

## Personalized Medicine: A Novel Way to Drug Delivery System

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### ABSTRACT:

Personalized medicine (PM) is a rapidly growing field of healthcare and medicine. The advantage of a personalized medicine is the availability of each person's unique genetic and genomic print. The healthcare that incorporates personalized medicine provides coordinated, continuous patient-specific data. The goal of personalized medicine is to promote health wellness, satisfaction, and to increase the likelihood of a successful disease prevention, detection and treatment. The individualization of medicine and healthcare appears to be following a general societal trend. The terms "personalized medicine" and "personal health" are used to describe this process. Here it must be emphasized that personalized medicine is not limited to pharmacogenomics, but that the spectrum of personalized medicine is much broader. Applications range from individualized diagnostics, patient-specific pharmacological

therapy, therapy with individual prostheses and implants to therapy approaches using autologous cells, and from patient model-based therapy in the operating room, electronic patient records through to the individual care of patients in their home environment with the use of technical systems and services. Although in some areas practical solutions have already been found, most applications will not be fully developed for many years to come. Medical and information technology are essential to personalized medicine and personal health.

**Keywords:** Personalized medicine, Pharmacogenomics, Pharmacology, Technology

### I. INTRODUCTION:

From the ancient times to promising future. It aims at confronting every obstacle prevention, diagnosis, and treatment of diseases by targeting each patient individually[1].

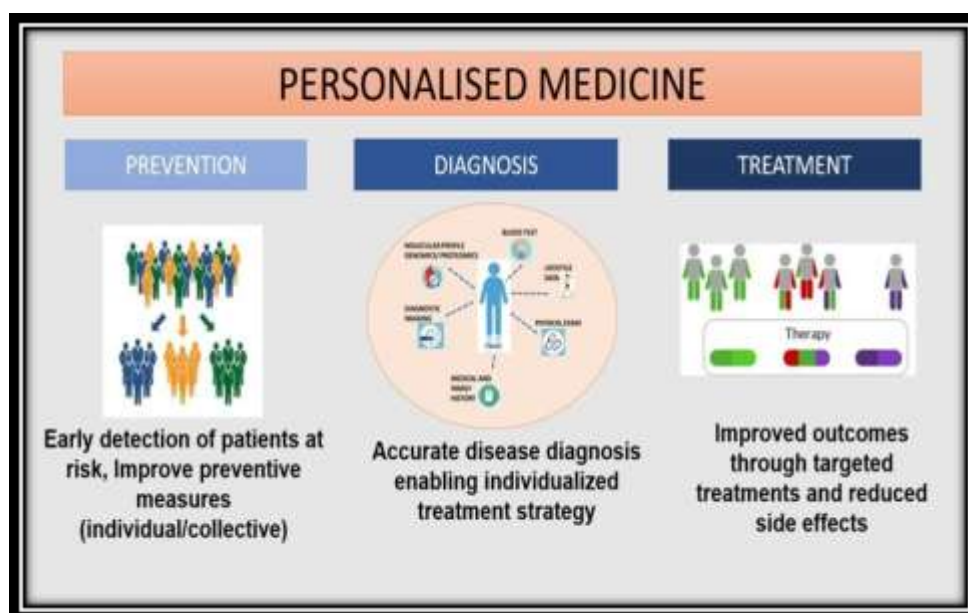


Figure 1: Personalized Medicine

1. More than 100 years ago, a renowned Canadian physician, William Osler, quoted that, "If it were not for the great variability among individuals, medicine might as well be a science, not an art. Over the past century, most therapeutic strategies were developed based on randomized clinical trials and applied for

"statistically average patient". Although medicine may continue to remain an art, the 21<sup>st</sup> century brings a new hope with success; for example, the human genome project to take consideration of genetic variability and deliver personalized therapy solutions [2].

2. Personalized medicine (PM) has the potential to tailor therapy with the best response and highest safety margin to ensure better patient care. By enabling each patient to receive earlier diagnoses, risk assessments, and optimal treatments, PM holds promise for improving health care while also lowering costs.

3. We are now able to bring out best treatment options for a particular individual leading to better therapeutic outcomes and decreased adverse effects. It also has the potential to identify the disease at an earlier stage [3].

