Reporting Violations of European Charter of Patients’ Rights: Analysis of Patient Complaints in Croatia

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Abstract

Background

The European Charter of Patients' Rights (ECPR) presents basic patients' rights in health care. We analysed the characteristics of patients' complaints about their rights through the official system and non-governmental organizations in Croatia.

Methods

The official system for patients' complaints in Croatia does not have a common protocol but there are different modes for addressing patient complaints. In this cross-sectional study, we analysed the reports about patients' complaints from the regional committees sent to the Ministry of Health and mapped the complaints received by the Croatian Association for the Protection of Patient's Rights (CAPR) to ECPR.

Results

The official data from the Ministry of Health in 2017 and 2018 included only 289 individual complaints from 10 out of 21 counties. Complaints were most frequently related to secondary and tertiary healthcare institutions and details were not provided. CAPR had 301 complaints about violations of patients' rights. The most common complaint was the Right of Access to health care (35.3%) followed by the Right to Information (29.9%) and the Right to Safety (21.7%). The fewest complaints were about the Right to Complain (1.9%), Right to Innovation (1.4%), Right to Compensation (1.4%), and Right to Preventive Measures (1.0%).

Conclusions

Reporting and dealing with patients' complaints about violations of their patients' rights is not effective in systems with parallel but uncoordinated complaints pathways. Mapping patient's complaints to the ECPR is a useful tool to assess the perception of patients' rights and to plan actions to improve the complaints system for effective health care.

Background

The rights of patients in Europe have been defined by the European Charter of Patients' Rights (ECPR), which was drafted in collaboration with 12 citizens' organizations from different EU countries in 2002 (1). The document lists 14 patients' rights: 1. Right to Preventive Measures; 2. Right of Access; 3. Right to Information; 4. Right to Consent; 5. Right to Free Choice; 6. Right to Privacy and Confidentiality; 7. Right to Respect of Patients' Time; 8. Right to the Observance of Quality Standards; 9. Right to Safety; 10. Right to Innovation; 11. Right to Avoid Unnecessary Suffering and Pain; 12. Right to Personalized Treatment; 13. Right to Complain; and 14. Right to Compensation (2).

These rights aim to guarantee a "high level of human health protection", as defined by Article 35 of the Charter of Fundamental Rights of the European Union (3), and assure high quality of services provided by the national health services in Europe. A recent analysis of the national legislature of the EU member states showed a varying degree of implementation of these 14 rights in national laws and regulations (4). The rights to information, consent, care quality, and prevention were more often covered by existing national laws compared to the rights to avoid pain, the right to innovation, and the right to respect patients' time (5).

The protection of patients' rights in different countries varies based on differences in the laws, organization of the healthcare service as well as economic, social, cultural, religious, and moral values (6). The extent of effective implementation of the ECPR also varies across the EU. While no specific provisions exist, the laws in many EU Member States regarding informed consent, privacy, and access to the health record, apply to health care (7).

One way to study how the rights of the patients are addressed in the healthcare system is the analysis of patient complaints. Although they are often unstandardized and provide an emotional description of individual patient experience (8) they are a valuable source of information on safety and a unique indicator of the quality of care and potential problems (9). When analyzed at an accumulated level, they can point out problematic trends in the health system (10).

This study aimed to describe the characteristics of the complaint system for patients' rights in Croatia, at the official level and the non-governmental level. Croatia is a new EU member and has not been included in previous studies of patient rights implementation. The Croatian Ministry of Health is responsible for health policy, including regulation and governance of health (11). The rights of patients in Croatia are generally protected by the Healthcare Act (12). In 2004, a special Act on the Protection of Patients' Rights (PRPA) was adopted (13) as a result of the civil society initiative for legislative protection of patients' rights by the then newly founded Croatian Association for the Protection of the Patients' Rights (CAPR) (14).

Methods

Analytical framework

The Republic of Croatia has a universal health care system regulated by the Healthcare Act (12). The Health Insurance Act provides mandatory insurance based on the principles of solidarity and reciprocity, whose primary aim is the provision of accessible, high-quality services to patients, including patient's
Croatian legislation generally draws from the ECRP and includes the Right of Access, Right to Information, Right to Consent, Right to Free Choice, Right to Privacy and Confidentiality, Right to Complain, and Right to Compensation (Patients’ Right Protection Act, PRPA), as well as the Right to Preventive Measures (Healthcare Act) and the Right to Safety and Right to the Observance of Quality Standards (Act on the Quality of Health and Social Care). The Right to Innovation, Right to Avoid Unnecessary Suffering and Pain, and Right to Personalized Treatment are not covered by Croatian legislation.

