



Centre for
**Strategy & Evaluation
Services**

Evaluation of the Project: Protection of Human Rights in Biomedicine

Final Report

5 November 2024

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Executive summary

The “Protection of Human Rights in Biomedicine” (PHRiB) is a Council of Europe (CoE) technical co-operation project implemented in Armenia. It aims to raise awareness of European human rights and ethical standards in the field of biomedicine and support national authorities in their efforts to align national legislation and practice with the principles of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (“the Oviedo Convention”).¹

The project was designed to (1) align legal norms and law-enforcement practices in the biomedical field with the principles enshrined in the Oviedo Convention, to (2) strengthen knowledge and capacity of healthcare and legal professionals to apply human rights standards in the biomedical field, to (3) improve the public dialogue on health issues.

The project is managed by a project team in the CoE Office in Yerevan and in the CoE headquarters in Strasbourg and implemented in partnership with national stakeholders. It is implemented in two phases: Phase I from June 2020 to December 2022; Phase II from January 2023 to December 2024. Activities supported by the project include:

- Legal analysis of the compliance of the national legislation of Armenia in the field of biomedicine with the standards enshrined in the Convention.
- Support for national authorities in developing legislation, rules and enforcement mechanisms relevant to the requirements of the Convention.
- Dialogue with and support for policymakers and legislators to support the move towards ratification of the Convention.
- Human Rights Education for Legal Professionals (HELP): customisation of an existing course enabling legal and health professionals to understand key human rights principles in biomedicine.
- Other training or capacity-building for healthcare and legal professionals.
- Support for journalists: including the provision of a specific HELP training course and support to raise their knowledge, thus encouraging more extensive and more informed reporting;
- Expert round-tables featuring discussions on human rights issues in biomedicine.
- Provision of publications and materials on human right issues in biomedicine.
- Communication activities to promote awareness of the project, its activities and the Convention.

This evaluation was undertaken in January-June 2024. It assesses the relevance, effectiveness, efficiency and sustainability of the project and of its main outcomes. The main findings of the evaluation are as follows.

1. The activities of the project were very relevant to the Oviedo Convention. Most notably, the legal analysis, support for legislators and policymakers, HELP training and many of the published materials directly related to the provisions of the Convention and were focused on helping Armenia move towards ratification of the Convention.
2. The project is directly relevant to and forms an integral part of the Action Plan for Armenia. It supports the Plan’s overall aim of bringing Armenia’s legislation, institutions and practice further into with European standards.

¹ <https://www.coe.int/en/web/bioethics/oviedo-convention>

3. The relevance of the project to national policy priorities was ensured through a process of co-development of the project concept with the national stakeholders, as well as through responding to specific requests from the national authorities.
4. The project was relevant to key healthcare needs in Armenia, namely the need to address weaknesses in the legislative framework for biomedicine, to raise ethical standards in medical practice and raise awareness of human rights amongst professionals and the wider population.
5. The project has been effective in helping Armenia prepare for future ratification of the Oviedo Convention. The project was a key driver, if not the primary driver, in the decision to sign the Convention. Expert advice and the legal analysis have inspired and directly informed proposals to align legislation, and helped bring law enforcement practices into line with the Convention by supporting the creation of the Ethics Committee.
6. Additional steps will be required for national legislation to fully address all the provisions of the Oviedo Convention. Most notably, there is a need to repeal the provision allowing the use of assisted reproduction technologies for the purpose of choosing a future child's sex where the family already has three children of the same sex (the "fourth child provision"). In a number of other areas, alignment could be strengthened so that provisions are better addressed and standard are raised.
7. The HELP courses on key human rights principles in biomedicine have increased awareness of the Oviedo Convention and its principles among medical and legal professionals. Significantly, Armenia has featured more iterations of the tutored HELP course and more participants than any other country, although action might be required to raise the rate of completion.
8. To sustain and widen improvements in medical practice, there is a need for the HELP course (or key aspects of it) and for the principles of the Oviedo Convention to be incorporated into mainstream medical and legal education and training.
9. Communication activities and support for journalists has contributed to increased awareness amongst medical and legal professionals, and offers the potential for wider public awareness.
10. There may be a need for a more sustained public information campaign implemented by national authorities. This would focus on the new requirements introduced by legislative revisions come into force (i.e. around obligations of professionals and rights of professionals). Here, the Council of Europe might play an advisory role.
11. Despite the Phase I budget being considerably below the initial assessment of budgetary need, the project has achieved much of the intended impact, particularly in terms of supporting Armenia's progress towards ratification of the Convention.
12. So important outcomes of the project will be sustained as they have already been incorporated into national legislation. These include the support in drafting legislative amendments and the establishment of the Ethics Committee.
13. Signature of the Oviedo Convention represents an important milestone towards the aim of raising human rights standards in biomedicine but with the project due to conclude at the end of 2024, there will be a need for the relevant national stakeholders to take full ownership of the process towards ratification and raising standards more generally.
14. The volume of participation in the HELP training, as well as the training of trainers, offers the potential for sustained improvements in medical practice in Armenia.
15. For improvements in medical practice to be sustained in the long run, there is a need for the HELP courses to be promoted and, ideally, offered in tutored format.

16. The sustainability of project effects could be ensured by the incorporation of human rights standards and relevant aspects of the HELP courses into mainstream higher education provision.

Drawing on these conclusions and on the evidence presented in the main report, the following recommendations are offered:

1. The CoE should consider how to support Armenia in its move from signature to ratification of the Oviedo Convention. This could include continued support for legislators and policymakers to help build the political case for ratification and continued expert support for the drafting of legislative revisions.
2. The CoE should consider how best to support national authorities to move towards repeal of the fourth child provision.
3. The CoE should encourage national authorities to consider if/what further legislative revisions are required to fully address all provisions of the Oviedo Convention. This should take into account any recommendations from the legal analysis that have not yet been addressed.
4. It is recommended to undertake further research into the alignment of national legislation with broader human rights standards in biomedicine, i.e. going beyond the specific provisions of the Convention.
5. It is recommended to undertake further research into extent to which medical practice is compliant with the Convention in practice. This would best be undertaken once the necessary legislative revisions have been made and would identify any additional steps necessary to raise standards.
6. The CoE should encourage national authorities to consider providing administrative and financial resource to the Ethics Committee. This would address the high and increasing workload (currently fulfilled on a voluntary basis) and the need to build trust amongst professionals and the public. Support could consist of a budget for support staff and administrative costs and payment of members. However, care should be taken to ensure that the payment of members does not affect perceptions of their independence.
7. The CoE should encourage national authorities to consider how to promote the availability of the online HELP course beyond the life of the project and if/how to provide further tutored iterations of the course.
8. The CoE should encourage national authorities to consider if/how to provide relevant training or capacity-building for judicial authorities to support the enforcement of legislation related to the Oviedo Convention, as and when such legislation comes into force.
9. The CoE should encourage national authorities to consider how to support the integration of the principles of the Oviedo Convention and the relevant legislation into curricula of university degrees in medicine and/or law.
10. The CoE should encourage national authorities to consider a public information campaign to raise awareness of the new obligations placed on medical professionals and the new rights available to patients resulting from legislative revisions. Such a campaign would be best timed to take place once all the relevant revisions come into force.
11. The CoE should consider sharing the lessons from this project with other countries that may be interested in technical co-operation in the area of biomedicine and human rights.

1 Introduction

1.1 About the evaluation

1.1.1 Subject of the evaluation

This report presents findings from the evaluation of the “Protection of Human Rights in Biomedicine” (PHRiB) project. The PHRiB project is a pilot project implemented by the CoE with the aim of raising awareness of European human rights and ethical standards in the field of biomedicine and supporting national authorities in their efforts to align national legislation and practice with these standards, which would help Armenia prepare to sign the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (“the Oviedo Convention”).²

The project is implemented under two consecutive Council of Europe (CoE) Action Plans for Armenia:

- “Protection of Human Rights in Biomedicine I” (2020/DGI/VC/2474)” (June 2020 - December 2022) pilot project under the 2019-2022 Action Plan;
- “Protection of Human Rights in Biomedicine II” (2023/DGI/VC/3383) project (January 2023- December 2024) under the 2023-2026 Action Plan.

A more detailed description of the project is provided in section 2.

1.1.2 Purpose of the evaluation

According to the CoE’s terms of reference, this is an end-of-project evaluation that serves the main purpose of identifying lessons from the implementation of the project for potential future such projects in other countries. The CoE’s Human Rights and Biomedicine Division and the Directorate of Programme Co-ordination are the key stakeholders of the evaluation. The wider audience for the evaluation includes the CoE management in general, the national partners of the project and healthcare and legal professionals.

The evaluation was commissioned by the CoE and carried out by the Centre for Strategy and Evaluation Services (CSES) in January-June 2024.

1.1.3 Evaluation objectives and scope

As per the terms of reference, the specific objectives of the evaluation were to:

- assess the efficiency and effectiveness of the methodology used by the project;
- assess the results achieved by the project;
- estimate the degree to which the project’s outputs will continue to have an impact in the future;
- assess the degree to which gender has been mainstreamed by the project.

The scope of the evaluation covered the first phase of the project (from 1 June 2020 to 31 December 2022) as well as the first six months of the second phase of the project (from 1 January 2023 to 30 June 2023). However, some of the evidence gathered also relates to the situation in the first half of 2024, most notably evidence from the interviews of stakeholders.

² <https://www.coe.int/en/web/bioethics/oviedo-convention>

1.1.4 Evaluation criteria and questions

The evaluation assessed the project against the criteria of relevance, effectiveness, efficiency, and sustainability. It provided answers to the following questions:

1. **Relevance:** To what extent do the selection activities of the Project reflect the needs of the Member State as well as the relevant Council of Europe legal instruments?
2. **Effectiveness:** To what extent has the project achieved its expected results? What have been reasons for achievement and/or lack thereof?
3. **Efficiency:** To what extent could alternative working methods have led to the achievement of comparable or better results with fewer resources?
4. **Sustainability:** To what extent can it be expected that the Member State's national authorities will continue to use the outcomes and results of the project?

A more detailed set of questions were articulated under each criterion. Annex 3 presents the Evaluation Matrix showing the full list of questions together with the associated indicators and data sources.

1.2 Methodology

The evaluation was conducted in accordance with the CoE's Evaluation Guidelines.³ The following sections describe the different methods used for data collection and analysis. All data were collected, treated and stored in accordance with CoE's data protection rules.⁴

The methodology involved a mixed method approach to data collection and analysis, involving document reviews, interviews and case studies. The collected data were then the subject of quantitative and qualitative analysis with triangulation undertaken wherever possible.

1.2.1 Data collection

The evaluation team reviewed relevant documents provided by the CoE or available from other sources in order to better understand the context for the project, identify activities undertaken and start to gather evidence of effects. The main types of documents included the Oviedo Convention and its Additional Protocols, broader literature about human rights in biomedicine, previous evaluation reports, the CoE's Action Plans for Armenia, project documentation and written materials produced by the project. Relevant websites were also reviewed such as those of the CoE (including pages relating to the PHRiB project) and national stakeholders.

Semi-structured interviews were conducted with 30 stakeholders. This included 9 staff of the CoE and 21 project partners and beneficiaries with some people interviewed multiple times. In April 2024, CSES visited the CoE's headquarters in Strasbourg to interview CoE staff there. In May 2024, a field visit was undertaken to Armenia to interview the project team at the CoE Office in Yerevan, as well as other stakeholders. These other stakeholders included the Human Rights Defender's Office, National Institute of Health, Ministry of Health, Ministry of Foreign Affairs, Ministry of Justice, National Assembly, and the Office of the Representative on International Legal Matters of the Government of Armenia. Interpretation was provided where necessary. The semi-structured interviews explored the

³ Council of Europe Evaluation Guidelines, available at <https://rm.coe.int/dio-evaluation-guidelines-revised-version-2020/1680a147d1>

⁴ Secretary General's Regulation of 17 April 1989 instituting a system of data protection for personal data files at the Council of Europe, available at <https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=0900001680684608>

role of each specific organisation in the project, as well as the views and the experience of the individual stakeholders concerning the relevance, effectiveness, efficiency, and sustainability of the project. In May and June 2024, CSES conducted additional online interviews to reach stakeholders who were unavailable during the visit and to clarify remaining questions.

Three case studies were undertaken, namely: i) law on reproductive health rights related to the provision of sex-selective abortions for a fourth child; ii) Ethics Committee for Healthcare Professionals; and iii) HELP training course on Key Principles in Biomedicine. The first case study was selected as it relates to the one direct incompatibility of the national legal framework with the Convention and thus represents a barrier to ratification. The other case studies were selected as they related to some of the most significant activities undertaken by the project and thus offered most potential to contribute to the objectives of the project. Evidence from the case studies was drawn from the document review and interviews, with additional evidence gathered from other documents or online sources, as necessary.

1.2.2 Data analysis

Evidence was triangulated from the different sources, i.e. literature, the project documentation and data, and the interviews. The evidence was analysed with reference to the indicators in the evaluation matrix in the Concept note. Evidence from different sources was compared and, in the case of any contradictory or uncertain evidence, was further investigated to ensure the robustness of the results.

The text of the Oviedo Convention and its Additional Protocols, as well as the Council of Europe Action Plans for Armenia were analysed to help establish the context for the project (see section 2.1). All documents relating to the project and its activities were reviewed in order to identify the objectives, activities and budget (see sections 2.2 and 2.3) and the method of implementation (section 5.1), as well as to identify evidence of effectiveness (section 4), efficiency (section 5) and sustainability (section 6). The published report of the analysis of the current legal framework for biomedicine in Armenia provided evidence of the situation in Armenia (section 4.1.1) and also served as a baseline against which to map steps taken by the project to support a strengthening of the legal framework (section 4.1.2). Broader literature about human rights in biomedicine informed the analysis of relevance of the project (section 3.2) and the case studies (Annexes 5, 6 and 7). Analysis of Council of Europe Action Plans informed the context (section 2.1.2) and the analysis of relevance (section 3.1.2).

Responses to interview questions were coded against the main issues addressed by the evaluation questions, thus allowing the team to identify common messages and divergent viewpoints, as well as effects not captured in the project documentation. In this way, evidence from the interviews informed all parts of the analysis (and thus sections 3 to 6 of this report).

The case studies involved analysis of all relevant evidence and the development of in-depth summaries (Annexes 5, 6 and 7). This analysis then also informed the overall evaluation findings, most notably those relating to the “fourth child provision” (sections 4.1.1, 4.1.2, 4.4 and 6.1), support in developing legislation, rules and enforcement mechanisms (section 4.1.2) and the HELP training (4.2.1).

1.2.3 Limitations and constraints

Overall, the available evidence was sufficient to satisfy the objectives of the evaluation. Nonetheless, some limitations and constraints were faced.

First, the conception of the project was not accompanied by an analysis of the situation prevailing at the time regarding the protection of human rights standards in biomedicine in Armenia (although an analysis of the compliance of national legislation with the Oviedo Convention was undertaken early in the project; see section 4.1.1). To address this, additional documentary research was undertaken which provided evidence of national policy priorities and healthcare needs (see section 3.2).

Second, comprehensive quantitative evidence was not available in relation to the effectiveness of the HELP courses. Tutor reports were provided for seven iterations, of which only five reported the results of participant feedback surveys; the results of those surveys are reported in section 4.2.1 and Annex 7. Follow-up surveys have not been undertaken to identify subsequent effects, such as improved practice. The evaluation has therefore made use of the partial data from participant feedback surveys, data on the completion rate for the HELP courses and qualitative evidence from the interviews of stakeholders (see section 4.2.1 and Annex 7).

