Research Article

A value driven future approach in Precision Medicine for health sustainability in New Zealand- A perspective

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The concept of personalized and precision medicine originated with the emergence of pharmacogenomics tools. It aims to predict disease risk before time, regular surveillance of human health status, reducing the cost over huge trials to make it more personalized. A personalized ecosystem does require more developments to make real-time decisions and predict the target medicines to be used for the welfare of the community. Theranostic and companion diagnostics are the tools to be utilized for imaging diagnosis, drug delivery, and monitoring for desired & specific therapeutic responses. Pharmacogenomics and Pharmacogenetic testing might harbor the capacity to determine the response against the precisely used therapeutics and even occurred adverse reactions. OMICS-based testing along with sequencing and molecular docking platforms holds the promise for better prediction. The reproducible pieces of evidence with precise standards are the pre-requisite to translating precision medicine for their effective use and implementing the policies could help serve the purpose. Valid science standards, protocols, research methods, and the right references are pre-requisite for better outcomes for the regulation of precision medicines.

1. Precision Medicine

Genomic & molecular testing are being used all over the world to predict the disease risk in context to an individual / or a group of population based on their environmental exposure, epigenetic characteristics, or variation that occurs because of infectious and non-communicable diseases. Application of

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pharmacogenomics emerged with a concept of precision and personalized medicines (Vogenberg et al., 2010), which is considered to develop opportunities in real-life such as:

- Prevention of risks involved with disease.
- Optimized therapy at the individual level.
- Safer use of drugs to avoid adverse reactions.
- Reduce the costs of large clinical trials, rather than complying with the treatments based on individual or a group population identified to have some similar characteristics based on their genomic profiles.

Healthcare to be driven by precision medicine is a novel concept, to understand the biological events of disease prognosis and developed pathogenesis to use the target treatment modalities for an individual and a group of population. That will impact the overall healthcare system with decision-making of lifespan to be considered from reproductive & prenatal life to the final detailed molecular typing of autopsies at death.

Personalized healthcare ecosystem can be built by integrating data science, digital health, and precision medicine. Patients (participants), providers, clinical laboratories, researchers & clinicians are the main stakeholders of the personalized medicine healthcare ecosystem. Large- scale collection of biological, radiological, and translational bioinformatics data sets are being formed from digital-sensing devices, and multi OMICS information will help support making decisions in real-time for research and target medicines. Hence, Electronic Medical Records (EMR) and Robust IT systems could effectively support the delivery of research and healthcare. Patients being the valued participant of the research projects are deemed to provide the biospecimens for testing along with the information of family history, environmental exposure (life-style), other medications, epigenetic errors, etc. This all data will be shared for further IT processing which is linked to digital phenotypes utilized by the clinical healthcare (Ginsburg & Philips, 2018). Secured data sharing is a valued strategy to integrate high-quality data into healthcare, and must be a priority for the best possible information available for research and patient care.

A managed electronic platform could process EMRs joined with a sequencing platform providing standardized, comparable, and consistent results. The electronic data storage platform would facilitate reusing the data for further studies & analysis to improve personalized medicines in healthcare. Just-in-time information guidelines for clinical actions could help clinicians to use the system effectively in following compatible practices.

The analysis of therapeutic efficacy and adverse toxicity effects through genomics and molecular testing will determine the optimized dosing to be recommended for appropriate clinical use. The clinical uptake can be varied, for example, the severe side effects of taking the HIV drug abacavir are detected by genotyping for major histocompatibility type I allele HLA-B*5701. Similarly, genotype HLA-B* 1502 recommends avoiding the antiseizure drug carbamazepine could produce side effects. Therefore, therapeutic efficacy would be determined by genotyping sequences in some cases (Ginsburg and Philips, 2018).

In Aotearoa (New Zealand) the Te Nohonga Kaitiaki Guidelines have been set for all genomic projects to conduct. The target treatment is selected to understand using a stratified medicine approach in a group population. Regular communications with the community to keep the Whenua/ interested participants informed and engaged, to ensure the integrity of the system, at every step of the ongoing project (Genomics Aotearoa).