4. It essentially means using the right drug for the right patient [4].

5. Among 14 Grand Challenges for Engineering, initiative sponsored by National Academy of Engineering (NAE), personalized medicine has been identified as a key and prospective approach to achieve optimal individual health decisions, therefore overcoming the challenge of Engineer better medicines [5].

#### A. Development of Concept

In personalized medicine, diagnostic testing is often employed for selecting appropriate and optimal therapies based on the context of a patient's genetic content or other molecular or cellular analysis. The use of genetic information has played a major role in certain aspects of personalized medicine (e.g. pharmacogenomics), and the theory was first coined in the context of genetics, though it has since broadened to encompass all sorts of personalization measures, [including the use of proteomics, imaging analysis, nanoparticle-based theranostics, among others] [6].

#### B. Basic of Personalized Medicine

The concepts of personalized medicine can be applied to new and transformative approaches to health care. Personalized health care is based on the dynamics of systems biology and uses predictive tools to evaluate health risks and to design personalized health plans to help patients mitigate risks, prevent disease and to treat it with precision when it occurs. The concepts of personalized health care are receiving increasing acceptance with the Veterans Administration committing to personalized, proactive patient driven care for all veterans [7].

#### C. Personalized Medicine the Ability to Offer

- 1) The right drug
- 2) To the right patient
- 3) For the right disease
- 4) At the right time
- 5) With the right dose [8].

## II. PHARMACOGENOMICS

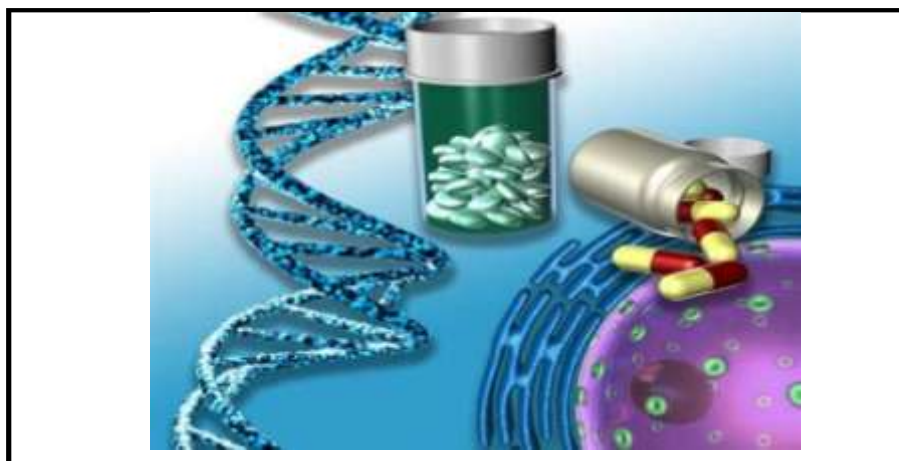


Figure3:Pharmacogenomics

### a. Definition

The study of how genes affect a person's response to drugs.

### b. What is...? Genomic Sequencing

A laboratory method that is used to determine the entire genetic makeup of a specific organism or cell type. This method can be used to find changes in areas of the genome. These changes may help scientists understand how specific diseases, such as cancer, form. Results of genomic sequencing may also be used to diagnose and treat disease [9].

### c. Genetic Test

- 1) CYP450 genotype test:-  
To determine how quickly and effectively these agents are eliminated from the body
- 2) Thiopurine methyltransferase test:-  
To treat leukemia and autoimmune disorders [10].

## III. IMPLEMENTING PERSONALIZED MEDICINE

Although there is increasing evidence to support the implementation of pharmacogenetics in certain clinical scenarios, the adoption of this approach has been limited. The advent of preemptive and inexpensive testing of critical pharmacogenetics variants may overcome barriers to adoption. We describe the design of a customized array built for the personalized-medicine programs of the University of Florida and Stanford University. We selected key variants for the array using the clinical annotations of the Pharmacogenomics Knowledgebase (PharmGKB), and we included variants in drug metabolism and transporter genes along with other pharmacogenetically important variants [11].