Third, the influence of the project on Armenia's progress towards signing and ratifying the Oviedo Convention cannot be isolated from the influence of other factors. There already existed a degree of support amongst various stakeholders (i.e. legislators, authorities, practitioners, etc.) in favour of signature and ratification and for improving human standards in general. The actions of some of these stakeholders (for example, steps taken by National Assembly members to build political consensus) have served the aims of the project, even if taken outside the context of the project. Thus, when considering high-level effects, this evaluation should be seen as identifying the contribution made by the project rather than as attributing the responsibility for any positive changes to the project (though there are direct effects that can be attributed, such as numbers of professionals trained).

Last, linked to the previous point, there are limits as to the extent to which the evaluation can identify the effect on improved public dialogue on or awareness of human rights issues. The activities undertaken are identified (section 4.3) but the effects are by their very nature diffuse and intangible, i.e. the communication of messages to a wide audience (e.g. comprising medical and legal practitioners, the general public, etc.) and the positive reception of those message by that audience. An extensive analysis of the effects of the communication campaign was not undertaken by the project and such an analysis would, arguably, not be feasible or realistic given the scope of the project budget. Instead, this evaluation offers pointers based on the evidence of activities undertaken and the views offered by stakeholders.

1.3 Structure of the report

The rest of this report is structured as follows:

- Section 2 presents the project, including its context, objectives, activities and budget;
- Sections 3 to 6 present the evaluation findings against the criteria of relevance, effectiveness, efficiency and sustainability;
- Section 7 presents the overall conclusions, as well as recommendations for the Council of Europe
- Annexes present a detailed list of activities implemented by the PHRiB project, evaluation tools (bibliography, evaluation matrix, list of interviewees) and three case studies.

2 The Protection of Human Rights in Biomedicine project

2.1 Context of the project

2.1.1 Oviedo Convention

The rationale of the project stems from the commitment of the CoE to promote the protection of human rights in the area of biomedicine, as stipulated in the Oviedo Convention. The Convention, which draws upon the principles set out in the European Convention on Human Rights (ECHR), is the only legally-binding instrument aimed at safeguarding human rights in the area of biomedicine. To date, 37 countries have signed the Oviedo convention, whilst 30 have ratified it and implemented it into their national law.⁵

Key provisions concern the primacy of the human being, the interests of the human being prevailing over the interest of society or science (Article 2), equitable access to health care (Article 3), informed consent to medical interventions (Article 5), and confidentiality with respect to information about the individual's health (Article 10).

In the area of genetic testing, the Oviedo Convention stipulates that tests to predict genetic diseases can only be carried out for health or research purposes (Article 12). It prohibits the use of medically assisted procreation to choose a future child's sex, except to avoid serious hereditary sex-related disease (Article 14).

In the area of scientific research, the Oviedo Convention lays out principles guiding research on a person. For instance, projects need to receive approval by a competent body after examination of its scientific merit and a review of its ethical acceptability (Article 16). The risks of the research cannot be disproportionate to its potential benefits, and the persons undergoing research need to provide their explicit consent, which they can freely withdraw at any time (Article 17). The Convention prohibits the creation of human embryos for research purposes. Wherever the law does allow research on embryos in vitro it must ensure adequate protection of the embryo (Article 18).

In the area of organ and tissue transplantation, the Oviedo Convention only allows the removal of organs or tissue from a living person for transplantation purposes if there is no alternative therapeutic treatment and no suitable organ or tissue available from a deceased person. Generally, the Oviedo Convention stipulates that donors must have given their consent. Exceptionally, it specifies conditions under which the organs or tissue removal may be authorised from a person who does not have the capacity to consent (e.g. the recipient is a brother or sister; and donation has the potential to be life-saving for them, Article 20). Finally, the Oviedo Convention prohibits financial gain with respect to the human body and its parts (Article 21).

2.1.2 Council of Europe Action Plans for Armenia

The CoE Action Plan for Armenia is a strategic programming instrument that aims to help bring Armenia's legislation, institutions and practices further into line with European standards in the areas of human rights, the rule of law and democracy. Under the Action Plan, the CoE and the Armenian authorities have agreed to carry forward jointly, through co-operation programmes, reforms aiming to enhance the effectiveness of the ECHR system and the protection of human rights. The current iteration (2023-2026) builds on the previous Action Plan for 2019-2022.

The overall goal of the Action Plans for 2023-2026 and 2019-2022 is "to ensure successful reforms in Armenia which will bring its legislation, institutions and practice further into line with European

⁵ <https://www.coe.int/en/web/conventions/full-list?module=signatures-by-treaty&treatynum=164>

standards in the areas of human rights, the rule of law and democracy, and therefore support the country's efforts to honour its obligations as a Council of Europe Member State".⁶

The PHRiB project features as one of the actions within the human rights pillar in the Action Plans for 2023-2026 and for 2019-2022. The intended thematic outcome of the human rights pillar for 2023-2026 is "Human rights protection, equality and human dignity are enhanced through the well-structured and co-ordinated implementation of human rights standards, including those on gender equality, freedom of expression and freedom of the media and an improved effectiveness of the European Convention on Human Rights (ECHR) system".⁷

Within that thematic outcome, the Action Plans specify four specific outcomes, along with indicators measuring its success.

- Armenian legal framework and related practices are more in line with the principles enshrined in the Oviedo Convention.⁸ Achievement of this outcome is indicated by the level of responsiveness of authorities in introducing changes to the legal and policy framework, in line with the Oviedo Convention (Action Plan 2023-2026).
- Public awareness of the challenges related to human rights applied to the biomedical field is enhanced.⁹ Achievement of this outcome is indicated by the number of public debates and level of public engagement in the field of human rights and biomedicine (Action Plan 2023-2026).
- The overall level of human rights protection in the biomedical field is increased.¹⁰ Achievement of this outcome is indicated by the level of changes in attitudes among the professionals (Action Plan 2023-2026).
- Armenia takes further steps towards the accession to the Oviedo Convention¹¹. Achievement of this outcome is indicated by the level of interest expressed and concrete steps taken by the Armenian authorities to accede to the Oviedo Convention.

2.2 Objectives

The aim of the PHRiB project is to "contribute to enhancing awareness of the European human rights' and ethical standards in the field of biomedicine (e.g. informed consent to any medical intervention, the importance of medical secret and confidentiality, voluntary non-remunerated organ donation, preservation of genetic heritage)". In addition, it aims "to support national authorities in their efforts to align national legislation and practice in the field of biomedicine and healthcare with the European human rights' and ethical standards in the field of biomedicine." Finally, the project sought to support Armenia prepare to join the Oviedo Convention.

The project features three specific objectives:

⁶ Council of Europe. "[Action Plan for Armenia 2023-26](#)," p.43. The stated goal in the Action Plan for 2019-2022 differed very slightly, i.e. "to support the reforms in Armenia...".

⁷ The thematic outcome in the Action Plan for 2019-2022 differed very slightly in that it did not include the reference to "human dignity" or "freedom of expression and freedom of the media".

⁸ The stated outcome in the Action Plan for 2019-22 read "Relevant legal texts and law-enforcement practices are brought into line with the principles enshrined in the Oviedo Convention" (Council of Europe Action Plan for Armenia 2019-2022, p. 18)

⁹ The stated outcome in the Action Plan for 2019-22 read "Further public awareness and public discussion on main challenges to the human rights protection in biomedicine are fostered (Council of Europe Action Plan for Armenia 2019-2022, p. 18)

¹⁰ The wording in the Action Plan for 2019-22 was the same.

¹¹ The stated outcome in the Action Plan for 2019-22 read "Armenia is better prepared for the possible future accession to the Oviedo Convention." (Council of Europe Action Plan for Armenia 2019-2022, p. 18)

- Supporting the national authorities in their efforts to bring the legal norms in the biomedical field closer to the European human rights' and ethical standards.
- Supporting the national authorities in their effort to bring the law-enforcement practices in the biomedical field close to the European human rights' and ethical standards.
- Strengthening medical and legal practitioners' knowledge and capacity to apply human rights standards and obligations in biomedical fields (e.g. informed consent for medical intervention, protection of private life and right to information, non-discrimination, etc.)

2.3 Activities

The project is managed by a project team in the CoE Office in Yerevan and is supervised by the CoE's Human Rights in Biomedicine Division in Strasbourg. Implementation of the project also involves a range of partners and stakeholders within Armenia.

The project is implemented in two phases.

Phase I lasted from June 2020 to December 2022 under the CoE's 2019-2022 Action Plan for Armenia. Different activities were undertaken to create a critical mass of awareness and support for the Oviedo Convention. This was done mostly through provision of legal expertise and capacity-building both among national policymakers, and in parallel also among medical and legal professionals, journalists and others.

Phase II is being implemented from January 2023 to December 2024 under the CoE's 2023-2026 Action Plan for Armenia. This phase has featured activities more explicitly focussed on helping Armenia prepare to sign and ratify the Convention and increase public awareness more generally.

The project activities can be seen as falling into three main pillars. In summary, they are as follows.

First, alignment of legal norms and law enforcement practices in biomedicine and with the principles enshrined in the Oviedo Convention. Activities included:

- Analysis of legislation: a legal analysis of the compliance of the national legislation of Armenia in the field of biomedicine with the standards enshrined in the Oviedo Convention; a diagnostic study on legislation pertaining to human rights issues in emergency situations.
- Support in developing legislation, rules and enforcement mechanisms: provision of expert support to help draft legislative reforms in response to requests from national authorities, notably the Ministry of Health.
- Dialogue with and support for policymakers and legislators: the project team and CoE experts engaged in dialogue with and provided capacity-building sessions for key policymakers to promote awareness of the Convention and help support the political case for ratification, including visits of CoE staff from Strasbourg and visits of key Armenian policymakers to Strasbourg.

Second, strengthening knowledge and raising awareness of healthcare and legal professionals in Armenia. Activities included:

- Human Rights Education for Legal Professionals (HELP): prior to the project, the CoE had operated this programme to build the capacity of legal professionals in all member states to apply the ECHR in their daily work. The programme was adapted to the Armenian legal order, translated into Armenian and provided to medical and legal professionals, as well as journalists.
- Other training or capacity-building for healthcare and legal professionals: as a complement to HELP, the project provided sessions on the Oviedo Convention and on other human rights issues in biomedicine in general; preparations were made to provide training to support the integration

of refugee healthcare professionals from the Karabakh region and to enable them to address post-traumatic syndrome.¹²

Third, improving the public dialogue on healthcare issues, as a means of building support for ratification of the Convention and raising awareness of the importance of ethical standards in biomedicine (including patients' rights). Activities included:

- Support for journalists: including the provision of a specific HELP training course and support to raise their knowledge, thus encouraging more extensive and more informed reporting;
- Expert round-tables: discussion on specific human rights issues led to recommendations for policymakers and stimulated policy dialogue more generally;
- Provision of resources: existing CoE materials were translated and disseminated, whilst outputs of the project (notably the legal analysis) were published, printed and disseminated.
- Communication activities: promoted awareness of the project, the Convention and human rights activities in general.

The activities are described in more detail in sections 4.1, 4.2, and 4.3, respectively, whilst the table in Annex 1 lists them by year of implementation.

2.4 Budget

The initial budget for Phase 1 of the project (01/06/2020-31/07/2021) was EUR 350 000. Following the COVID-19 pandemic and the military conflict with Azerbaijan in September 2020, the project received an extension of its timescale until the end of 2021 and then a second extension until the end of 2022. As part of the second extension, the project budget was increased to EUR 610 000. All funding for Phase I was provided by the CoE Action Plan for Armenia 2019-2022.¹³

The initial budget for Phase 2 of the project (01/01/2023-31/12/2024) was EUR 600 000. Following the arrival of refugees from the Karabakh region in Armenia, the budget was increased by EUR 300 000, reaching a total of EUR 900 000. All funding for Phase 2 was provided by the CoE Action Plan for Armenia 2023-2026.¹⁴

The increases in the project budget in Phases 1 and 2 were made in response to additional requests from national partners for project activities, new needs resulting from the COVID-19 pandemic and the arrival of refugees from the Karabakh region.

The table below shows the budgetary allocation to each category of expenditure. Staff costs rose only slightly in Phase II, reflecting the fact that the same team was kept in place regardless of the increased budget. Most of the additional budget in Phase II was allocated to other costs/services, as well as travel, reflecting the increased provision of training, capacity-building and visits to Strasbourg. The additional budget also allowed entirely new activities to be undertaken, which had not featured in the original project concept, such as the development of ethical rules for medical professionals and support for the establishment of the Ethics Committee for Medical Professionals.

¹² The training was implemented in 2024, i.e. after the period covered by this evaluation.

¹³ <https://www.coe.int/en/web/yerevan/protection-of-human-rights-in-biomedicine-i>

¹⁴ <https://www.coe.int/en/web/yerevan/protection-of-human-rights-in-biomedicine-ii>

Table 1 Project expenditure (Phases I and II)

Category	Phase I		Phase II		% increase in Phase II
	EUR	%	EUR	%	
Human resources	337 270	63.6	356 206	39.6	6
Travel	13 338	2.5	54 315	6.0	307
Local office	26 220	4.9	32 116	3.6	12
Other costs/services	118 500	22.4	398 404	44.3	236
Administrative costs	34 673	6.5	58 879	6.5	70
TOTAL	530 001	100.0	899 920	100.0	70

Source: *Protection of Human Rights in Biomedicine I VC 2474 - BH 8721, Interim financial report covering the period from 01/06/2020 to 31/12/2021; Protection of Human Rights in Biomedicine II VC 2474 - BH 8721, Interim financial report covering the period from 01/01/2023 to 31/12/2023.*

3 Relevance

This section considers the relevance of the project and its activities. Two main dimension are considered: first, the relevance to legal and policy instruments of the CoE, namely the Oviedo Convention and the Action Plans for Armenia (section 3.1); second, the relevance to the needs and priorities of Armenia in the field of human rights in biomedicine (section 3.2).

3.1 Relevance to Council of Europe instruments

To what extent is the project in line with the priorities of the Oviedo Convention and other Council of Europe instruments?

3.1.1 Oviedo Convention

The main activities of the project were very relevant to the Oviedo Convention.

First, the legal analysis very directly assessed the compatibility of national legislation with the detailed requirements of the Convention and its Additional Protocols. Detailed conclusions were offered stating whether the legislation was incompatible. The analysis highlighted where provisions of the Convention were not properly addressed or only addressed in a general rather than a specific sense. Specific recommendations were offered to remove any incompatibilities, better address provisions and raise ethical standards more generally (i.e. going beyond mere compliance with the Convention).

Second, much of the support for and dialogue with legislators and policymakers was very directly focused on helping Armenia move towards ratification of the Convention. This included the provision of expert support in helping draft legislation to better align it with the Convention. It also included the high-level visits of Armenian policymakers to the CoE in Strasbourg, which was crucial in building political support for ratification.

Third, the HELP training provided to medical and legal professionals and journalists directly explored the main issues covered by the Oviedo Convention. These included informed consent, medical confidentiality, protection of the embryo and procreation, genetic testing, research and transplantation of human organs and tissues. The HELP training also covered relevant case-law of the European Court of Human Rights.

Last, many of the materials that were translated, published and disseminated directly related to the Oviedo Convention. These included the text of the Convention and its Additional Protocols.

3.1.2 Council of Europe Action Plan for Armenia

The project is directly relevant to and forms an integral part of the 2019-2022 and 2023-2026 Action Plans for Armenia. The primary aim of the project is to support progress towards ratification of the Oviedo Convention; this aim is fully aligned with the overall aim of the CoE Action Plan for Armenia, which is to bring Armenia's legislation, institutions and practice further into with European standards.