Oncology and Pediatrics genomic sequencing are being used to find new variation patterns in New Zealand, responsible for developing the disease risk. These variations are used to make informed decisions for targeted medicine against that disease. The development of the infrastructure of the scalable National Genomic Centre in Aotearoa is underway. The genomic information and its protection of Maori interests, rights, authorities, etc. are described in the reference (Genomics Aotearoa). Clinical geneticists, genetic pathologists, and counselors work closely on the analytical decision-making and right communication tools to be established between counselors and patients receiving the targeted and personalized treatment. Regulatory guidelines are established to access the clinical genetic data and are not allowed to use for open source. Implementation of genomic health in NZ is currently based on the data profile of the European population. Māori Guidelines and principles are based on specific levels of responsiveness in the genomic projects, organizational structure, and at the system level can be seen in the given reference (Genomics Aotearoa).

2. Theranostics and Companion Diagnostic Testing

Theranostic platform uses an imaging agent for diagnosis, drug delivery, and monitoring the accurate therapeutic response. Iron oxide, nanoparticles, quantum dots, carbon nanoparticles, gold nanoparticles, and silica nanoparticles are being used in real imaging to analyze the target drug delivery. Nanoparticles cargo small molecules such as, proteins, peptides, and nucleic acids to make a comprehensive biomolecular nano-structural therapeutic bearing a higher capacity to target cancers (Xie J et al., 2010).

The nanoparticles are designed to recognize the surface marker of tumor cells than normal cells, comparable with higher permeability and retention effects. To understand the true potential of nano drug delivery system is underway, that could be optimally metabolized and expelled out of the body to meet the preclinical and clinical standards (Xie J et al., 2010).

Radiotheranostics are being applied in nuclear medicines for imaging and radiotherapy. The radioactive molecules are attached with gamma/ positrons, emitters of SPE-CT- single positron emission tomography or PET – positron emission tomography imaging and beta, alpha, or Auger electron imaging and spectroscopy. For example, radioactive iodine treatment for thyroid cancer, radio-labeled anti-CD-20 antibodies (for Hodgkin's lymphoma), radium 223 for bone metastasis, and fluorodeoxy glucose are the most commonly used isotope fluorine -18 (Aboagye et al., 2023).

Certain medications produce irreversible side effects in some individuals ending up with costly hospitalization, but some others don't show any adverse reaction using similar medication. The new pharmacogenetics and pharmacogenomics testing can mount the variable response for drugs including the toxic effects. Genomic profile in individuals predicts the risk for the disease to assess the response of medication in disease prevention. The cytochrome enzymes P450 (Cyp 450) metabolize the medicines that are attributed towards their absorption, distribution, metabolism, and finally excretion. CYP 2D6 enzyme converts codeine into morphine, 5% population doesn't metabolize codeine rendering it ineffective for pain relief. Trastuzumab medication is given in context with body weight, age, medical history, and blood reactions mainly prescribed based on dosing guidelines. Overexpression of certain gene e.g., HER2 gene is related to breast and stomach cancer prompting to use of the target drug trastuzumab. Only HER+2 patients will be treated with trastuzumab. Diagnostics MSK-1 MPACT^{TM} screens 468 genes and CdX^{TM} screens 324 genes, these oncogenes can identify the number of variables in the diagnosis of certain tumors in patients (Bilkey et al., 2019). Therefore, the therapeutic effects of morphine and trastuzumab are considered to be under a personalized approach.

The activation of abl-driven protein signaling is inhibited by BCR-abl fusion gene. Imatinib, an inhibitor of tyrosine kinase is the prime example of rational drug design against cancer, blood disorders, and leukemia (Priyadharshini and Teran, 2016).

It is imperative to justify the ethical clarifications and legality in developing precision genetic medicines, including the quality education of healthcare professionals, and inform the public of the implications of companion genetic testing (Vogenberg et al.,2010).

Companion tests predict who is going to benefit from the medicine. Some biomolecular therapies are also to be considered along with companion testing. These are as: a) Genetic therapy using oligonucleotides (anti-sense) gene silencing of the defective gene. b) Voretigene neparvovec (Laxturna) is an adeno associated vector-based one-time gene therapy for the treatment of patients with confirmed biallelic RPE-65 mutation-associated retinal dystrophy, to restore eye function. C) gene editing and modifying the functions of programmable nucleases to alter the gene function. CRISPR Cas-9, Zinc Finger Nucleases, and transcription activation-like effector nucleases have been translated to patient care (Bilkey et al., 2019). d) Mesenchymal Cell Therapy- Chimeric antigen receptor T-cell therapy is used to transform T-cells to fight against cancer cells. f) Immunological activation of DCs by using the autologous tumor lysate will be working as an effective immunotherapy against cancer and would be the better choice to replace chemotherapy.

