Personalized medicine
(*A biological approach for treatment*)

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ABSTRACT:
Personalized medicine in the field of distinctive rational, genetically, and environmental data of every subject informs the huge and quickly developing, utilizing our molecular data understanding of disease and integrating technologies (such as clinical decision support) are essential components of personalized medicine in order to maximize preventive health care initiatives. With the help of human genome information, healthcare professionals can now design tailored treatment regimens for patients at each state of a disease, changing the emphasis from not only cure but also leads to prevention. Several boundaries were seen in education, accessibility, legislation, and indemnification must be removed in order to better integrate personalized medicine into clinical workflow. This review aims to provide a thorough overview of personalized medicine, from laboratory bench research to the incorporation of these novel approaches to keep the data according to personalized manner.

KEY WORDS: Personalized medicine, Genomic technology, Systemic medicine, Theranostics, ethical, legal, regulatory issues, pharmacogenomics.

1. INTRODUCTION:

[1] The medical and healthcare businesses are currently very interested in the fresh and fascinating concept of personalized medicine (PM). It is a notion that has the ability to revolutionize medical interruptions by offering efficient, personalised therapeutic solutions based on a patient's genetic, epigenomic, and proteomic profile, while also taking into account the patient's unique symptoms. PM is a unique extension for prevention not only limited for therapy.

[2] Medical personnel will have solid data to base treatment plans for specific patients due to increased use of physiologicaldifferentiation of patients, such as checking for sudden change in gene that cause repellant to particular medications. With this advancement, there will be less reliance on the unfavorable results of trial-and-error prescribing techniques.

[3] Now-a-days, the patient may change to a new medicine if the one they were prescribed is non-therapeutic. As of negative side effects, drug interactions, potential illness progression while proper therapy is restricted, and subject discontent, this method of trial-and-error results in worse outcomes for patients. Thus, PM offers such a prove and preventative structural strategy for effective healthcare. It is specific for patients and their doctors with help of electronic health records (EHR) make optimal treatment decisionwhich is linked with clinical and molecular data. To make up for hereditary susceptibilities, PM involves patients in habitual decisions and proactive health management.

2. STRATEGIES:

[1] Although doctors have known for many years that some medications act better in particular subjects, they do not yet understand why, and they are certainly unable to anticipate which medication will be both safe and efficient for any given patient. [4] Ten people may react substantially differently to the same drug for cancer, heart disease, or seizures. A cancer treatment may decrease a tumour in one person but not in another, depending on how severe or even life-threatening the side effects are for one individual, while they have little or no side effects.

People inherit different gene variations, and even small changes in medication can have an effect on specific treatments that how the body reacts. This is one of the main causes of this disparity. The field of science known as pharmacogenetics investigates how genetic variations in people affect how they react to drugs. Pharmacogenomics is the study of genetic differences due to medical development.

2.1 TOOLS FOR IMPLEMENTING PERSONALIZED MEDICINE:

A. FAMILY HEALTH HISTORY(FHH):[5] A straightforward but essential method for providing information on personal health risks is family health history (FHH). A strong FHH comprised of genetic/genomic risk information and incorporate it into

patient care since it reflects the complex interaction of shared genetic and habitual factors. FHH assessments would assist in identifying those who are more susceptible to disease, allowing for proactive and preventive measures like lifestyle adjustments, health examination and early treatment when necessary. Three crucial factors are involved in the difficulty of integrating FHH into public health:

(a) Accessible methodsfor standard collection FHH.

(b) Access from health care providers and

(c) Clinical guidance for explanation and use.

[27] Presently, the gathering of FHH data may be insufficient, may be challenging to analyse, and/or may differ greatly among a patient's healthcare physicians in terms of medication. Additionally, healthcare professionals can lack the expertise and training necessary to correctly interpret FHH for the risk of inherited genetic disorders and/or other prevalent complicated illnesses.

B. ASSESSMENT OF CHRONIC DISEASE RISK:

[6] A conventional health risk assessment (HRA) to determine a person's probability of getting the mostwide spreadlong-term diseases is a vital part of customized care. evaluation of a patient's illness risk and c of clinical categorize methods to address, it will be made easier by the combination of evidence-based HRAs and predictive models. [7] The Framingham coronary heart disease model, which was created from the Framingham Heart Study, which was started in 1948, is one of the most well-known HRAs.