The project also complements two other CoE activities in Armenia. First, by supporting higher standards in medical confidentiality, the project complements other CoE activities to enhance the protection of data in Armenia in line with international standards.¹⁵ Second, the support for addressing human rights in biomedicine in the context of refugees from the Karabakh region very directly

¹⁵ Council of Europe. "Action Plan for Armenia 2023-26," p.17.

complemented the CoE’s comprehensive response package to address the refugee influx, even if the Oviedo Convention itself does not directly relate to human rights in the context of displacement.¹⁶

The project was relevant to the “strategic triangle” of standard setting, monitoring and co-operation, which guides the implementation of the CoE Action Plan for Armenia. This approach features the development of legally-binding standards which is linked to their monitoring by independent mechanisms and supplemented by technical co-operation to facilitate their implementation. Activity within the project addressed all three aspects.

There was some relevance to the transversal objective of gender equality. However, this was most often indirect as the principles enshrined in the Convention apply equally to men and women, such as informed consent, medical confidentiality, research and transplantation of organs and human tissues. Nonetheless, some principles, although framed in gender-neutral language, do in practice have a gender dimension. Most notably, the prohibition of sex-selection in medically-assisted procreation (Article 14) typically has a gender dimension in practice, i.e. sex-selection more often manifests itself in a preference for boys rather than girls. Similarly, equitable access to healthcare (Article 3) would imply a gender dimension, for example, in ensuring that females have access to gender-specific services.

3.2 Relevance to needs and priorities in Armenia

To what extent is the project in line with the needs and priorities of Armenia?

3.2.1 Relevance to national policy priorities

The relevance of the project to national policy priorities was ensured through a process of co-development of the project concept with the national stakeholders, as well as through responding to specific requests from the national authorities with regard to the technical co-operation activities. Such co-operation formed part of and benefitted from the broader consultation of and co-operation with national authorities in respect of the overall Action Plan for Armenia. Following such an approach, the issues addressed by the project in co-operation with national stakeholders resonated with the ongoing activities of key institutions (e.g., Human Rights’ Defender’s Office, Ministry of Health, Ministry of Justice).

The project objectives and activities support the goals of the National Strategy for Human Rights Protection and the Action Plans for 2020-2022 and 2023-2025.¹⁷ The Strategy sets goals including the effective protection of and guarantees for human rights, implementation of consistent state policy aimed at protection of and guarantees for the fundamental human and civil rights and freedoms, improving the mechanisms for protection of rights and raising public awareness on human rights and measures of protection. Similarly, the project can be seen as supporting the aims of the European Union-Armenia Comprehensive and Enhanced Partnership Agreement (CEPA), in particular the aim of reinforcing respect for human rights and fundamental freedoms, including through domestic reforms.¹⁸

The project was also relevant to national policy objectives related to the reform of public services. In the field of healthcare, this includes the overall modernisation of the country’s public health

¹⁶ <https://www.coe.int/en/web/yerevan/refugee-response-package>

¹⁷ <https://moj.am/en/article/2546>

¹⁸ [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:22018A0126\(01\)](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:22018A0126(01))

system.^{19,20} It also includes the movement towards digitalisation of public services and improvements to public administration,²¹ increasing cooperation with international partners, as well as reforms to the national (in some cases - post-Soviet) legislative framework, improvements to public administration and improvements to law enforcement. The project was relevant to these broader national policy priorities thus, supporting the country in addressing the problems resulting from its Soviet institutional heritage.²²

The project was also relevant to changes in national priorities resulting from external circumstances. First, the project supported the broader national response to COVID-19, for example, by providing resources to support communication around human rights and bioethics (although it should be noted that the pandemic caused delays and difficulties in the implementation of the project more generally; see section 4.6). Second, the project supported the broader national response to the arrival of refugees from the Karabakh region, for example, by planning training for refugee healthcare professionals.

3.2.2 Relevance to healthcare needs

The following needs in the area of biomedicine were addressed by the project.

The project was relevant to the need to address weaknesses in the legislative framework for biomedicine. As identified by the legal analysis undertaken by the project, some of the provisions of the Oviedo Convention were not properly addressed and there was one direct incompatibility (see section 4.1.1.²³ The World Health Organisation (WHO) highlighted a need for Armenia to “implement revised clinical guidelines and protocols, ensure alignment between clinical pathways and guidelines”.²⁴ In many areas covered by the Oviedo Convention, the relevant regulations had been missing (for instance, one of such underdeveloped areas was mental health protection). Another challenge was the lack of tools to enforce the existing regulations. Such a gap undermined individual accountability of medical professionals in the context of legal regulations and led to a poor trust of patients towards the country’s medical system.^{25,26,27}

The project was relevant to the need to raise ethical standards in medical practice. Perhaps reflecting the weaknesses in the legislative framework, Armenia faced challenges around lack awareness of or, in some cases, disregard for ethical standards in medical practice. The challenges in this area result partly also from the cultural specificity of Armenia and its specific provinces (one of the examples

¹⁹ World Bank. 2010. From Rags to Riches: Armenia’s Health Care System is Modernizing, [World Bank Document](#).

²⁰ WHO (2022) Armenia takes steps to improve its primary health-care system, [Armenia takes steps to improve its primary health-care system \(who.int\)](#).

²¹ World Bank. 2022. Armenia to Improve Public Sector Performance through Digital Solutions, with World Bank Support, [Armenia to Improve Public Sector Performance through Digital Solutions, with World Bank Support](#).

²² Zopunyan, V., Krmoyan, S., Quinn, R. 2013. Identifying the gaps: Armenian health care legislation and human rights in patient care protections, Health and Human Rights Journal 15/2, [Identifying the gaps: Armenian health care legislation and human rights in patient care protections – Health and Human Rights Journal \(hhrjournal.org\)](#).

²³ Council of Europe. 2022. Protection of Human Rights in Biomedicine Concept Report Comparative analysis of the compliance of the national legislation of Armenia in the field of biomedicine with European Human rights and ethical standards enshrined in the Oviedo Convention on Human Rights and Biomedicine, [1680aa2d74 \(coe.int\)](#).

²⁴ WHO. 2023. Armenia takes steps to improve its primary health-care system, [Armenia takes steps to improve its primary health-care system \(who.int\)](#).

²⁵ Shekherdimian, S. 2021. Transforming Armenia’s Healthcare System: From Quantitative Misconceptions to Qualitative Sustainability, [Transforming Armenia’s Healthcare System: From Quantitative Misconceptions to Qualitative Sustainability - EVN Report](#).

²⁶ Richardson, E., 2013, Armenia Health system review, “Health Systems in Transition”, vol. 15, no. 4., [HiT Armenia \(who.int\)](#), WHO, p. 21.

²⁷ WHO (2022) Health Systems in Action 2022 Edition, Armenia, <https://www.bing.com/ck/a?!&&p=9405aae24596f1a2JmIttdHM9MTcyMDEzNzYwMCZpZ3VpZD0xOTYxM2M1My03NzcxLTU0OWYtMTY2NC0yZjI2NzZiZDY1YzEmaW5zaWQ9NTlwOA&ptn=3&ver=2&hsh=3&fclid=19613c53-7771-649f-1664-2f2676bd65c1&psq=who+health+system+in+action+Armenia+2022&u=a1aHR0cHM6Ly9hcHBzLndoby5pbmQvaXJpcy9yZXN0L2JpdHN0cmVhbXMvMTQ2Mzc2MS9yZXRyaWV2ZQ&ntb=1>, p. 7

being the difficulties in enforcing medical confidentiality rules in the provinces outside of Yerevan). In addition, medical knowledge tends to be centralised in the capital,²⁸ there is a “negative selection” of doctors working in remote rural areas (i.e. some are not located there by choice but because they are unable to get jobs in urban areas), and there are challenges around monitoring of the developments in medical practice in rural areas.^{29,30}

The project was relevant to the insufficient levels of expertise and knowledge of ethical standards and the relevant legal framework among medical and legal professionals. Some professionals were considered to lack skills to apply such knowledge in their every-day work. Armenia was seen as having an insufficient expert base in the area of biomedical ethics amongst both medical and legal professionals. This was linked in part to biomedical ethics not being sufficiently covered in higher education courses in medicine and law. Moreover, the continuous education offer for medical professionals in Armenia is reported to be under-developed.³¹ Where materials and information was available for medical and legal professionals, it tended not to be translated into Armenian. For these reasons, there was a strong need to network Armenian stakeholders with their foreign counterparts, in order to transfer international best practices and expertise.

The project activities were relevant also to the problem of low awareness of human rights in biomedicine in the Armenian population. The poorer and rural population in Armenia was previously found to have a particularly poor access to health education, relatively more often missed by the information campaigns run by the authorities.³² Primarily, patients lack awareness of their own rights³³, while at the same time a changing legislative framework creates a need to inform the population on the new developments.

²⁸ Ibid, p.7, p.11.

²⁹ Global Union Europa, nd., Mapping the Health & Social Care Sector and its Actors In Eurasia, Armenia, [Country-Report-ARMENIA.pdf \(uni-europa.org\)](#), p. 6.

³⁰ Tonoyan, T., Muradyan, L., 2012. Health inequalities in Armenia - analysis of survey results, “International Journal for Equity in Health”, vol. 11, [“Health inequalities in Armenia - analysis of survey results” | International Journal for Equity in Health | Full Text \(biomedcentral.com\)](#).

³¹ Chekijian, S., et al. 2020. Continuing Medical Education and Continuing Professional Development in the Republic of Armenia: The Evolution of Legislative and Regulatory Frameworks Post Transition. Journal of European CME, 10 (1): DOI: 10.1080/21614083.2020.1853338.

³² Richardson, E., 2013, Armenia Health system review, “Health Systems in Transition”, vol. 15, no. 4., HiT Armenia (who.int), [WHO](#), p. 63.

³³ E.g., in the area of palliative care, see: Barros de Luca, G., Zopunyan, V., Burke-Shyne, N. et al. 2017. Palliative care and human rights in patient care: an Armenia case study. Public Health Review, 38, 18 DOI: 10.1186/s40985-017-0062-7.

4 Effectiveness

This section analyses the effectiveness of the PHRiB project with reference to the objectives set for it (see section 2.2). It considers the extent to which the project has achieved its expected outputs, results, and (as far as possible) impacts. The analysis is based on the three main pillars of activities:

- Alignment of legal norms and law enforcement practices in the biomedical field of healthcare and with the European human rights principles enshrined in the Oviedo Convention;
- Strengthening knowledge and raising awareness in the biomedical field of healthcare and legal professionals in Armenia;
- Improving the public dialogue on healthcare issues.

For each pillar, the activities undertaken are described before evidence is offered of the main effects.

4.1 Alignment of legal norms with the Oviedo Convention

To what extent has the project supported national authorities in their effort to align legal norms in the biomedical field with the European Human Rights principles enshrined in the Oviedo Convention?

The main activities to support national authorities in their effort to align legal norms with the Oviedo Convention included:

- Analysis of the compliance of national legislation with the Convention;
- Support in developing legislation, rules and enforcement mechanisms;
- Dialogue with and support for legislators and policymakers.

These are discussed in the three sub-sections that follow. The overall effectiveness of the activities are then discussed in section 4.1.4.

4.1.1 Analysis of compliance with the Oviedo Convention

One of the first activities was a legal analysis of the compliance of the national legislation of Armenia in the field of biomedicine with European human rights and ethical standards enshrined in the Oviedo Convention on Human Rights and Biomedicine. In 2020, preparatory work was undertaken to compile a list of national legislation relevant to the Oviedo Convention. The full analysis was then undertaken by a team of six national experts and six international experts who were selected following two open calls. This culminated in a final report credited to three national experts and three international experts, with a fourth international expert reviewing the final report. The report was published in December 2022 in Armenian and in English.³⁴

Overall, the analysis concluded that some of the provisions of the Convention were not properly addressed but that there was only one direct incompatibility. This related to Article 11(3) of the 2020 Law on Human Reproductive Health and Reproductive Rights, which allowed the use of assisted reproduction technologies for the purpose of choosing a future child's sex where the family already has three children of the same sex, and which is incompatible with Article 14 of the Convention (the

³⁴ Council of Europe. 2022. Protection of Human Rights in Biomedicine Concept Report Comparative analysis of the compliance of the national legislation of Armenia in the field of biomedicine with European Human rights and ethical standards enshrined in the Oviedo Convention on Human Rights and Biomedicine, [1680aa2d74 \(coe.int\)](#).

“fourth child provision”). The report offered recommendations to ensure that all provisions were addressed and the incompatibility removed. Other recommendations were offered with a view to strengthening the legal framework, even where the provisions of the Convention were fully addressed.

Once published, the analysis was then used extensively by the CoE and the other project partners in the subsequent project activities, namely support in developing legislation, rules and enforcement mechanisms (section 4.1.2) and the dialogue with relevant policymakers and legislators (section 4.1.3) and served as a point of reference for subsequent legislative reforms. In the interviews, various stakeholders confirmed that the completion of the legal analysis at the outset of the project was a key driver of the subsequent achievements of the project.

At the same time, it should be noted that the analysis had a very specific remit, i.e. the compliance of national legislation with the provisions of the Convention. This was essential for identifying the specific legislative revisions required to comply with the Convention. However, some stakeholders suggested that there would be merit in additional analysis focussed on: i) the alignment of national legislation with broader human rights standards in biomedicine (i.e. not limited to those issues addressed by the Convention); ii) compliance with the Convention in practice (once the necessary legislative revisions have been made) and the steps necessary to raise standards.

Steps were taken towards a wider legal analysis in the form of a diagnostic study on human rights issues in emergency situations. The study was prompted by the challenges arising from the military conflict with Azerbaijan. It featured an analysis of existing laws and law-enforcement practices on the protection of human rights in emergency situations and provided recommendations for national authorities. The diagnostic study and the associated guide are intended to be guiding tools for decision-makers and practitioners who face such challenges. At the time of writing, the study had been completed but the report had not been published.³⁵

4.1.2 Support in developing legislation, rules and enforcement mechanisms

From 2021 onwards, the project has offered expert support to legislators and policymakers related to the development of legislation, rules and enforcement mechanisms in the field of human rights in biomedicine. This support has reflected the analysis of the compliance of national legislation with the Convention (see section 4.1.1) and has related to various issues, as explained below.

Ethical rules for healthcare professionals: in response to a request from the Ministry of Health, CoE experts provided legal expertise in the development of the draft legal act on ethical rules and code of conduct of healthcare professionals. Based on the output of the collaboration between the experts and the MoH, the act was subsequently adopted by the Government decision 182-N of 17 February 2022.³⁶ It provides a basis for the work of the Ethics Committee for Healthcare Professionals.³⁷

Ethics Committee for Healthcare Professionals: in response to a request from the Ministry of Health, CoE experts supported the design of a new Ethics Committee tasked with the investigation of any breaches of the new ethical rules. The draft order on “Ethics Committees for healthcare professionals developed by the expert group of the Project with the Ministry of Health was approved by the Order of the Minister 75-N from 8 November 2022.³⁸ The Committee is an independent body that adjudicates on the cases of breaches of medical ethics. It is composed of highly experienced, impartial legal professionals. It guarantees stakeholders in the Armenian health system access to support when they fall victim to a mistreatment within the area of medical ethics. The Committee was established

³⁵ <https://rm.coe.int/achievements-yerevan-office/1680aa963f>

³⁶ <https://www.coe.int/en/web/bioethics/-/the-government-of-the-republic-of-armenia-has-approved-the-rules-of-professional-ethics-of-the-healthcare-professionals>

³⁷ <https://rm.coe.int/rules-of-professional-ethics-e/1680a68d31>

³⁸ <https://rm.coe.int/achievements-yerevan-office/1680aa963f>

only recently and there is no data to assess the impacts of its work. However, according to the interview feedback, the stakeholders in Armenia are becoming increasingly aware of the Committee's work and the number of cases referred to it is expected to rise. There is though, a need to review the workload of the Committee, consider providing administrative support and payment for members, and take steps to increase understanding of its independent role (see Case study 2, Annex 6).