Using the commonalities in the biological functional pathways in a specific type of population could help discover that new diagnostics and therapy are considerable approaches to improve the equity base to access precision medicine in healthcare. It can also assist in revealing the associated pathologies to facilitate cancer screening (Bilkey et al., 2019).

3. Population Studies

The potential technologies viz., gene microarray, cell-tissue array, and imaging (micro-CT) are in practice to evaluate the prognosis of cancer. Cancer prediction provides useful information on reoccurrence, susceptibility, and survivability. The accurate prognosis for tumor type and other risk factors significantly delivers the information through precise molecular and clinical data. Phylogenetic scores obtained through genotyping could help determine the associated genetic link to the diseases like diabetes, cancer, and coronary heart disease. Additionally, individual genetic information is an important factor to learn the predictive analysis in a large population. It is difficult to align the associated genetic variations more accurately in context to hereditary characteristics or environmental factors in the population, certainly requires more precise and spot-on instruments and methods to discriminate among the many syndromes (Vogenberg et al., 2010).

4. Respiratory diseases & personalized medicine

Chronic lung conditions e.g., asthma, chronic obstructive pulmonary disease (COPD), idiopathic pulmonary fibrosis, etc. caused by infections are the common cause of morbidity and mortality across the

globe. These are heterogenous and always need an early diagnosis. The early symptoms are highly non-specific that are confirmed later on by clinical diagnosis. Proteomics is the best-selected tool to find out the specific biomarkers involved in cancer. Protein-protein interactions can easily assess whether they respond to the treatment well or are non-responders. Chronic lung condition diagnosis is made based on one marker is not always sufficient to understand the disease pattern in real-time. It is possible to know the poor or good prognosis, drug resistance, and other parameters while working on different markers. MALDI Tof MS is used to determine the relevant markers in the clinical samples such as serum, BALF, blood, etc. Recently respiratory proteomics has made progress to provide better information on targeted therapy in the field the lung cancer (Priyadharshini and Teran, 2016).

The heterogeneity of ARDS prevents to identify the phenotypic functions. Its sub-phenotypic identifications using OMICS tools and technology could offer further opportunities to develop new diagnostics and personalized treatments in ARDS (Battaglini et al., 2022).

5. Genetic diagnostics market

Further exploration of novel research techniques such as genomes, proteomes, and metabolomes would assist physicians to attain a detailed profile of patients' altered genomes, metabolic functions, and other notable characteristics that can monitor the occurred response and outcome of therapeutic regimen. Companion diagnostics may play a significant role in bridging the theragnostic and precision medicine (Vogenberg et al., 2010).

Polymorphism ~1.0% occurs among the population and would be utilized to study the epidemiology, drug response, and human diseases including clinical trials. In the era of genomics, it is imperative to establish relevant guidelines regarding the use of reference genome. DNA variants are defined as single nucleotide polymorphisms and DNA mutations for the same event to compare with the reference genome could contribute to the impact on accuracy in context with interpretation and functional state of genome of acquired disease (Karki et al.,2015).

Pharmacogenomics and theranostics are considered to deliver the benefits of standardized molecular analysis for optimized dose, and selection of the right medication depending upon the altered genes to avoid the occurrence of adverse reactions. Therefore, increase the drug's effectiveness in the treatment of patients and disease management (Vogenberg et al., 2010).