## IV. PERSONALIZED MEDICINE FOR DISEASE

### 4.1 Cancer Management

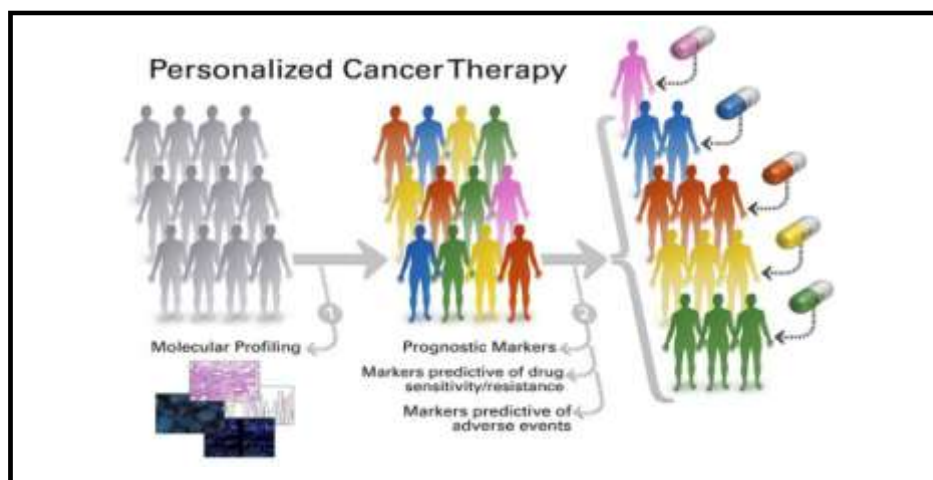


Figure 4: Personalized Cancer Therapy

Oncology is a primary section of medicine consisting of various cancer phases, measured in centimeters in most cases, and types with regard to their anatomy and pathology. Cancer genetics is a subgroup falling under the category of oncology that is focusing on genes and is associated with inherited cancer risk (Mansour & Schwarz, 2008). There is a limited number of cancerous disorders in which homogeneity separates in an autosomal dominant fashion, leading to considerably higher risk for certain cancer types. It is considered that inherited cancer genetics factors explain only about 5-10% of all cancer cases. Nevertheless, other genetic modifications with more indirect effects associated to cancer risk may trigger detailed cancer risk valuation to patients who are not associated with a family history (Yan, 2008). Examples of personalized cancer management [12].

### 4.2 Renal Carcinoma

Kidney, or renal, tumors are often discovered at an early stage and are frequently treated with partial nephrectomy, a surgical procedure in which the tumor and part of the kidney are removed. However, some patients, including those with chronic kidney disease, are poor candidates for surgery.

-There may be clear-cut risks with an operation in these patients, said study lead author Stella K. Kang, M.D., M.S., assistant professor of radiology and

population health at NYU Langone Health in New York City. -Patients may have significant heart disease or other comorbidities, or a limited life expectancy for some other reason [13].

## V. PATIENT NEED FOR PERSONALIZED MEDICINES

The current set-up of conventional pharmaceutical manufacturing is based on mass production of selected dosage strengths. This creates challenges especially for treatment of chronic diseases including cardiovascular diseases, type 2 diabetes as well as brain disorders. Many of the disease treatments require multiple doses to be delivered to the patient based on severity of the disease, lifestyle changes, co-administration of other medication, as well as going off medication. Furthermore, different subgroups of patients such as, pediatrics and geriatrics would require age-appropriate [14].

### 5.1 Additive Manufacturing (AM) as a Digital Technology for Personalized Drug Delivery Systems (PDDS)

To overcome the challenges of the currently marketed drug products, innovative solutions with improved functionalities are needed. One such innovation is personalized drug delivery systems (PDDS) defined in this review as solid dosage forms, containing the patient-tailored precise dose of a single or multiple APIs and possessing customized appearance that can aid in drug identification, swallowability, release and

monitoring of the treatment. Additive manufacturing (AM), based on different two-dimensional (2D) and three-dimensional (3D) printing

techniques, has recently emerged as a new technology for PDDS due to its versatile possibilities of producing on-demand flexible doses [15].