Register of organ donors: as noted above, the legal analysis of the compliance of national legislation with the Oviedo Convention offered a recommendation to establish a donor registry and central reporting and management system. In 2021, the MoH requested and received support from the project in drafting such a register. Subsequently, the 2024 revision of the 2002 Law on organ transplantation and/or tissues of the person (No. ZR-324) included a provision for a register of donors and recipients of bodies and human tissues and for a unified information system.³⁹

Law on public health: CoE experts provided recommendations on the draft law on public health.⁴⁰ The Law on public healthcare No ZR-114 was subsequently adopted on 25 March 2024.⁴¹ Amongst other things, the law specifies the rights and obligations of physical persons and legal entities in the field of public healthcare.

Legislative framework of protection of rights of persons with mental health problems: the expert discussion on human rights in the field of mental healthcare services identified a set of issues that required attention. Recommendations were made regarding possible revisions to the legislation, as well as capacity-building needs of healthcare and legal professionals working in the field.

Revision of the institute of legal capacity: it was reported that the project is providing support to the Ministry of Justice to update legal definitions of legal (in)capacity, such as in the case of people subject to compulsory psychiatric treatment. This includes providing examples of international best practice.

Artificial Intelligence (AI) in healthcare: the project provided support in preparing the legal basis for efficient application of AI in healthcare.

Introduction of Comprehensive healthcare insurance system: CoE experts provided recommendations on the package of draft Law which will greatly contribute of the improvement of the quality of medical services provided to the patients.

Individual licensing system for healthcare professionals: CoE experts submitted recommendations to the Ministry of Health regarding possible improvement of the professionals' standards of healthcare professionals (in accordance with Article 4 of the Oviedo Convention). Such a development will support Armenia in holding accountable any individual medical practitioners who commit ethical breaches.

Reproductive health rights: CoE experts provided recommendations to the National Assembly for further improvement of the law on reproductive health rights, most notably the "4th child" provision.

4.1.3 Dialogue with and support for policymakers and legislators

Given the overall objective of bringing Armenia's legal framework into line with the Oviedo Convention, a key activity was engaging in dialogue with policymakers and legislators. Such dialogue aimed to make policymakers and legislators more aware of the Convention and informed about issues around human rights in biomedicine and about the current compliance of national legislation with the Convention based on the analysis undertaken by the project (see section 4.1.1). It also aimed to encourage and build political commitment towards signature and ratification of the Convention.

³⁹ <https://cis-legislation.com/document.fwx?rgn=22407>

⁴⁰ <https://rm.coe.int/achievements-yerevan-office/1680aa963f>

⁴¹ <https://cis-legislation.com/document.fwx?rgn=158743>

The main activities included:

- Training and capacity-building for staff of the Ministry of Health and the NIH aimed at developing their understanding of the Oviedo Convention and of human rights issues in biomedicine more generally.
- Annual meeting of chief advisors of the Ministry of Health, with a particular focus on Article 3 of the Oviedo Convention on equitable access to health care.
- Capacity-building for Assembly Members and their staff to raise awareness of the Oviedo Convention and the benefits of signature and ratification.
- A presentation by project experts to Assembly Members on the issue of informed consent in the context of Armenia's possible signature and ratification of the Convention.
- A visit by a delegation from the Ministry of Health to the CoE in Strasbourg in November 2022.⁴² The delegation included the heads of Legal, Human Resources for Health and Healthcare Policy Development. It was reported that, subsequent to the visit, the delegation shared their learning and experience more widely amongst staff within the Ministry.
- A visit by a delegation of CoE staff in Strasbourg to the Ministry of Health in Armenia in April 2023 to discuss co-operation.⁴³
- A visit by a delegation from the National Assembly to the CoE in Strasbourg in January 2024,. This last visit was seen as instrumental in the lead-up to Armenia's signature of the Oviedo Convention four months later. It included Assembly Members serving on three of the National Assembly's Standing Committees: Health; Human Rights and Public Affairs; and European Integration.⁴⁴

4.1.4 Summary of main effects

This sub-section describes the main effects of the project in terms of aligning legal norms in biomedicine with the principles enshrined in the Oviedo Convention. It does so with reference to the project's intended outcomes, as specified in the two most recent iterations of the CoE's Action Plan for Armenia.

Intended outcomes

- Armenia is better prepared for future ratification of the Oviedo Convention (Action Plan 2019-2022)
- Armenia takes further steps towards the accession to the Oviedo Convention (Action Plan 2023-2026)

The first main intended outcome of the project was that Armenia would be better prepared for and making steps towards ratifying the Oviedo Convention. Here, the evidence demonstrates that the project has been successful.

⁴² Council of Europe. 2022. "[Delegation from the Ministry of Health of Armenia visits the Council of Europe](#)". 14-16 Nov 2022.

⁴³ Council of Europe. 2023. "[The delegation of the Council of Europe visited the Ministry of Health of the RA](#)". 12 April 2023.

⁴⁴ Council of Europe. 2024. "[Armenian MPs have discussed the possibilities of the ratification of the Oviedo Convention](#)". 22-24 April 2024.

A first effect of the project, and arguably the most important, is the signing of the Oviedo Convention. The Convention was signed on behalf of Armenia by Mr Ararat Mirzoyan, Minister of Foreign Affairs, during a visit to Strasbourg on 1 May 2024.⁴⁵

The consensus amongst the interviewed stakeholders was that the project was a key driver, if not the primary driver, in the decision to sign the Convention. First, the legal analysis showed in concrete terms what needed to be done and that most of the provisions of the Convention were addressed and that there was only one incompatibility, i.e. the provision allowing the use of assisted reproduction technologies for the purpose of choosing a future child's sex where the family already has three children of the same sex (the "fourth child provision"; see section 4.1.1). Second, and capacity-building sessions had raised awareness of the Convention and the legislative steps that needed to be taken (see section 4.1.3). Third, the dialogue with the CoE which involved National Assembly Parliamentarians and senior policymakers, particularly the visits to/from Strasbourg had been crucial to building political support for signing the Convention (see section 4.1.3). With the Convention now signed, the interviewed stakeholders report that the political environment remains favourable towards progressing towards ratification.

However, it should be noted that **Armenia took the opportunity allowed by Article 36 of the Convention to make a reservation when signing the Convention.** This reservation provides a declaration that a law currently in force in Armenia is not in conformity with the Convention. The reservation is contained in a Communication from the Ministry of Foreign Affairs of Armenia, handed over at the time of signature of the instrument, on 16 May 2024. According to Article 36 of the Convention, the Republic of Armenia declares that the Article 14 of the Convention defines the prohibition of gender selection as follows: "*The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided.*". This contradicts Part 3 of the Article 11 of the Law "On Human Reproductive Health and Reproductive Rights" according to which it is not allowed to plan the sex of the future child in the case of the use of assisted reproductive technologies, except for the cases where there is a possibility of inheriting a sex-linked disease, or the family has 3 children of the same sex.⁴⁶ On this basis, Article 14 of the Convention will not be applied to medical care and services using assisted reproductive technologies in the Republic of Armenia. Activities undertaken by the project during the period covered by this evaluation tended to focus on building support for the Convention in general rather than on addressing this specific incompatibility. However, project stakeholders reported a willingness to engage with the issue in future, although a key condition will be ensuring political support (see Case study 1 in Annex 5).

Intended outcomes

- Relevant legal texts and law-enforcement practices are brought into line with the principles enshrined in the Oviedo Convention (Action Plan 2019-2022)
- Armenian legal framework and related practices are more in line with the principles enshrined in the Oviedo Convention (Action Plan 2023-2026)
- The overall level of human rights protection in the biomedical field is increased (Action Plan 2023-2026)

⁴⁵ Council of Europe. 2024. Armenia signed the Oviedo Convention, [Armenia signed the Oviedo Convention - Human Rights and Biomedicine \(coe.int\)](https://www.coe.int/en/web/conventions/full-list?module=declarations-by-treaty&numSte=164&codeNature=0).

⁴⁶ <https://www.coe.int/en/web/conventions/full-list?module=declarations-by-treaty&numSte=164&codeNature=0>

The second main intended outcome of the project was that national legislation and law enforcement would be brought into line with the principles enshrined in the Oviedo Convention, which would increase the level of human rights protection in the biomedical field in law.

The PHRIB project and the legal analysis have inspired and directly informed various proposals to align legislation. The legal analysis set out the legislative revisions that would increase alignment with the Convention and raise standards in practice. This was complemented by the dialogue and support for policymakers. Most notably, the CoE experts provided recommendations around the drafting of revisions in response to direct requests from the relevant national authorities (see section 4.1.2). Thus, the project has made a positive contribution to the following legislative revisions:

- Legal acts on ethical rules and code of conduct for healthcare professionals
- Methodology for the functioning of ethical committees
- National register of transplantation of organs and tissues
- Law on public health
- Legislative revisions relating to human rights issues in mental healthcare services
- Institute of legal capacity
- Legal basis for efficient application of Artificial Intelligence in healthcare
- Law on a comprehensive healthcare insurance system
- Law on individual licensing of health professionals
- Law on reproductive rights

The project has directly helped bring law enforcement practices into line with the Convention by supporting the creation of the Ethics Committee. As shown in Case study 2 (Annex 6), the project supported both the design of the ethical rules and code of conduct and the design of the Committee tasked with enforcement. The early signs are that the operation of the Committee is raising awareness of ethical standards and thus positively influencing medical practice. However, the full impact of the Committee will only be felt once its decisions becoming legally-binding.

Whilst the project has supported progress, additional steps may be required for national legislation to fully address all the provisions of the Oviedo Convention. Although one incompatibility remains (i.e. the “fourth child provision”), there remain a number of areas where alignment could be strengthened so that provisions are better addressed and standard are raised. To illustrate this, the table below provides a summary of the recommendations made by the project’s legal analysis and the subsequent steps taken or needing to be taken.

Table 2 Steps taken towards ensuring full alignment with the Oviedo Convention

Recommendations offered by the legal analysis	Steps taken
Concepts and provisions around informed consent should be clarification (although there is no incompatibility with the Convention).	It is uncertain whether any clarification is (to be) proposed. It was reported that the PHRiB project is providing support to the Ministry of Justice to update legal definitions of legal (in)capacity, such as in the case of people subject to compulsory psychiatric treatment. This includes providing examples of international best practice.
The legislative framework around medical confidentiality and medical secrets could be	The Law of the Republic of Armenia of 4 April 1996 No. ZR-42 on Medical Assistance and

Recommendations offered by the legal analysis	Steps taken
better structured, for example, in a single piece of legislation.	Service of the Population was amended on 07-06-2024. ⁴⁷ It is not certain whether this amendment took into account the recommendation of the legal analysis.
Revisions to the legislation on research on embryos are recommended: i) either to prohibit such research or to define clear provisions regulating such research; ii) to clarify the definition of “saving embryos for monetary compensation”; iii) to prohibit the creation of human embryos solely for research.	It is uncertain whether any legislative revisions or clarifications are (to be) proposed.
The creation of human embryos solely for research should be prohibited.	It is uncertain whether any legislative revisions are (to be) proposed.
It is recommended to align the “fourth child provision” with the Convention.	<p>The provision remains in place in contradiction with the Oviedo Convention.</p> <p>Based on the recommendations of the Council of Europe, the National Assembly has initiated the hearings on a possible amendment to the Law on "Reproductive health rights" related to the provisions of sex-selection.</p> <p>No concrete legislative revision has yet been adopted. However, legislators and policymakers suggest that such a revision may be possible in the coming years, although some potential political opposition is reported.</p> <p>It is understood that the number of actual cases in practice allowed by the provision has been minimal since its adoption in June 2021. The low use of this provision might therefore strengthen the political case for its removal.</p>
<p>It is recommended to:</p> <ul style="list-style-type: none"> • Clarify issues around informed consent, relationship between donor and recipient, risks to donors’ lives, follow-up care, compensation for damages, sanctions against financial gain and advertisement. • Establish a donor registry and a central reporting and management system. • Adopt legislation to ensure international co-operation • Establish a body to certificate conditions of transplantation 	<p>It was reported that a proposal to revise the legislation on transplantation of organs and tissues of human origin has been (or is being) developed by the Ministry of Health and has been (or will be) presented to the National Assembly. The legislative revision would address the identified gap with the Oviedo Convention, for example, around ensuring the informed consent of donors and recipients.</p> <p>The 2024 revision of the 2002 Law on organ transplantation and/or tissues of the person (No. ZR-324) included a provision for a register</p>

⁴⁷ <https://cis-legislation.com/document.fwx?rgn=3059>

Recommendations offered by the legal analysis	Steps taken
	of donors and recipients of bodies and human tissues and for a unified information system.
<p>It is recommended to:</p> <ul style="list-style-type: none"> • Include provisions stipulating potential consequences related with transfusion in the scope of the informed consent of recipients and donors. • Include provisions stipulating the information to be provided to a recipient regarding alternatives, such as artificial blood components used in case of emergency. • Make explicit that a recipient or donor gives his/her consent in the absence of any pressure from anyone. • Make explicit that the law includes prohibits financial gain. 	It is uncertain whether any legislative revisions are (to be) proposed.
<p>It is recommended to:</p> <ul style="list-style-type: none"> • Introduce robust legislation before allowing interventions on the human genome or genetic testing. • Providing training for healthcare professionals to comply with scientific and technical standards. • Revise legislation to include criteria to assign a genetic test to a person or group of persons. • Revise legislation to ensure that right to be informed on genetic test results. • Ensure legislation on genetic testing (when introduced) provides for genetic counselling. 	<p>It is uncertain whether any legislative revisions are (to be) proposed.</p> <p>The HELP course has provided training for healthcare professionals in Key Human Rights Principles in Biomedicine, including genetic testing.</p>
It is recommended to regulate biomedical research (including clinical trials) in accordance with the Convention.	It is uncertain whether any legislative revisions are (to be) proposed.

4.2 Alignment of practice and institutional mechanisms with the Oviedo Convention

To what extent has the project helped healthcare and legal professionals align their practices and institutional mechanisms with the standards enshrined in the Oviedo Convention?

The main activities to help healthcare and legal professionals align their practices and institutional mechanisms with the standards enshrined in the Oviedo Convention included:

- Human Rights Education for Legal Professionals (HELP)
- Other training for professionals, expert discussions and workshops.

These are discussed in the sub-sections that follow. The overall effectiveness of the activities are then discussed in section 4.2.3.

4.2.1 Human Rights Education for Legal Professionals (HELP)

The European Programme Human Rights Education for Legal Professionals (HELP) is a broader CoE programme to support CoE member states in implementing the European Convention on Human Rights (ECHR) at the national level.⁴⁸ Since June 2018, the CoE has made available a customised HELP course on “Key Human Rights Principles in Biomedicine”.⁴⁹ The course assists legal and health professionals to understand key human rights principles in biomedicine. It covers binding legal instruments, notably the Oviedo Convention, relevant case-law of the European Court of Human Rights, and non-binding instruments adopted by the Council of Europe Committee on Bioethics. (See Case study 3 in Annex 7 for a longer description of the HELP activities and effects.)

