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Usage of Antibiotics as a Legal and Policy Dilemma in Pakistan

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ABSTRACT

The misuse of antibiotics is widespread in Pakistan and poses a significant risk to public health due to the increasing prevalence of antibiotic resistance. Despite existing regulatory structures, there are numerous challenges affecting their effective implementation. This research paper aims to explore the legal and policy issues related to antibiotic usage by employing ethnographic techniques, including participant observation and interviews. Data were collected from a sample of 26 participants residing in District Khairpur Mir's in Sindh, selected through purposive and snowball sampling methods. Thematic analysis of the data reveals that negligence by authorities, loss of interest, lack of awareness, and poor enforcement of legal measures contribute to the rise of antibiotic resistance in healthcare facilities across Pakistan. The paper contributes to the field of medical ethics at the intersections of medical practice, law and pharmaceuticals in the context of Pakistan.

Keywords: Antibiotics, Antibiotic resistance, Medical ethics, Policy, Legal dilemma.

INTRODUCTION

Antibiotics have transformed modern biomedicine, combating disease-causing viruses and saving countless lives. However, their overuse can negatively impact beneficial bacteria in the body. Additionally, the continuous use of antibiotics and other drugs may impair disease resistance (WHO, 2016). This issue poses a significant public health challenge worldwide, and Pakistan is no exception. The rise of antibiotic resistance presents a severe threat to global health. It also underscores the urgent need for an effective legal and regulatory framework to govern antibiotic use. Medical Anthropology offers valuable contributions to public health policies by providing insights at social, cultural, economic, and political contexts. Much of the existing research on the appropriate use of antibiotics has focused on practice-level education, with the most effective strategies combining education for both patients and clinicians (Gonzales et al., 2008).This research paper aims to address the gaps in the implementation of policies or programs and highlight the complex landscape of antibiotic consumption in the country. It seeks to help identify the causes of health disparities at the policy level.

Antimicrobial resistance threatens the foundations of modern medicine and the long-term viability of an effective global public health response to infectious diseases. Without coordinated and rapid global action, the world is headed towards an era of antibiotic resistance in which common infections can once again be deadly. Alarmingly, the World Health Assembly in May 2015 adopted the Global Action Plan on Antimicrobial Resistance to address the issue, which outlines five objectives, i.e., awareness, surveillance and research, reduction of the cause of infections, optimizationof the use of antimicrobial drugs, and creation of asustainable

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investment(WHO, 2016).This approach aims to provide high-quality,safe, and effective drugs to treat and prevent infectious diseases.Numerous publications around the world have reported a decline in the overuse and misuse of antibiotics in recent years, and they have proposed various policies and strategies at both international and national levels. Various institutions, including government bodies, public health organizations, and health administrations, have contributed to these legislative efforts. Additionally, many awareness campaigns have been conducted globally to address irregular use and distribution of antibiotics. For example, between 1997 and 2007, twenty-one European countries collaborated on initiatives to highlight the issues of antibiotic overuse and misuse.

The research reports indicate that the low-to-middle-income countries (LMICs) in Asia and the Pacific face numerous barriers to controlling antimicrobial resistance. According to the United Nations (UN, 2018), by 2030, 43 of the largest cities will be located in this region, emphasizing the need for cooperation with regional institutions. To address this challenge, stakeholders and legislators should consider establishing dedicated organizations, such as local Centers for Disease Control and Prevention (CDCs). These regional CDCs could enhance national efforts and highlight the importance of collaboration with international and regional entities. A regional CDC would help advance the antimicrobial resistance agenda beyond individual countries, enabling them to achieve their global health objectives (Yam et al., 2019).In 2018, the Ministry of National Health Services, Regulations, and Coordination referenced the World Health Organization's (WHO) recommendations for strategic plans focused on Antimicrobial Resistance (AMR). The ministry emphasized the need to raise awareness and understanding of AMR through effective communication, education, and training. It is essential to prioritize AMR politically at all levels. Additionally, the government should tackle this issue at both national and provincial levels by establishing one-health coalitions.

The rising rates of antimicrobial resistance (AMR) have led to the establishment of Antimicrobial Stewardship Programs (ASPs), which aim to promote and optimize the use of antimicrobials, including antibiotics, both in hospitals and community settings (McGowan &Gerding, 1996). Since antimicrobials are considered a nonrenewable resource, it is crucial to encourage their rational use by avoiding unnecessary prescriptions. In 2011, efforts to enhance antimicrobial stewardship focused on addressing the ‘5 D's’: drug selection, diagnosis, therapy discontinuation, treatment de-escalation, and dosage (Doron & Davidson, 2011). The goal of these programs is to improve patient outcomes, reduce microbial resistance, and curb the spread of infections caused by multidrug-resistant organisms. In low and middle-income countries (LMICs), such as Pakistan, the increasing prevalence of multidrug-resistant (MDR) bacterial infections has made infection prevention and control (IPC) as well as antibiotic stewardship programs critical components of the healthcare system (Atif et al., 2021). Additionally, the Pakistan Antimicrobial Resistance Network (PARN) has played a vital role in raising awareness by providing reports and guidelines on antibiotic resistance and other infectious diseases (PARN, 2022). Various legal acts have been enacted to optimize antibiotic use and combat antibiotic resistance at both national and provincial levels. For instance, the Punjab Health Commission Act of 2010 addresses medical negligence by healthcare practitioners who over-prescribe antibiotics. Under Section 19 of this Act, medical negligence is considered a serious offense, ensuring that healthcare practitioners are held accountable for excessive antibiotic prescriptions. Additionally, the Rules of the Allopathic System of Misuse Prevention in West Pakistan, established in 1968, outline strict licensing requirements for all physicians wishing to prescribe antibiotics. This clearly indicates that prescribing antibiotics is a serious matter that should only be undertaken by practitioners who comply with legal guidelines.

