

**MIXED METHODOLOGICAL EXPLORATORY
STUDY OF KNOWLEDGE, ATTITUDE AND
PRACTICE AMONG HEALTHCARE
PRACTITIONERS ON THE APPLICATION OF
PRECISION MEDICINE IN CANCER
PATIENTS AT LAHORE, PAKISTAN**

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UNIVERSITI SAINS MALAYSIA

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by

NAEEM RIDA

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for the Degree of
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LIST OF ABBREVIATIONS

ALK	Anaplastic Lymphoma Kinase
AMR	Anti-microbial Resistance
ANAI	Alaska Native and American Indian
ASCO	American Society of clinical oncology
BRCA	Breast Cancer Gene
CME	Continuous medical education program
CPE	Continuing Professional Education
eGFR	Estimated Glomerular Filtration Rate
ESMO	European Society of medical oncology
FDA	Food and Drug Administration
GDP	Gross Domestic Product
HCC	Hepatocellular Carcinoma
HCP	Healthcare Practitioner
HCS	Healthcare System
HEC	Human Ethics Committee
HER-2	Human Epidermal Growth Factor Receptor 2
HGP	Human Genome Project
IARC	International Agency for Research on Cancer
IFA	Individual Financial Assistance
LMIC	Lower-and-Middle-Income Country
MTB	Molecular Tumor Board
NCD	Non-communicable Disease
NGO	Non-Government Organization

NRC	National Research Council
OCE	Oncology Center of Excellence
PAEC	Pakistan Atomic Energy Commission
PCAST	President's Council of Advisors on Science and Technology
PD-11	Programmed Cell Death Ligand-1
PD-L1	Programmed Cell Death Ligand
PGx	Pharmacogenomics
PIK 3CA	phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha
PM	Precision Medicine
PMC	Personalized Medicine Coalition
PMI	Precision Medicine
RCT	Randomized Controlled Trial
SACGHS	Secretary's Advisory Committee on Genetics, Health, and Society
SMOP	Society of Medical Oncology Pakistan
TCA	Thematic Content Analysis
TDM	Therapeutic Drug Monitoring

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**KAJIAN EKSPLORATORI METODOLOGI BERCAMPUR MENGENAI
PENGETAHUAN, SIKAP DAN AMALAN PENGAMAL PENJAGAAN
KESIHATAN TERHADAP APLIKASI PERUBATAN KEPERSISIAN
DALAM KALANGAN PESAKIT KANSER DI LAHORE, PAKISTAN**

ABSTRAK

Perubatan kepersisian (PM) telah membawa kemajuan revolusi di dunia barat terutamanya bagi rawatan kanser. Ia membolehkan pengamal penjagaan kesihatan merawat setiap pesakit mengikut penemuan genetik pesakit secara individu dengan mengambilkira ciri-ciri fisiologi dan persekitaran. PM merupakan pendekatan rawatan yang agak baru secara relatif di Pakistan. Oleh itu, adalah amat penting untuk meninjau dan melihat tahap pengetahuan, sikap dan cabaran yang dihadapi oleh pengamal penjagaan kesihatan terutamanya doktor dan ahli farmasi yang merupakan tulang sistem penjagaan kesihatan. Rekabentuk pencarian jujukan kaedah bercampur telah digunakan bagi tujuan ini yang melibatkan fasa I- kajian kualitatif dan fasa II- kajian kuantitatif. Populasi sasaran adalah doktor dan ahli farmasi yang bekerja di hospital di Lahore, Pakistan. Temuramah bersemuka secara kualitatif dijalankan dengan menggunakan persampelan bertujuan bagi merekrut peserta. Atas persetujuan peserta, temuramah semi struktur ini direkodkan audionya, ditranskrip secara verbatim dan dianalisa secara tematik. 14 doktor dan 11 ahli farmasi ditemuramah memandangkan penemuan data telah dicapai. Kajian kuantitatif merupakan satu tinjauan kajian rentas berdasarkan penemuan fasa I. Ia mensasarkan 165 peserta menggunakan teknik persampelan mudah. Data yang diperolehi kemudiannya dianalisa menggunakan SPSS v22. Daripada temuramah yang dijalankan, dapat disimpulkan bahawa walaupun