The official system for patients’ complaints in Croatia does not have a common protocol but there are different modes for addressing patient complaints. The procedure to protect patients’ rights begins with a complaint by a patient who considers that one of his/her rights established by the PRPA has been violated (16). The Ministry of Health has established the Commission for the Protection of Patients at the national level. The Commission has a consultative status and can act as an advisory body for the regional committees, where the patient can file a complaint directly arising from the PRPA. At the regional level, County Committees in 21 counties are independent bodies that also arise from PRPA and cover problems at the regional level, where patients can directly submit a complaint (13).

Healthcare providers are usually the first instance for patients’ complaints (17); every health institution has a unit for insurance and improving the quality of healthcare and a Health Care Quality Commission (18).

The patients can also file complaints regarding the conduct of health professionals to their professional chambers, which monitor the protection of patients’ rights from the perspective of professional ethics and deontology (19).

Another possibility for patients is a direct complaint to the Public Ombudsman of the Republic of Croatia (20).

Apart from regional or national bodies, patients can file complaints directly to The European Court of Human Rights (21,22). The Court has previously been involved in cases including patients’ right violation (6).

Outside the institutional framework, the Croatian Association for the Protection of the Patients’ Rights (CAPR) is a non-profit organization that provides direct legal and expert advice to the patients (23). CAPR is now considered a key non-government organization dealing with patients’ rights in Croatia (24,25).

Study design

We used a cross-sectional study design to analyse patients’ complaints at two levels: 1) annual reports of the local committees sent to the Ministry of Health (public data), 2) patient complaints received via an official email to the non-governmental CAPR.

Data extraction

We analyzed reports submitted by 21 county committees to the Ministry of Health in 2017 and 2018, which we had obtained by a written request for public information (26). It was possible to get only the aggregated data organized into categories by the type of health care profession/institution.

For queries submitted to the CAPR in 2017 and 2018, we analyzed the texts of all reports to identify the rights addressed by the complainants. Two authors (JK, MV) discussed each individual report and mapped the content of the complaints to the 14 ECPR categories of patients’ rights (1). In cases of disagreement, the third author (AM) was consulted. We also extracted the data on the age and gender of the person in the report, location of the health facility, level of care, and the type of health facility (public or private).

Ethical considerations

The official written reports of the regional authorities were available in aggregated form and were publicly available. Text analysis of CAPR complaints was performed on an anonymous dataset provided by the CAPR officer responsible for patients’ complaints and was analysed by the two authors who are CAPR members (JK and MV). The third author, who served as an adjudicator for unclear cases (AM) did not have access to the database but was consulted by the two authors who provided necessary and anonymous information on the issue in question.

Results

Complaints to the Croatian Ministry of Health

The Ministry of Health received 289 individual complaints in 2017 and 2018. These complaints came from 10 regional committees. Data from the other 11 regional committees were not available. Of 289 reports, 77.5% (n=224) were from the City of Zagreb (Figure 1). The counties with the next largest number of complaints were Primorje-Gorski Kotar County (6.2%) and Osijek-Baranja County (5.5%) (Figure 1).

These reports could not be mapped to ECPR as the content of the complaint was not available. According to the categorization of the Ministry, most frequent complaints were related to secondary and tertiary healthcare institutions (regional and university hospitals), followed by primary healthcare (family doctors and general practitioners), other (unspecified reports), and Croatian Health Insurance Fund (Table 1).

Complaints to CAPR
CAPR received 440 letters from patients by email in 2017 and 2018; 242 (55.0%) letters involved female and 151 (34.3%) male complainants, 6 (1.4%) letters involved patients of both genders, and in 41 (9.3%) letters the gender was not recorded or could not be inferred from the text of the complaint.

Details about the person or institution about which the complaint was made were not provided in 46.1% of the letters. The letters where this information was included (n=237) came mostly from the capital city (20.5%) and the Split-Dalmatia County (8.6%), which includes Split, the second-largest city in Croatia (Figure 2).

Most of the comments in patients’ letters (233, 52.9%) were general questions about the healthcare system in Croatia. In 207 letters that included complaints about the alleged violations of ECPR, we identified a total of 301 complaints that included violations of patients’ rights as outlined in the ECPR. The median number of complaints about patients’ rights violations was 1 (interquartile range=1-2, range=1-5).