Recent studies have demonstrated that public campaigns can significantly reduce the global use of antimicrobials (Filippini et al., 2012). The motivations behind this collective effort have led to changes in policies and a decrease in antibiotic consumption. Doctors and pharmacists are becoming increasingly accountable for their roles in antibiotic misuse and the resulting resistance. However, implementing these policies, programs, and legal frameworks in Pakistan faces several challenges. One major issue is the lack of resources and capacity at the district level, which hampers effective law enforcement. Additionally, there is resistance from the healthcare industry and practitioners who often refuse to comply with regulations due to their personal interests. Moreover, a lack of interest, awareness, and understanding of the laws among the public, healthcare professionals, and law enforcement agencies has further obstructed implementation efforts. There is also a pressing need for a robust system for reporting and investigating cases of medical negligence, which is currently lacking in Pakistan. Continuous monitoring and evaluation of the law's effectiveness are essential to address the issues it aims to tackle.

It may also be pointed out that despite legal restrictions on obtaining medication without a prescription, individuals from lower socioeconomic backgrounds often choose to consult and purchase medicines from local pharmacies to avoid the costs associated with visiting a doctor. This practice is particularly common in countries facing economic

challenges or with lower levels of medical knowledge (Schwartz, 2004). In that context, anthropologists have highlighted the cultural, social, political, and economic structures that affect the actual implementation of health policies. They have recognized the critical, contesting role of antibiotics in alleviating suffering and have worked, especially in low- and middle-income countries (LMICs), to understand how to improve access to essential medications and how their usagehas evolved (Manderson, 1998). This research study paper examines the challenges associated with antibiotic use within the context of regulatory frameworks.

RESEARCH METHODS

This ethnographic study utilized participant observation and in-depth interviews as methods for data collection in the Khairpur Mir's District of Sindh province, Pakistan. The participant observation aimed to understand the realities of antibiotic usage and the implementation of policies in healthcare institutions and the local community. The first author conducted this research over a three-month period from November 2022 to January 2023. In ethnographic research, having a reliable key informant or gate keeper can significantly help in establishing rapport with respondents and bridging cultural gaps. To access knowledgeable participants, two key informants were selected from the research area. The first key informant was Dr. Nazar, a 32-year-old physician working at Taluka Hospital KotDiji. The second key informant was Dr. Salman Kerio, a 38-year-old child specialist and a faculty member at a prominent medical college. These key informants facilitated connections with various participants and provided access to healthcare administrative offices and institutions with which they were already familiar and well-regarded.

A total of 26 respondents were selected as research participants using purposive and snowball sampling techniques to meet the study's objectives. Specifically, 11 participants were chosen through purposive sampling to provide diverse insights relevant to the research goals. Additionally, 15 participants were selected through snowball sampling based on recommendations from key informants and existing participants. The sample included medical practitioners, medical and pharmacy teachers, students, medical officers, and healthcare administrators, all of whom were relevant to my research objectives. Pseudonyms have been used to protect the identities of the respondents and ensure anonymity throughout the study. Before data collection, formal consent—both verbal and written—was obtained from all participants. They were also provided with detailed information about the research and its objectives.

Thematic analysis was employed to analyze the data collected during fieldwork, following several steps: familiarization with the data, coding, theme development, theme review, categorization and labeling of themes, and documentation (Braun & Clarke, 2006). A visual representation of the thematic analysis process is shown in the figure below.