Presently, commercial products based on companion diagnostics and theranostics are very low in number (Vogenberg et al., 2010). Genotypic test for trastuzumab-Herceptin- Trastuzumab, the monoclonal antibodies are used in the treatment of gastroesophageal and breast cancer, targeting the epidermal growth factor in overactive HER2 (ERBB2) gene. The other biosimilar products equivalent to Herceptin are also available e.g., Kanjini, Trazmera, Ontruzant, herzuma, and Ogivri. Trastuzumab increases the effectiveness against these cancers with least adverse effects including cardiac toxicity (Vogenberg et al.,2010, Dean et al., 2012). BRCA1/BRCA2 test for breast and ovarian cancer (Neff et al., 2017). The germline BRCA 1 and BRCA2 are associated with mutations in high-grade serious ovarian cancer (HGSOC). Amplichip CYP 450- a genotype test for the prediction of the therapy risk detecting the activity / or reduced activity of cytochrome P450 enzyme (Dodgen et al., 2013). Genotyping HIV test to detect the mutations in protease and reverse transcriptase the main cause of drug resistance in HIV. The mechanistic enzymes used for HIV propagation and an important target for anti-HIV drugs (Shafer RW. 2002).

Pharmacogenomics provides informed drug prescriptions. The genotype VKORC1 (Vitamin K epoxide reductase) encodes the anticoagulant response, which would allow physicians to optimize the warfarin dosage for great therapeutic efficacy (Vogenberg et al., 2010, Ginsburg et al., 2018). Pharmacogenetics-DNA fingerprint is an approach to optimize the treatments with statins linked-phenotype statin-associated muscle symptoms (SAMS). Genes SLC01B1, COQ2, HTR7, GATM, etc. are activated to develop myopathy and myalgia using simvastatin and atorvastatin. Statins are lipid-lowering strategies to prevent cardiovascular diseases. The testing is used to lower the dose of statins eventually reducing the morbidity and mortality in SAMS-linked syndromes (Brunham et al., 2018).

6. Precision Medicine Practice

Oncology Dx genomic assays predict early-stage cancer to provide chemotherapy for high-risk patients (Marchionni et al., 2008). Precision test OMICS based could recommend the therapy from 1 out of 5 undiagnosed individuals.

Artificial Intelligence and Machine Learning Algorithm could help solve the challenges of precision medicine, especially in translational research, in healthcare (Sahu et al., 2022). Multidisciplinary expertise with AI and machine learning can also provide the predictive algorithm for groups of people who are not identified by clinicians would help guide the selection of specific groups of patients for early treatment of the disease. A pilot study on cognitive computing technology (Watson) was configured to

support researchers to analyze the medical literature of patients, genomics, chemical, and pharmacological data. Most importantly identification of target medicine and appropriate drug positioning to discover novel target drugs can only be achieved by analyzing the big data (Chen Y et al., 2016). The personalized treatment eliminates the trial errors and inefficiencies which increase the associated cost in population trials which could undermine patient care.

Direct-To-Consumer market is projected at 19.5% during the forecast period of 2022-2030. Direct -To-Consumer tests presenting moderate to higher risks in the context of medical testing for healthcare should always demand a comprehensive review by regulations to determine the validity of the tests. According to this report 65% of individuals are willing to use home genetic tests, but the major concern was to share the data with third-party companies such as healthcare data processing companies (Buisiness Wire-2022).

Theranostic platform can be adopted to test several biomarkers using various diagnostics to guide appropriate therapy. They involve medical imaging (MRI), fluorescent markers (organic dye and inorganic quantum dots), spectrophotometry, and nuclear imaging agents, DNA sequencing, and deep learning algorithms for accurate analysis (Vogenberg et al., 2010, Ginsburg et al., 2018).

Personal genome analysis qualifies the need for specific anticancer drug effectiveness, even though this is allowed for the small population. Therefore, it does assist to finalize the exclusion and inclusion of the patients for particular drug regimens. Gene CYP2D6 variation increases the resistance to the drug Tamoxifen, which is normally breakdown by relative enzymes to enhance its efficacy leaving the drug ineffective for treatment in women with breast cancer. Epidermal genetic information retrieval (EGIR, or Derm Tech) is the non-invasive method for harvesting the stratum corneum of naevi mole, used to detect melanoma by 17-gene genomic biomarker (Watchman et al., 2011). These tests are often not very expensive.

Most of organizations around the world are tirelessly working on high throughput sequencing not only to study personalized medicine. It is infect considered an effective tool to enhance genetic studies. Pharmacy compounding is customizing the unit doses and fixed doses used in combinations may also be accepted as the area of personalized medicine. Computational and mathematical approaches to study the interactions among the drugs and individual biomarkers or enzymes (Molecular docking) are also considered as a personalized approach (Vogenberg et al. 2010).