berhadapan dengan praktis dan sumber yang terhad termasuk krisis kewangan dalam sistem penjagaan kesihatan, pengetahuan dan sumber pembangunan kemahiran yang terhad, profesional kesihatan mempunyai pengetahuan yang mencukupi mengenai penggunaan PM terutamanya bagi rawatan kanser. Mereka sangat berminat dan menunjukkan kesanggupan serta sikap yang optimistik untuk belajar dengan lebih mendalam mengenainya. Mereka berharap pemberian sokongan kewangan, peralatan diagnostik dan penghasilan ubatan lokal dalam negara dengan kolaborasi antara kerajaan, syarikat farmaseutikal dan pemegang taruh di dalam sistem akan memudahkan pembekalan PM. Keputusan kajian kuantitatif menunjukkan pengetahuan yang boleh diterima serta sikap dan praktis yang baik dalam kalangan peserta terhadap perlaksanaan PM dalam negara ini yang sama bandingnya dengan penemuan dalam fasa kualitatif. Tiada perbezaan yang signifikan dalam pengetahuan, sikap dan praktis didapati dalam kalangan doktor dan ahli farmasi semasa fasa kuantitatif. Walaubagaimanapun, didapati pengamal penjagaan kesihatan yang mempunyai kelayakan daripada institusi swasta menunjukkan sikap yang lebih baik. Dan mereka yang bergraduasi sebelum tahun 2002 menunjukkan praktis yang lebih baik jika dibandingkan dengan kumpulan yang lain. Kesimpulannya, kajian ini telah menunjukkan dengan jelas keperluan untuk memudahkan pengamal penjagaan kesihatan dengan pengetahuan yang lebih baik dan memperbaiki sikap mereka bagi memajukan lagi praktis PM di Pakistan. Pemberian bantuan kewangan, alatan diagnostik dan pengilangan ubat local dapat memastikan peluang rawatan terbaik kepada setiap populasi Pakistan.

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CANCER PATIENTS AT LAHORE, PAKISTAN**

ABSTRACT

Precision medicine (PM) is bringing revolutionary advancements allowing healthcare practitioners to treat every cancer patient according to the patient's genetic findings. But it is relatively a new treatment approach in Pakistan. So, it is important to explore and look into the level of knowledge, attitude, and challenges faced by health practitioners for its practice in the country. A sequential exploratory mixed-method design was adopted for this purpose, comprising of a phase-I qualitative study and a phase-II quantitative study. Targeted population was oncology physicians and pharmacists working in oncology hospitals in Lahore, Pakistan. Qualitative face-to-face interviews using purposive sampling were opted to recruit participants. Upon participant's agreement, semi-structured interviews were audio-recorded, transcribed verbatim and thematically analyzed. 14 physicians and 11 pharmacists were interviewed altogether keeping in view the saturation of data reached. Quantitative study was a cross-sectional survey based upon results from phase I. It targeted 165 participants using the convenience sampling technique. Data obtained was then analyzed using SPSS v22. From interviews, it was concluded that despite having constricted practice, financial crisis in the health care system and limited knowledge and skill development sources, healthcare professionals have sufficient knowledge on precision medicine use, especially for cancer treatment. They showed their willingness

and optimistic attitude to learn more about it. They were hopeful that the provision of financial support, diagnostic equipment, and manufacturing of local medicine in the country with the collaboration of government, pharmaceutical companies, and different stakeholders of the system can facilitate PM provision. Results of the quantitative study showed acceptably well knowledge, positive attitude, and good practice among participants towards the implementation of PM in the country. No significant difference in knowledge, attitude, and practice was found among physicians and pharmacists during the quantitative phase. However, it was seen that healthcare practitioners qualified from private institutes showed better attitude. And those who had graduated before the year 2002 showed better practice as compared to other groups. In conclusion, the findings clearly expressed the need for facilitating healthcare practitioners with better knowledge and improving their attitude to bring advancements in the practice of PM in Pakistan. Provision of financial support, diagnostic equipment, and manufacture of drugs at the local level can ensure the best treatment opportunities for every population in Pakistan.

CHAPTER 1

INTRODUCTION

1.1 Background of the study

In recent years, precision medicine (PM) has shifted the treatment strategies, significantly enhancing the healthcare landscape. This is reflected by the more accurate and timelier prognosis with more cost-effective treatment plans. Consequently, the science of PM and targeted treatment has superseded the conventional “hit and trial” approach (Kanesvaran, 2017).

PM introduces genetically tailored techniques that advance both diagnosis and therapeutically targeted treatment (Ashley, 2016). It offers a personalized treatment approach that allows healthcare practitioners (HCPs) to choose suitable diagnostic tools and therapeutic intervention based on genetic findings. It is a molecular-level treatment that decides a person’s treatment according to unique genomic profile, considering both physiological and environmental characteristics (Porche, 2015; Ramaswami, Bayer, & Galea, 2018) (Ginsburg & Phillips, 2018).

Proving to be the most efficient treatment method, PM has succeeded in minimizing unnecessary diagnostic tests and therapeutic interventions while concurrently enhancing the overall quality of life in recent years. It has particularly advanced the prognosis of diseases influenced by both environmental factors and genetics (Ginsburg & Phillips, 2018; Haque, Islam, Sartelli, Abdullah, & Dhingra, 2020). PM has made significant contribution to both research and practice in cancer therapy (Drake, Knight, Harrison, & Søreide, 2018).

PM has witnessed great success in the Western world by contributing significantly to various aspects of healthcare (Bilkey et al., 2019; Boccia et al., 2019; Gameiro, Sinkunas, Liguori, & Auler-Júnior, 2018; Hamburg & Collins, 2010; Lee et al., 2021; McGrath & Gherzi, 2016; Mini & Nobili, 2009) as compared to limited adoption in lower- and middle-income countries (LMICs) (Haque et al., 2020; Rehman, Awais, & Baloch, 2016; Stewart et al., 2016). Besides providing the best treatment strategies, PM gradually broadened and now covers a number of exceptional services in the Western world by putting together knowledge of biomarkers, new drugs discovery and their benefits on healthcare, shared decision-making concept and treatment consideration based on extensive research.; However, due to limitations of resources like financial crisis, lack of knowledge and education, limited practice opportunities and shortage of expertise, healthcare system in LMICs cannot afford these technology-based facilities. (Kosorok & Laber, 2019; Stewart et al., 2016). However, PM in LMICs is more practiced for infectious diseases like tuberculosis than for NCDs like cancer (Cox, Hughes, Black, & Nicol, 2018; Drake et al., 2018).