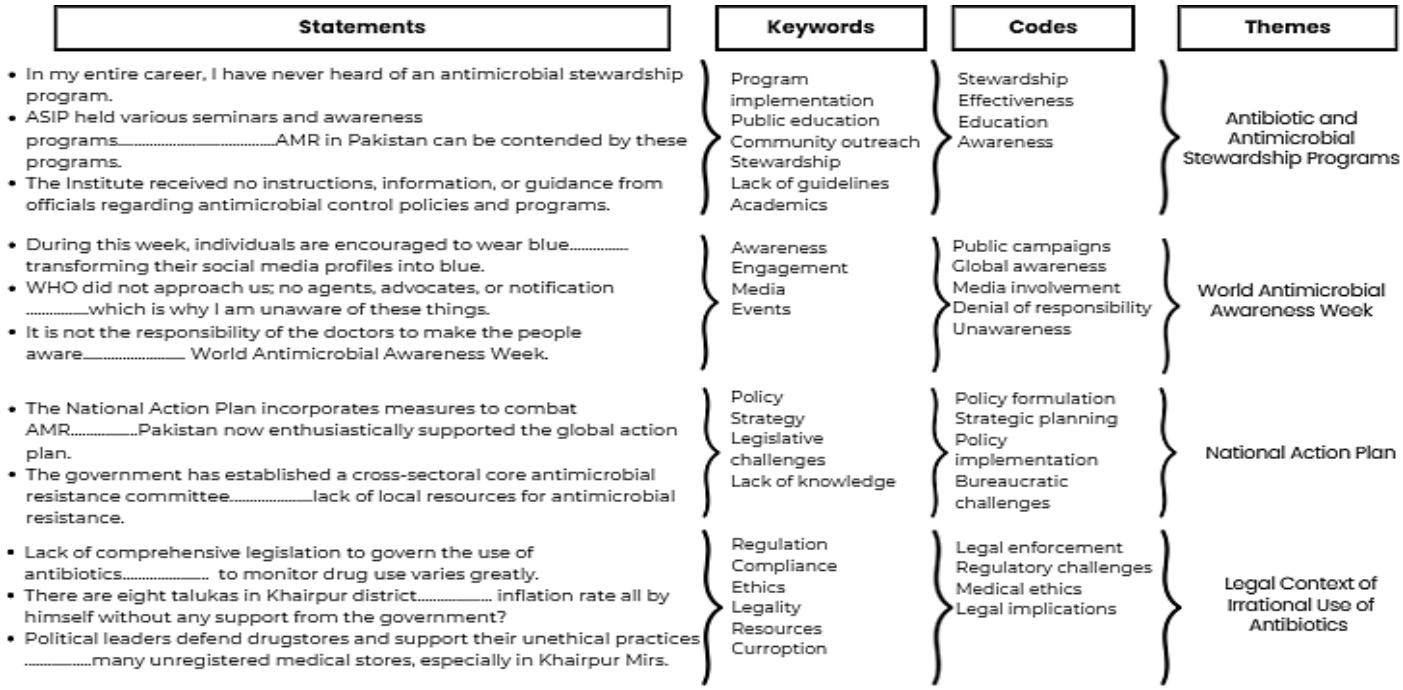

Figure 1. Systematic Thematic Analysis Process.

The analysis process began with reviewing and familiarizing with all the collected data. We transcribed interviews, field notes, and observational notes gathered during the fieldwork while keeping the research objectives and their subthemes in mind. Specific statements or keywords were then extracted for coding. These codes were organized into patterns to develop overarching themes. Additionally, the researchers focused on identifying similarities among the ideas as they created these themes. The themes were subsequently reviewed and categorized with labels based on the research objectives and subheadings. Finally, all the themes were documented in detail, incorporating the identified patterns.

RESULTS AND DISCUSSIONS

Antibiotic resistance presents significant ethical concerns due to the profound and often unjust impacts of certain actions and policies. This section aims to examine antibiotic resistance as a legal and policy challenge. It will focus on the legal framework surrounding the irrational use of antibiotics and other drugs, as well as various provincial and national policies designed to address this pressing issue. The policies and legal acts discussed include Antibiotic Stewardship Programs (ASPs), the Antimicrobial Stewardship Program, World Antimicrobial Awareness Week, the National Action Plan, the Drug Regulatory Authority of Pakistan (DRAP), the Pakistan Medical and Dental Council (PMDC) Code of Ethics for medical and dental practitioners, and the Sindh Healthcare Commission (SHCC).

Antibiotic Stewardship Programs and Antimicrobial Stewardship Programs

The goals of Antimicrobial Stewardship Programs (ASPs) are to eliminate the misuse of antibiotics worldwide by educating community members, general practitioners, policymakers, and users (Dellit et al., 2007). The experiences from the implementation and outcomes of ASPs in Sindh have highlighted both the challenges and benefits of these strategies at a regional level. Ethnographic data gathered in this research paper from District Khairpur Mir's indicate that the use of antibiotics and programs aimed at preventing their misuse are complex issues. The awareness and application of ASPs among healthcare professionals in Sindh are at low to moderate levels. For example, Dr. Nazar, who works at Taluka Hospital KotDiji, stated that although standard operating procedures for prescribing antibiotics exist, adherence to these procedures is inconsistent. He noted that practicing clinicians often do not receive ongoing training and adequate resource support. Additionally, child specialist Dr. Salman Kerio supported this observation, but pointed out a key difference between private and public hospitals. He explained, "In private hospitals, there is greater emphasis on ASPs; however, we still face infrastructure challenges in public hospitals."

Awareness programs have become a crucial component of Antimicrobial Stewardship Programs (ASPs) due to their high demand. Mr. Rehman Chandio, a District Health Officer, emphasized the importance of raising public awareness about the dangers of antibiotic misuse. He expressed that while professional training initiatives are vital, they need to be accompanied by comprehensive community mobilization efforts. He stated, "Public awareness is essential. It is impossible to launch a major campaign aimed at eradicating the misuse of antibiotics without first properly sensitizing the community." However, several challenges hinder the effective implementation of ASPs. These include a lack of funding, insufficient human resources, and resistance from some stakeholders. An official from the Khairpur Drug Regulatory Authority highlighted various organizational factors that need to be addressed to enhance ASPs. He noted that implementing any regulation is often difficult due to political influences and a lack of support from leadership.

The healthcare providers in Sindh made several suggestions to improve Antimicrobial Stewardship Programs (ASPs). They emphasized the importance of prescribed training and Continuing Medical Education (CME) sessions to ensure that the standard of care for patients is maintained. Additionally, they identified that upgrading the infrastructure in various public hospitals is crucial, along with improving the surveillance and reporting systems for antibiotic use and resistance profiles. Unfortunately, implementing effective antimicrobial control programs in Pakistan faces significant challenges. Primary care practitioners reported that they do not use antibiotics rationally and lack sufficient knowledge and understanding of antibiotic resistance. These findings were confirmed by the author's fieldwork, which highlighted a general lack of awareness regarding community-specific differences in antimicrobial treatment regimens.

It was highlighted that many healthcare professionals, including MBBS students, pharmacy technicians, and academic staff, do not have a sufficient understanding of antibiotic management policies. Most respondents indicated they were unaware of the importance of these policies or how to effectively implement antibiotic management systems and communities in Sindh, Pakistan. Thishighlights significant gaps in knowledge that need to be addressed. To mitigate the negative impact of antimicrobial resistance in Pakistan, targeted education and awareness programs are essential. Nayab Ali, a 32-year-old doctor working in a private hospital, remarked, "In my

entire career, I have never heard of an antimicrobial stewardship program."According to Nadir Kerio, a 28-year-old regional manager at Sehat Kahani, the organization operates throughout Pakistan, providing telehealth services to patients. Patients share their health stories, and doctors can search for and prescribe medications online. Kerio emphasized that health information is utilized to prescribe antibiotics. However, the organization has not received any instructions, information, or guidance from officials regarding antimicrobial control policies, programs, or strategies.Sarfraz Memon, a 22-year-old MBBS student at Gambat Medical College in Khairpur, Sindh, noted that he has not attended any seminars, lectures, or awareness campaigns on antibiotic resistance during his three years as a student. This highlights a concerning lack of knowledge and exposure to current medical debates among medical students and doctors in Pakistan.