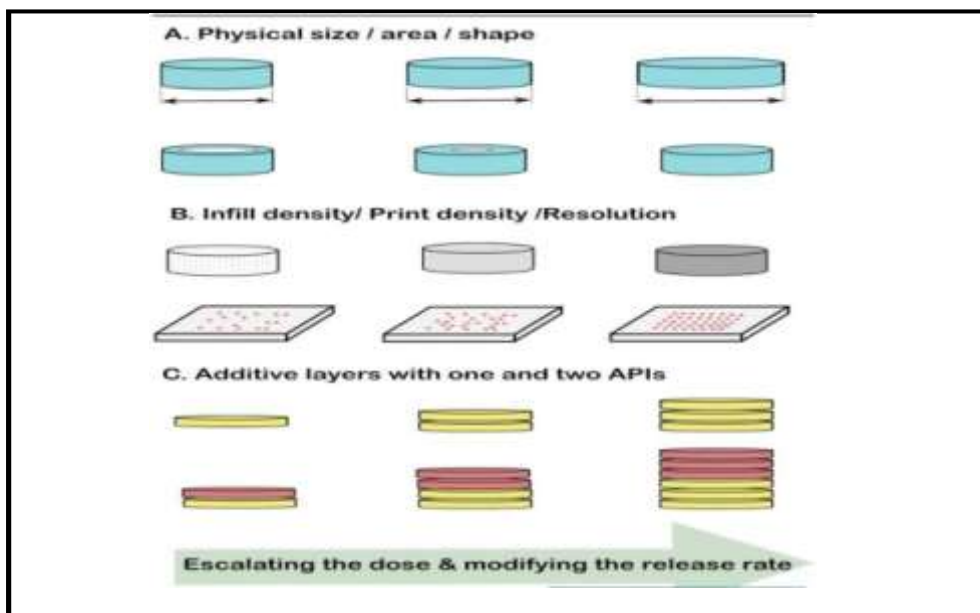


Figure 5: API of Personalized Medicine

### 5.2 Standard Smartphone

Over the past decade, 85% of the European and mobile US phone users had a smartphone. A smartphone, its sensors and associated mobile applications can be used as a tool for gathering quality data for medical research, or regular healthcare practice, as data can be gathered from the subjects unobtrusively for long periods of time, in a laboratory, as well as in a subject's natural environment. The smartphone can also become a sensor for medication adherence—either by acting as a reminder or engagement service to take the medicine or avoid double dosing, or relying on smartphone sensors—quantifying human states and behaviours related to adherence or tracking symptoms (or lack of those) in the individual's daily life environment. It is also used as a processing and displaying tool with a sharing possibility to track the drug intake [16].



**Figure6:Digital Health Care System of Personalized Medicine**

**5.3 Digital Therapeutics**

1) They rely on some existing hardware (wearable and/or smartphone) and, are providing, among others, game-based and questionnaire-based diagnostic tools and suggestions for treatment and, potentially, feedback



**Figure7:Digital Therapeutics**

Loop-driven alteration in the treatment regime. In the long term, digital therapeutics aim to have the potential to make patient's life drug-free for certain conditions

2) They come into play and gain user acceptance as —the illusion that all therapy must be delivered in-

person is now fading! In October 2020, the Digital Health care Act (DVG) officially granted doctors in Germany permission to prescribe insured health apps to their patients for the first time. Currently, ten apps have been approved; among which there are for example are (1) Kalmeda® app, which aims to help with tinnitus and (2) Velibra®, a therapy program for anxiety disorders [17].

### 5.4 Apps Used for Health Care



## VI. POTENTIAL OF 3D PRINTING IN PERSONALIZED MEDICINE

One of the major potentials of 3D printing in the pharmaceutical sector is its ability to tailor the dosage forms to individuals. This can be done by fabricating adequate dosage forms, adjusting the doses, combining them or by varying their release profiles of the dosage forms according to the need of patients.