Healthcare practitioners (HCPs) serve as crucial intermediaries between patients and treatment facilities, with patients relying on their HCPs for optimal treatment plans. HCPs play a pivotal role in ensuring patient adherence to treatment plans and medications, contributing not only to the patient's well-being but also to the overall effectiveness of the healthcare system (Boulware, Cooper, Ratner, LaVeist, & Powe, 2016). For cancer patients, it is especially challenging to bear the sufferings of treatment. Patient needs mental and emotional support and empathy along with physical treatment from his provider to trust his treatment plan especially when the plan is not fully established (Nicolai et al., 2016). For this purpose, healthcare practitioner's point of view is considered valuable.

PM is an important treatment options that have yet not been thoroughly studied and implemented in Pakistan. Health practitioners in Pakistan still believe in classical cancer treatment plans (S. M. Ali, Adnan, & Ali, 2021). Therefore, exploring more about the knowledge and attitude towards PM practice and barriers faced by healthcare practitioners (HCPs) for its implementation will help to identify the limitations faced by the HCPs and find areas that need to be further improved to implement PM and further strengthen Pakistan's healthcare system. This study has been planned in Pakistan to sketch its current state and future prospects in the country.

1.2 Concept of Precision Medicine

The concept of tailoring treatment is not new but centuries old. As Hippocrates mentioned, *"It is more important to know what sort of person has a disease than to know what sort of disease a person has"*. He presented the idea of evaluation on the basis of age, physique, and season when prescription was done to individualize the therapy for every patient. This proved to be the simplest yet most comprehensive plot to define PM (Kohler, 2018) (Bardakjian & Gonzalez-Alegre, 2018; Kosorok & Laber, 2019). During twentieth century, the advent of genomic revolution in the era of one-size-fits-all treatment agreements brought the concept of precision medicine (PM) in light. Previous approaches are based on a standardized treatment plan according to average personal conditions linked to the population. It may be successful in treating some diseases but not all patients can be treated by using the same approach.. (Sur, 2019) (Bardakjian & Gonzalez-Alegre, 2018; Karim Awad et al., 2020). With the arrival of information-technology, a much easier approach to accessing scientific information and data; the health sector took advantage in terms of research and

healthcare delivery (Ginsburg & Phillips, 2018; Saria & Goldenberg, 2015; Ta, Cayabyab, & Coloso, 2019).

The term PM was introduced by Clayton Christensen in 2008 (Zhang, 2015) as a precise diagnostic tool for disease care with pre-owned perception in terms of personalized preventive and treatment strategies. But its concept is modified in terms of recent advancements in precise genomic sequencing providing individualized treatment based on genetic parameters and clinical and behavioral analysis that distinguishes patients with similar clinical presentations to provide outcomes with minimum side-effects, re-occurrence chances. and economic hardships (Hodson, 2016; Sur, 2019; Zhang, 2015) (Collins & Varmus, 2015; Desmond-Hellmann, 2012; Jameson & Longo, 2015; Karim Awad et al., 2020; Koenig, Fuchs, Hansen, von Mutius, & Kopp, 2017). It has taken into consideration every differential factor that can help individualize treatment (Kohler, 2018)

PM has made revolutionary advancements in cancer prognosis, diagnosis, treatment, and prevention (Drake et al., 2018) (Ginsburg & Phillips, 2018; Porche, 2015) The notion of precision medicine changed from targeted therapy of a particular organ to targeted molecular therapy concerning about cancer treatment with time. This theory synchronizes best in the case of cancer prognosis (Ramaswami et al., 2018). (Sur, 2019) in his paper subjected Adam L. Cohen's idea of "*Merging genomic and pharmacologic analyses for therapy choice*" to find the most suitable drug according to tumor type based on genetic analysis.

1.3 Definitions of Precision Medicine

The Institute for Precision Medicine, US National Library and Precision Medicine Initiative define PM in almost similar way by connecting individual genetics with environment and lifestyle (Ginsburg & Phillips, 2018; Haque et al., 2020; Ramaswami et al., 2018) US National Library defines PM as “an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person” (Garrido et al., 2018; Haque et al., 2020) The Institute for PM defines PM as “ a medical approach that proposes to prevent and treat disease based upon a person’s unique genetic makeup and their lifestyle habits” (Medicine, 2022) PM is defined by the National Research Council as “the tailoring of medical treatment to the individual characteristics of each patient, classify individuals into subpopulations that differ in their susceptibility, therapeutic interventions can then be concentrated on those who will benefit, sparing expense and side effects for those who will not” (Council, 2011). Meanwhile, President’s Council of Advisors on Science and Technology (PCAST) views PM as “the tailoring of medical treatment to the individual characteristics of each patient to classify individuals into subpopulations that differ in their susceptibility to a particular disease or their response to a specific treatment. Preventative or therapeutic interventions can then be concentrated on those who will benefit, sparing expense and side effects for those who will not” (Qoronfleh, Chouchane, Mifsud, Al Emadi, & Ismail, 2020). In 2016, the “Cancer Moon-shot” program introduced by the President of U.S focused on knowledge of cancer disease and how to deal with it through its treatment, prevention, and precise and early diagnosis with the goal of curing cancer and decreasing its mortality rate in U.S. Cancer Moon-shot program brings the best suitable technology for curing of cancer in U.S and PM is among the best available treatment for

