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IN THE FIELDS OF BIOMEDICINE AND HEALTH (CDBIO)

Report on the replies to the questionnaire on patients' rights legislation

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Overview

19 Member States, i.e. just over 40%, and one Observer State replied to the CDBIO's questionnaire on the protection and promotion of patients' rights legislation. This report provides a general overview of the replies without going to the granular level of individual State's approaches focusing instead on identifying general trends and good practices. It then identifies the areas of challenge and gaps, which may need further consideration at the domestic level and finally, on this basis it proposes possible avenues for further action for the States and/or the CDBIO.

There are a few general observations that are worth noting. First, all States that replied to the questionnaire answered questions Nos 2 (on patients' rights in other legislation), 8 (on free and informed consent), 10 (on consent for the collection and processing of personal health data), 11 (on protective measures for the collection and processing of personal health data), 12 (on access to individual health data) and 13 (on mechanisms for recourse when the human rights of patients have been violated).

The second group of most popular questions that were answered by 19 States were questions No 1 (on patients' rights legislation), 3 (on equitable access to health care), 4 (on information about health care availability and access), 5 (on safeguards and support for the vulnerable), 6 (on measures for ensuring the safety and quality of health care) and 9 (on safeguards for persons who are not able to consent).

The question that attracted the fewest replies was the open-ended question No 15, which invited comments regarding the possible gaps and areas for further development. 12 States replied to it. The second group of least answered question were No 7 on whether domestic legislation provides for human rights training of healthcare professionals and No 14 on whether domestic legislation provides for public dialogue or consultation on health-related issues. 16 States provided replies to these two questions.

1. *Is there a specific domestic legislation on patients' rights in your country?*

Overview

19 of the 20 States responded. All states that replied stated that they had relevant domestic legislation. The majority, i.e., 11 States, reported having a law on patients' rights or a section of a law with the title 'patients' rights'. There was some nuance in the other replies. For example, 2 of the States did not directly refer to 'patients' rights' in their legislation but instead referred to 'treatment contract'. The terms, however, largely followed the content of patients' rights legislation, although appeared to focus more on obligations to provide information and seek consent. One of the State's legislation framed patients' protection as standards for health professionals rather than rights while another State's provision of patient rights cut across a number of instruments, without a single act specifically targeted at patients' rights.

States with regional administration also differed. One State did not report having specific federal or regional legislation on patients' rights but rather uses their administration to uphold principles, while all health management is deferred to regional governments. Another State similarly deferred its health management to its regions but had regional legislation on patients' rights.

Gaps and challenges

Patients' rights seem to be generally well-incorporated in the legislation of the Member and Observer States that answered the questionnaire.

Avenues for further action

The States without designated legislation or parts of legislation on patients' rights might want to consider introducing such legislation for increased clarity, transparency and ease of access by individuals.

States that do not have specific federal or regional legislation on patients' rights should consider incorporating the relevant principles and practices into law.

2. *Are there patients' rights provisions under other legislation, concerning the fields below?*

Overview

All 20 States answered this question. The responses are organised by common themes below.

General medical practice

16 of the States mentioned different provisions of their legislation concerning various aspects of general medical practice, including:

- Data protection, processing, record keeping and access (including electronic) was reported by 12 States;
- Health care quality (including physician selection, choice of care, professionals, access) by 10 States;
- Self-determination (including using tracking systems; in relation to biological material etc) by 4 States;
- Right to compensation for damage to health by 3 States;
- Palliative care/sedation/cessation of life-sustaining care by 3 States;
- Medical insurance by 3 States;
- Protection of vulnerable groups (elderly, children, gender-based violence) by 3 States;
- Communicable diseases by 3 States.

Individual States reported having domestic law provisions concerning health care during prison care and internment, specific legislation on drug and alcohol addiction, as well as on blood

collection. One State reported having legislation on medical preventive measures, which stood out as good practice. Another has an act regulating the professional activities of doctors.

Mental healthcare

15 States reported having legislation regarding mental healthcare, one at the regional level only. 7 States informed of having a specific mental health statute. 2 States stated they have limited regulation of certain aspects of mental healthcare, i.e., regarding the admission of psychiatric patients to institutions, the restrictive measures applicable during their care or the provision of health services in comprehensive medical-psychiatric hospital care units. 3 States reported having no legislation regarding mental healthcare.