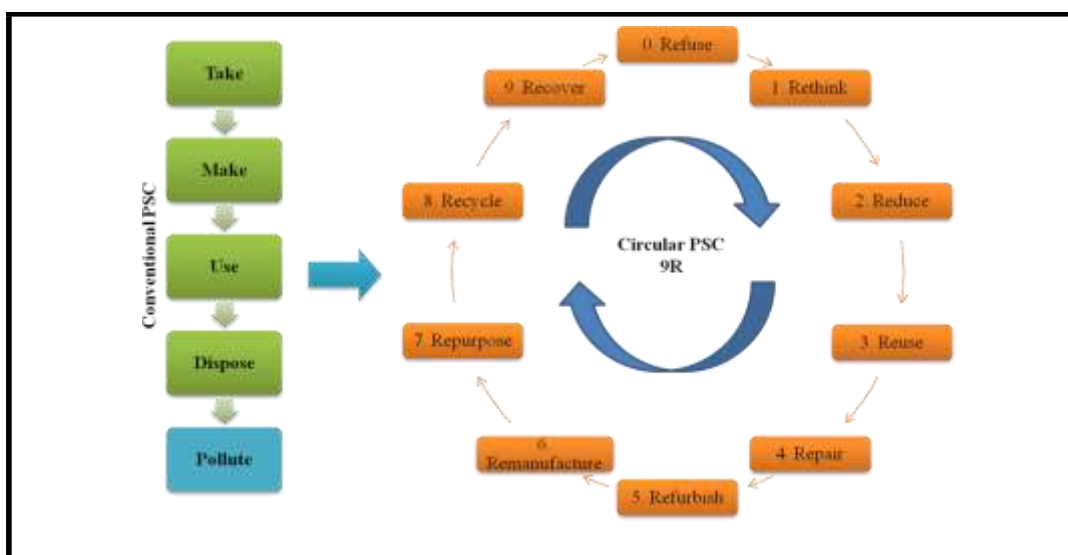
Dose Personalized In ODF formulations, this can be easily done by modulating the amount of liquid API dispensed on the film. ODFs can also be subjected to changes in shape and dimension to individualize treatments [18].

## VII. PHARMACEUTICAL SUPPLY CHAIN (PSC)

### 7.1 Conventional Supply Chain Model

The Pharmaceutical Supply Chain (PSC) is quite complex and has special characteristics, which are typically not seen in supply chains for other consumer goods. These special characteristics include the need for higher security, complete traceability and secured record keeping, especially if records contain sensitive information. A study by McKinsey & Company found that in the United States, supply chain accounts for nearly 25% (\$230 billion) of pharmaceutical cost. This fact alone is indicative of the complex nature of the conventional PSC model and engagement of multiple stakeholders (Fig. 3). It involves the flow of raw materials to pharmaceutical manufacturers, followed by a flow of finished pharmaceutical products through the chain of wholesalers and distributors, retailers, and ultimately to end-users patients and healthcare professionals.

Figure 8: Conventional Supply Chain Model



The ultimate goal of the series of regulations enforced in the PSC is to achieve unit-level traceability by 2023, where unit is defined as a single sealable entity. A sealable unit can be the primary package with multiple dosage units, e.g., a blister package with tablets or, or a primary package with a single dosage unit, e.g., an oral film [19].

### 7.2 Diagnosis and Intervention

Having the ability to look at a patient on an individual basis will allow for a more accurate diagnosis and specific treatment plan. Genotyping is the process of obtaining an individual's DNA sequence by using biological assays [20].

### 7.3 Personalized Medicine

#### Matching Treatments to Your Genes

You're one of a kind. It's not just your eyes, smile, and personality. Your health, risk for disease, and the ways you respond to medicines are also unique. Medicines that work well for some people may not help you at all. They might even cause problems. Wouldn't it be nice if treatments and preventive care could be designed just for you?

The careful matching of your biology to your mental care is known as personalized medicine. It's already being used by healthcare providers nationwide [21].

### 7.4 Personalized Medicine and Drug Safety

By matching the drug to the right patient, a consequence of personalized medicine is improved drug safety. There is, however, a limit to which drug safety can be designed into a molecule based on physicochemical and pharmacokinetic considerations. Consequently, additional interventions are required. They include designing targeted drug-delivery systems targeted for the target cells [22].

### 7.5 Method

In order for physicians to know if a mutation is connected to a certain

disease, researchers often do a study called a genome-wide association study (GWAS). A GWAS study will look at one disease, and then sequence the genome of many patients with that particular disease to look for shared mutations in the genome. Mutations that are determined to be related to a disease by a GWAS study can then be used to diagnose that disease in future patients, by looking at their genome sequence to find that same mutation. The first GWAS, conducted in 2005, studied patients with age-related macular degeneration (ARMD). It found two different mutations, each containing only a variation in only one nucleotide (called single nucleotide polymorphisms, or SNPs), which were associated with ARMD [23].