The data suggests a pressing need for targeted awareness and educational campaigns aimed at reducing the negative impact of antibiotic resistance in the country. Effective implementation of antimicrobial stewardship programs (ASPs) requires collaboration among various stakeholders, including patients, healthcare providers, and regulators. To ensure the safe use of antibiotics, Antimicrobial Guidelines should be developed with a focus on local medications, antibiotic resistance, and drug stability, based on an evaluation of current prescribing practices. Both patients and healthcare providers must enhance their understanding of antibiotics and the ethical use of alternative therapies. In addition to offering ongoing training and education, ASPs should include monitoring and delivery systems to identify areas for improvement. Policymakers can support the appropriate use of antibiotics by investing in research, providing financial incentives, and establishing regulations. Moving forward, antibiotics will continue to play a crucial role in treating malaria, but this will only be achievable if all stakeholders commit to enhancing the implementation of ASPs.

There are significant challenges in improving healthcare providers' and patients' understanding of how to prevent viral infections and the overprescribing of antibiotics, particularly in less developed areas. These issues are major obstacles to the expansion of the antibiotic surveillance program (ASP) in Khairpur Mir’s, Sindh. Additionally, a lack of formal funding and difficulties in identifying areas that need improvement pose further barriers to ASP implementation. However, some healthcare settings are beginning to adopt ASPs, and both patients and physicians are starting to recognize the importance of using antibiotics judiciously. Policymakers play a crucial role in providing financial incentives and formal funding for research initiatives. Overall, implementing ASPs in Khairpur Mir’s is an important step towards conserving effective antibiotics.

World Antimicrobial Awareness Week

The World Health Organization (WHO) endorsed "World Antibiotic Awareness Week" during the 68th World Health Assembly in 2015. In 2020, this week was rebranded as "World Antimicrobial Awareness Week" (ReAct, 2022). This awareness campaign is observed annually from November 18 to 24. The primary goal of the week is to reduce the misuse and overuse of antibiotics, optimize their use, and raise awareness about antibiotic resistance on both medical and non-medical levels worldwide.

In 2021, a global color campaign, "Will you "Go Blue for AMR"?" was held. This campaign was celebrated in organizations and on individual and community levels. During this week, individuals were encouraged to wear blue while participating in the WAAW events and transforming their social media profiles into blue. Moreover, individuals and organizations were also motivated to post their or group photos in blue using the hashtags *AntimicrobialResistance* and*DWAAW*to create a trend of awareness campaign over the internet and social media (FAO et al., 2020). Organizing an awareness event at the community level was encouraged to inform people and highlight the community's concerns and commitments to address Antimicrobial Resistance. The theme of the campaign changes annually, bringing to fill all the gaps of the previous year's campaign. However, the slogan remains "Antimicrobials: Handle with Care". The theme of this awareness week in 2022 was based on the united actions of all to prevent it. This theme was entitled "Preventing antimicrobial resistance together," calling for cross-sectoral collaboration from all sectors to minimize and prevent AMR not only among human beings but also among animals, plants, and the environment, as AMR affects all. Pan American Health Organization (PAHO), with the collaboration of the UN environment program, World Health Organization (WHO), World Organisation for Animal Health (WOAH), and Food and Agriculture Organization of the United States (FAO) published a guideline for the WAAW campaign to curb AMR globally. The campaign guide instructed some actions to be followed globally to minimize AMR. These strategies prevent the spread of infectious diseases and reduce the use of antibiotics by improving infection control around healthcare facilities, farms, and food processing plants work, ensuring access

tosafe water, sanitation andvaccination, best practices in food and agricultural production, and the use of proper waste and sanitation disposal. A reduces the risk of AMR.

The guidelines provided are beneficial for policymakers, healthcare providers, and other stakeholders when developing evidence-based interventions to address antimicrobial resistance (AMR). The success of this initiative relies on the collaborative efforts of all involved parties and a unified approach to health that acknowledges the interconnectedness of human, animal, and environmental health.The World Antimicrobial Awareness Week (WAAW) conference, titled "Preventing Antimicrobial Resistance Together," is a joint initiative organized by Khyber Medical University's Institute of Basic Medical Sciences (IBMS), the Public Health Reference Laboratory (PHRL), the Dosti Welfare Organization (DWO), and the Global Education Campaign (GEC). During this event, panelists highlighted the crucial role of antibiotics and the rising incidence of antimicrobial resistance (Report, 2022).They explained that antimicrobial resistance occurs when diseases caused by bacteria, viruses, fungi, and other parasites develop resistance to medications, thereby complicating treatment options. As a result, the morbidity and mortality rates associated with infectious diseases continue to rise. This makes it increasingly difficult to treat such diseases, and it raises concerns that future generations may lack effective drugs for contagious ailments.