Transplantation

17 States reported regulating transplantation with 14 having a specific law on the matter. More general regulation of transplantation within a broader human rights framework was reported by 2 States. One of the replies did not list any legal provisions on transplantation beyond general patients' rights.

Research

14 States informed of regulating research, the majority, 10, regulate research generally, 7 also regulate research involving medicinal products, 5 mentioned research involving medical devices, 2 reported provisions on the ethics of biomedical research and another 2 mentioned research on embryos and/or embryonic stem cells.

2 States reported not having legislation on research involving people and 2 said they have no legislation regarding research.

Genetics/genomics:

Domestic regulation of genetics and genomics was quite variable across the Member and Observer States. 14 reported having legislation in the field with some focusing only on research, others regulating genetic technology, material, testing and/or treatment. 6 States listed no legislation.

There is room for further regulation by the Member States who do not yet have genetic legislation, as well as for more homogenous regulation of more aspects of genetic interventions, particularly the high-risk ones involving new technologies like genome editing.

Reproductive health

This was the area of health care with the greatest variation among the Member and Observer States, which is not unexpected. 16 States reported having legislation on assisted reproduction, some focusing on reproductive health and rights, others on the protection of embryos, the health of mothers, prenatal testing, sterilisation and/or termination of pregnancy, as well as population

planning. 2 States reported provisions on the termination of pregnancy only. 2 States reported having no legislation on reproductive health at all.

Gaps and Challenges

The areas with greatest variation of Member and Observer States' approaches are genetics and reproductive health, followed by the regulation of mental health and of research.

A third of the States that answered the questionnaire have no legislation on genetics and genomics and a quarter have no or only limited regulation of certain aspects of mental healthcare. The variation of approaches towards reproductive health is well within the margin of appreciation of the Member States, given their different cultural, moral, social and religious contexts. However, despite the differences, comprehensive regulation of the field taking into account all country-specific characteristics would be highly desirable.

Avenues for further action

It may be desirable to encourage Member States that do not do so yet to regulate genetics, especially high-risk interventions and new technologies, as well as to introduce comprehensive legislation on all aspects of mental healthcare and reproductive health. The CDBIO may be able to guide and assist Member States with recommendations or model laws in these areas.

3. *Does domestic legislation include provisions/provide for measures to ensure equal access for equal needs (equitable access) to healthcare?*

Overview

19 States answered this question. There were some nuances in the reported legislative practices with 12 States providing for 'equal access', often coupled with the prohibition against discrimination based on protected characteristics, 4 requiring health insurance from everyone and 5 States reported having special laws to ensure access to health care to vulnerable and/or marginalised groups, including those in more remote areas, adults with difficulties and people without social security. The term 'equity' or 'equitable access' was reported to be used expressly in the legislation of only 2 States, however other States too described what giving equitable access to health care is in effect. Some States listed specific mechanisms to assist equitable access, i.e., providing care free of charge or with the payment of a participation fee, or having a regime on prioritisation of care based on need. A few States framed access as an individual or human right: one State reported providing equal access framed as a human right to health care, another framed it as a right to have the best possible standard of health, a third as a right to quality medical care. The latter two approaches can be seen as instances of good practice.

Gaps and Challenges

Whilst nearly all States that replied to the questionnaire make provision for some form of equal access and prohibit discrimination, not all seem to guarantee equitable access to health care, especially with respect to marginalised groups and non-citizens or those who are not part of a public health insurance system, such as asylum seekers or the homeless.

Avenues for further action

- States should do more to ensure that marginalised groups and non-citizens are guaranteed access to health care through positive measures and focused mechanisms;
- Equality acts could prevent refusal by providing mechanisms to challenge discrimination, rather than by only declaring broad and general rights of non-discrimination;
- States could consider including obligations to ensure timely access;
- States could do more to ensure that health care is both economically and physically accessible, including by adopting positive legal measures, specific mechanisms and by framing equitable access to health care as an individual right, in line with Article 3 of the Oviedo Convention.

