Review Article

PRECISION MEDICINE AND CLINICAL PHARMACISTS

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ABSTRACT

The term "bedside pharmacist" also applies to clinical pharmacists. Pharmacists are in a position to take the lead in pharmacogenomic testing, clinical interpretation of data, and recommendations for individualized medication therapy because pharmacogenomic testing can offer patient-specific predictors for drug response. There are career paths for pharmacists in both inpatient and outpatient settings, including managing clinical pharmacogenomics consultation services and teaching families and patients about pharmacogenomic screening. Therefore, clinical pharmacists play a crucial role in improving lives through proper medical management. The pharmacy curriculum includes coursework that offers opportunities to gain knowledge and skills in pharmacogenomics. These opportunities also extend to postgraduate education (such as residencies, fellowships, and continuing education). The Clinical Pharmacy Advocacy Group emphasizes the need for improved training for chemists in practice as well as students to take precision medicine into account. This review elaborates on the scope of precision medicine, its applications, and the role of a clinical pharmacist in advocating this practice.

***Key words*:** Clinical pharmacist, precision medicine, oncology, pharmacogenomics

The concept of "precision medicine" has gained popularity in recent years, owing to scientific and political perspectives. Despite its popularity, it is unclear what it means and how it differs from other popular concepts such as "stratified medicine," "targeted therapy," or "deep phenol-typing." Commonly used definitions focus on patient stratification, also known as a novel taxonomy, and are created using large-scale data sets that include clinical, lifestyle, genetic, and additional biomarker information, thereby going beyond the traditional "signs-and-symptoms" approach. While these points are important, the description raises several problems. When, for example, does precision medicine begin? In what ways can patient classification translate into improved medical care? And, as implied, is precision medicine the end-point of a novel classification of patients, or is it part of a larger whole? Furthermore, are our pharmacists' important members of the precision medicine clinical care team? [1].

Personalized medicine is a more traditional concept that is frequently used interchangeably with precision medicine. It aims to use therapies or prevention techniques that are specific to a person's disease process or symptoms [2]. Treatment procedures utilized a one-size-fits-all framework in which all individuals presenting with a comparable constellation of symptoms received the same treatment. This practice has led to a reasonable desire for more exact forms of diagnosis and treatment, allowing patients with specific symptoms to receive more individualized care. In many ways, communicable disease management has long been congruent with precision medicine goals, including identifying causal organisms and building data warehouses to drive particular treatments for infections. Infectious illness management has integrated technology over time to acquire a better understanding of resistant organisms and to safeguard people [3].

Personalized medicine then aims to incorporate technology with medicine to develop a data ecosystem capable of better identifying and treating a patient's ailment. This strategy intends to integrate clinical characteristics and biological details, from imaging to testing in laboratories (including -omics data) and health records, in a seamless manner. The reasoning behind this is to create an entirely novel classification of human disease based on molecular biology. The National Council Report of 2011 has implied that this will lead to better diagnosis, treatment selection, and novel therapies [4]. Precision medicine has also had an impact on

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non-communicable disease therapy. Notionally, precision medicine approaches will help to inform and improve disease taxonomy, leading to greater specificity about the pathogenesis of complex conditions such as cancer, heart disease, and overweight and obesity, as well as a paradigm shift in potential therapeutic interventions that maximize disease treatment while minimizing adverse events [5]. Although many consider precision medicine to be one of the most exciting advancements in medicine, it has also generated important problems at multiple levels. Many of these concerns relate to what Kimmelman and Tannock refer to as the 'paradox of precision medicine'. Interestingly, ambiguity appears to be a significant feature of precision medicine in practice [6]. With the advent of various treatment-related threats, it is important to identify the role of precision medicine in treatment practice [7]. Clinical pharmacists play an important role in identifying various problems within the treatment regimens of a patient and could be pivotal in implementing precision medicine strategies [8].

With this backdrop, we must fully understand the potential of precision medicine and its effectiveness in treating various diseases using a customized approach.

METHOD AND MATERIALS

Precision medicine and the epigenetic landscape of various diseases

The metabolic condition with the fastest-rising incidence in the world, type 2 diabetes mellitus, is linked to epigenetics, according to groundbreaking studies conducted over the past few decades [9]. Importantly, these investigations found epigenetic alterations in the pancreatic islets, adipose tissue, skeletal muscle, and liver of people with type 2 diabetes mellitus, including altered DNA methylation [10]. Since epigenetic changes have been linked to non-genetic factors that influence the risk of type 2 diabetes mellitus in healthy persons, including obesity, a poor diet, physical inactivity, aging, and the intrauterine environment, epigenetics is likely also a factor in the development of type 2 diabetes mellitus. Additionally, the epigenome in human tissues is impacted by genetic variables linked to type 2 diabetes mellitus and obesity [11]. A notable finding of causal mediation analysis was the identification of DNA methylation as a potential mediator of genetic correlations with metabolic characteristics and disease. Translational studies conducted in the last few years have found blood-based epigenetic markers that may be further refined and used in precision medicine to enable patients with type 2 diabetes mellitus to obtain the best care possible and to identify people at risk of problems [12].