C. CLINICAL DECISION SUPPORT:

[8] Clinical decision support (CDS) systems offer doctors and people havingawareness intended to guide and improve healthcare in order to maximize the utilisation of FHH and HRAs. Patient-medical data, such as weight, current medications, prior medical history, and even FHH, can be linked into user-friendly forms using computerized CDS systems, which can aid manage diagnosis and treatment. The use of personal health data should become moresmooth as CDS integrates with electronic health records, allowing access to doctors for patient information to aid in developing patient health plans up to individual requirements.

D. HUMAN GENOME INFORMATION:

[9], [10], [11] By incorporating data from genomes, their sequences, making to take medical decision, for personalised medicine is more strengthened. Genome-based health assays can be used to diaognise risk, screen for carriers, establish clinical and prognoses for specific people, and guide clinical regulation. [12] As a result, the emphasis has shifted from reactive to preventative healthcare as a result of the availability of human genetic information.

3. THERANOSTICS:

3.1 PHARMACOGENOMICS AND GENE TESTING:

[4] These new technologies have essentially given birth to a new field of study called pharmacogenomics, which aims to study specific genetic variations influencing each patient's therapy through medication. By doing this, it is possible to target a disease sensitive genes that could serve as potential new drug targets. These all accompany to produce brand-new techniques for medication discovery, personalised drug therapy, and fresh perceptions on illness prevention.

Even though there may be individual, genetically based variations in treatment response, the current paradigm in drug therapy treats vast patient populations as groupings. Pharmacogenomics, on the other side, may aid in concentrating effective medication on smaller patient individuals that, despite exhibiting the same symptoms, are characterized by different genetic profiles. It is still unknown if this strategy will lead to better, more affordable therapy.

All human cells include genes, which is basic unit of DNA. Genes can trigger how a person responds to medicines. DNA essentially functions as a main component of the body's physiological operating system, giving instructions to cells on how to behave and interact. A fundamental gene can take on a wide variety of shapes and chemical messengers. These interactions have an impact on how drugs operate within the body. And this explained by giving two examples:

Ex-1:[13] How the metabolism of codeine varies genetically. In 5% of people Codeine is ineffective because it does not relieve pain because only they are unable to convert codeine to morphine. Using the CYP2D6 enzyme, codeine can be changed into morphine. However, due to gene variability this enzyme lead to insufficient or excess enzymatic activity, leads to insufficient absorption.

Ex-2:[14] Breast cancer is a frequent instance needing the usage of many drugs that have multiple adverse effects. Today, scientists can select a treatment, such trastuzumab, based on the accepted pharmacological therapy and dosage recommendations

for that condition. Additionally, they may take into account a patient's height, weight, age, medical past reports, and responses of other blood relatives to the same medication.

Pharmacogenomics holds out the prospect of accelerating this procedure while enhancing results. For example, a blood tests might be performed to determine which genetical variants are there prior to a patient receiving a single dose of treatment for breast cancer. After testingthey may reveal a variations due to gene, that will nothave probable effect on the patient's response. In this situation either we change the medication or dose to better suit the patient's genetic profile.

[15] Pharmacogenomics is auspicious field. At present, a normal tests that may conclude some of these variations in gene and screen how a patient will likely respond to specific drugs are recentlymarkedlyavailable.

Within the next several years, pharmacogenomics has the possibility to provide numerous wide spread applications. Among the most significant advantages are:
1. A better selection of medications.
2. Safer dosage alternatives
3. Advances in pharmaceutical development.

5. ETHICAL, LEGAL AND REGULATORY ISSUES:
4.1 ETHICAL CONSIDERATIONS:
1. [16] Modern medicine has increased patients' quality of life and lengthened their lives. However, the healthcare system in our country is a moral disaster.
2. Patients still struggle to get access to care, which places a strain on the system.
3. Cost containment for both clinical use and research and development (R&D) appears to be impossible, especially for novel technologies like customised medicine.
4. [17] In a 2009 report, the National Academy of Sciences stressed the importance of adopting a new strategy to keep observation on enable each patient's health state and to treat any defect in a way that is specific to that person.
5. Thus, if completely achieved, the assurance of PM has the possibility to have a huge impact on the country's health care.
6. Adopting safe and efficient, individualized diagnostic and treatment procedures is now extremely difficult.
7. Doctors can simply continue to examine treatment approaches using some trial-and-error procedures in the absence of the knowledge required to deliver PM.

[18]Despite having a duty to do no harm in accordance with the Hippocratic oath, prescribing compounder frequently there is no chance of knowing in advance if a substance they are prescribing would hurt a patient. Because prescribing information regarding how specific medications impact patients is so limited, we can question if doctors are abiding by their obligation to do no harm.

