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IMPLEMENTATION OF PATIENTS' RIGHTS LEGISLATION IN THE REPUBLIC OF MACEDONIA: GAPS AND DISPARITIES

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ABSTRACT

Background: Since its formation after the breakup of Yugoslavia, Macedonia has made major strides in formulating a framework for protecting patient rights through extensive legal reform. The impact of this reform had not been assessed before the work of this project.

Methods/Objectives: Within the context of a larger project on improving human rights in patient care, this paper provides an overview of patients' rights legislation in Macedonia and uses research, case reports, and other empirical information to highlight the gaps in the implementation of patient rights' legislation on the ground.

Results: The Law on the Protection of Patients' Rights (2008) and attendant legislation governing health care provision and other aspects of the social contract in Macedonia provide extensive protections for the rights of patients in such domains as the right to access health care, the right to information, and the right to remedy. This legislation also outlines several new procedural channels to enable patients to vindicate their rights within institutional and governmental structures on the local and national levels. Data from a number of studies and case file reviews suggest, however, that the implementation of many key provisions is lacking, both in terms of quality and presence of services or mechanisms contemplated by Macedonian law. Gaps in implementation disproportionately affect vulnerable and marginalized groups, including women, rural residents, and Roma.

Discussion: Although the letter of Macedonian law generally complies with international best practices in patients' rights, these rights are not fully implemented and the mechanisms implied are not fully functional. Additional investment must be made in monitoring systems, education, and incentive mechanisms to ensure effective implementation, including the formation of a mandated commission for the protection of patients' rights.

INTRODUCTION

Providing appropriate and high-quality health care for the population is a challenge for any society, regardless of the state's level of development. Macedonia emerged from the Socialist Federal Republic of Yugoslavia in 1991, inheriting a highly decentralized, highly autonomous, socialist health system, with financing and control primarily at the local level.¹

As was the case during the period of socialism, after declaring independence from Yugoslavia, Macedonia enshrined the right to health in the Constitution of the Republic.² Since gaining independence, Macedonia has adopted an extensive set of legal reforms regulating rights within the health care sector, including the *Law on Health Care* (1991), which devotes a separate chapter to rights. Additional legislation, including the *Law on Health Insurance*, *Law on Mental Health*, and other related laws adopted

since independence, address distinct aspects of rights within the patient care field.³

However, likely the most significant among these laws is the 2008 *Law on the Protection of Patients' Rights*.⁴ The primary focus of this paper, this law marked a milestone in the field of human rights in patient care by providing an excellent basis for promotion of patients' rights.⁵ The law outlines patients' and providers' rights and obligations, as well as the mechanisms for protection of these rights.⁶ As the title suggests, the primary focus of the law is on patients' rights, with an extensive range of provisions that includes the right to preventive measures, right to access, the right to privacy and confidentiality, among others. The law also outlines a range of patients' responsibilities. According to Article 29, patients during their stay in the health care facility, in line with their health status, are obliged to: 1) care about their own health; 2) provide truthful and sufficient data on their health status according to their personal capacity and information; 3) provide active help to the health care workers who take care of their health condition; 4) act in accordance with health care workers' advices on their medical care, treatment, and rehabilitation; 5) respect the code of conduct and internal rules of the health care facility; 6) accept engagement that is part of their rehabilitation and re-socialization, for the purpose of reactivating their social skills and 7) respect the professional and human dignity of health care workers. Additionally, this law contains a special chapter on the responsibilities of health care institutions (Article 33) and health care workers (Article 38). It introduces a number of new mechanisms for protection and vindication of patient rights.

Macedonia has also signed and ratified numerous international instruments to affirm its commitment to a functional health care system and protecting patients' rights. This includes the International Covenant on Civil and Political Rights, the International Covenant on Economic, Social and Cultural Rights, the International Convention on the Elimination of All Forms of Discrimination against Women, and the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, among others.⁷ The most significant regional human rights instruments adopted by Macedonia include the European Convention on Human Rights and the Convention on Human Rights and Biomedicine.⁸ Generally, the laws in Macedonia are harmonized with the principles and norms of

international law, especially European Union guidelines that were adopted as part of the process of applying for membership.