4. *Does domestic legislation provide for measures to ensure appropriate information about healthcare availability and access?*

Overview

19 States answered this question. There was significant variation in the reported approaches with some States having no law requiring access to information about health care availability and access, others providing only for general information about health services and some for personalised information.

8 States listed obligations requiring health care professionals to inform patients of various matters relating to availability and access. All but 2 provided greater detail about what information ought to be provided. For 2 States, it is the insurer who has to assist with the provision of such information. 1 State provided for a right in specified circumstances, such as the use of force in mental health care. 6 States reported requiring the more specific provision of information about the individual's health, often framed as a right to information.

Others did not require the provision of appropriate measures. 3 States noted the lack of relevant legislation explicitly, for 2 this was implicit in the content of their answer.

Gaps and Challenges

There seems to be a recurring gap in the domestic legislation of States with respect to adopting specific measures for ensuring appropriate information about health care availability and

access. The right to information about health care seems to be incorporated more generally and not always coupled with a corresponding duty to actually provide the information.

Avenues for further action

- States could be more proactive in obliging their competent authorities to adopt measures that will ensure information about health care availability and access;
- More States could consider adopting the specific model whereby doctors and not just private insurers are obliged to provide such information;
- States could consider imposing specific obligations with respect to different types of health care information, including personalised one, to help ensure patients receive greater care;
- Broader publication of rights and obligations to provide health care information would be beneficial.

5. *Does domestic legislation provide for specific safeguards and support for persons in vulnerable situations (including migrants, and other marginalized groups such as ethnic minorities)?*

Overview

19 States answered this question. There was significant variation in defining who is 'vulnerable' and protected, as well as with respect to the scope of the specific safeguards that were provided.

6 States reported having non-discrimination provisions but no positive safeguards to support persons in vulnerable situations. Some States mentioned positive measures, such as: the provision of intercultural mediation; requirements for interpretation, taking into account language, needs and culture, specific services for persons with disabilities, and cross-border health care; free health care for groups including disabled, insecure families, migrants, trafficking victims; special safeguards for the vulnerable; emergency health care for all; free of charge treatment of conditions caused by FGM/abuse/sexual violence; power to exempt from charge humanitarian detainees and armed forces; and special rights for mental health patients. Different States defined the scope of who they consider 'vulnerable' differently, including: minors, abuse victims, detainees, invalids, persons with rare/chronic/specific diseases, prisoners, pregnant women, autistic people, foreign citizens, welfare recipients, jobseekers, pregnant women/those on maternity leave, persons raising children, minors, students, disabled persons and their caregivers, persons with infectious diseases, detainees, asylum seekers, pregnant women in disadvantaged areas, victims of modern slavery, humanitarian detainees, armed forces, mental health patients and persons not being able to consent.

States with mandatory insurance had some safeguarding mechanisms too, be they limited, i.e., to provision for precarious life situations. A few considered financial issues such as having provision to assist during financial difficulties and providing support for uninsured asylum

seekers. Illegal residents in some States were entitled to urgent medical assistance. There were special provisions for refugees in 4 States, 1 commented that despite the mandatory insurance requirements, refugees were included in their public health insurance system.

2 States reported limited support for vulnerable persons, i.e., only in relation to privacy; with respect to tuberculosis testing, being mandatory for groups such as refugees. 2 States listed no measures of support, 1 repeated general obligations.

Gaps and Challenges

- There are significant gaps in the reported standards of protection for vulnerable groups;
- There are substantial differences in defining who is considered 'vulnerable';
- Very few States reported support for refugees and asylum seekers;
- Many States reported imposing only negative safeguards for the vulnerable in the form of non-discrimination.

Avenues for further action

- States should consider defining who is 'vulnerable' broadly to include different classes of vulnerable persons;
- It would be highly desirable to adopt specific positive measures to support the vulnerable building on but going beyond the standard of non-discrimination in order to ensure their effective protection and equitable access to health care;
- Refugees and asylum seekers should be supported and given access to health care to the extent possible;
- Broader cultural aspects, such as providing interpreters, should be considered where possible.