It is conceivable that insurers would ask for genetic testing to evaluate the safety and effectiveness of drugs in order to save wasteful costs, however this practice is unethical if it involves coercion of individuals. Although it is improbable that people would be turned down for health insurance because they do not respond to a particular medication or because a certain medication formulation is harmful to them, it is feasible that insurers might do this in order to minimize unneeded financial burdens.

4.2 LEGAL AND REGULATORY CONSIDERATIONS:
Health Insurance Portability and Accountability Act: (HIPAA)
[19] The Health Insurance Portability and Accountability Act of 1996 (HIPAA) was passed to make sure that a set of privacy standards are followed when personal medical information is stored, accessed, or processed. These security guidelines lay forth steps to properly protect all digitally protected health information (PHI).
1. Enhancing the transferability and consistency of health insurance coverage for both groups and individuals. HIPAA changes the Internal Revenue Code of 1986.
2. preventing waste, fraud, and abuse in the provision of healthcare and health insurance.
3. urging people to open medical savings accounts.
4. expanding access to insurance and services for long-term care.
5. Making health insurance administration simpler.
B. American Recovery and Reinvestment Act of 2009
[20] Executive Director of the Association of Clinical Research Organizations; For a while, the clinical investigator-clinical research organisation interface may become more difficult due to law encouraging the deployment of electronic health records has resulted in a new set of government privacy and security regulations (EHRs). The increased data use constraints go well beyond the privacy rules established by HIPAA in 1996 and de facto mark a move to what is now known as HIPAA-2..

[20],[21]The sentinel event was the president's signing of the American Recovery and Reinvestment Act (ARRA), sometimes known as the so-called stimulus bill, on February 17, 2009. According to Mr. Peddicord, the law made dozens of changes to HIPAA-1 and offered more than $19 billion in incentives for doctors and institutions to employ EHRs. Companies offering personal health records, including Microsoft and Google, are now subject to some privacy and security regulations (PHRs). Patient registries, clinical trial portals, disease group databases, and numerous websites where users can go and freely complete a personal health survey might all be included in the definition of PHR.

One major worry among providers is the possibility that when information is placed online and qualifies as de-identified, circumventing the HIPAA Privacy Rule, it may be re-identified by computer "geeks" or hackers. Thus, within the year, the Department of Health and Human Services (DHHS) is likely to announce guidelines urging more stringent de-identification of PHI, which "may render data more expensive and/or less usable.

C. Health Information Technology For Economic and Clinical Health Act: (HITECH)
[21] Health Care Providers, Health Plans, and Other Entities Covered by HIPAA Must Notify Individuals When Their Health Information Is Breached, Per Regulations Issued by the Department of Health and Human Services (DHHS). The Health Information Technology for Economic and Clinical Health (HITECH) Act is being implemented through these regulations.
As a result, starting in February 2010, medical practitioners must adhere to the new HIPAA privacy and security rules that go along with ARRA and the HITECH Act.

5. CHALLENGES:

1. [1] PM is regarded as an innovation in the healthcare field because it is proactive, coordinated, and tested.
2. Consumers and stakeholders in the present healthcare system still do not completely understand the advantages of PM.
3. [22] According to recent studies, PM development is hampered by the following factors.
[24], [25] The following issues must be addressed: Scientific difficulties, Economic difficulties and Operational difficulties; and protection of personal data during the investigation and development phases.
4. [23] The relationship between public research and regulatory agencies also faces policy difficulties.

6. BENEFITS:

[24] PM has the potential to improve medication selection and targeted therapy, reduce side effects, increase patient compliance, shift the focus of medicine from reaction to prevention, strengthen cost effectiveness, [25],[26] and increase patient confidence following marketing by approving novel therapeutic strategies and altering how people view medicine in the healthcare system.

7. CONCLUSION:

PM may be able to meet the need for better health outcomes by cutting back on time, money, and healthcare expenses associated with drug development. The change in the health care system will be feasible with the equal participation of patients and consumers in clinical trials. The development of smart tools and the analysis of genetic data by innovators and entrepreneurs, education of consumers and providers by regulators, understanding of diseases at the molecular level by doctors, and support from academic researchers who will work alongside innovative research projects, instruments, target therapy, and other individualized treatment plans. The impact of PM on the medical management may be advantageous. In future, each person will obtain their complete genomic information on the day of their birth to be entered into a unique medical record using the tailored approach.

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