The concept of human rights in patient care

Unlike the concept of "patients' rights," which articulates particular rights specific to patients, the concept of "human rights in patient care" refers to applicable general and universal human rights principles to all stakeholders in the delivery of health care services.⁹ Among others, state obligations to ensure equality, non-discrimination, freedom of assembly, freedom from torture, transparency, and accountability have been recognized by the international community as essential to the attainment of health.¹⁰ By specifically acknowledging these rights and responsibilities as applicable to both patients and providers, the concept of human rights in patient care embodies this broader, more holistic scope.

It is critical to note that patients' and providers' rights are interdependent. Just as patients face the risk of violations of rights to informed consent, confidentiality, privacy, non-discrimination, and even egregious abuses that rise to the level of torture and cruel, inhuman, and degrading treatment, health care providers may also face abuses such as unsafe working conditions and denial of due process when patients make complaints against them. Another example of interdependency centers around information: patients have the right to information on their health status, and health care providers have a responsibility to provide this information to them.¹¹ This dovetailing of provider and patient rights and responsibilities supports the delivery of quality health care services and contributes to a human rights environment that strengthens the provider-patient relationship.

This paper provides an assessment of the implementation of a national framework for the protection of patients' rights in Macedonia. It is part of a larger project, discussed in the next section.

METHODS

This project is part of a multi-site, networked research effort to identify gaps in national legislation addressing human rights in patient care in countries in transition from political environments where individual rights historically have not received much emphasis.¹² Using a research framework rooted in the European Charter of Patient Rights, the first phase

of the project comprised the formulation of country-specific Practitioner Guides to inform and facilitate the utilization of legal tools to advance human rights in patient care. These guides were developed through a collaboration of international experts with national interdisciplinary working groups comprised of lawyers, legal educators, judges, health care providers, public health and health management professionals, government regulators, patient representatives, ethicists, and others. The second phase consisted of these working groups engaging in systematic research, reviewing the legal canon applicable to the rights and obligations of patients and health care providers, integrating a desk review of the legislation, highlighting illustrative cases, systematically searching interdisciplinary literature, and providing an overview of the relevant procedural mechanisms. The research findings were circulated and debated, resulting in finalized versions of the guides. Other aspects of this project include dissemination and training activities for lawyers, judges, and health care providers based on the practitioner guides, a research fellowship, production of patient-friendly materials with a focus on marginalized populations, gaps analysis comparing domestic legislation with international and regional human rights standards, a dedicated website, and a Compendium Guide integrating the findings from across the sites. The legal fellow with a special interest in human rights in patient care in Macedonia coordinates updates to the Practitioner Guide, the web page (www.healthrights.mk), and training, as well as the development of patient-friendly versions in collaboration with host nongovernmental organizations (NGOs) and representatives of vulnerable groups. The role of the Macedonian fellows in this project was also to study the Macedonian legislation, compare it with international standards, identify where and why there is non-compliance with international standards or a lack of implementation of the regulations, and to point to possible solutions. Findings from this project were presented by the fellows and country representatives at the 18th World Congress on Medical Law in Zagreb, Croatia in 2010. Additionally, workshops were organized by Open Society Foundations within the frameworks of the Congress to address issues of human rights in patient care.

Reflecting the structure of this broader international project, the first phase of this project was to convene the Macedonian Working Group on Human Rights in Patient Care. This group included attor-

neys, judges, public health and health management experts, academics, advocates, members of civil society, and other relevant stakeholders. In the second phase, the Working Group conducted a desk review of Macedonian legislation and regulations in the realm of human rights in patient care. The group also obtained and reviewed all publically available documents on the implementation of these legal instruments issued by government institutions, academic researchers, civil society organizations, and international agencies between 2008 and 2013. These findings have been comprehensively laid out in the publication *Human Rights in Patient Care: A Practitioner Guide—Macedonia*.¹³

The analysis below synthesizes the information from the Macedonian practitioner guide about the current state of black letter law with the latest available information regarding the implementation of these legal provisions, including the *Law on the Protection of Patients' Rights*. To enable the review of jurisprudence on cases involving the vindication of rights provided under this law, the authors filed Freedom of Information Act requests with the General Court Skopje Regions I and II for years 2009–2012. Out of the broader framework of human rights in patient care offered by the guide, in this article, we focus particularly on six most fundamental and critical patients' rights. Our principal objective is to assess whether current provisions are sufficient to secure the full exercise of Macedonian patients' rights.