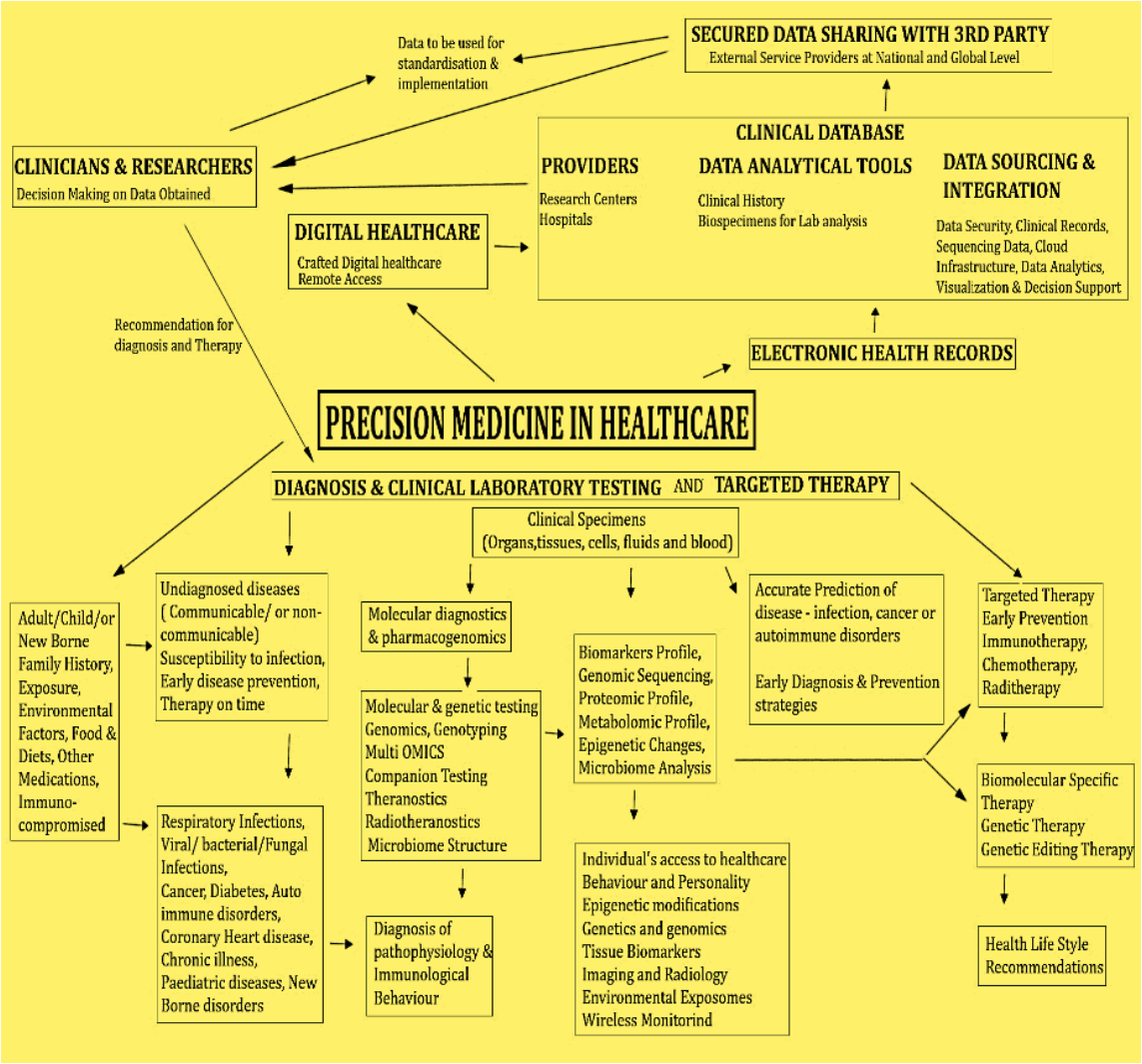

Figure 1. Representation of a model for precision and personalized medicine in healthcare. Recommendations for the diagnosis and specific therapy are provided by Physicians and Clinicians and all the health records are maintained in a clinical database likely to be shared securely with third-party companies after obtaining consent from patients for further analysis. Artificial intelligence, machine Learning, and genetic sequencing data are analyzed and standardized by clinicians & researchers for decision-making.