The etiology of lung disorders is influenced by both genetic predisposition and environmental risk factors. Epigenetic mechanisms indicate possible biological pathways that could close this gap [13]. There is growing evidence of abnormal epigenetic marks, primarily DNA methylation and histone modifications, which mediate reversible alterations to the DNA without changing the genomic sequence, in individuals with COPD, asthma, and pulmonary arterial hypertension. MicroRNAs and post-translational processes may have a role in the development of diseases and be controlled epigenetically. Thus, peripheral blood, sputum, nasal and buccal swabs, or lung tissue may be able to detect novel disease pathways and possible biomarkers [14]. Additionally, environmental exposures may have an impact on DNA methylation during the early stages of fetal development, which may then affect an individual's eventual susceptibility to COPD, asthma, and pulmonary arterial hypertension [15]. Modeling epigenetic variability in a network framework rather than as individual molecular abnormalities offers insights into potential molecular pathways underlying the pathogenesis of COPD, asthma, and pulmonary arterial hypertension thanks to advancements in omics platforms and the use of computational biology methods. Clinical applications for epigenetic alterations as non-invasive pulmonary disease indicators are possible [16]. To further improve the primary prevention of lung diseases and their subsequent clinical management, network analysis of epigenomic data combined with molecular tests may help to elucidate the multistage shift from a "pre-disease" to a "disease" state.

Throughout the natural course of tumor formation, epigenetic abnormalities such as aberrant covalent histone modifications and DNA methylation deficiencies are selected for [17]. Changes are detectable in early initiation, progression, and eventually recurrence and metastasis. It is becoming more clinically relevant to discover these markers and use them to categorize patient populations at risk, improve diagnostic standards, and provide prognostic and predictive indicators to help with treatment choices [18]. A great potential to change therapy paradigms and offer new therapeutic alternatives for patients whose cancers have these aberrant epigenetic alterations is also presented by the targetable nature of epigenetic modifications, opening the door to novel and personalized treatments [19]. Due to its stability and comparatively simple testing, DNA methylation has been demonstrated to be quite useful in therapeutic settings. Therefore, both precision medicine and epigenetics go hand in hand while working on the treatment of cancers.

Precision medicine and cancer treatment

The rapidly developing amount of information regarding the roles of genetics and the immune system in cancer has allowed for the creation of medicines that target specific molecular abnormalities or other biologic traits, such as those involved in immune suppression. However, genomics has revealed a convoluted truth about malignancies that necessitates a

significant shift in the therapy paradigm: away from tumor-type-centered treatment and towards gene-directed, histology-agnostic treatment that is tailored to each patient based on biomarker analyses. The rise of precision medicine trials with creative design reflects this paradigm shift [20]. Next-generation sequencing of advanced malignancies has revealed that genomic changes do not neatly fall into categories defined by the tumor organ of origin. Furthermore, metastatic tumors have extraordinarily complicated and distinct genetic and immunological landscapes [21]. As a result, to target cancers with "precision," treatment must be personalized.

Although immunotherapy has a limited ability to treat ovarian cancer, it may be more effective if sensitive/resistant target treatment subpopulations are assessed based on tumor biomarker stratification. Tumor mutation burden, PD-L1, tumor-infiltrating cells, homologous recombination deficit, and neoantigen intratumoral heterogeneity are among these markers. The use of these biomarkers to determine suitable candidates is one of the next directions in the treatment of ovarian cancer [22]. Furthermore, precision medicine and targeted therapies have a long history of use in the treatment of breast cancer and continue to hold promise for more specialized and personalized care. Targeted medicines and precision medicine continue to push the management of breast cancer towards more individualized care, from the discovery of endocrine and HER2-targeted medications to multigene arrays in chemotherapy for more specific patient selection, to radionics and genetic subtyping [23].