6. *Does domestic legislation provide for specific measures/include provisions to ensure safety and quality of healthcare (e.g. training requirements for healthcare professionals, ...)*

Overview

19 States answered this question. There was some variation in the approaches and difference in emphasis but most States, i.e., 16, reported requiring quality of health care and imposing safety standards, most commonly through registration and qualification requirements for health professionals, which were reported by 14 States. Many informed of additional mechanisms in place, such as: internal, external and public review mechanisms, which were reported by 4 States; guarantees of professional freedom, reported by 1 State; guarantees of or requirements to improve quality, reported by 5 States; financial incentives for improvement, reported by 1 State; having a guide on patient safety, reported by 1 State and requiring continuing education for doctors reported by another. Only 1 State reported having no requirements to ensure safety and quality of health care and another listed broad general principles.

Gaps and Challenges

There are no significant gaps or challenges in the reported legislation on the safety and quality of health care.

Avenues for further action

Drawing from the good practice of some, States may consider requiring internal and external quality and safety assessment systems, as well as making the results of such assessments public.

7. *Does domestic legislation provide for human rights training of healthcare professionals?*

Overview

16 States answered this question. Most, i.e., 8 States, reported not having legislation providing for human rights training of healthcare professionals. 3 States reported having general ethical training. Some reports were vague. 3 States mentioned having patients' rights training. Only 3 States require healthcare professionals to take courses on human rights.

Gaps and Challenges

Most States don't seem to have legislation requiring human rights training of healthcare professionals.

Avenues for further action

It would be highly desirable to have specific human rights training of healthcare professionals going beyond 'ethics' and focusing on the individual patients' rights in addition to the doctor's ethical obligations.

8. *Does domestic legislation include provisions on free and informed consent to intervention in the health field?*

Overview

All States answered this question and all listed relevant laws in response. The specified nature of free and informed consent varied.

14 States informed us of detailed legislative requirements guaranteeing free and informed consent to medical interventions. 4 reported having a general requirement of consent without specification of the conditions it needs to meet. 7 States listed exceptions for when medical procedures may be conducted without consent, such as in cases of a threat to the person's life,

a disease posing a danger to the public and emergency situations. Only 2 States didn't seem to have a general express requirement of free and informed consent in their legislation but had related rights - one of them has a general legal requirement elsewhere that touching a patient without valid consent may be illegal. The other set out the general rights to information and self-determination.

Gaps and Challenges

Nearly all States have legislation requiring free and informed consent to medical interventions. The degree of specificity as to what constitutes free and informed consent and how it is guaranteed in practice vary.

Avenues for further action

- It would be highly desirable for all States to expressly require free and informed consent to interventions in the health field;
- States that don't do so already should consider setting out specific requirements of what constitutes informed consent and what information should be given to the patient;
- States could draw inspiration from the good practice of other States and consider adopting requirements on 'clear, truthful, sufficient, timely and objective manner' and a rights-based approach respecting the patient's wishes and their right to self-determination.

9. *Does domestic legislation include special safeguards for persons who are not able to consent with regard to possible intervention in the health field, including on their participation in decision-making process?*

Overview

19 States answered this question. There were small variations in their approaches. Most, i.e., 10 States, defer the consent to a parent/guardian/representative. Some require in addition the involvement of the person not able to consent as much as possible. There are also those that provide an extra layer of protection either through the involvement of a medical professional or a judicial authority.

2 States reported taking into account what the personal interests 'would be'. In one State minors aged 14+ can seriously object, in which case the court must consent to the treatment before it can be carried out; in another, the treatment of 12–15-year-olds requires consent of both the minor and the guardian; in one State children aged 12-15 could consent regarding conditions the parents weren't aware of. 5 States noted that the person not able to consent should be involved, as far as possible, taking into account their capacity to understand. One State provides that minors have a right to receive information regarding their health and medical care, corresponding to their age and development. This can be seen as instance of good practice.

7 States provided for doctors or similar to intervene in limited circumstances, such as for mental health treatment – in the last resort; with court consent; or for all incapable adults following information by next of kin.

Gaps and Challenges

There is some variation with respect to which categories of persons who are not able to consent may be involved in the decision-making with respect to their health and to what extent.