individualized therapy in cancer patients (Kolesar & Vermeulen, 2021; Singer, Jacks, & Jaffee, 2016). The “All of Us” program introduced by the United States as a component of their national research agenda recruited 1 million participants with a similar set of characteristics like lifestyle, environment, and biology to learn their complete genomic structure based on these characteristics with the aims of learning risk factors of a specific disease, figure out the best treatment option for a set of people with same disease background and get knowledge of appropriate technology for treatment purpose. The motto of this movement is to improve healthcare by research (Ginsburg & Phillips, 2018; Health, 2015; Kolesar & Vermeulen, 2021).

1.4 Precision Medicine and Other Similar Terms

Precision medicine is often related to other terms including “personalized medicine”, “targeted therapy”, “genomic therapy”, and “stratified medicine”. However, similarities and differences among these terms are still not completely studied (Koenig et al., 2017). David J. Duffy in his research on perspectives of PM collectively explained all terms coined in different times as PM. All terms are given in table 2.1.: (Duffy, 2016)

Table 1.1 Similar Terms for Precision Medicine

Name/ Term	Year
Pharmacogenetics/pharmacogenomics	1961
Systems medicine	1992
Systems biomedicine	1992
Precision medicine	1997
Personalized medicine	1999
Genomic-era medicine	2000
Predictive, preventative, personalized, and participatory (P4) medicine	2004
Me medicine	2013
P4 systems medicine	2014
Computational systems biomedicine	2015

Unlike personalized medicine which considers patient's genetic makeup with their preferences, PM relates patient's unique genetics with data, analytics, and information obtained from their lifestyle habits for disease treatment and prevention (Desmond-Hellmann, 2012; Ginsburg & Phillips, 2018; Haque et al., 2020).

1.5 Precision Medicine and Pharmacogenomics

Pharmacogenomics also known as pharmacogenetics is the foundation of PM that deals with an individual's genetic response towards a selected drug. It helps in drug selection and/or dose adjustment of medicine by decoding a person's genetic makeup and hence achieving the target of minimal injurious side effects of medication (Mufwambi et al., 2021). American Food and Drug Administration (FDA) approved PGx testing implementation as a basis of PM (Nawaz, Ali, Nadeem, & Rehman, 2021).

A larger population around the world has not been yet considered for genomic research and genome-based treatment (Beans, Woodbury, Wark, Hiratsuka, & Spicer, 2020). PM provides not only treatment options, but it facilitates disease prevention by

working on its etiology. Finding the mechanism of disease through PGx testing narrows down the treatment option by targeting the exact molecule involved in disease spread at an early stage (Ginsburg & Phillips, 2018).

1.6 Healthcare System of Pakistan

Islamic Republic of Pakistan is situated in South Asia (Development, 2022). With a population of 220 million, Pakistan was placed on the list of LMICs in 2020 (F. Badar & Mahmood, 2021; GLOBOCON, 2021) with a 2% annual growth of population and has been ranked as the fifth most populous country in the world. Pakistan shares 2.83% of the total world population.

The Ministry of Health, Government of Pakistan was responsible for addressing the overall healthcare needs of the Pakistani population with a vision to improve the health of all Pakistanis, particularly women and children, through universal access to quality essential health services and ensuring financial protection, with a focus on vulnerable groups, and delivered through resilient and responsive health systems. The spending of the government on health was last recorded in 2019 as only 3.38% of the gross domestic product (GDP), which is substantially low (Development, 2022). Currently, Pakistan's healthcare delivery system is the primary responsibility of provincial governments except for the federally administered areas (WHO, 2022) They have to provide preventive, promotive, and curative services to their population.

Pakistan's health profile is characterized by an unbearable burden of communicable and non-communicable diseases, COVID-19, high fertility, low life expectancy, a young age structure, high maternal and child mortality, high incidence

of infectious and communicable diseases, and wide prevalence of malnutrition especially among children and women. (Nations, 2020)

Healthcare in Pakistan is provided by both public and the private sectors. The private sector caters nearly 70% of the population's healthcare needs due to increased healthcare demands which cannot solely be covered by public healthcare units. About 10% of the population gets covered by government and semi-government organizations through employee "health card" facility (WHO, 2022).

1.6.1 Healthcare System of Lahore

Population of Lahore is 6,310,888. It is the capital and the largest metropolitan city in Punjab province. Lahore is the most populous city in the province and the second largest in Pakistan (Punjab, 2016; WORLDOMETER, 2022). All the health offices of government functionaries are situated in Lahore. There are a total of 60 public healthcare facilities in Lahore. In addition to the public health care facilities there are more than 20 specialized hospitals run by the private sector in Lahore.