FINDINGS

Our formal review of Macedonian legislative space suggests that the adoption of the *Law on the Protection of Patients' Rights* was a significant step forward in further fleshing out human rights in patient care protections already established by various national, regional, and international instruments. Thus, the passage of this law in 2008 helped further align Macedonia's human rights legal framework with accepted best practices on human rights. We analyzed this legislative canon with a focus on actual implementation of this and other laws relevant to patient rights using current empirical data.

Right to preventive measures

The *Law on the Protection of Patients' Rights* contains no separate provision for the right to preventive measures, but this public health focused right is incorporated in other legislation, including the *Law on Health*

Care, the *Law on the Health Insurance*, the *Law on the Protection of the Population from Communicable Diseases*, the *Law on Safety and Health at Work*, and supporting regulations. For example, Article 10 of the *Law on Health Care* stipulates the inclusion of every citizen in the health care system, including health promotion and disease prevention services, as well as early diagnosis, treatment, and rehabilitation. Each year the Ministry of Health also mounts a set of targeted preventive and treatment programs.¹⁴ They cover a range of activities from monitoring to health promotion to vaccination in a range of priority areas, including addiction, child and maternal health, cancer, and infectious disease, such as tuberculosis and HIV/AIDS.

Despite comprehensive legislative coverage and ostensible commitment to public health prevention programming, substantial gaps remain at ground-level implementation of the right to preventive measures in Macedonia. We illustrate these gaps in the areas of early cancer detection, immunization of Roma children, and visiting nurse outreach services (known as patronage nursing in Macedonia).

The program for early detection of malign diseases in Macedonia in 2011 focused on early detection and prevention of cervical and breast cancers. According to one analysis, despite substantial investment in materials and instrumentation, only 43% of the planned activities were implemented due to a lack of trained staff.¹⁵

The World Health Organization (WHO) estimates that only 50% of Roma children in Macedonia are fully immunized compared to the national rate of 94%. The 2012 progress report provided by the European Commission also addresses the problem of low vaccination rates among Roma children, stating that many Roma children are either not fully vaccinated or not vaccinated at all.¹⁶ NGOs working in the field of Roma health offer similar statistics based on field research. Their surveys show that the pediatric vaccination coverage rate in Macedonia exceeds 95%, but the rates among Roma children are substantially lower. According to a 2010 study of Roma communities in 10 municipalities, rates among children (up to 18 years old) varied from 35% to 81% for different vaccines. Additionally, the coverage rate is especially low for vaccines that are given to children of school age.¹⁷ The vaccination rates in Roma chil-

dren in 2012 showed no improvement. According to a 2012 study on the immunization coverage of Roma children conducted in eight municipalities, the scope of vaccination in Roma children aged up to six years varied from 20% to 94%. These gaping disparities result from many factors, including flawed informational and logistical outreach to Roma households and lack of awareness of the importance of regular vaccinations among Roma parents.¹⁸

In the general population, widespread shortcomings exist in basic prenatal and neonatal nursing care coverage. Specifically, an assessment of sexual and reproductive health services suggests that 50.7% of first-time mothers did not receive the recommended free visit by a nurse during their pregnancy or after delivery due to an insufficient number of nursing staff, insufficient equipment (including vehicles), and other organizational issues.¹⁹ Similarly, according to the Institute for Public Health of the Republic of Macedonia, coverage of women by nurse visits is only 50% of what was planned in the program for active health protection of mothers and children.²⁰

These studies illustrate that, although formal law provides a right to preventive services, the realization of this right is still far from universal, and is characterized by egregious disparities impacting marginalized groups.