Avenues for further action

- States might want to consider involving more actively persons who are not able to consent in determining treatment to the extent possible;
- States could provide for a review by the competent authorities in limited circumstances where the treatment is necessary to provide an extra layer of protection for the persons who are unable to consent;
- States are encouraged to consider more human rights and dignity-based approaches when regulating this area, including conferring a right on the person not able to consent to receive health information.

10. *Does domestic legislation provide for consent for the collection and processing of personal health related data collected in the context of healthcare?*

Overview

All States answered this question. 6 States noted a lack of requirement for consent. Only 6 reported requiring consent by law, a number of the replies contained some ambiguity.

4 States provided detailed information about their regulation, management and processing of health data, including by reference to the GDPR and the ECHR. 6 States mentioned confidentiality and minimal access. 6 States noted that data was gathered only when necessary or where there is a legal basis for it to be processed. 1 State infers consent for processing of health date automatically where a person consents to the treatment.

As a general point it should be noted that the GDPR is relevant to this question in requiring consent for the collection and processing of personal data, including health data. The GDPR is directly applicable in all EU Member States. 12 of the 20 States that replied are also members of the EU.

Gaps and Challenges

This is an area that would benefit from further improvement given the ambiguities in the replies and the lack of an express legal requirement for consent for the collection and processing of personal health data in some of States that replied to the questionnaire.

Avenues for further action

- States that do not do so already should consider adopting an express legal requirement for consent for the collection and processing of personal health data;
- The CDBIO can make a recommendation to this effect ;
- As a matter of good practice, consent should be balanced with a needs-based collection of data as reported by one of the States.

11. *Does domestic legislation provide for any other protective measures for the collection and processing of personal health related data?*

Overview

All States answered this question. All but one indicated that they have additional safeguards.

2 States specified additional measures for certain types of data. 9 States included requirements regarding minimal access, 2 weighed the interests of patient and processor, and 1 added requirements like anonymisation, pseudonymisation, separation of data.

4 States reported having supervision, i.e. by the head of the institution managing the data, by a specialised authority or by providing for action or investigation in case of breach.

3 of the replies were vague and 2 noted that regulations could be made.

Gaps and Challenges

Minimal access and confidentiality requirements are broadly instituted by most but not all States.

Avenues for further action

- States that don't have minimal access or confidentiality requirements should consider adopting them;
- The use of anonymisation and separation of personal health data should be considered as an example of good practice;
- Greater use of supervision and monitoring may be beneficial.

12. *Does domestic legislation provide for access of the persons concerned to any data collected about their health?*

Overview

All States answered this question, all but 3 giving a positive response, 2 of the responses were ambiguous and 1 State reported not having such legislation.

Most, i.e., 14 States reported having explicit patient's right to consult their medical records, 6 also provide for a right to receive a copy of the record and 5 for a right to amend it.

3 States have limitations on the right to access, i.e., it can be restricted if it could cause harm to the patient's health or endanger their life.

Gaps and Challenges

The large majority of States who replied to this question provide for individual access to health data.

Avenues for further action

- States that don't do so already, should legislate to give access to individuals to their health data.
- States that only mention electronic access could consider other methods of giving access in case this restricts access in practice.
- States that don't do so already should consider enabling patients to amend inaccuracies in their health data.

13. *Does domestic legislation provide for specific mechanism(s) making it possible for patients to seek recourse if they consider their human rights have been infringed upon?*

Overview

All States answered this question and all but 2 reported having mechanisms for patients to seek recourse in cases of violation of their human rights. There was some variation within the reported approaches. For instance, some States provided for civil remedies, others for administrative and criminal proceedings or a combination thereof and there were those States that had a special procedure, often including a designated body to deal with human rights violations in a health care context.

Most, i.e., 13 States, reported having commissions or ombudsperson to hear health care complaints. 13 States also informed of the availability of general civil claims for such violations. 3 States have internal complaints procedures before the health care provider, reviewable by a competent administrative State authority. 1 State reported having special rules

on mediation in the context of health care, two States reported having special rules on compensation. 1 State informed of dealing with such violations through a bioethics body and another informed of having a mechanism for redress only in cases of violation of data protection rights.