Rehman Chandio is a 52-year-old district health officer in Khairpur Mir’s and a part-time doctor who practices at his private clinic. When asked about antibiotics, related policies, programs, and Antimicrobial Awareness Week, he expressed a lack of information on the subject. He stated that the WHO guidelines regarding antibiotic resistance, the antibiotic stewardship program, and Antimicrobial Awareness Week were not being communicated to them. He remarked, "The WHO did not approach us; no agents, advocates, or notifications have been sent regarding Antimicrobial Awareness Week. How are we supposed to know about these things if the WHO does not reach out to us for that purpose? These activities do not fall under the responsibilities of the District Health Officer, which is why I am unaware of them. It is not the doctors' responsibility to educate the public or conduct training and seminars related to antibiotic resistance, the antibiotic stewardship program, or World Antimicrobial Awareness Week."Furthermore, he has not only denied any knowledge of guidelines related to antibiotic use, antibiotic resistance, or antibiotic stewardship programs, but he has also claimed that he did not participate in antimicrobial awareness campaigns throughout his entire medical career. It is astonishing to learn that someone who is not only a doctor but also a senior health officer is unaware of issues that have been emphasized globally for years. Despite holding an administrative position, he acknowledged being aware of the Antimicrobial Resistance Prevention (AMRP), Antimicrobial Stewardship Programs (ASPs), the National Action Plan (NAP), and World Antibiotic Awareness Week (WAAW), yet he did not see it as his responsibility to educate doctors or the general public about these important global issues.

Dr Mohsin Channa, a 37-year-old physician serving as the District Focal Person of the Emergency Cell and the District Coordinator of Supplemental Immunization Activities, acknowledged that antibiotic resistance is a pressing global concern. He noted that numerous cases of antibiotic resistance have been identified in the city of Khairpur. However, he expressed disappointment that doctors and other relevant authorities do not prioritize this issue. Although Dr Channa is knowledgeable about the medical aspects of antibiotic usage and resistance, he was unaware of policies and programs related to antibiotics and their prevention launched by the World Health Organization (WHO). These include the Antibiotic Stewardship Program, the National Action Plan, and the Antimicrobial Awareness Week campaigns. Furthermore, he has never participated in seminars, campaigns, activities, or training sessions conducted by WHO officials.The District Health Officer in Khairpur Mir’s echoed Dr Channa's sentiments, admitting they had also never reported or communicated with any WHO staff. As a researcher, I found that none of the regional offices displayed any banners, policies, or posters regarding antibiotic resistance. Both officials were unaware of this global phenomenon and did not consider it part of their responsibilities.

Nadir Kerio, respondent, the regional coordinator for Sehat Kahani (e-health or telehealth), said there is no World Antibiotics Awareness Week, WHO policies on antibiotics, or any information about proper use. Emphasize the need for increased awareness campaigns and educational programs on the appropriate use of antibiotics to combat resistant infections. The text also highlights the role of the World Health Organization in initiating policies and programs on antibiotic resistance and prevention.

National Action Plan

The rise of antimicrobial resistance has become a significant global health issue, with projections indicating that it could lead to the deaths of 10 million people annually by 2050. At the 68th World Health Assembly in 2015, the World Health Organization (WHO) presented a global action plan to address this challenge. All countries, including

Pakistan—the sixth most populous country in the world, expected to become the fourth by 2050—enthusiastically supported this initiative.As a first step, Pakistan established a national strategy for controlling antibiotic resistance, known as the National Strategic Framework for Containment of Antimicrobial Resistance. This framework was later incorporated into Pakistan's National Action Plan to combat antibiotic resistance in 2017. The government of Pakistan has also formed a cross-sectoral core committee focused on antimicrobial resistance. This committee aims to identify key stakeholders and policy-making experts, assess the current situation regarding antimicrobial resistance, and develop policy recommendations and documents (NHSRC, 2017).

Pakistan has conducted a comprehensive external review of the International Health Regulations and the Global Health Security Agenda, aiming to identify critical areas for tackling antibiotic resistance (Tribune, 2017). The Pakistan National Institute of Health oversees antibiotic resistance surveillance in the country, thanks to its involvement in the Global Antimicrobial Surveillance System. However, these initiatives have not received adequate attention due to a lack of local resources to combat antimicrobial resistance and concerns about underfunding from the Pakistani Ministry of Health and various donors (Saleem et al., 2018). The WHO mission report indicates that Pakistan is well-equipped to detect, prevent, and respond to both internal and external health threats that could jeopardize the nation's population as well as impact travel and trade. While Pakistan is a signatory to the International Health Regulations and strives to comply with them, it still needs to address essential core functions, despite receiving some extensions (Tribune, 2017).

The National Action Plan (NAP) emphasizes three critical issues to prevent the misuse and overuse of antibiotics in Pakistan. First, there is an urgent need to restrict access to over-the-counter antibiotics and to avoid unnecessary antibiotic prescriptions. Second, the policy encourages the promotion of improved infection control measures in healthcare settings. To effectively manage antimicrobial resistance (AMR), the medical curriculum should include structured training and evaluation on the appropriate use of antimicrobials. Lastly, to tackle the increasing risk of antibiotic-associated infections, Pakistan should adopt the practices recommended by the NAP (Saleem et al., 2021).

A new National Action Plan (NAP) on Antimicrobial Resistance (AMR) was developed for the World Health Organization (GOP, 2017) by the Ministry of National Health Services Regulations and Coordination in Pakistan, working alongside representatives from the agriculture, livestock, and health sectors. The plan includes several crucial measures aimed at addressing this global health issue (Saleem et al., 2021). One of the main strategies is to organize seminars and awareness programs to educate the public about the risks of overusing antibiotics. This approach will help people better understand the potential dangers associated with antibiotic overuse and misuse. The NAP also recognizes the importance of improving disease surveillance methods and creating new policies to combat antimicrobial resistance.Additionally, the plan highlights the need to enhance community health, nutrition, agriculture, and environmental conditions, as these factors can contribute to the worsening of vector-borne diseases (Saleem et al., 2021). It proposes the use of appropriate growth replacements and prebiotics in animal feed. Furthermore, the NAP emphasizes the necessity of incorporating antimicrobial resistance into vaccines and other public health research programs.