Complaints about the Right of Access were most common (n=73, 35.5%), followed by the Right to Information (n=62, 29.9%), the Right to Safety (n=45, 21.7%), the Right to Respect of Patients’ Time (n=38, 18.4%), and the Right to Avoid Unnecessary Suffering and Pain (n=38, 18.4%). The Right to Complain, the Right to Innovation, the Right to Preventive Measures, the Right to Compensation and were least reported (fewer than 2% of the cases for each right; Table 2).

The majority of complaints dealt with patients’ rights in secondary and tertiary healthcare institutions (n=112, 54.1%), followed by primary healthcare providers (including general practitioners, family medicine doctors, primary care pediatricians, emergency medicine, and state-employed dental medicine doctors; n=46, 22.2%). Complaints were less common about palliative care (n=7, 3.4%), private medical specialists or institutions (n=5, 2.4%), or private dental medicine providers (n=5, 2.4%). Three complaints (1.4) dealt with more than one category, and health institutions could not be identified in three complaints (1.4%). There was a total of 10 (4.8%) complaints against private healthcare institutions.

Discussion

This is the first study, to the best of our knowledge, to map the complaints about violation of patients’ rights according to the ECPR. The charter itself is not a law but has been developed as a consensus document and a valid tool for analysis and charting of patients’ complaints about violation of their rights.

The main finding of the study was that the official documentation about patients’ complaints was not informative with regard to the violation of their right. Although there are several official pathways for patients to complain about violations of their rights, the official information was available only for less than a half of the administrative and geographical units of the Republic of Croatia. We did not receive the information on why these counties were omitted from the report. It is highly unlikely that no patients submitted complaints in missing counties, as patients’ complaints received by non-governmental CAPR came from 20 out of 21 counties.

In contrast, the analysis of the complaints to a specialized non-governmental organization for the protection of patients’ rights showed that the most commonly reported violation was the Right to Access, followed by the Right to Information and the Right to Safety. The majority of alleged violations were related to health care institutions in the City of Zagreb, followed by the Split-Dalmatia County, the second largest administrative unit in Croatia. The majority of communications from patients to the CAPR dealt with institutions from the city of Zagreb. Healthcare system in Croatia is centralized, and a large majority of official reference centres for the Ministry of Health are in different hospitals in the Zagreb area (27). More than half of all complaints dealt with hospitals (secondary level institutions), university hospital centres (tertiary level institutions) and specialists. We could not find studies from Croatia dealing with the comparison of patients’ complaints in primary and secondary healthcare settings, but a recent systematic review shows that patients generally more often express concern regarding the secondary and tertiary level of care, including problems with communication and coordination (22). Patients more often develop trusting and well-connected relations with their primary care physician (28), which has been proven to reduce the number of malpractice suits (29).

Previous analysis of the ECPR by Mathuna et al. (30) codified 15 rights of the ECPR into five different groups, to create a more workable analytical framework. The first theme is “Access to Healthcare”, including the Right to Preventative Measures, Right to Access, Right to Free Choice, Right to Respect Patients’ Time, Right to Innovation, and Right to Personalized Treatment. These rights are considered to be basic patient rights (31). The Right of Access and the Right to Respect Patients’ Time were among the most commonly identified violations in our study, accounting for more than a third of all identified violations. Access to healthcare in Croatia is recognized as a problem, particularly for patients with lower socioeconomic status (32). The Ministry of Health’s Strategic Plan for 2018-2021 emphasizes the importance of equal healthcare access, especially for isolated parts and islands (27), but the is not data on whether the measures have been successful.

The Right to Health Innovations was identified in just a few cases. The knowledge of Croatian patients about clinical trials is overall rather low, and they are mostly not aware of trial registries and the availability of information for patients on clinical trials (33). Furthermore, the number of clinical trials in Croatia is declining (34). Patients’ complaints regarding the Right to Preventive Measures were also identified in just a few cases. This may be the reflection of Croatia’s long tradition of preventive public health (35). The Croatian Institute for Public Health provides broad support for different public health campaigns, including vaccination and screening (36).

The other themes in the analytical framework of Mathuna et al. (31) are “Informed consent” (the Right to Information and Right to Consent), “Safety and Quality Assurance” (the Right to Observance of Quality Standards, the Right to Safety and the Right to Avoid Unnecessary Suffering and Pain), “Privacy and Confidentiality” (the Right to Privacy and Confidentiality) and “Redress” (the Right to Complain and the Right to Compensation). The right to information and right to informed consent are recognized in all Croatian laws regulating patients’ rights since 1993 (37).