1.7 Cancer Prevalence in Pakistan

Non-communicable diseases (NCDs) stand among top 10 mortality and morbidity causes in Pakistan (Rafique et al., 2018) Number of cancer cases have increased exponentially to the alarming situation in the last 25 years due to lack of awareness, lifestyle and environmental factors. (*Health and Nutrition-Pakistan Economic Survey Report*, 2015-16). Pakistan faces 0.17 million cancer cases annually.(Khokhar et al., 2020) As shown in figure 1.1; annual report by Globocan published in March 2021 presented 178,388 new cancer cases with 117,149 mortality

numbers. The mortality rate was inclined towards the female gender. And breast cancer was leading the chart with the highest number of cases (Sung et al., 2021).

Summary statistic 2020			
	Males	Females	Both sexes
Population	113 672 007	107 220 324	220 892 332
Number of new cancer cases	88 015	90 373	178 388
Age-standardized incidence rate (World)	107.0	113.7	110.4
Risk of developing cancer before the age of 75 years (%)	11.5	12.3	11.9
Number of cancer deaths	60 783	56 366	117 149
Age-standardized mortality rate (World)	75.6	72.8	74.3
Risk of dying from cancer before the age of 75 years (%)	8.3	8.2	8.3
5-year prevalent cases	150 048	179 499	329 547
Top 5 most frequent cancers excluding non-melanoma skin cancer (ranked by cases)	Lip, oral cavity Lung Oesophagus Colorectum Leukaemia	Breast Lip, oral cavity Cervix uteri Oesophagus Ovary	Breast Lip, oral cavity Lung Oesophagus Colorectum

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Figure 1.1 Globocan Annual Report on Cancer Prevalence in Pakistan

Several government, private, semi-government, and trust hospitals are contributing to providing treatment to every cancer patient. Pakistan Atomic Energy Commission (PAEC) is playing a huge role in different cities of Pakistan by providing 19 cancer-specialized hospitals (*Health and Nutrition-Pakistan Economic Survey Report*, 2015-16). Other than that Shifa International Hospital-Islamabad, Aga Khan Hospital-Karachi, Quaid-e-Azam International Hospital-Islamabad, Sheikh Zayd Medical Complex-Lahore, Cancer Care Hospital-Lahore, Shaukat Khanum Cancer Hospital-(Lahore, Karachi, Peshawar), Jinnah Hospital-Lahore, Mayo Hospital-Lahore are among the few government and private hospitals who are doing best to facilitate cancer patients.

To maintain a complete record of cancer patients including demographics, type of cancer, and all other requirements, a cancer registry is maintained. It is of 2 types, i.e. hospital-based cancer registry and population-based cancer registry. Both of them are formulated on the basis of standards stated by WHO's International Agency for Research on Cancer (IARC) (D. F. Badar, 2017)

1.7.1 Cancer Prevalence in Punjab and Lahore

According to the cancer registry of Punjab 2021, 7539 neoplasm cases were registered from January 2021 to December 2021. Out of which 1032 benign and 6507 malignant cases were reported with a ratio of 3887: 2620 between females and males. Most frequently reported was breast cancer (SKMCH&RC, 2021) as shown in Figure 1.2.

Study done recently (Khokhar et al., 2020) have reported oppressive burden of population on medical oncologists in Pakistan. Every oncologist is dealing with 1300 to 1500 patients per annum. And the ratio of oncologist to population is calculated as 0.027:100,000. In addition, out of total population of Punjab, only 21.4% of population have access to radiotherapy treatment (Khokhar et al., 2020). Since Lahore is the capital and most facilitated city of Punjab, so people from all around Punjab come to Lahore for treatment of Cancer and hence registry record is maintained in Lahore only (SKMCH&RC, 2021).

Total cases reported	Count	%
Total malignancies reported	6,507	100
Female	3,887	59.74
Male	2,620	40.26
Ten most frequently reported cancers-All age groups, both sexes combined (N=6,507)		
Breast	1,774	27.3
Brain & nervous system	392	6.0
Colon, rectum, & anus	383	5.9
Non-Hodgkin lymphoma	316	4.9
Lip & oral cavity	253	3.9
Leukemia	230	3.5
Urinary bladder	206	3.2
Corpus uteri & uterus	195	3.0
Ovary	168	2.6
Trachea, bronchus, & lung	157	2.4

Figure 1.2 Cancer Prevalence in Punjab (SKMCH&RC, 2021)

1.8 Precision Medicine in Pakistan

Precision medicine is still in its early years of practice in Pakistan and only a few public and private hospitals are practicing it at a limited scale. All of the tests were currently out-source from the US and Europe due to unavailability of testing facility. After obtaining test results medical oncologists and their team work on further treatment in public and private hospitals. In addition, medicine for this purpose is not manufactured in Pakistan and hence it needs to be imported from other countries. This reason makes it more expensive as compared to conventional medicine and hence difficult to be accessed by everyone.