The government has not implemented any strict policies regarding antimicrobial resistance. In the district of Khairpur Mir’s, many clinical practitioners prescribe third and fourth generation antibiotics. Both community members and medical officials lack awareness about antibiotics; physicians often prescribe them for profit, and patients typically do not wait long for treatment. The researcher found that 90% of the population in Khairpur Mir’s is unaware of antimicrobial resistance. Additionally, local civil society members and the educated population of the city have not organized any awareness campaigns or seminars to address the overuse and misuse of antibiotics.According to the report on the national action plan, “50% of Pakistan's population engages in self-medication”. In Khairpur Mir’s, a significant portion of the population purchases medication at their own risk, and the district government has not taken any legal actions to address this pressing issue. The misuse and overuse of antibiotics lead to serious problems, including drug resistance, the overgrowth of pathogens, and various health conditions such as weakened immune systems, rheumatoid arthritis, diabetes, asthma, and anxiety disorders (Malik, 2020). Additionally, antibiotics negatively affect many beneficial bacteria in the body (GOP, 2017).The report on Pakistan's National Action Plan highlights that many private clinical practitioners in the country prescribe medication irrationally, often giving 3 to 4 antibiotics per patient. The researcher observed that in this area, doctors tend to prescribe antibiotics for nearly every health condition, despite this practice being illegal and contrary to health policies. This trend persists because antibiotics often provide quick relief to patients, which subsequently leads to an increase in outpatient department (OPD) visits at clinics.There is a significant lack of adequate diagnostic facilities, particularly in primary and tertiary

health centers. This situation enables the administration and use of antibiotics without conducting culture susceptibility or sensitivity tests (Hayat et al., 2020). One major research concern is the presence of unlicensed physicians providing healthcare. Furthermore, many physicians and pharmacists do not have the necessary training or equipment to prevent the misuse of antibiotics. Due to the absence of proper diagnostic tools, misdiagnosis and overprescribing are common occurrences. This issue is highlighted by the fact that a majority of physicians and pharmacists in Khairpur Mir's prescribe medications to unlicensed doctors without first performing diagnostic tests. To address these challenges, healthcare providers should be encouraged to adopt evidence-based practices. This can be achieved through training and education programs, the provision of appropriate resources, and the strengthening of regulatory frameworks to ensure access to safe and effective healthcare.

Pakistan, like the rest of the world, is facing significant challenges due to the rising risk of antibiotic resistance. One of the primary issues in Pakistan is the lack of education regarding antibiotic resistance and the proper use of antibiotics. This situation enables people to purchase antibiotics over the counter without a prescription, leading to self-medication and, consequently, increased antibiotic resistance. Additionally, there is a shortage of adequate facilities, resources, and training for healthcare staff, especially in rural areas, which hampers effective antimicrobial resistance (AMR) control and stewardship programs. The problems associated with the overuse and misuse of antibiotics may be further compounded by existing regulations concerning their sale, distribution, and use. Furthermore, the development of new antibiotics is progressing slowly, while antimicrobial-resistant diseases can spread quickly across international borders, making prevention and control efforts even more challenging.

The introduction of the National Action Plan (NAP) in Khairpur Mir's has made progress in addressing the issue of antimicrobial resistance (AMR). However, continuous efforts are necessary to enhance the surveillance system, improve infection prevention and control (IPC) practices, promote the rational use of antibiotics, and increase public awareness about the importance of responsible antibiotic usage.

Legal Context of Irrational Use of Antibiotics and Various Drugs

It is widely recognized globally that physicians must exercise great caution and responsibility when prescribing antibiotics. However, a comprehensive review of the regulatory framework, particularly in developing countries, reveals a significant lack of legislation governing antibiotic use. Additionally, providing counseling for patients and animals regarding antibiotic use, as well as conducting unnecessary antibiotic testing, is considered a violation of human rights and medical ethics in civilized societies.

A significant number of medical practitioners in Pakistan have been found to prescribe antibiotics without conducting microbial testing, which is the violation of medical ethics. This situation underscores the urgent need for strict measures, such as implementing minimal antibiotic use guidelines and ensuring antimicrobial testing. These shortcomings contribute to the overuse of antibiotics and the rise of antimicrobial resistance. To mitigate the risks associated with antibiotic resistance, it is essential to establish protocols for identifying physicians who prescribe antibiotics indiscriminately. This is particularly important in countries lacking effective regulatory frameworks to control antibiotic usage. Antibiotic resistance has developed largely due to widespread overuse and misuse of these medications, which can be attributed to poor regulation and the absence of legal consequences for healthcare professionals who prescribe antibiotics inappropriately or do not provide adequate explanations for their use.Regional drug enforcement officials are tasked with enforcing national drug laws, but the effectiveness of these authorities in monitoring drug use varies significantly. Many regional drug enforcement agencies lack the trained staff or resources necessary to perform their duties effectively.

Inadequate regulatory authority, a lack of legal responses to non-compliance, and the unreasonable use of antibiotics and other drugs all contribute to the increasing rate of antimicrobial resistance (AMR) in Pakistan. Currently, Pakistan's drug and antibiotic policies are primarily based on the Drugs Act of 1976. This Act regulates antibiotics and other medications, overseeing their import, manufacture, sale, and distribution within the country.