Right to access

According to Article 3 of the *Law on the Protection of Patients' Rights*, health care access must include the following conditions:

1. health care services constantly available and accessible to all patients on equal basis and without discrimination;
2. continuity of health care, including cooperation among all health care workers and health care facilities along the continuum of care;
3. just and fair procedure for choosing/selecting medical treatment, under conditions of limited resources and rationing, whereby prioritization is based on medical criteria and without discrimination;
4. choice of and ability to change health care provider and health care facilities;
5. availability of home visits and services in the community where the patient lives; and

6. equal opportunity for protection of health care rights for all patients in the territory of the Republic of Macedonia.²¹

The health care system in Macedonia is highly centralized despite the process of decentralization which has been underway in all segments of government in the country since 2001. As currently implemented, this highly centralized health system negatively impacts the right of access, with geographical disparities in provision of health care especially having negative effects for marginalized groups of the population.²²

The implementation of the right to access can be assessed through a number of studies. For instance, although general practitioner coverage for women nationally appears adequate (among 1,012 women, 88% stated that an office of the general practitioner is less than three kilometers from their place of residence) there are substantial disparities in the access to reproductive health services in urban and rural areas. Namely, only one-fourth of the women interviewed said that they have access to gynecological services near to their place of residence; the remainder responded that they face logistical barriers accessing such services.²³ For 15% of women, health care facilities providing reproductive health services are more than 10 kilometers from their residence. Here too there are substantial disparities: more than 60% of women from urban areas have regular annual gynecological exams, compared to less than 40% of women from rural areas. In terms of access to abortion services, more than one-fifth (20.1%) of the women interviewed felt that the price of the services was a barrier for access.²⁴

Regarding access to medicines, the financial allocations for the subsidy of medications on the List of Essential Medicines, posted by the Health Insurance Fund of the Republic of Macedonia in pharmacies around the country, present another barrier to access. Namely, the Health Insurance Fund determines the amount of money allocated to pharmacies in each unit of local government to cover medicines on the Essential List. Based on these allocations, funds are usually exhausted in the first 10 to 15 days of the month.²⁵ These limits are a significant barrier for socially vulnerable groups who are then forced to pay the full cost of medications in order not to interrupt the prescribed therapy. For example, a study among

Roma population showed that 55.5% of those interviewed have a chronic health condition that requires regular health services and long-term treatment. However, almost three out of four (72.4%) of those respondents reported not being able to afford the medicines necessary to control and treat their illnesses.²⁶

Regarding access to contraception, official data show that 35% of women aged 20 to 24 years in the general population and 40% of Roma women aged 25 to 29 years have an unmet need for contraception.²⁷ There are several factors that influence the rate of use of contraceptives among women of reproductive age in Macedonia. First and foremost, the List of Essential Medicines of the Health Insurance Fund does not include a single oral contraceptive product, which means that these products can only be purchased at full price. The lack of financial subsidy or coverage certainly contributes to the low contraceptive use rate in Macedonia: according to a survey, only 5.7% of women of reproductive age use oral contraception.²⁸ A survey by the Ministry of Health found the low motivation of health care workers to provide counseling services for family planning, the high price of contraception, and the inability of the Health Insurance Fund to cover these costs are the main causes for the low rate of contraceptive use.²⁹

Further, intravenous drug users in Macedonia face serious obstacles accessing to methadone substitution treatment. Available data indicate that the number of intravenous drug users in Macedonia is between 20,000 and 30,000, among which 6,000 to 8,000 are heroin users with serious health problems. In 2012, the public health facilities which provide methadone substitute therapy treated only about 1,100 patients who were included in the free national program, while approximately 150 patients received self-financed methadone substitute therapy in private health care institutions.³⁰ A major influence on the ability of drug users to exercise the right to access to treatment and the right to quality health care is the low number of drug treatment centers. Existing capacity is insufficient to provide treatment for all who want to be treated. According to one survey, an additional barrier medical treatment in this realm is the geographical inaccessibility of the treatment centers. These logistical barriers are also directly linked to the economic hardship that may result from treatment and drug use.³¹

People living with HIV/AIDS also face problems accessing antiretroviral drugs because of insufficient budget allocation and complex procedures for procurement of antiretroviral therapy, which lead to stock outages. Patients living with HIV/AIDS have been forced to procure their life-saving therapy with their own financial assets.³²

These and other data suggest that the *Law on the Protection of Patients' Rights* offers a good theoretical basis for every citizen's right to access quality and affordable health care, but in actuality citizens face a number of significant barriers that are especially pronounced among marginalized groups including women from rural areas, Roma, intravenous drug users, and people living with HIV/AIDS.