Precision medicine has emerged as a key concept in the treatment of biliary tract tumors (BTCs). Although the prognosis remains dismal, advances in molecular characterization, as well as the approval of numerous targeted medicines by the US Food and Drug Administration, have altered the therapeutic landscape of advanced BTC. Chronic inflammation of the liver and biliary tract, independent of anatomical subtype, is a hallmark of BTC oncogenesis [24]. BTC subtypes correspond to various molecular properties, making BTC a molecularly diverse group of tumors. Up to 40% of BTCs have a potentially targetable molecular aberration, according to the National Comprehensive Cancer Network guidelines, and molecular profiling is recommended for all patients with advanced BTC [25]. The use of circulating tumor DNA, immunohistochemistry, and next-generation sequencing for biomarker-driven management and molecular surveillance of BTC is expanding. Improving outcomes for non-targetable tumors utilizing biomarker-agnostic treatment is also a focus, and combinational treatment techniques such as immune checkpoint blockade plus chemotherapy have promise for this patient group [26].

With the development of precision medical tools, research, and treatments, the diagnosis and treatment of diseases such as cancer are getting more accurate and specialized. Diagnostic tests can determine particular, individual information from each patient and direct clinicians to a more accurate treatment plan by reaching down to the cellular and even sub-cellular level. With this increased knowledge, researchers and providers may better assess the efficacy of medications, radiation, and other therapy, resulting in a more accurate, if not more optimistic, prognosis. New methodologies, equipment, materials, and testing methods will be necessary as precision medicine becomes more entrenched (Figure 1).

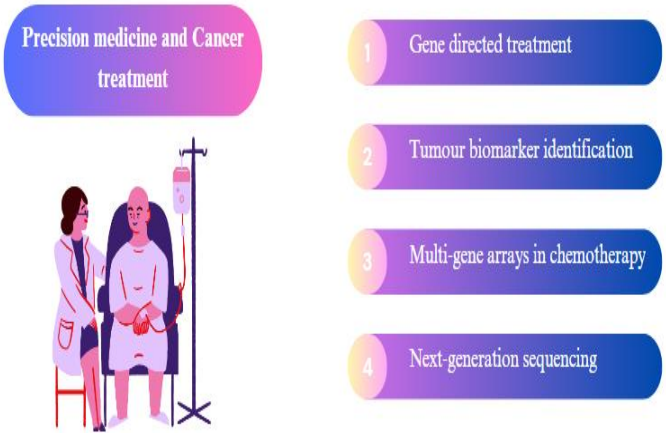

Figure 1 – Evolving precision medicine techniques for cancer treatment

Ethical Issues in precision medicine

Precision medicine bases disease treatment and prevention on a patient's unique gene, environmental, and lifestyle variations. It is a logical continuation of existing research that profiles and identifies therapeutically useful markers utilizing multi-omics-based laboratory tests. In essence, the objective is to gather genotypic and phenotypic data to guide precise and efficient patient therapy. Typically, significant and difficult testing would be needed before any practical clinical applicability to patients. Precision medicine's integration into healthcare will heavily rely on clinical laboratories. Reflex testing based on algorithms or specific case judgments is frequently required for laboratory work. Laboratory and clinical data will be integrated to provide the basis for interpretation [27]. The clinical laboratory must become a more active collaborator in clinical treatment as a result of both indirect and direct transmission of test data to patients.

Large databases of research and clinical data, as well as numerous multi-omics-based laboratory experiments, serve as the foundation for both research and the emerging clinical practice of precision medicine. This situation may lead to moral conundrums involving justice, autonomy, additional findings, consent, and privacy. Precision medicine's requirements must be balanced with the idea that patients' interests come first, which leads to conflicts that frequently can go unresolved.

In precision medicine, data collection and analysis go further than is required to look into specific clinical conditions [28]. Over time, the data gathered and research objectives frequently change. This makes it difficult to gain informed consent based on proper counseling. Some of the issues might be resolved with flexible permission that can alter over time. In other circumstances, assumed consent will be regarded as sufficient [29].

Data profiles can be used to identify people in anonymous databanks, which raises serious privacy concerns in databanks used for precision medicine. How can data access be restricted to preserve privacy without jeopardizing support for precision medicine, and under what circumstances should this be permitted? In this area, we are still in the early phases of determining the appropriate standards and stakeholder ratio [30]. Individuals must face just a small amount of information risk, or no appreciable additional risk, as a result of having their data processed in the databanks.