The Drug Regulatory Authority of Pakistan (DRAP) is responsible for ensuring that any drug imported, manufactured, or sold in Pakistan is registered in accordance with the Drugs Act of 1976, which aims to maintain quality control. The 1976 Drugs Act also placed antibiotics and other drugs under the jurisdiction of drug courts, which have the authority to impose penalties such as fines, imprisonment, and revocation of licenses on manufacturers and distributors who violate the Act. Under DRAP's supervision, compliance with the national legal framework on drugs, includingantibiotics, is monitored. DRAP was established as the primary regulatory body in Pakistan, replacing the Federal Drug Control Authority in 2012 through the Drug Regulatory Authority of Pakistan Act.The Drug Regulatory Authority of Pakistan (DRAP) operates within the framework established by the DRAP Act of 2012, overseeing the

NationalHealth Service's Regulatory and Coordinating Division. The Drug Act of 1976 grants DRAP the authority to issue licenses to manufacturers and importers, inspect and approve drug products for marketing, and regulate the safety and efficacy of drug products in Pakistan. The authority is also responsible for implementing penalties, with drug courts authorized to impose fines, imprisonment, and license revocation on offenders. While DRAP regulates the drug industry and strives to enhance health facilities across the country, it faces significant challenges in implementing its mandate. Issues such as corruption, a lack of resources, insufficient personnel, and inadequate funding hinder its effectiveness. Additionally, the prevalence of self-medication among doctors and patients leads to the irrational use of antibiotics and other drugs, contributing to the growing problem of antibiotic resistance.

It may be argued that one significant factor affecting the implementation of the DRAP Act is the lack of resources and capacity within the regulatory authority. This body is tasked with enforcing the Act but has encountered numerous challenges due to limited resources, inadequate infrastructure, and low levels of institutional capacity. During fieldwork, officials from the Khairpur Drugs Regulatory Authority expressed their frustration toward the government and political groups. Shahid Ali, a 30-year-old official, pointed out that Khairpur district consists of eight Talukas, yet there is only one drug inspector responsible for the entire area. Furthermore, the government has not taken responsibility for transportation expenses, such as vehicles and fuel. In this situation, one may pose a question that how can one individual effectively manage these responsibilities amidst the current inflation without any support from the government?

Thus, the lack of resources and capacity within the regulatory authority reflects a failure on the part of the government, as the needs of communities—particularly marginalized ones—have not been adequately prioritized. Additionally, officials have noted that political leaders often defend drugstores and support their unethical practices, such as selling expired or counterfeit medicines. The prevalence of corruption in the district is evident in officials' admissions of accepting bribes from medical stores in exchange for support, as well as the existence of many unregistered medical stores, particularly in Khairpur Mir’s.Despite being against medical ethics, practices such as selling expired medications, dispensing over-the-counter drugs indiscriminately, hiring untrained drug practitioners, and operating unlicensed medical stores and laboratories are still prevalent in Pakistan. Furthermore, the official responsible for regulating the drug sector in Khairpur Mir’s seems to lack awareness of the ethical considerations surrounding drug distribution and professional responsibilities. Shahid Ali has pointed out that the political influence over the Drug Regulatory Authority is a fundamental reason for the promotion of antimicrobial resistance and the misuse of antibiotics. Even after seven years in the field, he remains surprised by the absence of official awareness events or discussions regarding the threats posed by antibiotics.

PMDC Code of Ethics for Practice Medical and Dental Practitioners

The Pakistan Medical and Dental Commission (PMDC) was established under the Drugs Act of 1976 to regulate medical and dental education and the practice of medicine and dentistry in Pakistan. The PMDC sets standards for medical education, including the proper use of antibiotics and medications in clinical practice. It also has the authority to impose disciplinary actions against doctors who violate the ethical and professional standards established by the Council.The Ethics of Practice for Medical and Dental Practitioners outlines the ethical standards that physicians must adhere to. According to Section 9 of the Act, it is crucial for doctors to use medications responsibly, keeping in mind that the lives and safety of their patients depend on their vigilance, skill, and judgment.

Following the Drugs Act of 1976, the Pakistan Medical and Dental Commission (PMDC) was established to regulate medical and dental education and practice of medicine and dentistry in Pakistan (The Drugs Act 1976, 1976). The PMDC also sets standards for medical education, including the appropriate use of antibiotics and drugs in clinical practice. The PMDC has the power to impose disciplinary action against doctors found guilty of violating ethical and professional standards set by the Council. The Ethics of Practice for Medical and Dental Practitioners sets the ethical standards doctors should follow (PMDC, 2011). Section 9 of the Act requires the responsible use of medicines and encourages doctors never to forget that the lives and safety of their patients depend on vigilance, skill, and judgment.

Integrity and ethics are hallmarks of the respected medical and dental professions. Medical and dental professionals have a lot of autonomy and the ability to maintain while treating their patients fairly and honestly, providing freedom to choose their professions and employ patients accordingly. In treating patients, dentists and physicians are responsible for behaving according to established ethics and standards of conduct. Accurate diagnosis, treatment recommendations, and conflict avoidance are paramount in healthcare services. To earn the trust of their patients and be effective in general, healthcare professionals must adhere to ethical standards.Dentists and physicians should be free to choose their patients, cooperate with everyone, and set their rates and conditions of patient care.

Patients' lives and health depend on competent healthcare professionals and their care. Healthcare practitioners must prioritize the needs of their patients above all else and provide timely and appropriate care. If a patient is in urgent need of treatment or diagnosis and the treatment is not accessible, the doctor or physician should find a suitable alternative capacity to advise the patient.Medical and dental practitioners have a responsibility to respond to their patients' needs according to moral and professional ethics. It is appropriate for a doctor or dentist to encourage a patient to seek care from another practitioner only in cases of emergency. However, the initial responsibility lies with the medical or dental professional to treat the patient themselves unless they believe that providing care is inappropriate or the patient's condition is outside their area of expertise. Refusing to treat a patient is generally unacceptable unless there is a valid reason. The responsibilities of healthcare professionals to their patients are critical; any deviation from these ethical standards can have negative consequences for both patients and the healthcare system. By adhering to professional ethics and standards, healthcare providers can ensure that patients receive quality care and treatment.