Right to information

The right to information is extensively covered in the *Law on the Protection of Patients' Rights*, reflecting international best practices.³³ According to Article 7 of this law, "the patient, during all stages of health care, shall have the right to be fully informed of:

1. his health status, including a medical assessment of the prognosis and outcome of a particular medical intervention;
2. recommended medical interventions, as well as dates planned for their realization (including a treatment and rehabilitation program);
3. possible advantages and risks of the realization and non-realization of recommended medical interventions;
4. his right to decide upon recommended medical interventions;
5. possible alternatives to recommended medical interventions;
6. reasons for possible differences in the result achieved by medical interventions as compared to the expected result;
7. the course of the procedure when providing health care;
8. recommended lifestyle; and
9. the right to health care and health insurance, as well as the procedure for exercising these rights."

Furthermore, information "...must be provided to the patient in an understandable and appropriate manner, minimizing technical or expert-level terminology." According to Article 12, the patient has the

right to refuse information on the nature of his or her health status and the expected outcome of the proposed or undertaken medical interventions, with an exception for cases when such refusal may endanger others. In such cases, patients have the right, by way of written consent or other valid means, to appoint a person who shall be given the information instead (Article 13). Additionally, Article 22 of the law establishes patients' right to be informed of their medical records and grants patients the right to access medical records. Namely, patients have the right to receive an excerpt or copies of data and documents from their medical records and have the right to ask for clarification of data in their medical records.

Violation of the right to information is considered a misdemeanor. According to Article 64 of the *Law on the Protection of Patients' Rights*, the health care facility and the responsible person will be fined if they fail to comply.

Furthermore, according to Article 65a introduced with an amendment to the *Law on the Protection of Patients' Rights*, the health care facility and the responsible person will be fined if they do not provide the patient with information and insight into the medical record.³⁴ Apart from the fine, the health care facility may be prohibited from performing some specific activities, while the responsible person may be prohibited from performing his or her professional duties.

Based on existing research, there are significant shortcomings in Macedonia's health care system's ability to fulfill this right. According to one assessment on sexual and reproductive health, less than a quarter of the women that had at least one delivery have received the recommended counseling, educational, or similar services related to pregnancy, delivery, and motherhood during their first pregnancy. Access to information was even more limited in rural areas.³⁵ Women from rural areas have limited access to family planning counseling, since it takes place in gynecological facilities, which are predominantly located in urban areas.³⁶ The situation is even worse among Roma. Data obtained from a survey conducted among Roma population show that 82.4% of those interviewed had not received any information from their general practitioner, gynecologist, or social worker regarding contraception or family planning. More than 25% of the interviewed Roma

women expressed dissatisfaction with the interaction and information presented by health care providers during their prenatal or neonatal visits.³⁷

Article 7 of the Macedonian *Law on the Protection of Patients' Rights* and WHO guidelines require information and counseling for the patient on abortion procedures before they occur, as an integral part of health service. After counseling is provided, the patient should give her informed consent.³⁸ Findings on abortion in Macedonia indicate that, of the women interviewed, one-fifth did not receive counseling or information on contraception, the abortion procedure, possible complications and consequences, and other related services.³⁹

In the Roma community, 92.7% of respondents who suffer from chronic diseases reported not being informed that their medical condition requires regular check-ups. According to the same report, new bureaucratic requirements further limit health workers' ability to dedicate adequate time to consultations with Roma patients.⁴⁰