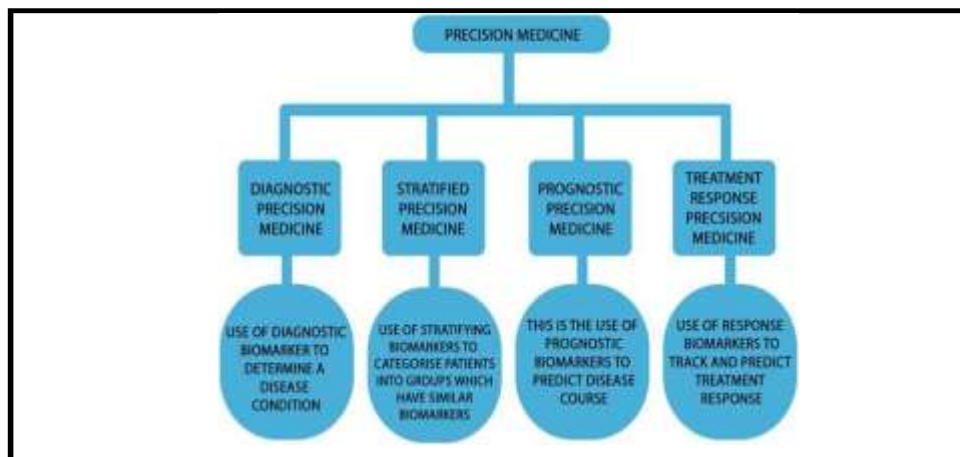
### 7.6 Tissue Engineering for Drug Discovery and Personalized Medicine

During the past century, animal models have provided a wealth of knowledge and understanding of the mechanism of human disease and therapy and played a vital role in medicine and drug discovery. However, the use of these models in research and industry remains the focus of intense ethical debate and brought further into focus by government agencies and research bodies who have endorsed the implementation of the 3R's initiative aimed at the Replacement, Reduction, and Refinement of animals in all areas of research. Coupled to this, the lack of translational research often found in animal models that have led to several examples where toxicity and damage have not been found in animal models and efficacy either over or underestimated has led to costly and sometimes fatal drug failures during human clinical studies [24].

## VIII. WHAT IS PRECISION MEDICINE?

Precision medicine aims to customize healthcare, with decisions and treatments tailored to each individual in every way possible. Pharmacogenomics is part of precision medicine.





**Figure9: Precision Medicine**

Although genomic testing is still a relatively new development in drug treatment, this field is rapidly expanding. Currently, more than 200 drugs have label information regarding pharmacogenomics biomarkers—some measurable or identifiable genetic information that can be used to individualize the use of a drug [25].

**IX. THE GREAT PROMISE PERSONALIZED MEDICINE**

A patient is diagnosed with non-small-cell lung cancer. A DNA test costing \$1,000 reveals the subtype of his cancer. The test indicates that the most effective treatment will be an oral drug rather than chemotherapy. Thus, through genetic testing of the tumor, the patient is treated more effectively and with a longer survival benefit.

A woman with atrial fibrillation, a heart condition, is prescribed the widely used blood-thinning drug Warfarin. A \$350 genetic test is performed, looking for variations in two specific genes that affect the body's metabolism and response to the drug. Combined with other factors, the test indicates a proper dosage range for her. Thus, with a test that looks at her genetic profile, she is prevented from suffering uncontrolled bleeding or life-threatening blood clots and risk of stroke that can accompany the use of this powerful drug.

These are examples of personalized medicine in practice. Of course, physicians have always been alert to variations between patients. But the term personalized medicine reflects the growth of scientific understanding and medical tools

that can help individualize care at a new level. Such tools can help match treatments to individual genetic variations, or differentiate between subtypes of disease. And that can help take the guesswork out of medicine, making healthcare decisions more precise and effective, often at a lower cost.

The opportunity of personalized medicine stems from advances in molecular biology, especially the explosion of new knowledge of the human genome. It is already working for patients with some conditions, and it has the potential to transform the effectiveness of medical care in the immediate future. For example, most drugs prescribed in the United States are effective for fewer than 60 percent of treated patients. This is not because of shortcomings of the drugs, but rather because each of us is biologically unique. The tools of personalized medicine can help direct the right treatment to the right patient. The potential improvements in health as well as savings in health costs are vast.

Likewise, our conception of disease needs to be more precise in order to better individualize care. For example, when we refer to asthma, it is a respiratory disease but there are many varieties. From a treatment perspective, they are different diseases, but we are just at the cusp of identifying them accurately and providing the right treatment on the first encounter. We refer to breast cancer, yet in reality there is no such single disease. Rather, cancers of different kinds may arise in breast tissue. One result is that most women who are treated with painful and expensive chemotherapies are receiving treatments that are actually ineffective for their condition.