The researchers in this paper found that implementing the code of ethics in Sindh is challenging due to several factors, including corruption, cultural and social barriers, a lack of knowledge, and limited resources. One significant obstacle is the unfamiliarity many healthcare professionals in Sindh have with the code of ethics and their associated responsibilities. This gap in understanding can lead to inadequate and non-compliant care. Additionally, health facilities in Sindh often lack the necessary resources and infrastructure to provide high-quality care, making adherence to the code of ethics difficult. According to the Pakistan Medical and Dental Council (PMDC) code of ethics, cultural and social barriers can further complicate care provision in some areas of Sindh. For instance, some patients may be hesitant to discuss certain health issues due to cultural conditioning.

Corruption remains a significant issue within Pakistan's healthcare system, particularly in the province of Sindh. This situation poses challenges to compliance with the Pakistan Medical and Dental Council's (PMDC) code of ethics and may lead to accountability issues for physicians who violate these standards. To effectively address these concerns, policymakers and health authorities in Sindh must provide healthcare professionals with the necessary resources and support to implement a robust code of ethics.

Sindh Healthcare Commission (SHCC) Act 2013

The Sindh Assembly enacted the Sindh Health Care Council Act in 2013 (Sindh Provincial Assembly, 2014). The primary objective of this Act is to regulate and register healthcare institutions, including private hospitals, maternity homes, dental clinics, laboratories, and homeopathic clinics. It aims to combat quackery in healthcare by collaborating with organizations such as the Pakistan Nursing Council (PNC), the Pakistan Medical and Dental Council (PMDC), the National Council for the Control of Tibs (NCT), and the National Council for Homeopathy (NCH) to address unacceptable medical practices (Sindh Provincial Assembly, 2014). The Act underscores the significance of monitoring and evaluating healthcare practices to ensure ethical standards in medical and healthcare institutions. It applies to both medical and health organizations across various sectors, including private and public organizations, non-profit entities, charitable hospitals, trust hospitals, as well as out-of-state and voluntary medical organizations.

The Act requires medical facilities to obtain a license to operate and emphasizes the importance of ethical considerations in healthcare systems, particularly regarding medical malpractice. It holds healthcare providers accountable in cases where patients suffer injury or die due to a lack of proper surveillance or unreasonable prescriptions driven by vested interests. While the Act aims to reduce quackery and ensure ethical practices in healthcare institutions, it also highlights the necessity of surveillance. It ensures that healthcare providers are held accountable for medical malpractice, thereby safeguarding patients' access to safe and effective medical treatment. However, our research indicates that these legal provisions are not successfully implemented in Sindh, especially in Khairpur Mir’s, the area under study. Several factors contribute to this lack of implementation, including a general unawareness of such policies among healthcare facilities and communities, unchecked commodification of medical practice, privatization of medical practice, insufficient monitoring of the regulation and implementation processes, and inadequate oversight of the authorities responsible for enforcing these policies. Additionally, unskilled health practitioners and instances of quackery contribute to the alarming rise of antimicrobial resistance, as these individuals often prescribe antibiotics unnecessarily.

CONCLUSION

In this research study, which draws on medical anthropology and public health perspectives, we have identified a significant medical ethical dilemma in Pakistan: the unchecked overuse of antibiotics and the resulting issue of

antibiotic resistance. Despite the implementation of numerous national, provincial, and international policies aimed at curbing antibiotic overuse, these measures often remain unfulfilled and are little more than promises on paper. Our data indicate that these policies and legal guidelines have not been effectively executed in medical practice within the area under study, specifically District Khairpur Mir's. Our anthropological approach has shed light on the question of medical ethics related to pharmaceutical use and practice. In this way, our study contributes to a deeper understanding of the intersection between law and medical practice at the micro level, that is, within district-level clinical settings and their relationship to the community—issues often overlooked in discussions of ethical medical practice.Our research revealed that many practitioners and medical professionals have a limited understanding of the existing legal frameworks and do not view addressing antibiotic resistance as part of their responsibilities. Instead, they often blame the World Health Organization (WHO), stating it has failed to provide adequate guidelines or notifications concerning these policies. Furthermore, there is a significant lack of surveillance and assessment in Pakistani medical institutions and healthcare facilities.This research has underscored the problems of bureaucracy within the health sector, highlighting poor governance and legal issues related to medical ethics and clinical practice. In this context, our study offers a fresh perspective on the challenges facing medical practice by examining its political, economic, and sociocultural dimensions.

This research paper has discussed the pressing public health concern of antibiotic and drug overuse in Pakistan, highlighting the need for solutions rooted in anthropologically informed social science and humanities perspectives. Our approach to medicine and health emphasizes humanistic and ethical considerations in medical practice. This work contributes to critical medical anthropology by offering new insights into healthcare, particularly by critiquing the commodification and marketization of health. Despite the development of regulatory frameworks aimed at controlling the use of antibiotics and pharmaceuticals, several challenges hinder their effective implementation. A decline in moral responsibility among medical practitioners and the prioritization of market interests over public health threaten the ethical integrity of the healthcare system. Factors such as a lack of knowledge and education among health professionals and the general public, easy access to antibiotics and prescriptions by physicians, and the availability of over-the-counter antibiotics without prescriptions encourage self-medication and elevate health risks for local populations.

The paper also highlighted the limited resources of the Drug Regulatory Authority of Pakistan (DRAP) and the Pakistan Medical and Dental Council (PMDC), which pose significant challenges to the effective enforcement of regulatory systems and legal frameworks. Addressing these issues requires critical medical knowledge, education, advocacy, and awareness to promote responsible use of antibiotics and drugs in Pakistan. In this regard, the study emphasizes the legal responsibilities surrounding antibiotic resistance and the need for improved surveillance and assessment within medical institutions and healthcare facilities across the country.

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