Right to complain

Chapter 4 of the *Law on the Protection of Patients' Rights* is dedicated to the patient's right to complain. This law is the first to introduce several procedural mechanisms for filing and resolving patient grievances, including: the appointment of a counselor for protection of patients' rights in every inpatient health care facility; requiring the appointment of a person for protection of patients' rights in every primary health care facility; requiring the appointment of a person for protection of patients' rights at the Ministry of Health; instituting a local commission for the promotion of patients' rights in every unit of local government; instituting a state commission for the promotion of patients' rights; and organizing offices for expert assistance to insured patients for the implementation and protection of their rights regarding health insurance in every regional office of the Health Insurance Fund.⁴¹

According to a report on the implementation of the *Law on the Protection of Patients' Rights*, the Ministry of Health has appointed counselors for protection of patients' rights in only five of the 56 inpatient public health care facilities, while the number of the persons appointed for protection of patients' rights in the primary health care facilities cannot be accurately

calculated because the responsibility to protect the patients' right is usually given to some of the existing employees in the facility. The Ministry of Health has yet to appoint a person for protection of patients' rights within the Ministry; as of July 2012, the state commission for the promotion of patients' rights has yet to be formed. During the same period, only 25% of the units of local governments nationally had formed a Local Commission for the Promotion of Patients' Rights, as required by the law. What is even more concerning is that not all of these commissions are functional. The Health Insurance Fund set up offices for expert assistance to insured patients for the implementation and protection of their rights regarding health insurance in 24 out of its 30 regional offices.⁴²

Right to compensation

The right to compensation is stipulated within the Macedonian *Law on Obligation Relations* (contract law).⁴³ This law, in part, protects citizens' rights to "life, physical and mental health ...dignity, the privacy of one's personal and family life," and requires that just compensation be provided for violations of these rights. Article 9 of this law states that "every person is obliged to refrain from a conduct that can cause harm or damage to another person" and that "the person who causes proven harm or damage to another person must issue compensation for such harm or damage" (Article 141, Paragraph 1). The law defines damage as "a decrease in one's property (plain damage), the prevention of an increase in one's property (loss of value), and the harm or violation of one's personal rights (non-material damage)" (Article 142).

Data obtained from the General Court Skopje II (civil court) show that between 2009 and 2012, a total of 53 requests for compensation of damages were initiated against health care facilities within the city of Skopje.⁴⁴ Although not necessarily generalizable, data from General Court Skopje II covers a jurisdiction where the majority of the population of Macedonia lives and therefore illustrates the magnitude of the issue.

In its 2012 Annual Report, The National Ombuds Office (for human rights) reported on the many complaints that it received pertaining to the exercise of the right to a refund of payments for medi-

cal treatments, medicines, and medical devices that had caused patient harm. Although such refunds should be covered by the National Health Insurance Fund, many patients complained that the Fund had refunded their assets only partially. Patients also complained about the long procedure for obtaining such refunds.⁴⁵

Right to safety

The right to patient safety is established by Article 5 of the *Law on the Protection of Patients' Rights*, which states that patient dignity must be respected and that patients have the right to personal safety during a stay in a health care facility. The right to safety is not explicitly provisioned in any other article of Macedonian legislation. This right could also be related to the right to quality health care and to the issue of negligent treatment of patients sanctioned under the Criminal Code of the Republic of Macedonia.⁴⁶

The data gathered shows a low number of medical malpractice cases in the Macedonian health care system. Cases concerning medical errors are very rarely heard by the courts. For example, between 2009 and 2012 a mere four cases were initiated on the basis of “negligent treatment of patients” in the General Court Skopje I (criminal court). Notably, the Court did not enter a judgment of conviction in any of these cases. It is not clear whether the low number of these cases reflects a very low rate of medical errors, or whether systemic barriers discourage the filing of formal complaints of medical malpractice.⁴⁷

A patient's right to safety from communicable diseases is provided for in the *Law on the Protection of the Population against Communicable Diseases* (Article 13), while Article 14 of the *Law on Mental Health* stipulates the right of personal safety for the persons with mental disabilities during their stay in a health care facility.⁴⁸ According to the *Law on the Protection of Patients' Rights* and the *Law on Mental Health*, violations of the right to safety are sanctioned as misdemeanors.