The right to information is emphasized heavily in PRPA, and patients have the right to information about their health, including the right to second medical opinion, right to information provided in the understandable way, as well as right not to know (13). The right to information was second most often reported.
In PRPA (13), the right to shared decision making includes both the right to be informed and the right to consent. A recent study demonstrated that the implementation of informed consent is satisfactory, but identified problems in the informed consent process, such as low quality and understandability of written forms used to obtain consent (37). Moreover, studies from Croatia show that shared decision-making education in medical schools’ curricula often lacks, and this aspect of the non-curriculum may be translated into everyday clinical practice (38). On the other hand, there were only a few cases where we identified potential violations of the Right to Consent, which is most probably the consequence of strict legal rules, as providing treatment without consent is considered both criminal and civil offense in Croatia (13).

The violation of the right to complain was reported in a small number of cases. We believe this reflects the fact there are several instances where patients can file a complaint in Croatia (such as healthcare institutions where the violation possibly occurred (17, 18), Ministry of Health (16), regional committees for protection of patients (13) or health professional chambers (19). The Right to Compensation was identified in just a handful of cases. There are no data available on the number of lawsuits for compensation and possible trends, except for rare cases that gain media attention in Croatia, often following long and strenuous legal proceedings and huge monetary compensations (39).

In order to impact the quality of care, patients’ complaints should be comprehensive and context-specific (40-43). While we categorized the complaints according to the rights outlined in the ECPR, the majority of complaints were actually questions about the healthcare system in Croatia. This contrasts similar research, where the majority of complaints have dealt with actual patients’ rights infringements, such as in Ireland (44). Many questions about the healthcare system as well as infringement of the Right to Information, which was the second most common patient complaint to the CAPR, could point out to low health literacy in Croatia. Health literacy is a broad concept – a set of skills needed to function and understand the healthcare environment (45), ranging from understanding health information to health numeracy (46). Low health literacy seems to be associated with poorer health outcomes (47), and different information about health or healthcare system should be easily accessible to low-level health literacy patients (48). Overall, health literacy in Croatia in hospitalized patients is less than adequate (49). Future studies are needed to explore health literacy in general public, as well as among those seeking help from the CARP, and identify specific characteristics and risk factors for low health literacy and how this may be linked to the understanding of patients’ rights.

Our study showed that the patient complaint system in Croatia is not well organized, as there are no developed standardized procedures for responding to patient complaints, and no defined approaches to the legal protection, promotion, or recognition of patients’ rights, despite different official pathways to submit patients’ complaints. While in other EU countries the relationship between health care professionals and patients is built on confidence and cooperation, gratified with person-centred communication, the Croatian health care system is still built on paternalistic doctor-patient relationship where patients often do not know the names of their healthcare providers (50).

Research into patient complaints is important as it helps identify problems in patient rights and safety. To achieve this, it is necessary to standardize how patient complaints are analysed and interpreted. Although patient complaints provide a unique insight into the problems that occur in the healthcare system, there is no systematic approach to evaluate and analyse these complaints at a central level. The existence of several parallel pathways to report violations of patients’ rights in Croatia does not seem to increase the confidence of patients, but is rather confusing as there are no clear instructions for patients about their rights and the procedures to protect them. The official bodies responsible for the protection of patients’ rights do not collaborate and do not follow protocols. Based on the results of our study, the recommendation for the Ministry of Health, would be the adoption of clear pathway for complaints about health services, such as that of the National Health Service in the UK, which provides detailed instruction on how to complain to the health services, either online, in the waiting room or at the service provider website (51). The patients filing the report can complain only to a single body, either directly to the NHS or the commissioner of services. In this way, health care organizations have to work together to ensure that the person filing the complaint receives an answer (51).

Limitations

This was a cross-sectional study with several limitations. The data from the Ministry of Health was incomplete and available only in an aggregate format, so we were not able to map the complaints of patients’ rights violations to the ECPR. Eleven regional committees’ reports were missing. Secondly, we analysed patient complaints received by the CAPR official email. This could be a potential selection bias as it could exclude older patients which do not use electronic communication. Moreover, violations of patients’ rights could be reported by individuals with certain characteristics, who may not be representative of the whole population. The complaints made directly to the hospital or those including legal representatives without consulting the CAPR or regional committees were not available for analysis.

