi-target techniques include chemogenomics or reverse transfection.

One other use of personalized treatment is in pharmacy compounding. Even if genetic data isn't always used, Contrary to mass-produced unit doses or fixed-dose combinations, the customized production of a drug whose various properties (e.g., dose level, ingredient selection, route of administration, etc.) are selected and crafted for an individual patient is accepted as an area of personalised medicine. Drug interactions are also being predicted by mathematical and computational methods that are being developed. Phenotypic response surfaces, for instance, simulate the connections between medications, how they interact with one another, and the biomarkers of an individual.

Research is now being conducted on the effective delivery of customized medications created via pharmacy compounding to the body's illness locations. Researchers, for example, are attempting to design nanocarriers that may use real-time imaging and pharmacodynamic analysis to precisely target the desired spot for drug delivery. Numerous possible nanocarriers are being including silica, carbon nanotubes, iron oxide, quantum dots, and gold nanoparticles are being studied. The possibility of drug-loaded nanoparticles and immune response avoidance is made possible by surface chemistry modification, which paves the way for theranostics based on nanoparticles. The disease-specific targeting techniques of nanocarriers differ. To achieve recognition and binding, for instance, if the disease is cancer, a common strategy is to identify the biomarker expressed on the surface of cancer cells and load the targeting vector associated with it onto nanocarriers. Additionally, the size of the nanocarriers will be engineered to achieve enhanced permeability and retention effect (EPR) in tumor targeting. When a disease only affects a single organ, like the kidney, the surface of the nanocarriers can be covered in a particular ligand that attaches to the receptors in that organ to deliver drugs specifically to that organ while preventing non-specific absorption. Although this nanoparticle-based medication delivery method has a lot of promise, there hasn't been much advancement in the industry, and nanocarriers still need to be studied and improved upon to fulfill therapeutic requirements.[17-21]

## 13. Conclusion

By cutting healthcare expenses, medication development costs, and development time, PM can potentially meet the need to enhance health outcomes. Patients and consumers must equally contribute to clinical trials; entrepreneurs and innovators must develop intelligent tools and analyze genetic data; regulators must educate consumers and providers and support necessary policy and regulatory revolutions; physicians must comprehend disease at the molecular level; academic researchers must support innovative research to uncover new insights into the molecular basis of disease and support target-based drug development; the IT sector must create unique electronic tools to collect and secure patient information; and stakeholders, payers, and policy makers must consider new business models and novel diagnostics. tools, target therapy, and further individualized treatment plans. The potential impact of PM on the healthcare system is favorable. With the adoption of the personalized approach, every person will obtain their complete genetic information on the day of their birth to be entered into a unique medical record in the future. With the use of this knowledge, medical professionals might tailor their treatment to patients' individual exposure to various diseases, leading to more effective outcomes.

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