DISCUSSION

Our research suggests that the letter of Macedonian law provides extensive substantive and procedural protections in the realm of patients' rights. Within the framework of the larger project on Human Rights in Patient Care, we have observed that the wide-ranging post-independence reforms have brought the Macedonian legal canon generally in line

with international best practice in patients' rights.⁴⁹ The present analysis suggests, however, that these rights are not fully implemented and the mechanisms implied or mandated by law are not fully functional. These findings parallel a wealth of research into the policy implementation gaps that generally plague legislation in human rights, public health, and other arenas.⁵⁰ Better tracking and more systematic monitoring of these gaps can help improve the implementation of these laws, as well as informing possible additional legislative or regulatory steps that are needed to better realize both the letter and spirit of existing law.

We found systematic disparities in the coverage of patients' rights laws in Macedonia, particularly affecting rural women, drug users, Roma, and other marginalized groups. Unfortunately, these findings add to a body of existing evidence that those who most need rights protection in the health care settings enjoy it the least.⁵¹ The causes of these disparities are likely many and varied, including structural factors such as education, socio-economic status, institutional discrimination, and deep-seated distrust of formal systems among marginalized groups like the Roma.⁵²

Ultimately, the observed disparities in health status among these populations highlight the urgency of efforts to eliminate the gaps in the implementation of patients' rights laws, not just as a normative human rights matter, but as a matter of critical public health importance. Additional investment must be made in monitoring, education, and incentive mechanisms to ensure effective implementation of these laws. Through our research and education efforts that are a part of this project, we hope to continue to inform the ongoing public debate about health care reform in Macedonia and advocate for increased investment in better implementation of patients' rights legislation going forward.

LIMITATIONS

This study should be considered in light of important caveats. Our findings in the realm of ground-level implementation of national laws regarding patients' rights rely on available government, academic, and civil society resources and not on specific field research conducted by the Working Group or by the article's authors. The scarcity of information on these issues produced by the relevant government institutions means that we have had to base much of the analysis on data presented by civil society organiza-

tions working in the field of health rights protection. Within the context of the Macedonian legal system, we also had to file specific Freedom of Information Act requests to obtain data on the number and nature of cases brought before the courts on specific issues. Because of logistical limitations, data were obtained only for the jurisdictions of General Court Skopje I and II. Although these jurisdictions cover the majority of the Macedonian population, they do not provide a comprehensive national picture, nor is the prevalence of cases necessarily generalizable to other districts. These limitations notwithstanding, our goal was to highlight existing gaps using available information; such gaps and disparities are readily evident, as are the broader structural gaps in enforcement, research, and monitoring efforts.

CONCLUSION

Although in theory Macedonian legislation complies with international standards for patients' rights, it is still not adequately implemented and fully functional. Further steps need to be taken in order to establish a system of patient care that is fully responsive to national and international human rights norms, including through efforts to raise awareness about and improve the enforcement of the legal protections and obligations set out by the laws in Macedonia.

In order to facilitate a more robust framework for the protection of patients' rights, we recommend the coordinated development of annual and multi-year plans for enforcement of legal instruments with input from key stakeholders. This also implies the need for the appropriate allocation of necessary funds to enable enforcement mechanisms for the protection of patients at national and local levels. In order to increase transparency and accountability, it is also critical that responsible authorities on national and local levels attach systematic and independent monitoring systems to existing legal mechanisms. Improved gathering and analysis of data on gaps and violations will enable more comprehensive, timely, appropriate, and meaningful interventions to protect human rights in patient care.

One principal way to operationalize such monitoring and implementation is through the establishment of the state commission for promotion of the rights of patients. This body would be tasked with undertaking investigative and enforcement actions to implement the 2008 *Law on the Protection of Patients' Rights*

and related laws and regulations. This body can also inform and promote efforts to comprehensively integrate human rights principles in the operational design of health care programs and services. Despite the government's long-articulated plans to do so, this commission is yet to be established. The numerous gaps and disparities identified in this article highlight the urgent need for this enforcement and monitoring body.

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