Through the PHRiB project, the HELP course on biomedicine was updated, tailored to the Armenian context and translated into Armenian. Following this, in early 2021, the project trained 17 trainers to deliver the course. These participants included representatives of the key public institutions in Armenia relevant to the subject of biomedical ethics. The first course in tutored format was then launched in a pilot form. By the end of December 2022, a total of 20 iterations of the tutored course were held featuring 326 participants. Of these, 212 (65%) completed the course and received the certificate.⁵⁰ Armenia had thus featured more iterations of and participants in the biomedicine HELP course than any other country. The Armenian version of the course was also made available online for self-study and attracted 53 enrolments, of which 3 completed the course and received the certificate.

Participants in the HELP courses were also provided with supporting materials, including relevant national legislation, the text of the Oviedo Convention (translated into Armenian), publications of the project (see section 4.3), other publications of the CoE and other materials available via the HELP on-line platform.

Overall, the feedback on the courses received from tutors and courses’ participants was very positive. For example, available evidence from the feedback surveys undertaken at the end of each iteration showed that 50/52 (96%) participants reported the course as “excellent”, “very good” or good”, whilst 1 (2%) reported it as “satisfactory” and only 1 (2%) as “bad”.⁵¹ This positive view was confirmed by the interviews undertaken as part of this evaluation. The usefulness of the knowledge provided under the course was stressed by project beneficiaries, and some anecdotal examples of participants using the courses to improve their individual professional practice were provided (see the Case study 3, Annex 7). The contents of the course were adjusted by the convenors to the needs of specific course groups and to the national context of Armenia. Moreover, the direct access of participants to trainers, and numerous one-to-one exchanges on specific subjects covered by the course facilitated provision of knowledge to the participants. According to the stakeholders and HELP participants interviewed for this evaluation, the HELP course has provided knowledge that is not otherwise provided to medical

⁴⁸ <https://www.coe.int/en/web/help/about-help>

⁴⁹ <https://www.coe.int/en/web/bioethics/-/the-help-course-on-key-human-rights-principles-in-biomedicine-launched-on-the-help-platfor-1>

⁵⁰ Council of Europe (2023) Report Human Rights Education for Legal Professionals Data and Information For 2015-2022, 1680ab591b (coe.int), p. 48

⁵¹ Evidence from the feedback surveys was available in tutor reports for five iterations of the HELP course and thus does not cover all iterations. Feedback was provided only by participants who completed the course. The reports do not give a full disaggregation between those selecting ““excellent”, “very good” or good”.

and legal practitioners, for example, in the existing academic education and professional training available to them.

A second HELP course has been developed by the project and is expected to be published online in the autumn of 2024: “Human Rights Issues in Mental Healthcare Services.”⁵²

4.2.2 Other training for professionals

In addition to the HELP courses, the project provided other training for professionals. In Phase I, these included the following.

- **E-course on ethical rules of health professionals:** in co-operation with the National Institute of Health, the project developed this course aimed at strengthening the capacities of healthcare professionals on Armenia’s new ethical rules, as well as national and international standards in the fields of medical secret and confidentiality and informed consent.⁵³
- **Around 75 medical professionals at the Prison Medical Centre** (representing around half of all staff) received training on medical ethics, thanks to the co-operation of the project and another CoE project organised in Armenia. Utilisation of such a synergy on the ground can be seen as a good practice in efficient management and an achievement of the project team.
- 25 staff of the **National Centre for Diseases Prevention and Control**, and 25 representatives of the **National Centre for Infectious Diseases** were trained on international principles of the protection of human rights in biomedicine and healthcare law in a 2-day capacity building session, to support them in application of the international standards in their daily work.
- **Ministry of Health staff** received training on the key principles of the Oviedo Convention and its Additional Protocols through a 2-day training and capacity-building session. The implementation report stressed that the training was addressed to decision-makers to channel the agenda promoted by the project through their daily standard-setting work.
- The **Research Ethics Committee** was supported through a two-day training session attended by 20 members.⁵⁴ The value added of this capacity-building should be particularly stressed, as the Committee is a new body in a great of need of training, to promote in Armenia best practices around functioning of research ethics committees internationally. The capacity-building supported the Committee, for example, in so far as it had to develop its standard operation procedures to function effectively.
- **An expert discussion on artificial intelligence considered the implications for human rights in healthcare.** The session was attended by representatives of the Ministry of Health, Agency of Personal Data Protection, Yerevan State Medical University, Ministry of Justice, National Institute of Health and civil society organisations.

In Phase II, other training for professionals have included the following:

- 25 **National Institute of Health staff members** participated in a 2-day capacity-building session, focusing on the main principles of the Oviedo Convention and its Additional Protocols.
- 13 Members of the **Research Ethics Committee** participated in a 2-day follow-up training session.
- At the time of writing, it was reported that the project is discussing with the Ministry of Health the possibility of providing capacity-building for members of the judicial system of Armenia (e.g. judges). This training would cover issues around the introduction and enforcement of legislative revisions, for example, reforms of the legislative framework on legal incapacity.

⁵² CSES Consultations.

⁵³ <https://www.coe.int/en/web/bioethics/-/new-e-course-on-ethical-rules-for-healthcare-professionals->

⁵⁴ <https://rm.coe.int/achievements-yerevan-office/1680aa963f>

4.2.3 Summary of main effects

This sub-section summarises the main effects of the project in terms of aligning practice and institutional mechanisms with the principles enshrined in the Oviedo Convention. It does so with reference to the project's intended outcomes, as specified in the two most recent iterations of the CoE's Action Plan for Armenia.

Intended outcomes

- Extent of knowledge, level of protection of patients' rights and degree of implementation
- The overall level of human rights protection in the biomedical field is increased (Action Plan 2023-2026).

The HELP courses on key human rights principles in biomedicine have increased awareness of the Oviedo Convention and its principles among medical and legal professionals. (See Case study 3, Annex 7). The courses were delivered with high relevance to the needs in Armenia and assessed positively by the tutors and participants. For example, it was reported to be beneficial to have the opportunity to discuss practical cases of application of Oviedo Convention principles. Some of the tutor reports also suggested that participants intended to apply the knowledge gained in their everyday work. By the end of December 2022, Armenia had featured more iterations of the tutored course and more participants than any other country. The completion rate (65%) is lower than in most other countries although only slightly below the average across all countries (68%).

Other training and capacity-building has supported awareness of the Convention and the capacity of key stakeholders to promote it and comply with it. Such training has also covered Armenia's new ethical rules for healthcare professionals (see section 4.2.2). According to the feedback collected by the project, participants expressed high satisfaction with the training sessions, giving an overall rating of 4 or 5 out of 5. The interviewed stakeholders were positive about the impact on their own institutions and across all institutions in general.

For impact to be sustained and widened, there is a need for the HELP course (or key aspects of it) and the principles of the Oviedo Convention to be incorporated into mainstream medical and legal education and training. Whilst the numbers of professionals participating in HELP is positive, broader cultural change in medical and legal practice will best be ensured by relevant university degree courses and professional development courses incorporating the principles of the Oviedo Convention into their curricula. This will become all the more important once recent legislative revisions come into force, not least once the decisions of the Ethics Committee become legally-binding.

4.3 Improvements in public dialogue on human rights issues in healthcare

To what extent has the project improved public dialogue on human rights issues in healthcare among national authorities, as well as healthcare and legal professionals, and the public at large?

Activities to improve public dialogue on human rights issues in healthcare, although not constituting one of the main pillars of project activities, served as an important complement to the activities to align legal norms and medical practice with the principles of the Oviedo Convention.

The main activities included:

- Engagement with and support for journalists

- Provision of resources and communication activities.

These are discussed in the sub-sections that follow. The overall effectiveness of the activities are then discussed in section 4.3.3.

4.3.1 Engagement with and support for journalists

One important objective was to address the issue of low awareness of human rights issues and the need to raise ethical standards. Here, the project aimed to raise awareness of medical and legal professionals, as well as the population in general. This was particularly important given the new requirements linked to new or imminent legislative revisions, i.e. making professionals more aware of their obligations and patients aware of their rights.

A first key activity was to build the capacity of journalists to understand and accurately report on issues of human rights in biomedicine. To this end, the project provided a customised version of HELP, namely “HELP training for journalists on the Key Principles on Bioethics”. This was an innovation, with the HELP course on biomedicine not having previously been customised in this way in any other countries. This pilot involved 20 journalists, supporting them in raising awareness on ethical rules among the wider public and also more specifically, among medical professionals.

The project also developed a guide for journalists, addressing the subject of communication in the field of biomedicine in the context of a public health crisis. The guide for journalists was developed in the context of the COVID-19 pandemic outbreak, focusing on communication on biomedicine in the context of a public health crisis.

4.3.2 Provision of resources and communication activities

At an early stage, the project addressed the availability of Armenian translations of key information about human rights issues in biomedicine. This was an essential first step and supported later activities, e.g. by providing relevant materials to support HELP courses. It was also a key output of activity in 2020, when the COVID-19 pandemic and the military conflict with Azerbaijan limited other activities.

In addition, at least eight new publications were developed specifically for the Armenian context. Printed copies were provided, where relevant, to project partners and other key stakeholders, participants in training and capacity-building activities. The materials were also made available online for the general public. The main resources provided are as follows:

- Publication of the Oviedo Convention and its Additional Protocols (250 copies)
- Ethical rules for healthcare professionals in English and Armenian (250 copies in each language)
- Report on the impact of artificial intelligence on the doctor-patient relationship (200 copies)
- Concept report on the analysis of Armenian legislation in the field of biomedicine vis a vis Oviedo Convention (100 copies)
- Leaflet on Bioethics at the Council of Europe (200 copies)
- Guide on prohibition of financial gain with respect to human body and its parts (200 copies for each)
- Guide for research ethics committee members (200 copies)
- Compendium of good practices to promote voluntary measures in the field of mental healthcare (200 copies).⁵⁵

Amongst the publications developed specifically for the Armenian context, were two guides:

⁵⁵ <https://rm.coe.int/achievements-yerevan-office/1680aa963f>

- Guide to Public Debate in Human Rights and Biomedicine: translated by the project, adapted to local needs, and disseminated among medical workers and national authorities.
- “Guide to health literacy for equitable access to health care” - translated to Armenian, layouts disseminated to other stakeholders to promote their use in Armenia. delivered by CDBIO and used when implementing the activities. The aim of the guide was to widen general capacity of individuals, including those in more vulnerable situations, to advocate for better access to healthcare services

Throughout the project, the CoE project team has implemented a communication strategy to promote the project, its activities and achievements. This includes a dedicated page on the main CoE website, where key information and documents are provided. News items have been released at key points to highlight specific activities or achievements, such as the high-level visits to/from Strasbourg. A representative of the CoE’s Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO) was interviewed by the Public Radio of Armenia. The project has also worked with public relations specialists to produce a range of leaflets, brochures, posters, and a short video clip explaining the new rules of professional ethics for healthcare professionals and the role of the Ethics Committee. The project also translated and disseminated a video prepared by the CoE on "Human rights and bioethics in times of COVID-19". The printed materials (see the bullet point list above) have also been distributed to stakeholders and HELP participants. The communication activities of the CoE have been complemented by the efforts of national stakeholders, for example, through promoting the project or its activities and achievements on their own websites. The project held discussions with the Journalism Faculty of the Yerevan State University on the possible involvement of journalism students in development of its communication strategy.

4.3.3 Summary of main effects

This sub-section summarises the main effects of the activities to improve public dialogue on human rights issues in healthcare. It does so with reference to the project’s intended outcomes, as specified in the two most recent iterations of the CoE’s Action Plan for Armenia.

Intended outcome

- Further public awareness and discussion on main challenges to human rights protection in biomedicine are fostered (Action Plan 2023-2026).

It has been beyond the scope of this evaluation to gather comprehensive data on changes in public awareness and discussion on the main challenges to human rights protection in biomedicine. However, qualitative evidence (e.g., from the interviews of stakeholders) suggests that **the various activities have contributed to increased awareness amongst medical and legal professionals and on journalists.**

It is unrealistic to expect the project to have had a measurable impact on public awareness; indeed, it the main objective was to raise awareness amongst, first, legislators and policymakers and, second, amongst professionals. Looking ahead, as Armenia moves towards ratification and as the new requirements introduced by legislative revisions come into force (i.e. around obligations of professionals and rights of professionals), **there may be a need for a more sustained public information campaign.** The scale of such a campaign will require it to be and financed and implemented by relevant national bodies, although there may be scope for the CoE to play an advisory role.

4.4 Gender mainstreaming

To what extent have gender issues been mainstreamed in the project's design and implementation?

Key gender issues in human rights in biomedicine were supported through the project. As noted earlier, the principles enshrined in the Convention apply equally to men and women, such as informed consent, medical confidentiality, research and transplantation of organs and human tissues. Nonetheless, some principles, although framed in gender-neutral language, do in practice have a gender dimension. Most notably, the prohibition of sex-selection in medically-assisted procreation (Article 14) typically has a gender dimension in practice, i.e. sex-selection more often manifests itself in a preference for boys rather than girls. Similarly, equitable access to healthcare (Article 3) would imply a gender dimension, for example, in ensuring that females have access to gender-specific services. However, as noted above, more action is required to remove the “fourth child provision” (which tends to result in sex-selection against girls).

A positive impact on gender has been achieved through the introduction of the ethics code for medical professionals. This includes provisions relevant to gender. Enforcement will be supported through the subsequent establishment of the Ethics Committee for Healthcare Professionals, which will assess the ethical conduct of medical professionals. Such developments helped promote gender equality within the Armenian healthcare institutions, improving access to impartial support for medical personnel and patients who experience gender-based mistreatment or violence.

The project was aligned with CoE tools for gender equality but could have benefited from more concrete support for gender mainstreaming from the CoE. The project referred to the CoE Gender Equality Strategy 2018-2023¹⁵ and the Gender Mainstreaming Toolkit for Cooperation¹⁶ throughout its implementation. However, the wider CoE Action Plan for Armenia anticipated the appointment of a gender mainstreaming advisor to serve the CoE's overall activities in the country. However, the support provided to the PHriB project appears to have been limited in practice.

The project faced challenges around achieving equal number of male and female participants in HELP courses. As described in Case study 3 (Annex 7), the original intention was to aim for a gender balance in each HELP group and a requirement to that effect was placed on the trainers when recruiting participants. However, in some cases it was not feasible to enrol a sufficient number of men to ensure a gender parity with women accounting for 77% of participants (across the groups sampled by this evaluation). This rate of female participation may be related to the wider gender balance amongst healthcare professions; according to the WHO, women account for 67% of the global health and social care workforce.⁵⁶

4.5 Drivers of effectiveness

Overall, this evaluation has identified a number of drivers of the effectiveness:

- **A holistic, step-by-step project design.** The project holistic, step-by-step approach focussing on a few key areas with each activity building on those that came before. For instance, to promote the ethical behaviour of healthcare professionals, the project supported the establishment of rules of ethics, supported the establishment of the Ethics Committee, a body to enforcing compliance with those rules, trained the members of the Committee, helped it set up a website, and helped promote it through a country-wide public relations campaign.