Conclusions

Our findings suggest that the health system in Croatia provides a complex framework for reporting and dealing with patients’ complaints, including both officially recognized bodies and non-government organizations. However, this system is not effective in accurately capturing and reflecting the actual state of protection of patients’ rights in the Croatian health system: publicly available data from the regional committees do not specify complaints related to possible violations of patients’ rights, and the comments sent to non-governmental patients’ right organizations are not official and are probably not fully representative. More transparency and a clear process of lodging complaints are needed in order to better understand patients’ needs, resolve allegations, prevent future complaints, thus increasing the quality and safety of the health care system.

List Of Abbreviations
ECPR: European Charter of Patients' Rights
HCA: Healthcare Act
PRPA: Protection of Patients' Rights Act
CAPR: The Croatian Association for the Protection of Patient Rights

Declarations

Ethics approval: Not applicable.
Consent for publication: Not applicable.

Availability of data and materials: The datasets generated and/or analysed during the current study are not publicly available due to privacy but are available from the corresponding author on reasonable request.

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Authors’ contributions: JK and AM conceived and planned the study; JK acquired the data; JK and MV analysed the data; JK, MV and AM interpreted the data; JK drafted the manuscript and MV and AM revised it for intellectual content; JK, MV and AM agree to the publication of the manuscript and are accountable for the article.

Competing interests: JK and MV are members of the Croatian Association for the Promotion of Patients’ Rights. JK is the creator of the International Council of The Patient Ombudsman (https://patientombudsman.eu/). AM declares no conflict of interest.

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**Tables**

**Table 1.** Analysis of patients’ reports from the Ministry of Health, mapped according to institution included in the report (N=289)

|                         | Total | Zagreb (city) | Zagreb county | Osijek - Baraja | Bjelovar - Bilogorje | Krapina Zagonje | Istra | Primorje - Gorski kotar | Sisak - Moslavina | Zadar | Požega - Slavonia |
|-------------------------|-------|---------------|---------------|-----------------|-----------------------|----------------|-------|-------------------------|-------------------|-------|---------------------|
| Primary health care     | 59    | 43            | 1             | 3               | 3                     | 2              | 1     | 4                       | 2                 |       |                     |
| Secondary health care   | 77    | 56            | 1             | 3               | 1                     | 2              | 8     | 2                       | 1                 | 1     |                     |
| Medical specialists     | 27    | 20            | 1             | 1               | 1                     | 3              | 1     | 1                       |                   |       |                     |
| Dental medicine         | 9     | 6             |               |                 |                       | 1              | 1     |                         |                   |       |                     |
| Psychologists           | 3     | 3             |               |                 |                       |                |       |                         |                   |       |                     |
| Nurses                  | 20    | 19            |               |                 |                       |                |       |                         |                   |       |                     |
| Croatian Health Insurance Fund | 31 | 26           | 3             |                 |                       |                | 1     | 1                       |                   |       |                     |
| Drugs’ committee        | 3     |               |               |                 |                       |                |       |                         |                   |       |                     |
| Legal expertise         | 1     |               |               |                 |                       |                |       |                         |                   |       |                     |
| Emergency medicine      | 3     | 1             | 1             |                 |                       |                |       |                         |                   |       |                     |
| Laboratory medicine     | 1     |               |               |                 |                       |                |       |                         |                   |       |                     |
| Physical therapy        | 2     |               |               |                 |                       |                | 1     | 1                       |                   |       |                     |
| Other                   | 53    | 51            | 2             |                 |                       |                |       |                         |                   |       |                     |
| Total                   | 289   | 224           | 4             | 16              | 7                     | 3              | 18    | 3                       | 4                 | 4     |                     |

**Table 2.** Patients’ complaints to the Croatian Association for Patients’ Rights according to European Charter of Patients’ Rights (N=207)

| Charter Right                              | N (%)* |
|--------------------------------------------|--------|
| Right of access                            | 73 (35.3) |
| Right to information                       | 62 (29.9) |
| Right to safety                            | 45 (21.7) |
| Right to respect of patients’ time          | 38 (18.4) |
| Right to avoid unnecessary suffering and pain | 38 (18.4) |
| Right to personalized treatment            | 8 (3.7)  |
| Right to consent                           | 7 (3.7)  |
| Right to the observance of quality standards | 7 (3.7)  |
| Right to free choice                       | 6 (2.9)  |
| Right to privacy and confidentiality       | 5 (2.4)  |
| Right to complain                          | 4 (1.9)  |
| Right to innovation                        | 3 (1.4)  |
| Right to compensation                      | 3 (1.4)  |
| Right to preventive measures               | 2 (1.0)  |
Total number of charter rights violations is higher than a number of complaints analysed (N=207) as some complaints included more than one charter right violations.