With personalized medicine, we can improve the current paradigm. The explosive growth of scientific Discoveries at the molecular level, accompanied by advances in technology and analytical capabilities, Bring the promise of greater precision and effectiveness in medicine. Over time, we should be able to Prescribe medicines with foreknowledge as to their effectiveness for individual patients and disease Subtypes. Over time, increased knowledge of genetics and molecular biology should also enable us to detect Disease before symptoms appear, making possible earlier treatment and even preemption of the disease. Personalized medicine, as promising and as transformative as it is, cannot be implemented if it is going to Result in a great increase in healthcare costs. But the practice of personalized medicine can be an Important part of achieving higher value in healthcare. In the case of warfarin, for example, adverse events Related to dosage problems make this drug a leading cause of drug-related emergency room episodes. More accurate dosing, enabled by a relatively low-cost genetic test, might save as much as \$1 billion per Year while delivering better-quality care and better health [26].

## X. CHALLENGES

As personalized medicine is practiced more widely, a number of challenges arise. The current approaches to intellectual property rights, reimbursement policies, patient privacy, data biases and confidentiality as well as regulatory oversight will have to be redefined and restructured to accommodate the changes personalized medicine will bring to healthcare [27].

### 10.1 Benefits

1. Shift the emphasis in medicine from reaction to prevention
2. Predict susceptibility to disease
3. Improved disease detection
4. Preempt disease progression
5. Customized disease-prevention strategies
6. Prescribe more effective drugs
7. Avoid prescribing drugs with predictable side effects
8. Reduce the time, cost, and failure rate of pharmaceutical clinical trials
9. Eliminate trial-and-error inefficiencies that inflate health care costs and undermine patient care [28].

### 10.2. The Use of Pharmacogenetics Information is Central to the Concept of Personalized Medicine

Understanding pharmacogenetic differences in drug response and tolerability has been investigated mainly through the study of pharmacokinetic and pharmacodynamic processes. The hope and promise of pharmacogenetic testing have led to the commercial availability of several testing products. With the exception of the relationship between certain types of adverse drug reactions and immune response genes such as the human leukocyte antigen, a growing body of research has not yet established the clinical utility of pharmacogenetics testing. Variance in findings from pharmacogenetics studies conducted to date may be due to epistasis (gene-gene and gene-environment interactions), epigenetics (non-DNA sequence-related heredity), or other genetic factors, which have been largely unexplored in pharmacogenetics research [29].

## XI. PSYCHIATRIC PATIENTS

Tend to exhibit significant interindividual variability in their response to psychoactive, as well as an irregular clinical course. For these (and other) reasons, increasing numbers of psychiatrists are turning to genotyping for help in selecting the psychopharmacologic agents best suited to an individual patient's distinctive metabolic characteristics and clinical presentation. Fortunately, routine genotyping is already available for gene variations that code for proteins involved in neurotransmission, and for drug-metabolizing enzymes involved in the elimination of many medications. Thus, genotyping-based personalized psychiatry is now in sight. Increasing numbers of clinically useful DNA microarrays are in the development stage, including a simplified procedure for genotyping patients for CYP2D6, which metabolizes a high proportion of the currently prescribed antidepressants and antipsychotics. It has been pointed out that psychiatric disease is rarely a consequence of an abnormality in a single gene, but reflects the perturbations of complex intracellular networks in the brain. Thus, analysis of functional neuronal networks is becoming an essential component of drug development strategies. The integrated use of technologies such as electroencephalography, magnetoencephalography, functional magnetic resonance imaging (fMRI), and diffusion tensor imaging (DTI), in combination with pharmacogenetics, promises to transform our understanding of the mechanisms of

psychiatric disorders and their treatment. The concept of network medicine envisions a time to come when drugs will be used to target a neural network rather than simply components within the network. Personalized medicine in psychiatry is still at an early stage, but it has a very promising future [30].