7. Digital and Tele- Healthcare in Personalized Medicines

The digital healthcare concept is associated with using novel modalities to use apps prescribing therapeutic interventions for patients under certain conditions. Clickotine is a smartphone used to study engagement, efficacy, and safety. The self-reported cessation outcomes were attained of 7-30 days the abstinence from smoking and negative health results (Lacoveillo et al., 2017).

Telehealth/ digital health has arrived in real practice during the COVID-19 peak pandemic. Personalized medicine healthcare and associated technologies use advanced analytics. Digital technologies like Artificial Intelligence (AI), Machine Learning (ML), the internet of Things (IoT), and block-chains, are established to manage patient's treatment at individual level. It has already integrated with business processes in most hospitals. Hospitals, clinics, pharmacies, caregivers, etc. form a complex network to deliver personalized treatment support to patients in need. For more complex and advanced developments, it does require a huge volume of patients, therapeutics, and genomic data to provide personalized solution. Virtual care via digital healthcare provided seamless facilitation to view health records, check prescriptions, and book appointments at any time from home. It is a cost-effective method that saves patients time to be in queues, remote access, faster appointments, symptoms check-up, live chat or bot chat, and further consultation to achieve the desired result increasing the life cycle of patients.

8. Challenges

Implementation of precision medicine is still a challenge to build evidenced-based clinical sequencing, hence, will require more research at the national and global level for researchers on the same portfolio to optimize the platform. Due to the absence of IT infrastructure, and lack of ability to standardize the data analytics and system precisely eliminating the biased output, translational healthcare, digital technologies, and standard policy procedures with common objectives to support the adoption and integration of precision medicine. The reproducible evidence to implement and translate precision medicine in clinical use and policies would help serve the purpose (Ginsburg & Philip, 2018).

Unfortunately, one size fit for all medications has been approved based on the large clinical trials for traditional medicines. But personalized medicine to integrate in practice will always require the evidence-based gold standard. Therefore, it enforces different rules to understand the accurate diagnosis for prediction of disease risk, the prognosis of disease, and for using target therapeutics. Implementation of policies would clearly define the need for standards in the context of applying therapeutics use to avoid unnecessary adverse reactions (Ginsburg & Philip, 2018).

i. **Regulatory approaches:**

A balanced approach should be adopted to fill the current gaps among diagnostics, drug discovery, and economic evaluations of precision medicines. The patient is the consumer and participant in the research projects; hence, the patient's engagement and trust are important. The participant should be provided with informed consent to ensure their privacy and beneficial outcomes.

Participants (consumers -healthy individuals and patients), service providers, third-party service providers, payers, governments, and regulators are the valued stakeholders to be considered in this process, and their successful contribution would, certainly, improve the quality of life, quality of medical care, efficiency and efficacy towards clinical care and cost, in coming future (Ginsburg & Philip, 2018).

The determination of regulatory science standards, validated protocols, and research methods, right references are the urgent requisite to be incorporated in the regulation of personalized medicines in healthcare, especially in terms of test validity of sequencing methodology platforms, are the utmost requirements to be implemented into the regulatory system. Therefore, it is still a challenge to fit personalized medicines into standard care.

The larger clinical trials in routine practice are conducted in larger cancer centers and hospitals. However, in the case of personalized treatments, there would be gaps between lab studies and conducting clinical trials by appointing the group population. Therefore, the treatments to be used outside the clinical trials might/ might not work precisely (American Cancer Society). To determine the prediction of cancer risk might not be related to the family history/ or there would be variability in the testing regimen. During cancer treatment, a frequent change in the gene and protein profile might not change the treatment regimen. There will be a concern for the involved cost of regular biomarker testing and treatment against particular cancer.