⁵⁶ <https://www.who.int/activities/value-gender-and-equity-in-the-global-health-workforce>

- **An inclusive, multi-institutional project design.** By targeting stakeholders across professions and across the country, including legislators, healthcare professionals, and lawyers the project laid the groundwork to reach all actors in society whose cooperation is required to achieve a lasting impact in the protection of human rights in biomedicine. By targeting all relevant institutions, including the National Assembly, the Ministry of Health, the Ministry of Justice, the Ministry of Foreign Affairs, the National Institute for Health, the Human Rights Defender Office, the project established the personal connections and facilitated the commitment required to take steps toward signature of the Oviedo Convention.
- **A relationship of trust between the project management team and stakeholders.** One of the main points of agreement among the stakeholders consulted for this evaluation was that it was well managed. The team's responsiveness, their willingness to help with matters large and small, and their positive and encouraging outlook built trust and motivated stakeholders to invest time and energy into the project.
- **Adaptation to evolving political circumstances.** The fact that the project reached its objectives despite a pandemic, military conflict, and a refugee crisis is due to adaptability, prioritisation and re-shifting of the focus in response to each crisis. Facing the pandemic, the team postponed capacity-building and other events that required face-to-face meetings and, instead, made considerable progress on other fronts, including the translation of CoE materials, the creation of the project website, the launch of tenders for local and international experts, the legal analysis, and the translation and customisation of the HELP course on Key Principles in Biomedicine.⁵⁷

4.6 Barriers to effectiveness

This evaluation identified a few barriers to the project's effectiveness:

- **COVID-19 pandemic.** The first major challenge was the fact that Phase I started at the height of the pandemic, in June 2020. This disrupted original plans for early capacity-building events but led the project team to start with desk work and other activities that did not require any face-to-face interactions.
- **Military conflict with Azerbaijan in Sep-Nov 2020.** The second challenge followed three months after the beginning of Phase I when Azerbaijan invaded the Karabakh region in September 2020. At that point, many actions had to be cancelled or postponed. However, capacity-building events originally planned for the autumn of 2020 were then held in the beginning of 2021, such as the training for trainers of the HELP course for legal and healthcare professionals.⁵⁸
- **A wide range of technical skills among course participants.** Another barrier is specific to the HELP courses. While these courses are freely accessible to legal and health professionals they require a minimum level of technical skills. This presents a challenge for trainers who spend a significant amount of time teaching not course contents but basic computer skills.
- **Communication among project partners.** A final potential barrier concerns the communication between some national-level project partners. A few stakeholders consulted for this evaluation have suggested that the commitment of institutional partners could be very dependent on the specific individuals having responsibility. Whilst engagement and commitment were generally high, few instances were highlighted of challenges faced in gaining the personal commitment of relevant individuals.

⁵⁷ Council of Europe. Draft Annual Report – Protection of Human Rights in Biomedicine I. 30 January 2021, p.4-5.

⁵⁸ Council of Europe. Draft Annual Report – Protection of Human Rights in Biomedicine I. 30 January 2021, p.7.

5 Efficiency

This section considers the efficiency of the project. Two aspects are considered: first, the approach to project management and whether alternative working methods might have been more efficient; second, the allocation of the budget and whether alternative activities might have been more efficient.

5.1 Efficiency in project management

Have there been any obvious (in)efficiencies in the working methods implemented?

To what extent could alternative working methods have led to the achievement of comparable or better results with fewer resources?

The working method adopted by the project has been the appointment of a dedicated project team supervised by the CoE's Human Rights in Biomedicine Division (HRBD) within the Directorate General Human Rights and Rule of Law in Strasbourg but located in the CoE Office in Yerevan. The costs of project staff in Yerevan are financed by the project budget, whereas staff in Strasbourg are financed by other CoE budget lines.

CoE staff reported that the organisational structure and composition of the project team (as just described) was efficient and effective. Although the project team was remotely managed by the Human Rights in Biomedicine Division in Strasbourg, staff in both locations reported a positive and close working relationship. Both the project team and the other CoE staff in the Yerevan Office also reported good working relationships. The CoE staff also reported satisfaction with the composition of the project team and its mixture of expertise and knowledge. Moreover, the CoE staff and some national partners reported that it was beneficial that the Senior Project Officer was previously an employee of the Ministry of Health and was thus knowledgeable about the state of human rights in biomedicine in Armenia and very familiar with the key stakeholders. The other CoE staff have also contributed to the implementation of the project, including efforts to encourage stakeholders' commitment to the Oviedo Convention. For example, the Head of Office had engaged in high-level dialogue with legislators, policymakers and other stakeholders in Armenia to promote their understanding of and commitment both to the project and to the process towards ratification of the Convention. Locating the project staff in Yerevan also helped to connect the project to other CoE activities in Armenia, as part of the wider CoE Action Plan for Armenia.

A key success factor in the management of the project has been the possibility to adjust activities, working methods and timescales in light of challenging external circumstances. Most notably, the COVID-19 pandemic and the military conflict in 2020 raised considerable challenges. In response to the pandemic, many activities were moved on-line, including the first meeting of the project Steering Committee in September 2020. The military conflict with Azerbaijan also meant that many staff of key stakeholder bodies were unable to give as much time to the project. In light of the pandemic and the military conflict, the project therefore focussed in the first year on activities that did not require active group participation, such as the preparatory work for the legislative analysis, contracting of experts, translation of materials and development of the project web page. Crucially, the timescale for completing Phase I was extended from the end of July 2021 to the end of December 2021.

The project team deployed the CoE's standard "multi-institutional approach" methodology.⁵⁹ In accordance with this approach, the team engaged with a range of key national stakeholders in the

⁵⁹ Council of Europe, Co-operation in Europe, [Co-operation in Europe - Directorate of Programme Co-ordination \(coe.int\)](https://www.coe.int/en/web/coe-operation).

process of planning and implementing the activities, including relevant ministries, the National Assembly, and the Office of the Human Rights Defender. This was essential to the achievement of many of the main intended effects. For example, changes to the legislation, rules or enforcement mechanisms can only be introduced by the national partners not by the CoE. The multi-institutional approach also provided some (albeit unquantifiable) efficiencies through leveraging the resources and expertise of national partners, for example, in terms of hosting activities, identifying HELP participants, disseminating materials, communicating messages, etc. Thus, the multi-institutional approach has allowed the project to promote progress towards signature and ratification of the Convention in a way that encourages ownership by national stakeholders. Such an approach is also likely to be translated into greater sustainability of the project's achievements, as with such a support among the national stakeholders, Armenia is more likely to carry on the work commenced by the project also after its implementation comes to an end.

5.2 Budgetary allocation

Were any specific activities particularly cost-effective or cost-ineffective?

To what extent could alternative working methods have led to the achievement of comparable or better results with fewer resources?

As described in section 2.4, the Phase I budget was EUR 530 000, of which the majority (64%) was accounted for by human resource costs. The Phase II budget was 70% larger than in Phase I at EUR 900 000. Most of the budget increase was allocated to other costs/services, as well as travel, whilst there was only a slight increase in human resource costs (including project staff and external consultants).

Despite the Phase I budget being considerably below the initial assessment of budgetary need, the project has achieved much of the intended impact. As noted in the evaluation of the CoE Action Plan for Armenia (2019-2022), it was intended that the Phase I budget would be EUR 980 000. However in practice, the initial budget was only EUR 350 000 and the final Phase I budget was only EUR 530 000.⁶⁰ As described in section 4 of this report, the project has succeeded in fostering political support for Armenia's signature of the Oviedo Convention and in enabling key stakeholders and a large number of healthcare professionals to become familiar with the principles enshrined in the Convention and with human rights issues in biomedicine more generally.

The creation of a project team in the CoE Yerevan office has proved cost-effective. Unlike some other CoE projects, the project team was entirely based in Armenia with no team members based in Strasbourg, which represents an example of good practice that might be applicable to some future projects. This was not only necessary given the need for proximity with national project partners and other stakeholders but also cost-effective given the lower salary costs in Armenia. Where necessary, support was offered by the Strasbourg-based Human Rights and Biomedicine Division of the CoE, although such costs were outside the project's budget.

Expenditure on national and international consultants was reported by stakeholders to be essential to the effectiveness of the project. Indeed, it was seen as essential that the project facilitate the transfer of international expertise to Armenia as a means of building national expertise in biomedicine. As shown in the table below, a total of 733 consultancy days were procured across both phases of the project, of which the majority (59%) related to national consultants. The main reason for the increase in consultancy days in Phase II was the greater number of in-person capacity-building sessions, where

⁶⁰ Council of Europe (2022), [Progress Review and Final Evaluation of the Council of Europe Action Plan for Armenia 2019-2022](#); p.27.

experts were needed. For example, Phase I featured only nine sessions, whilst Phase II has to date featured 27 sessions. Moreover, the additional sessions related to developments in the Karabakh region have involved teams of international and national consultants.

Table 3 Expenditure on national and international consultants

Category	Phase I		Phase II		TOTAL
	Days	Average rate EUR	Days	Average rate EUR	Days
National consultant days	198	303	238	308	436
International consultant days	88	358	209	379	297
TOTAL	286	-	447	-	733
National per diems	18	176	51	165	69
International per diems	68	178	291	168	359
TOTAL	86	-	342	-	428

Source: Council of Europe

The fees offered by the project were assessed as competitive by the Armenian stakeholders interviewed for this evaluation. One of the interviewed stakeholders suggested that the fees offered by the project might not be sufficient to attract some of the more renowned international experts. Asked about that issue, the project staff clarified that in the procurement procedures for selection of international experts, the choice was made to allow the experts to propose their own fee rate, with no maximum rate set formally by the CoE. According to the project team, the fees proposed in the received expert's applications, with the budget available to the project, allowed for securing of international expertise in the sufficient volume and with a sufficient quality.

One challenge in this area was delays in payments of fees to experts. The interviewee who highlighted such an issue described this problem as occurring persistently, in relation to their different engagements with the Council of Europe. As such, the problem of delayed payments was described as not specific to the project and a general feature of working for the CoE. Although this issue did not affect the delivery of the project, it risks disincentivising experts to participate in the future and harming the reputation of the CoE.

The balance of expenditure was revised in Phase II to allow more conferences and seminars to take place. Within Phase 1, the priority was both to undertake the legal analysis to identify the legislative revisions required to comply with the Oviedo Convention and also to build the project partnership and engage strategic stakeholders. The COVID-19 pandemic also limited the extent to which in-person meetings could take place. In Phase II, the lifting of restrictions made it possible for more in-person meetings to take place. There was also a need to shift the emphasis towards engaging a wider set of stakeholders in order to build political support for signature of the Convention, stimulate change in professional culture and practice in healthcare and promote public dialogue; this suggested a need for more in-person conferences and seminars involving legislators, policymakers, healthcare and legal professionals, journalists and others. Thus, the expenditure on "other costs/services" in Phase II was three times the level in Phase I. The majority of this increase relates to expenditure on conferences and seminars, which increased from EUR 42 160 in Phase I to EUR 290 338 Phase II. As noted earlier, this includes nine capacity-building sessions in Phase I compared with 27 sessions in Phase II. Translation and interpretation costs remained at a similar level, whilst the costs of publications decreased from around EUR 15 000 to roughly EUR 10 000, and the cost of visibility actions increased from about EUR 5 000 to around EUR 15 000. Some practical steps were taken to limit costs of events, including having international experts presenting on the same day to limit interpretation costs or splitting the agenda into sessions with interpretation and without interpretation or organising 2 group activities in parallel to save on rental of technical equipment and on event management services.

Administrative costs remained below the maximum level permitted by the CoE. Such costs were 6.5% in Phases I and II, which is in accordance with the relevant Decision taken by the Committee of Ministers (CM(2013)123), which sets a maximum of 7%. Within this budget heading, local office expenditure remained almost unchanged during both phases of the project. Allocation under this expenditure category included such costs as: local transportation, office supplies, office rent, furniture and equipment, or phone charges and related services.

The increased budget for international travel in Phase II allowed greater in-person input from international consultants, as well as visits of policymakers to Strasbourg. In Phase I, 18 return flights were budgeted, while in Phase II, the project budgeted 71 such flights. The increased number of flights in Phase II reflected the lifting of COVID-related restrictions on travel but also the need for increased face-to-face contact in terms of international consultants visiting Armenia to contribute to conferences, seminars and workshops and policymakers meeting with key CoE officials in Strasbourg.

6 Sustainability

This section considers the sustainability of the project, i.e. the potential for positive effects to endure beyond its lifetime. It considers two main dimensions: first, the extent to which the outcomes and results of the project are or will be incorporated into national legislation or policies; second, the extent to which the outcomes and results are or will be used in practice by medical or legal professionals.

6.1 Sustained improvements in legislation and policy

To what extent are outcomes and results incorporated into national legislation or policies?

Several important outcomes of the project will be sustained beyond the life of the project due to them having been incorporated into national legislation. As described in section 4.1, the project has supported the relevant national authorities in the drafting of legislation. In several cases, this has been adopted, including the legislation relating to Ethical Rules for Healthcare Professionals), Ethics Committee for Healthcare Professionals, Register of organ donors, and the Law on Public Health. With such concrete revisions to legislation having been made, the outcomes of the project will lead to sustained improvements in the protection of human rights in biomedicine in Armenia provided that the legislation is enforced.

The introduction of enforcement mechanisms will generate sustained improvements in protection of human rights. As described in section 4.1, CoE experts drafted a set of ethical rules for healthcare professionals response to a request from the Ministry of Health, which were subsequently adopted by the Armenian government in February 2022. The project also supports the development of the new law on individual licensing of healthcare professionals. To ensure compliance with these new rules, the project also supported Armenia in the design of a new Ethics Committee tasked with the investigation of any breaches of these rules. Moreover, the HELP training for legal professionals has increased the capacity of the country's legal system to enforce compliance with medical standards codified in the legal framework. In this way, the project has made a significant contribution to ensuring and maintaining high human rights standards in biomedical practice.

Signature of the Oviedo Convention represents progress but there is a need for further progress for the full potential to improve protection of human rights to be achieved in the long-term. Armenia's signature of the Convention in 2024 signals a political commitment to make the necessary legislative revisions to move towards ratification and to enhance human rights standards more generally. With the project due to conclude at the end of 2024, there will be a need for the relevant national stakeholders to take full ownership of the process towards ratification and to raising standards more generally. At the political level, this will involve maintaining support for ratification and for further legislative reform, most notably revision of the "fourth child provision" but also the other reforms recommended by the legal analysis. At the executive level, this will involve the practical task of preparing legislative reforms, operating enforcement mechanisms, promoting the acquisition of knowledge amongst practitioners and promoting public dialogue. Without a concerted effort by the relevant national partners, the risk is of a loss of momentum, both in political and operational terms; there is also a risk that the future political context might not be as favourable to ratification of the Oviedo Convention.

6.2 Sustained improvements in practice

To what extent will outcomes and results will be used in practice by medical or legal professionals?

The volume of participation in the HELP training offers the potential for sustained improvements in medical practice in Armenia. The evidence collected for this evaluation does not allow for a conclusive assessment of the extent to which the HELP training will generate sustained changes to medical practice. However, the first 20 iterations of the tutored course resulted in 326 enrolments with a 65% completion rate. This total far exceeds any other country in which HELP has been offered on a tutored basis. An additional 53 individuals enrolled in the self-learning online version (although the latest CoE report states that only 3 reached the certification stage). Given the small size of Armenia relative to many of those other countries, this suggests greater potential for systemic change in biomedical practice. Anecdotal evidence collected by this evaluation (e.g. based on interviews of stakeholders, HELP tutors and HELP participants) suggests that participants are making use of the knowledge they received, feeding it into their relevant professional and academic areas of activity, and passing on to their colleagues, hence, cascading the knowledge within their respective institutions.

For the improvements in human rights protection to be sustained in the long run, there is a need for the HELP courses to be promoted and, ideally, offered in tutored format. The CoE systematically maintains online access to all HELP courses in the relevant languages via the HELP online training platform. This offers the potential for continued participation on a self-taught basis and thus for sustained long-term impact. However, continued high participation will require the CoE and the relevant national partners to continue to promote the HELP courses to medical, legal and other professionals within Armenia. Greater long-term impact could be achieved through continued provision in the tutored format, although this would require additional resources. However, with the course material already developed and with the trainers already trained, the additional cost would be lower.