## XII. THE DEVELOPMENT AND PROSPECTS OF CONVENTIONAL THERAPEUTIC DRUG MONITORING

The development and prospects of conventional therapeutic drug monitoring (TDM) and pharmacogenetic testing as aids in personalized treatment with antidepressants and antipsychotics are described. Our own experience is discussed in relation to international guidelines for rational TDM. Emphasis is put on the usefulness of TDM combined with genotyping of cytochrome P450 2D6 (CYP2D6), the key enzyme involved in the polymorphic metabolism of the majority of antidepressants (both tricyclics and selective serotonin reuptake inhibitors) and antipsychotic drugs. This combination of methods is particularly useful in verifying concentration-dependent adverse drug reactions (ADRs) due to poor metabolism, and diagnosing pharmacokinetic reasons (ultra-rapid metabolism (UM)) for drug failure. This is because ADRs may mimic the psychiatric illness itself and therapeutic failure due to UM may be mistaken for poor compliance with the prescription [31].

## XIII. ADVANTAGES AND DISADVANTAGES OF PERSONALIZED MEDICINE

### 13.1 Advantages

- Increases the chances of a doctor to use the patient's genetic and molecular information.
- Enhances the ability to predict the best treatment for a specific patient
- It improves the ability to understand the underlying mechanisms of the disease.
- It helps in preventing, diagnosing and treating a range of diseases [36].

### 13.2 Disadvantages

- Despite numerous benefits of personalized medicine, as previously described, there are also many drawbacks which could prevent it from becoming the future of healthcare.

- A major concern of the increased use of personalized medicine is the ethical issue of patient privacy. For example, there are concerns that some may not use this information in an ethical way, such as insurance companies who may not offer certain policies to those with genetic predisposition.
- There are also other ethical concerns, such as incidental findings [37].

## XIV. BRIEF HISTORY OF PERSONALIZED MEDICINES

By the 20<sup>th</sup> century, clinicians had developed a kind of personalized approach to the treatment of patients. For instance, after the rise of blood transfusions, knowledge accumulated that indicated that individuals differ in blood groups. It was also noted that groupings such as people resulted in successful blood transfusions. The doctors later advanced in the documentation of individuals' relations to diseases depending on their families' histories. This was done in diseases that seemed to be passed from generation to generation.

The personalized medicine became more concrete at the beginning of the 21<sup>st</sup> century with the solidification of the Human Genome Project. This project took a new approach that connected the genetic makeup of individuals and their health. This enabled the doctor to conduct genetic mapping. Genetic mapping reveals that 99.1% of an individual's genetic makeup is identical. The rest is varied by the differences that exist in the species of human beings. This explains why different individuals respond differently to different medications, hence necessitating tailoring the medication to an individual based on their variations [38].

## XV. IN THE FIELD OF 4P MEDICINE

That is Predictive, Personalized, Preventive and Participatory. It is clear that personalized medicine is still at its infancy and its huge potential has yet to be unlocked. Claimed as supporting key healthcare players in addressing the promising field of personalized and precision medicine and promoting their development, from R&D to market access and adoption [39].

## XVI. KEY TECHNOLOGY ADVANCED, MAKING PERSONALIZED MEDICINE POSSIBLE AND FASTER PACE OF GROWTH, INCLUDING;

New tools to decode the human genome more rapidly and accurately using physically smaller yet more powerful machines. Large-scale studies and sample repositories that help link genetic variations to disease across multiple countries and continents. Health information technology (HIT) that fosters the integration of research and clinical data, which is already growing faster in the U.S. as a result of aggressive government incentives for adoption. Exploration of personal genomics and direct-to-consumer genetic testing and how the field affects PM.

Information about ground-breaking policy, legislation, and government initiatives in place and in development to support PM, including the Genetic Information Non-discrimination Act (GINA), passed in 2008, and proposed changes to health plan reimbursement policies. Real-world examples of hospitals, regional health care systems, and educational institutions promoting clinical adoption of PM through research, clinical practice, and medical education reform [40].

## XVII. CONCLUSION

As the new trend of Personalized Medicine has the potential to fulfil the requirement to improve health outcomes by reducing health care costs, drug-development costs and time. Now we can see people are more involving in this revolution in the health care system will only be possible to achieve by equal contribution of patient and consumers in participating in clinical trials, entrepreneurs and innovators to develop smart tools and analyze the genetic information, regulators by educating consumers and providers, and support essential revolutions in policy and regulation, physicians to understand the disease at the molecular level, academic researchers by accompanying innovative research to uncover new insights at the molecular basis of disease and supporting target-based drug development. So the new trend of Personalized Medicine is increasing day by day.

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