Although the personalized medicine practice is underway, but some issues, alongside regulatory gaps, are remained such as intellectual property rights, data biases, patient privacy, reimbursement policy (if available for some patients), and confidentiality is the commonly known challenges (Vogenberg et al., 2010).

ii. **Intellectual property Rights**: Intellectual property rights are always influenced by Innovations and investments. It is imperative to patent those genes-related technologies, which would likely produce repeatability and reproducibility confirmation after the initial tests.

iii. **Confidentiality**: Obtaining the patient's consent who is taking the gene therapy, and provide to the third party using AI and machine learning for genetic algorithms. Therefore the "Consent" obtained from patients should be used as of prominent concern by the third-party service provider.

In 2008, the genetic information non-discrimination act (GINA) was passed to minimize the patient's highest concern of having their information misused by employers or insurers.

iv. **Differentiation in data**: The diagnostic data of genomics and next-generation sequencing data for further analysis require an intensive computer processing system, which is the biggest challenge.

Interdisciplinary cooperation is needed from all experts in medicine, oncology, computer processing & AI, etc.

Prediction of disease risks based on genetic data algorithm should be comparable with other human populations (from different geography, race, and environment) to get rid of genetic bias in decision making.

The human genome roughly has appx. 30,000 errors, will not help easily to attain fidelity in the sequences and can become a hassle in accurate disease prediction. These unexpected variations in the genome-producing gaps would remain a question mark in implementing the technology for wider use.

9. New Opportunities

Early screening tests lower the risks for specific types of cancer or auto-immune disorders. Genetic, molecular, and genomic tests are commonly used terms in regular practice by healthcare providers (American Cancer Society).

Cancer Diagnosis is carried out by:

- Tumor testing, tumor genetics, biomarker, and sub-typing testing.
- Genomic testing, genomic profiling, and genomic sequencing.
- Molecular testing, Molecular profiling.
- Somatic testing.
- Next-generation Sequencing etc.

Two types of treatment are most often used in precision medicines – i) Targeted therapy for cancer cells based on a particular marker, ii) Immunotherapy to boost the immune system against the cancer cells.

The most common cancers where precision medicine is being applied are as colorectal cancer, breast cancer, lung cancer, leukemia, lymphoma, melanoma, esophageal cancer, stomach cancer, ovarian cancer, and thyroid cancer.

10. Future Prospects

The study of genetic variations, mutations through infections and non-communicable diseases, epigenetic modifications, specifically targeted medicines, development of immunocompromised conditions, etc. are the fields that will take the lead in foreseeable future. Health information technologies

to integrate with clinical and healthcare data systems can be intensified by providing incentives through governments. Through digital healthcare exploration, direct-to-consumer testing, and efficient outcomes from digital apps. will provide the benefit to a larger population even in remote areas saving time and extra cost. Participant-centered policies, legislations, and government initiatives could lead to implementing the process. Standardization of precision medicines via ground breaking research initiatives, clinical practice, and medical education including individual care right from the risk prediction, early treatment, and final recovery.

i. **Role of pharmacogenetics and pharmacogenomics in resolving the individual variables:** Quality healthcare management in the community could save millions of dollars, by utilizing efficient and effective genetic & molecular testing to control the disease to develop and even therapeutic dosing. Genetic testing is a fairly new technology not mature enough to deliver the expected results for every type of disease. Apart from genomics, there is a dire need to expand the research on proteomics, metabolomics, and microbiome analysis to calibrate the real status of disease conferring the elimination of interfering biases. The other environmental attributes including climate, diets, individual behaviour, etc. should be taken under consideration to prepare the prediction maps for the risks involved in the disease occurrence.

   Using multi-OMICS biomarkers could provide more relevant specifications than taking a monogenic biomarker. But there are still gaps in OMICS capacity of data integration, processing, and interpretation. Data standardization & development of central infrastructure for public databases for multi-OMICS data is yet to be implemented (Menyharta & Gyorffya, 2021).

   Healthcare planning for each individual including comprehensive genomic testing, multi-OMICS testing implementation, medical precision test model, companion test and therapeutics application model, theranostic and radio theranostic model, genome database planning (secured storage and sharing of data with the third party), digital healthcare model, etc. are the practical strategies to be integrated into the complex system of precision medicines.

   The ultimate goal of precision medicine is early diagnosis of communicable and non - communicable diseases and their risks, early disease prevention, and treatment with targeted safe drugs with no side effects to increase the healthy life cycle of patients for better patient stratification with an efficient personalized approach.

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