Sustained protection of human rights could be helped by the incorporation of human rights standards and relevant aspects of the HELP courses into mainstream higher education provision. One rationale for the project was that practising medical and legal professionals had not typically received sufficient training on human rights issues in biomedicine either in their university studies or in subsequent professional development. As described earlier (section 2.3), the project has discussed the possibility of including the HELP course in the curricula of higher education institutions and a HELP pilot was offered for medical students at the Russian-Armenian State University. There is also anecdotal evidence of academics participating in the course who have subsequently incorporating aspects of the EHELP course in their academic teaching. For the full long-term impact of the project to be ensured – and for a sustained improvement in standards in practice – there is a need for human rights issues to be more systematically incorporated into the relevant curricula of higher education institutions, e.g. university degrees in medicine. This may require additional targeted action by the CoE and other relevant partners.

7 Conclusions and recommendations

This section presents the conclusions from the evaluation and presents recommendations for the future programming of interventions around human rights and biomedicine in Armenia.

7.1 Conclusions

1. The activities of the project were very relevant to the Oviedo Convention. Most notably, the legal analysis, support for legislators and policymakers, HELP training and many of the published materials directly related to the provisions of the Convention and were focused on helping Armenia move towards ratification of the Convention.
2. The project is directly relevant to and forms an integral part of the Action Plan for Armenia. It supports the Plan's overall aim of bringing Armenia's legislation, institutions and practice further into with European standards.
3. The relevance of the project to national policy priorities was ensured through a process of co-development of the project concept with the national stakeholders, as well as through responding to specific requests from the national authorities.
4. The project was relevant to key healthcare needs in Armenia, namely the need to address weaknesses in the legislative framework for biomedicine, to raise ethical standards in medical practice and raise awareness of human rights amongst professionals and the wider population.
5. The project has been effective in helping Armenia prepare for future ratification of the Oviedo Convention. The project was a key driver, if not the primary driver, in the decision to sign the Convention. Expert advice and the legal analysis have inspired and directly informed proposals to align legislation, and helped bring law enforcement practices into line with the Convention by supporting the creation of the Ethics Committee.
6. Additional steps will be required for national legislation to fully address all the provisions of the Oviedo Convention. Most notably, there is a need to repeal the provision allowing the use of assisted reproduction technologies for the purpose of choosing a future child's sex where the family already has three children of the same sex (the "fourth child provision"). In a number of other areas, alignment could be strengthened so that provisions are better addressed and standards are raised.
7. The HELP courses on key human rights principles in biomedicine have increased awareness of the Oviedo Convention and its principles among medical and legal professionals. Significantly, Armenia has featured more iterations of the tutored HELP course and more participants than any other country, although action might be required to raise the rate of completion.
8. To sustain and widen improvements in medical practice, there is a need for the HELP course (or key aspects of it) and for the principles of the Oviedo Convention to be incorporated into mainstream medical and legal education and training.
9. Communication activities and support for journalists has contributed to increased awareness amongst medical and legal professionals, and offers the potential for wider public awareness.
10. There may be a need for a more sustained public information campaign implemented by national authorities. This would focus on the new requirements introduced by legislative revisions come into force (i.e. around obligations of professionals and rights of professionals). Here, the CoE might play an advisory role.

11. Despite the Phase I budget being considerably below the initial assessment of budgetary need, the project has achieved much of the intended impact, particularly in terms of supporting Armenia's progress towards ratification of the Convention.
12. Some important outcomes of the project will be sustained as they have already been incorporated into national legislation. These include the support in drafting legislative amendments and the establishment of the Ethics Committee.
13. Signature of the Oviedo Convention represents an important milestone towards the aim of raising human rights standards in biomedicine but with the project due to conclude at the end of 2024, there will be a need for the relevant national stakeholders to take full ownership of the process towards ratification and raising standards more generally.
14. The volume of participation in the HELP training, as well as the training of trainers, offers the potential for sustained improvements in medical practice in Armenia.
15. For improvements in medical practice to be sustained in the long run, there is a need for the HELP courses to be promoted and, ideally, offered in tutored format.
16. The sustainability of project effects could be ensured by the incorporation of human rights standards and relevant aspects of the HELP courses into mainstream higher education provision.

7.2 Recommendations

Drawing on the conclusions presented above and the evidence presented in the earlier sections, this sub-section offers a set of recommendations.

1. The CoE should consider how to support Armenia in its move from signature to ratification of the Oviedo Convention. This could include continued support for legislators and policymakers to help build the political case for ratification and continued expert support for the drafting of legislative revisions.
2. The CoE should consider how best to support national authorities to move towards repeal of the "fourth child provision".
3. The CoE encourage national authorities to consider if/what further legislative revisions are required to fully address all provisions of the Oviedo Convention. This should take into account any recommendations from the legal analysis that have not yet been addressed.
4. It is recommended to undertake further research into the alignment of national legislation with broader human rights standards in biomedicine, i.e. going beyond the specific provisions of the Convention.
5. It is recommended to undertake further research into extent to which medical practice is compliant with the Convention in practice. This would best be undertaken once the necessary legislative revisions have been made and would identify any additional steps necessary to raise standards.
6. The CoE should encourage national authorities to consider providing administrative and financial resource to the Ethics Committee. This would address the high and increasing workload (currently fulfilled on a voluntary basis) and the need to build trust amongst professionals and the public. Support could consist of a budget for support staff and administrative costs and payment of members. However, care should be taken to ensure that the payment of members does not affect perceptions of their independence.

7. The CoE should encourage national authorities to consider how to promote the availability of the online HELP course beyond the life of the project and if/how to provide further tutored iterations of the course.
8. The CoE should encourage national authorities to consider if/how to provide relevant training or capacity-building for judicial authorities to support the enforcement of legislation related to the Oviedo Convention, as and when such legislation comes into force.
9. The CoE should encourage national authorities to consider how to support the integration of the principles of the Oviedo Convention and the relevant legislation into curricula of university degrees in medicine or law.
10. The CoE should encourage national authorities to consider a public information campaign to raise awareness of the new obligations placed on medical professionals and the new rights available to patients resulting from legislative revisions. Such a campaign would be best timed to take place once all the relevant revisions come into force.
11. The CoE should consider sharing the lessons from this project with other countries that may be interested in technical co-operation in the area of biomedicine and human rights.

7.3 Lessons learnt

Based on the findings presented throughout the report, a number of lessons can be suggested.

The experience of the project shows that a range of complementarity activities can together contribute progress towards improving human rights standards in a CoE member state. These were: efforts to analyse and revise the legal framework; support for improving medical and legal practice (e.g. through training) and institutional mechanisms; promoting awareness and public dialogue. The experience shows that revising the legal framework both a technical task (i.e. requiring analysis of the existing framework, drafting of legislative revisions) and also a political one (i.e. requiring efforts to build political support through dialogue and build public support through awareness-raising). Revising the legal framework can help improve medical practice but only to the extent that effective enforcement mechanisms are in place but also to the extent that medical and legal practitioners had the necessary knowledge and expertise. Finally, helping citizens to assert their rights requires the legislation to grant those rights in the first place but also requires citizens to be aware of their rights (whether through information campaigns or through being informed by medical practitioners) and have recourse to enforcement or compensation mechanisms.

Bringing about improvements in human rights requires an inclusive, multi-institutional project design based on trust. As noted in section 4.5, the effectiveness of the project depended on involving a broad range of stakeholders included legislators, national authorities, healthcare professionals, and lawyers. The co-operation and active involvement of these players was essential to the effective implementation of activities and the generation of intended effects. This required not only relevant and well-designed activities but also relationships of trust between the project team and the partners and stakeholders.

Signing a CoE Convention can place a spotlight on weaknesses in human rights protection and help build support for change. In the case of Armenia, the signature of the Convention with one reservation has raised awareness of the “fourth child provision” within Armenia and internationally. This incompatibility with the Convention is tending to stimulate political support for revision: on the basis of protecting human rights but also on the basis of ensuring that Armenia is seen internationally as complying with international standards.

Three lessons have been learnt regarding the Ethics Committee for Healthcare Professionals (see Case study 2, Annex 6). First, there is a need for effective mechanisms to enforce ethical rules. Second,

there is a need for decisions of the Committee to be legally-binding. Third, there may be a need to pay Committee members (supported by a paid secretariat) if they are to fulfil the mandate of the Committee in the long run.

Annex 1: Summary of project activities by year

Table 4 Project activities

	2020	2021	2022	2023
Alignment of legal norms with the Oviedo Convention				
Analysis of legislation	<ul style="list-style-type: none"> • Compilation of list of national legislation relevant to Oviedo • Appointment of 6 local and 6 international experts (after two calls) • First on-line expert meeting (Dec 2020) 	<ul style="list-style-type: none"> • Progress on analysis of compliance of national legislation with the Oviedo Convention • Progress on diagnostic study on human rights issues in emergency situations 	<ul style="list-style-type: none"> • Publication and presentation of the analysis of compliance of national legislation with Oviedo • +40 recommendations for national authorities • Diagnostic study on human rights issues in emergency situations 	<ul style="list-style-type: none"> • [completed in 2022]
Support in developing legislation, rules and enforcement mechanisms	<ul style="list-style-type: none"> • [not undertaken] 	<ul style="list-style-type: none"> • Supporting the drafting of legal acts on: i) ethical rules and code of conduct for healthcare professionals • Drafting of methodology for the functioning of ethical committees (MoH request) • Supported drafting of national register of transplantation of organs and tissues 	<ul style="list-style-type: none"> • Provision of legal expertise in developing legal acts • Advice on draft law on public health (provision of European standards and principles) • Advice on legislative revisions relating to human rights issues in mental healthcare services • Supported a revision of the institute of legal capacity • Supported the preparing of the legal basis for efficient application of Artificial Intelligence in healthcare 	<ul style="list-style-type: none"> • Recommendations on draft law on a comprehensive healthcare insurance system • Recommendations on draft law on individual licensing of health professionals • Recommendations on revising the law on reproductive rights
Dialogue with and support for policymakers and legislators	<ul style="list-style-type: none"> • [limited due to COVID and war] 	<ul style="list-style-type: none"> • 2-day training on Oviedo principles for MoH staff • Bilateral discussions with MoH, OHRD and other national authorities regarding 	<ul style="list-style-type: none"> • Bilateral discussions with national authorities regarding possible ratification of the Oviedo Convention • Study visit to Strasbourg for MoH heads of Legal, Human Resources 	<ul style="list-style-type: none"> • Bilateral discussions with national authorities regarding possible ratification of the Oviedo Convention • 2-day capacity-building on Oviedo principles for Assembly Members

	2020	2021	2022	2023
		<p>possible signature of the Oviedo Convention</p> <ul style="list-style-type: none"> • Visit of the CoE Head of Bioethics Unit to Yerevan: bilateral discussions with national stakeholders 	<p>for Health and Healthcare Policy Development</p> <ul style="list-style-type: none"> • Annual meeting of 55 chief advisors to the MoH focussed on Oviedo Convention Article 3 	<p>and staff of the Standing Committee on Protection of Human Rights and Public Affairs of the National Assembly (14-15 December 2023)</p> <ul style="list-style-type: none"> • 2-day capacity-building on ethic rules, for Chief Advisors to the MoH • 2-day capacity-building for members of the Ethics Committee for Healthcare Professionals on “Key principles for ethics committees for healthcare professionals” (including European standards and international best practices) • Ethics Committee for Healthcare Professionals attend 2 x meetings of the National Ethics Councils (Sweden May 2023, Spain November 2023)
Alignment of practice and institutional mechanisms with the Oviedo Convention				
Human Rights Education for Legal Professionals (HELP)	<ul style="list-style-type: none"> • Adaptation of HELP course and translation into Armenian • HELP course made available online 	<ul style="list-style-type: none"> • Training of trainers in HELP courses • 8 iterations of the HELP course • Negotiations to include HELP course in curricula of higher education institutions • HELP pilot for medical students at Russian-Armenian State University • Two bodies commit to developing new courses based on HELP (Yerevan State Medical University, National Institute of Health) 	<ul style="list-style-type: none"> • 7 iterations of the HELP course • HELP integrated into curricular of universities (NIH, Yerevan State University, Medical State University, Russian-Armenian State University) • Pilot HELP course for 40 participants in universities 	<ul style="list-style-type: none"> • 4 iterations of the HELP course (80 participants) • Started developing new HELP course on “Human rights issues in mental healthcare services” (concept and choice of modules approved)

	2020	2021	2022	2023
Other training or capacity-building for healthcare and legal professionals	<ul style="list-style-type: none"> [not undertaken due to COVID and war] 	<ul style="list-style-type: none"> On-line training on biomedical topics for healthcare and legal professionals (informed consent, medical secrets and confidentiality, reproductive health rights, general principles of bioethics) Training for doctors on informed consent and medical confidentiality (request from NCID) 	<ul style="list-style-type: none"> 2 x 2-day training on informed consent and medical confidentiality for staff of NIH and NCID Training on Oviedo Convention for MoH senior staff Training on Oviedo Convention for members of Research Ethics Committees of NIH and NCID Guide on Oviedo Convention for members of Research Ethics Committees of NIH and NCID Research Ethics Committees connected to the European Network for Research Ethics Committees 4 x 2-day training on biomedical ethics for healthcare professional of the Prison Medical Centre New e-course on Ethical rules for healthcare professionals and standards in confidentiality and informed consent (adopted by MoH for 10 CPD credits) On-line training on biomedical topics for healthcare and legal professionals (protection of rights of persons with mental health problems, medical secrets and confidentiality, biomedical research, general principles of bioethics) Animated video on new ethical rules for healthcare professionals 	<ul style="list-style-type: none"> 2-day capacity building on Oviedo for NIH staff 2-day follow-up training for members of the Research Ethics Committee of the NIH Training on public speaking and communication for MoH managers Preparing training and educational support for healthcare professionals from the Karabakh region, including training to address post traumatic syndrome (implemented in 2024) Preparing activities to strengthen skills and capacities contributing to the integration of healthcare professionals from the Karabakh region into the healthcare system (implemented in 2024)
Improvements in public dialogue on healthcare issues				

	2020	2021	2022	2023
Support for journalists	<ul style="list-style-type: none"> • Guide for journalists on communicating in the biomedical field and during public health crises 	<ul style="list-style-type: none"> • Development of HELP course for journalists • 1st iteration of HELP course for journalists • 2-day training on Oviedo principles for journalists 	<ul style="list-style-type: none"> • [completed in 2021] 	<ul style="list-style-type: none"> • [completed in 2021]
Expert round-tables	<ul style="list-style-type: none"> • [not undertaken] 	<ul style="list-style-type: none"> • [not undertaken] 	<ul style="list-style-type: none"> • [not undertaken] 	<ul style="list-style-type: none"> • Human rights in mental health services • Human rights-based approaches to healthcare • Ethical rules for health care professionals and ethics committees
Provision of resources	<ul style="list-style-type: none"> • Translation and dissemination of CoE materials (Oviedo Convention, Protocols, guides, leaflet) 	<ul style="list-style-type: none"> • Dissemination of materials 	<ul style="list-style-type: none"> • Translation and subtitling of video on “Human Rights Protection and COVID-19” • Animated video on new ethical rules for healthcare professionals 	<ul style="list-style-type: none"> • Guide to Public Debate in Human Rights and Biomedicine translated, adapted and disseminated • Guide to health literacy for equitable access to health care translated
Communication activities	<ul style="list-style-type: none"> • Creation of project web pages on CoE website (on pages of Bioethics unit, and Yerevan office) • Co-operation with Journalism Faculty of Yerevan State University 	<ul style="list-style-type: none"> • Ongoing communication, including via webpages of CoE and national stakeholders • Ongoing dissemination of materials • Radio interview 	<ul style="list-style-type: none"> • Ongoing communication via webpages of CoE and national stakeholders • Ongoing dissemination of materials 	<ul style="list-style-type: none"> • Ongoing communication, including via webpages of CoE and national stakeholders • Ongoing dissemination of materials