Gaps and Challenges

The majority of States seem to have appropriate mechanisms in place to address human or patients' rights violations in a health care context. The slight variations in their approaches are well within the margin of appreciation.

Avenues for further action

- Those States that don't have a special procedure to deal with patient or human rights violations in a health care context but merely deal with those under civil, criminal or administrative procedure, should consider adopting a more tailored approach, so as to make remedies more easily accessible to patients.
- States could consider enabling their specialised health care commissions to deal with remedies for violations of individual rights, rather than just have monitoring or disciplinary roles in order to make them more effective.
- As a matter of good practice, setting out deadlines to deal with patient complaints may be beneficial.
- States should consider the power imbalance with this area: conversations with the institution as part of the internal complaints regime alone may silence victims.

14. Does domestic legislation provide for public dialogue and/or consultation on health-related issues?

Overview

Only 16 States answered this question, making it the second least popular one. The majority of those that replied, i.e., 10 States reported not having legislation providing for public dialogue or consultation on health-related matters. 5 States referred to general provisions on public consultation when passing legislation. Only 3 States reported having a legal requirement for public consultation on health matters, one in relation to matters concerning elderly people and ethics, another regarding the adoption or revision of the national health strategy and bioethics laws and the third one for biomedicine.

5 States provided limited forms of representation, through representative organisations. 7 States mentioned the general requirements that legislation be published, and for the public to provide proposals to the government.

Gaps and Challenges

This is an area with significant potential for improvement given the requirement for public debate of the fundamental questions raised by the developments of biology and medicine, including consultation on their possible application under Article 28 of the Oviedo Convention on Human Rights and Biomedicine.

Avenues for further action

- States who haven't done so yet should consider introducing a general legal requirement for public debate on all fundamental questions of biomedicine and for public consultation on the application of new technologies in the field.
- States could consider adopting or expanding the scope of patient representative organisations for all legislation and regulation concerning health.
- The CDBIO could provide further guidance on how to implement Article 28 of the Oviedo Convention in practice, building on the good practice reported by some of the States.

15. Possible gaps and areas for developments

Overview

Only 12 States replied to this question but they provided a broad variety of valuable suggestions based on their own experience and practice.

Some States mentioned recent or forthcoming legislative changes in their respective health care sectors, including: increasing the time limit for egg storage; introducing safeguards for mental health patients with respect to being given medicines against their will; strengthening the position of patients within the liability system in the event of treatment errors; statutory instruments giving regulators greater autonomy over the health framework; safeguards for deprivation of liberty for persons lacking capacity; and compensation for health damages based on a no-fault system.

Gaps and Challenges

General gaps identified by States in their replies include:

- Greater information and raising awareness of patients' rights;
- Introducing a Patient's Bill of Rights;
- Introducing a legal basis for triage decisions;
- Setting up a patients' fund for compensation for damages;
- Setting out a legal framework for assisted reproduction with a focus on human rights and bioethics;
- Allowing the use of human embryos for scientific purposes;

- Regulating the use of artificial intelligence in health care.

Avenues for further action

Based on the gaps identified by States in their replies, there are cross-cutting themes requiring further action:

- Improving the provision of information regarding patients' rights;
- Introducing legislative acts on patients' rights;
- Adopting a human rights-based focus when regulating health care;
- Improving the mechanisms for compensating health damages, including by setting up designated funds and introducing a no-fault system as a matter of good practice;
- Regulating new technologies in health care, including in assisted reproduction.

Further areas for action based on the replies to the questionnaire and on the first report on Human Rights-Based Approaches to Health Care

- Accessibility and availability or ensuring equitable access to health care, including by promoting economic and physical accessibility, information availability and positive measures to give access to a broad range of vulnerable groups.
- Participation in health-related decision making by requiring public discussion and consultation for legislative changes in the field of biomedicine and related technologies.
- Adopting a human rights-based approach to regulating health care, including by expressly formulating patients' rights, such as the right to health information, the right to consent and to privacy and confidentiality of health data; introducing a human or patients' rights training for health care professionals; and providing a right to effective remedy for violations of patients' rights.