1.9 Research questions

- i. What is the understanding and attitude of physicians and pharmacists on PM?
- ii. What is the current practice of precision medicine provided in Pakistan?

- iii. How prepared are the health practitioner for the practice change from PM implementation in the country?
- iv. What challenges and barriers are faced by HCPs for adopting precision medicine? And what resources can impact patient's life in LMICs like Pakistan?

1.10 Justification of Study

PM for cancer treatment is among those important treatment options that has yet not been thoroughly studied and implemented in Pakistan. Conventional treatment therapies are preferred over it (Rafique et al., 2018). None of the medical or pharmaceutical institutes have a clear stance regarding precision medicine as preventive or treatment strategy. Also, no research is yet conducted on it in Pakistan to know about its practice situation and problems faced in their healthcare setting. Some of research is done on the use of genomic testing (J. Ali & Afridi, 2018; Ilyas et al., 2021; Nawaz et al., 2021) which emphasizes on genetic testing use for accurate results, the need for using genetic testing and the benefits of using it in future. Therefore, it is crucial to explore more about the knowledge of HCPs on PM and their attitude towards its practice and barriers faced by healthcare practitioners (HCPs) for implementation of PM. Working on it will help strengthen healthcare system by endorsing PM as one of the most convenient and easily accessible treatment tools for every individual. In order to understand the implementation status of PM in health sector of one of the countries of LMICs list, study has been planned to exactly sketch its current state and future prospects in Pakistan.

HCPs are most relied on for treatment. They channel the research results in the best possible way by implementing its knowledge in their practice. This practice helps them not only in not providing the best results but also keeps on providing room for improvement with changing needs and evolving times. (Kristensen, Nymann, & Konradsen, 2015) Keeping this thought in view, they need to be mindful of the concept and ways of adopting of PM in cancer prevention and providing treatment according to tumor type. Discovery of interesting hotspots of innovations and variations in the research journey on precision medicine in cancer patients and how physicians and pharmacists are dealing with it in Pakistan can ensure bring new horizon in healthcare practice in Pakistan.

1.11 Significance of Study

- i. Ideas about the knowledge and attitude of HCPs on PM in Pakistan will not just add valuable insights to the existing literature but also help in designing future studies on PM in Pakistan and around the globe.
- ii. This study shall uncover barriers and hurdles HCPs face in PM implementation that have not been explored yet in Pakistan.
- iii. We'll be able to figure out the type of resources needed for its implementation in the country

1.12 Aims and Objectives

- i. To assess the knowledge, attitude and practice of healthcare practitioners on precision medicine and its implementation in Lahore, Pakistan

1.12.1 Specific Objectives covered in the Qualitative phase

- i. To assess the knowledge and attitude of healthcare practitioners including physicians and pharmacists on precision medicine implementation.
- ii. To identify barriers faced by healthcare practitioners in the implementation of precision medicine.
- iii. To outline the role of healthcare practitioners in precision medicine.
- iv. To obtain the viewpoint of healthcare practitioners on the effect of precision medicine on patient's quality of life.
- v. To identify the benefits of implementing PM in LMIC such as Pakistan.

1.12.2 Specific Objectives covered in the Quantitative phase

- i. To assess the knowledge and attitude of healthcare practitioners including physicians and pharmacists on precision medicine implementation.
- ii. To assess the willingness of healthcare practitioners to learn and practice precision medicine.

- iii. To identify the difference in knowledge, attitude, and practice of physicians and pharmacists in the country.

CHAPTER 2

LITERATURE REVIEW

2.1 Precision Medicine in Cancer Treatment

Oncology appears to be the evident option to boost the impact of PM (Collins & Varmus, 2015). Knowledge of genetic contribution to cancer can help in the most effective treatment possibilities. At present time, cancer constitutes 16% of the total population death rate with an estimated 19.3 million new patients and 10 million deaths in the year 2020 among four major chronic diseases (Organization, 2022; Sung et al., 2021). The rate is expected to increase to approximately 24 million by the year 2035 (Stewart et al., 2016). Studies have proved that each cancer has its own existent genomic identification structure. However, some characteristics of this structure are common to many types and known as tumor-specific features with which treatment options may vary. Comprehensive genetic testing is performed on the tumor to determine the genetic profile of the patient and genetic variants found within the tumor. Individuals respond differently to their prescribed treatment but in any case, the goal of treatment remains established i.e. minimizing extraneous side effects to a particular treatment and improving clinical outcomes for individual patients (Collins & Varmus, 2015; Jameson & Longo, 2015). Precision oncology, also known as Precision Cancer Medicine focuses on all genetic variations related to certain cancer types and the best suitable treatment according to those genetic changes for that tumor.

From surgical removal of cancer to the most advanced targeted treatment options, generations have witnessed and experienced many different treatment options in the changing world. Some worked and proved to be milestones in the history of oncology clinics whereas others just failed and had to be recalled apparently due to

their side effects (Jameson & Longo, 2015; Sudhakar, 2009). However, with the advancing age, treatment for some cancer types remains undiscovered and hence difficult to treat yet. Considering that, patients with the same tumor type may need different treatments due to different genetic makeup has opened up new ways for precision oncology (Collins & Varmus, 2015; Vetsch et al., 2019).