Fairness without discrimination for all is the foundation of justice. The key concern is how to deliver the benefits and advancements of precision medicine while maintaining equal access to healthcare. Precision medicine requires significant clinical and research work. Given the disparities in genetic makeup, habitats, and lifestyles, research data are typically generated from wealthy communities, and results may not apply to other less fortunate people [31]. Clinical testing on individuals will be costly, even though greater precision medicine effectiveness may occasionally result in cost savings. In this context, individual rights present one challenging ethical conundrum [32]. Can the state mandate that people adopt precision healthy lives in exchange for providing equitable access to precision medicine?

Precision medicine is an evolving field that raises both professional and patient expectations. Instead of being arrogant, the field should carefully manage expectations and avoid making promises that it cannot possibly keep.

Where does the clinical pharmacist fit?

Precision medicine has been used in clinical pharmacy practice for many years. As part of standard clinical practice, drug selection and dosage based on patient-specific clinical parameters such as age, weight, renal function, drug interactions, plasma drug concentrations, and nutrition are expected. While epigenetics and pharmacomicrobiomics are still mostly studied in the academic arena, clinical translation of these concepts into clinical practice is anticipated in the future. Pharmacogenomics is one of the more recent precision medicine concepts to be used in clinical treatment.

The following sections elaborate on the role of pharmacists or clinical pharmacists in the field of precision medicine. Chemists must be involved in these advancements as precision medicine research and its clinical applications continue to grow to provide patients with the best, most individualized medication regimens.

Adverse events in children are frequently unanticipated and patient response to pharmaceutical therapy is very diverse. Some patients might experience major side effects from conventional doses of a particular medication and need a lower dose, whilst other patients might need a significantly higher dose of the same medication to get a similar exposure and, hopefully, an analogous therapeutic response [33]. A clinical pharmacist's understanding of how differences in a single gene, gene networks, and/or the entire genome (pharmacogenomics) may affect drug responsiveness has dramatically improved over the past two decades. The adoption of pharmacogenomic testing in inpatient treatment is also made possible by growing genetic test availability in clinical laboratories (including direct-to-consumer testing) and falling analytical costs. Therefore, the promise of precision medicine is gradually making its way into clinical treatment [34]. Pharmacogenomics now unquestionably plays a significant role in medication development, regulation, and prescription. Pharmacogenomics is proving to be a potential clinical tool for pharmacists who can use it to create individualized treatment plans for children [35]. By choosing the right medication at the right dosage for the right patient, pharmacists can lower their risk of adverse drug events and/or treatment failure.

Since the original position statement's publication in 2011, the roles that pharmacists play in clinical pharmacogenomics have become more clearly defined, but there are still many opportunities for our profession and practice specialty to promote and establish the role of pediatric pharmacists in pharmacogenomics [36]. Pediatric pharmacists routinely recommend medications and dosages as members of the multidisciplinary team based on a variety of clinical considerations, such as a child's age, physiology, concurrent medications, and diagnosis. Knowing a patient's pharmacogenomic data, including the ontogeny of various drug-metabolizing enzymes, transporters, and receptors, increases the probability that a prescription will be chosen for the person that is both safe and effective. This information can be used by the pediatric pharmacist to prevent therapeutic failures and proactively lower the likelihood of unwanted adverse medication events [37]. Based on their education and expertise, pediatric pharmacists with a working grasp of pharmacogenomics are perhaps the most appropriate members of the medical team to prescribe pharmacogenomic testing and to provide an interpretation of results in the context of a child's pharmacotherapy. Additionally, pediatric clinical pharmacists frequently participate in pharmacy and therapeutics committees and collaborate closely with pharmacy IT support [38]. In these positions, they are in a good position to suggest

gene/drug pairings for institutional use and to develop clinical decision support tools specifically for prescribing doctors, physician assistants, and nurse practitioners.

Future Direction of Precision Medicine in Pharmacotherapeutics

Precision medicine is a new method for treating and preventing diseases that take into account each person's unique genetic makeup, environmental factors, and way of life. This method will enable medical practitioners and academics to forecast treatment and preventative plans for a condition that a specific person is experiencing more precisely. This strategy will alter clinical pharmacy practice in several significant ways. The link between pharmacogenomics and pharmacodynamics, pharmacogenomics and pharmacokinetics, and pharmacogenomics and pharmacodynamics is the subject of numerous studies that are now being conducted. To further comprehend the uniqueness of therapy response, more recent studies like metabolomics and epigenomics are being done. This new information will be crucial for managing highly effective, risk-free medication in the future.

CONCLUSION

Despite several examples being developed in various fields of pharmacy and medicine, the application of precision medicine in clinical practice is still largely constrained by factors like cost and accessibility of assays. Precision, personalized patient care could become a clinical reality thanks to developments in the "omics" sciences and the rising accessibility of health data.

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