2.2 Perspective of healthcare practitioners on precision medicine implementation

For the implementation of PM in a thorough manner, it is necessary for all stakeholders including physicians and pharmacists along with patients and their payers to be completely educated on PM for cancer treatment. For this purpose, oncologists can best guide and train other HCPs and counsel patients regarding the use of PM as a treatment option (Ciardiello et al., 2014). In conclusion, there is a need to identify and train physicians and pharmacists accordingly about PGx to improve their knowledge and attitude towards PM. This is the need of the hour for improving rational drug use and bringing everyone on one page regarding the practice of personalized care and its assistance (Mufwambi et al., 2021). This is high time to scrutinize the attitude and practice of HCPs towards the implementation of PM who are trusted most for individualized treatment and medicine (Bombard et al., 2015).

With the evolving times, HCPs seem more interested in utilizing big genomic data for treatment and individualized patient care where genomic sequencing has already helped them diagnose cancer at the molecular level (Foster, Mulvihill, & Sharp, 2009). They are more concerned with improving drug efficacy through dose adjustment and hence reducing ADR by utilizing PM properly. Not only this they are using principles of PGx and PM for clinical as well as research purposes. PM is still at

its infancy stage but technology is slowly shifting from scientists to the general public through HCPs who are struggling to hold on to PM principles and knowledge and are still divided on its utilization (Chakravarthy et al., 2020; *Precision Medicine: The Role of Pharmacists and Reimbursement Challenges*, 2017).

Alaska Natives and the American Indian community (ANAI) acknowledged PM use for health research purposes to deliver better services. Talking about their knowledge of PM, the effect of social determinants and environmental aspects on PM, were part of their major interest, which is one interesting thing to know about PM use and implementation. They were interested to know how these aspects can interfere with patient's propensity to utilize this facility of treatment. They considered PM as one the most vigilant and efficient tools for diagnostic purposes especially cancer treatment as one of the most useful areas to use PM for providing the most accurate medication instantly with precise diagnosis. However, they suggested elaborating the basic concept of PM on a public level for better implementation and to clear the public's concerns regarding its use as the general public is not used to technical terminologies like genetic testing, etc (Beans et al., 2020).

2.3 Barriers faced by healthcare practitioners in the implementation of precision medicine

Despite the agreement of their active role, studies have shown that due to ambiguity of basic concepts and knowledge on PM, accessibility to databases and professional practice gap due to fewer practicing opportunities available have made HCPs less confident and incapable of implementing PGx principals (Mufwambi et al., 2021; Nagy, Eirini Tsermpini, Siamoglou, & Patrinos, 2020; Yau & Haque, 2016).

Qoronfleh identified that training and practice were the biggest challenges that should be addressed on priority. It also stated the need for genetic counselors to better deal with and counsel patients (Qoronfleh et al., 2020). He also stated inadequate and little knowledge available in healthcare units as one of the challenges in the way for implementation of PM globally; as for HCPs and patients regarding PM. This makes it more difficult for them to implement it for preventive and diagnostic purposes. One of the most important issues highlighted was the lack of guidelines and outdated curriculum on genetics (Qoronfleh et al., 2020).

Google survey performed in Japan pointed out that technologically advanced medical requirement not covered by insurance was the biggest barrier to PM implementation (Tsuji et al., 2021). Meanwhile, Alaska Natives took privacy issues very seriously for future implementation of PM and wanted to make sure about transparency of using genetic and other personal data obtained from patients to be confidential (Beans et al., 2020).

In their study on the role of pharmacists and the opportunities provided to them for implementing PM, the authors stated that one of the biggest barriers to implementing PM through pharmacogenomics testing is financial distress overall. Payers and buyers both hesitate to adopt technology change for treatment purposes due to insufficient and poor financial practices that include testing costs, and clinical benefits with useful financial implications (Kolesar & Vermeulen, 2021).

In a descriptive literature review from the last 5 years of research papers, Wang identified that knowledge was one of the most lacking factors among pharmacists in terms of their role and the clinical use of PM. Almost 75% of pharmacists were not

confident to interpret PGx testing results for disease diagnosis and precise medication (Schwartz & Issa, 2017; Wang, Merl, Yang, Zhu, & Li, 2020).

2.4 Role of healthcare practitioners in the implementation of precision medicine

Healthcare practitioners (HCPs) comprehension and frame of mind have a lot to do with PM establishment. Acquisition of the latest advancements in the field of PM establishes their long-standing role as a trusted counselor (Mufwambi et al., 2021; Nagy, Eirini Tsermpini, et al., 2020; Yau & Haque, 2016).

CEO of the Personalized Medicine Coalition (PMC) advocacy and education group, Ed Abraham challenges, “This new era has enormous ramifications for pharmacists. They are on the front line of the actual prescribing,” he said, “and [this] will have to be individualized, based upon certain diagnostic tests in the future.” (*Precision Medicine: The Role of Pharmacists and Reimbursement Challenges*, 2017)

American Society of Health-System Pharmacists along with other prominent researchers clearly stated that pharmacists need to emphasize more on basic PGx knowledge and data and its implementation by improving skills for individualized patient care services (Karuna, Tragulpiankit, Mahasirimongkol, & Chumnumwat, 2020; Rahma et al., 2020). Their commendable role in promoting PGx with its principles and use in treatment to physicians, scientists, and the general public cannot be easily neglected (Karuna et al., 2020). However, poor drug management and decision-making due to lack of information on PGx diminishes its leading character (Rahma et al., 2020). It is expected from experts that in the coming times clinical pharmacists may lead the scenario by helping physicians in decision-making using decision-support tools and instant access to complete genomic and patient data (Nagy,

Eirini Tsermpini, et al., 2020; *Precision Medicine: The Role of Pharmacists and Reimbursement Challenges*, 2017). Both physicians and pharmacists claim to have better knowledge of PM and more understanding of the implementation of PGx (Nagy, Eirini Tsermpini, et al., 2020; Wanner, 2011).

In a review published on a survey done in 2016 on willingness to participate in genomic testing in Qatar; it was quoted that 90% of HCPs believed in providing PM for better healthcare and to make its implementation worthy. Hence physicians should be more vigilant and informative about the wide range of tests offered in this treatment method and how to convince patients accordingly for the most suitable one. In addition, primary care fails to get noticed in its practice in different countries. Furthermore, policymakers and responsible personnel are unable to provide clear information on its clinical and economic data as using it as new technology. They also fail to address the religious and ethical concerns and sentiments of the general public. It is also noted that HCPs do not include patients/payers in decision-making procedures regarding preventive or treatment facilities (Qoronfleh et al., 2020).

In America, cancer cases are expected to increase by 45% as compared to the present situation. According to the American Society of Clinical Oncologists (ASCO), due to the scarcity of present number of cancer experts, the demand for oncologists to provide necessary patient care is expected to increase to 42% by 2025. This increasing need for oncologists is due to the vast range of evolving yet promising cancer therapies. Not only clinical oncologists but oncology pharmacists are also expected to play their best role in delivering PM to cancer patients in the best possible way. For this purpose, they should ponder upon their extended role in PM implementation by providing precise and careful storage, distribution, and monitoring of therapy provided.

Moreover, they can play a huge role in counseling and assuring medication adherence during the whole process (Kolesar & Vermeulen, 2021).

Pharmacists and physicians must collaborate for better therapy outcomes. Pharmacist can make the treatment process easier with their expertise in therapeutic drug monitoring (TDM) and updating and guiding for daily optimized therapy use. But for pharmacists to leave a strong impact on therapy implications they must have a good basic molecular knowledge, and how to use it for diagnostic and therapeutic purposes and help the patient understand their genetic health (Kolesar & Vermeulen, 2021; Vermeulen et al., 2020).

2.5 Healthcare practitioners' point of view on the effect of precision medicine on patient's quality of life

PM promises extraordinary treatment along with the provision of tailored genetic products for every individual that can be utilized at anytime and anywhere in life for any treatment. This individualization of treatment brings the patient confidence in his HCP and the treatment designed by him (Desmond-Hellmann, 2012)

Shortly, patients will be segregated into treatment groups by not only determining their genetic mutation but also by using “omics” data as an output of disease network activation status. Using network-based PM approaches will likely translate to further improving patient stratification and outcomes, as a result of fully informed clinical decision-making. Bioinformatics is universally considered to be an integral part of PM. Although many clinicians contend that they have always practiced individualized and personalized medicine (Karuna et al., 2020; Ritzer, 2007) and that PM may just represent biomedical researchers and pharmaceutical companies catching up, many clinicians are not aware of the existence of PM. According to one poll, as of

2012, American physicians had recommended personal genetic tests for only 4% of their patients (Toloie-Eshlaghy, Chitsaz, Karimian, & Charkhchi, 2011). However, efforts such as the Precision Medicine Initiative (PMI) and Coordinating Action Systems Medicine (CASyM) are raising the awareness of PM in clinical circles, and attempting to encourage clinicians to embrace this healthcare transformation. It is unfair to expect numerous clinical success stories at this early stage. But even if it is accepted that this is the case, then the large-scale funding of PM precedes the evidence of its applicability (Duffy, 2016)

Based on patient's view on understanding and using PM, healthcare providers considered adding PM specialist in the healthcare team for better counseling and convincing patients as well as findings of PM based on genetic testing and their understanding of them (Beans et al., 2020)

2.6 Benefits of implementing precision medicine in lower-middle-income countries like Pakistan

Providing the right treatment at the right time to the right person has put a great financial load on many countries especially low and middle-income countries (LMICs). However, it will eventually cut short the expenses by eliminating unnecessary, undue, and ineffective treatment regimens and protocols (Haque et al., 2020). Knowledge management has been declared an important aspect for the establishment of healthcare sustainability. Following this fundamental rule, Iran among all LMICs has progressed promptly in its healthcare sector. Following its footsteps, Pakistan is also paving its path of knowledge management in the health sector (Karamat et al., 2019). Pakistan being on the list of Middle-Income countries (J. Ali & Afridi, 2018) caters PM as neonatal. Due to limited finances and resources,