Annex 2: Bibliography

Type of	Documents
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Evaluation report	<ul style="list-style-type: none"> • Council of Europe. Progress Review and Final Evaluation of the Council of Europe Action Plan for Armenia 2019-2022, 30 Sep 2022. • Council of Europe, 2023. Report Human Rights Education for Legal Professionals Data and Information for 2015-2022, https://rm.coe.int/2305-help-in-2022-report-final/1680ab591b.
Documentation regarding specific project components	<ul style="list-style-type: none"> • The HELP Programme (Human Rights Education for Legal Professionals) • HELP tutor report by Mikayel Khachatryan, 16 June 2023. • HELP tutor report by Karine Abrahamyan, 15 June 2023. • HELP tutor report by Anna Mkrtumyan, 16 Dec 2022. • HELP tutor report by Lilit Gevorgyan, 12 Feb 2022. • HELP tutor report by Yevgenia Muradyan, 11 Feb 2022. • HELP tutor report by Laura Gasparyan, 7 Feb 2022. • HELP tutor report by Gohar Ghukasyan, 31 Oct 2021.
Quality assurance and code of conduct	<ul style="list-style-type: none"> • Quality Assurance Checklist for Evaluation Inception Report • Quality Assurance Checklist for Evaluation Reports • Council of Europe Code of Conduct for Evaluation
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Type of	Documents
	<ul style="list-style-type: none"> • Tonoyan, T., Muradyan, L., 2012. Health inequalities in Armenia - analysis of survey results, "International Journal for Equity in Health", vol. 11, "Health inequalities in Armenia - analysis of survey results" International Journal for Equity in Health Full Text (biomedcentral.com). • UNFPA Armenia Country Office. 2013. "Sex Imbalances at Birth in Armenia. Demographic Evidence and Analysis." • UNFPA Armenia. 2022. "Research Report. Prevalence and Causes of Gender-Biased Sex Selection in the Republic of Armenia". • UNFPA Armenia. 2023. "Fact Sheet Armenia. Every Girl Counts. Son Preference and Daughter Aversion". • UNFPA Armenia. 2023. "Fact Sheet Armenia. Every Girl Counts. Son Preference and Daughter Aversion". • UNWOMEN. „Republic of Armenia. Review of the Implementation of the Beijing Declaration and Platform for Action Beijing+25". • WHO (2022) Armenia takes steps to improve its primary health-care system, Armenia takes steps to improve its primary health-care system (who.int). • WHO (2022) Health Systems in Action: Armenia; 2022 Edition. • World Bank. 2010. From Rags to Riches: Armenia's Health Care System is Modernizing, World Bank Document. • Zopunyan, V., Krmoyan, S., Quinn, R. (2013) Identifying the gaps: Armenian health care legislation and human rights in patient care protections, Health and Human Rights Journal 15/2, Identifying the gaps: Armenian health care legislation and human rights in patient care protections – Health and Human Rights Journal (hrjournal.org).

Annex 3: Evaluation matrix

Sub-question	Measure(s)/ Indicator(s)	Data Source(s)
Relevance – To what extent does the selection activities of the Project reflect the needs of Armenia as well as the relevant Council of Europe legal instruments?		
To what extent is the project in line with the priorities of the Oviedo Convention and other Council of Europe legal instruments?	<ul style="list-style-type: none"> • Extent of alignment of the project with the Oviedo Convention • Extent of alignment of the project with the Council of Europe Action Plans for Armenia 	<ul style="list-style-type: none"> • Oviedo Convention • Council of Europe Action Plans for Armenia • Project documentation • Interviews with Council of Europe (Strasbourg, Yerevan)
To what extent is the project in line with the needs and priorities of Armenia?	<ul style="list-style-type: none"> • Extent of alignment with Armenian policy priorities • Extent of alignment with needs as evidenced in literature or identified by experts and stakeholders 	<ul style="list-style-type: none"> • Project documentation • Wider literature (e.g. national policies, previous studies) • Interviews (Council of Europe, project partners, national bodies, other stakeholders, experts, etc.) • Case studies
Effectiveness - To what extent has the project achieved its expected results? What have been reasons for achievement and/or lack thereof?		
To what extent has the project supported national authorities in their effort to align legal norms in the biomedical field with the European Human Rights principles enshrined in the Oviedo Convention?	<ul style="list-style-type: none"> • Number and nature of legislative changes in Armenia to which the project has contributed • Extent of alignment of legal norms with European standards • National authorities reporting being supported effectively • Stakeholder perceptions on changes in legal norms 	<ul style="list-style-type: none"> • Project documentation • Documentation relating to project results (e.g. legislation) • Wider literature (e.g. national policies, other studies, reports in specialist media) • Interviews (Council of Europe, project partners, national bodies, other stakeholders, experts, etc.) • Case studies
To what extent has the project helped healthcare and legal professionals align their practices and institutional mechanisms with the standards enshrined in the Oviedo Convention?	<ul style="list-style-type: none"> • Number of medical and legal practitioners directly involved in activities • Practitioners reporting increased awareness, knowledge, and capacity (number, scale) • Number of practitioners indirectly reached by the project • Stakeholders and experts observing increased knowledge and capacity amongst medical and legal practitioners 	<ul style="list-style-type: none"> • Project documentation • Documentation relating to project results • Interviews (Council of Europe, project partners, national bodies, other stakeholders, experts, etc.) • Case studies
To what extent has the project improved public dialogue on healthcare issues among national authorities, as well as healthcare and legal professionals, and the public at large?	<ul style="list-style-type: none"> • Number and scope of legislatives debates on issues around human rights in biomedicine • Legislators reporting increased awareness • Number and scope of public debates, expert discussions and round-tables on issues around human rights in biomedicine 	<ul style="list-style-type: none"> • Project documentation • Documentation relating to project results • Interviews (Council of Europe, project partners, national bodies, other stakeholders, experts, etc.) • Case studies

Sub-question	Measure(s)/ Indicator(s)	Data Source(s)
What have been the reasons for achievement and/or lack thereof?	<ul style="list-style-type: none"> List of factors influencing the outcomes of the project in both positive and negative ways 	<ul style="list-style-type: none"> Project documentation Interviews (Council of Europe, project partners, national bodies, other stakeholders, experts, etc.)
To what extent have gender issues been mainstreamed in the project's design and implementation?	<ul style="list-style-type: none"> Gender aspects of human rights in biomedicine incorporated into project activities Revised legal norms and enforcement practices respect gender-specific issues Composition of project implementation team Gender balance in practitioners supported by the project Practitioners reporting better understanding of gender issues in human rights in biomedicine 	<ul style="list-style-type: none"> Project documentation Documentation relating to project results Interviews (Council of Europe, project partners, national bodies, other stakeholders, experts, etc.) Case studies
Efficiency - To what extent could alternative working methods have led to the achievement of comparable or better results with fewer resources?		
Have there been any obvious inefficiencies in the working methods implemented?	<ul style="list-style-type: none"> Concrete examples of inefficiencies or wasted resources Project partners reporting efficiency in implementation 	<ul style="list-style-type: none"> Project documentation Interviews (Council of Europe, project partners, national bodies, other stakeholders, experts, etc.) Case studies
Did any specific activities produce limited benefit? Were any specific activities particularly expensive?	<ul style="list-style-type: none"> Concrete examples of activities producing limited benefit Concrete examples of particularly expensive activities 	<ul style="list-style-type: none"> Project documentation Documentation relating to project results Interviews (Council of Europe, project partners, national bodies, other stakeholders, experts, etc.) Case studies
What alternative methods might have delivered better value for money?	<ul style="list-style-type: none"> Evaluator's expert judgement Suggestions of project partners or stakeholders 	<ul style="list-style-type: none"> Interviews (Council of Europe, project partners, national bodies, other stakeholders, experts, etc.)
Sustainability - To what extent can it be expected that the Member State's national authorities will continue to use the outcomes and results of the Project?		
To what extent are outcomes and results incorporated into national legislation or policies?	<ul style="list-style-type: none"> Concrete examples of outcomes and results (not) incorporated into national legislation or national policies 	<ul style="list-style-type: none"> Documentation relating to project results Interviews (project partners, national authorities, experts,.)
To what extent do national authorities report that outcomes and results are embedded into their culture and practice?	<ul style="list-style-type: none"> National authorities reporting that outcomes and results are (not) embedded into their culture and practice 	<ul style="list-style-type: none"> Documentation relating to project results Interviews (national authorities.) Case studies

Annex 4: Interview checklist

The following list of questions is used for the purposes of carrying out interviews for the evaluation of the Human Rights in Biomedicine Project, implemented by the Council of Europe in Armenia. The interview based on the following list will not exceed 45 minutes and the data collected will be kept confidential.

Relevance

- 1) To what extent is the Human Rights in Biomedicine project aligned with the priorities of the Council of Europe?
- 2) To what extent does the Human Rights in Biomedicine project address the needs of the Armenian society and specific professional and social groups within it?

Effectiveness

- 3) To what extent has the project contributed towards legislative reforms in the area of biomedicine in line with Council of Europe recommendations and European standards?
- 4) To what extent has the project helped healthcare professionals align their practices with the standards enshrined in the Oviedo Convention?
- 5) To what extent has the project helped legal professionals align their practices with the standards enshrined in the Oviedo Convention?
- 6) To what extent has the project helped start or maintain a public dialogue the standards enshrined in the Oviedo Convention?
- 7) To what extent has the project increased public awareness of the principles enshrined in the Oviedo Convention?
- 8) How does this project compare with other national and international policy initiatives: Do the relevant stakeholders perceive the Human Rights in Biomedicine project as creating more or less added value than any other projects or initiatives in the field of biomedicine?
- 9) Were there any factors that contributed to the success of the project?
- 10) Were there any factors that hindered to the success of the project?
- 11) To what extent was the project impacted by circumstances around the COVID-19 pandemic? What mitigating measures were taken, and how effective were they in ensuring continued progress toward the project objectives?
- 12) To what extent was the Human Rights in Biomedicine Project impacted by socio-political circumstances, including the 2020 military conflict?
- 13) Were there any adjustments between the two consecutive phases of the Human Rights in Biomedicine Project that interfered with its effectiveness?
- 14) To what extent have gender issues been mainstreamed in Human Rights in Biomedicine Project design and implementation?

Efficiency

- 15) Were the financial resources used in a cost-effective matter?
- 16) Are there any project components that were particularly cost-efficient, or created much value for money? If so, which ones? And why?
- 17) Are there any project components that were less cost-efficient, or created much value for money? If so, which ones? And why?

Sustainability

- 18) How long do stakeholders expect the project outputs to last? Do they expect them to lead to long-term, positive social change in Armenia?
- 19) To what extent it is possible to point to impacts of the project on the Armenian legal framework, legislative practice, and a broader society?
- 20) To what extent has the guidance provided by the Council of Europe through the Human Rights in Biomedicine project been sustained by beneficiary institutions and translated into further legal and organisational changes?
- 21) To what extent have the beneficiary institutions in Armenia taken ownership of the knowledge and practices promoted by the Council of Europe through the Human Rights in Biomedicine project activities?
- 22) Please share any additional insights with the evaluation team.

Thank you for your participation!

Annex 5: Case study 1. Law on "Reproductive health rights" related to provisions of sex selection

Context

In June 2021, following the military conflict with Azerbaijan in September 2020, Armenia amended its "Reproductive Health and Rights to Reproduction" law and allowed sex-based abortions for a fourth child (hereafter the "fourth child provision"). Article 11(3) of the new Law on Human Reproductive Health and Reproductive Rights states that "When using assisted reproduction technologies, it is not allowed to plan the sex of the future child, except in cases where there is a possibility of inheriting a sex-related disease, or the family has 3 children of the same sex."⁶¹ This provision is incompatible Article 14 of the Oviedo Convention, which states that "The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided."⁶² According to our interview partners, support for the fourth child provision resulted from a long-standing cultural preference for boys, exacerbated by the recent military conflict (e.g., where families might seek to replace sons killed).

Son preference in Armenia is rooted in a complex web of cultural, socio-economic, and historical factors. According to survey data collected by the United Nations Population Fund (UNFPA Armenia) in 2022 (n=1920), many Armenian families preferred sons because of their perceived roles in preserving family lineage (carrying the family name), because they inherit family property, because they defend the homeland in times of crises, and because they are seen as providing financial support.⁶³ In rural areas, in particular, families often see boys as an investment because sons are expected to support the household, and help with agricultural works. Meanwhile, girls are sometimes seen as a net loss because when they grow up, they leave the family and move in with their husbands' families.⁶⁴

Son preference is particularly strong among families who are concerned about military conflict, and who live geographically closer to conflict zones.⁶⁵ Men show a particularly strong preference for boys. In the 2022 UNFPA Armenia study, 39% of men expressed a preference for boys in their partner's first pregnancy, 19% expressed a preference for girls, and 41% said it did not make a difference to them. In contrast, only 28% of women expressed a preference for a boy in their first pregnancy, 27% expressed a preference for a girl, and 45% said it did not make a difference.⁶⁶

These preferences risk manifesting themselves in disproportionately high numbers of girls being aborted. Because numbers of abortions are difficult to estimate, the standard measurement of sex-based abortions is sex ratio at birth (SRB), where higher numbers of baby boys being born indicate a tendency to selectively abort girls. In 2013, sex ratio at birth in Armenia was estimated at 114-115 boys for every 100 girls, surpassed only by China (118) and Azerbaijan (116).⁶⁷ In 2016, Armenia passed an amendment of the Law on "Reproductive Health and Rights to Reproduction" banning sex-selective

⁶¹ Republic of Armenia. [RA Law on Human Reproductive Health and Reproductive Rights](#). Accepted December 11, 2022.

⁶² Council of Europe. 1997. [Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine](#).

⁶³ UNFPA Armenia. 2023. "[Fact Sheet Armenia. Every Girl Counts. Son Preference and Daughter Aversion](#)", p.5.

⁶⁴ UNFPA Armenia. 2022. "[Research Report. Prevalence and Causes of Gender-Biased Sex Selection in the Republic of Armenia](#)", p.53.

⁶⁵ Mavisakalyan, A., & Minasyan, A. (2023). The role of conflict in sex discrimination: The case of missing girls. *Economic development and cultural change*, 71(2), 443-484.

⁶⁶ UNFPA Armenia. 2023. "[Fact Sheet Armenia. Every Girl Counts. Son Preference and Daughter Aversion](#)", p.2.

⁶⁷ UNFPA Armenia Country Office. 2013. [Sex Imbalances at Birth in Armenia. Demographic Evidence and Analysis](#).

abortions.⁶⁸ (Implicitly, sex-selective abortions had not been legal before, either, because Soviet law restricted abortion after the first trimester).⁶⁹ The data suggests that the law is starting to have its intended effect of reducing in the gender imbalance. In the years following the 2016 amendment banning sex-selective abortions, from 2017 to 2021, sex ratio at birth in Armenia was stable at around 110 boys for every 100 girls. In the first quarter of 2022, sex ratio at birth rose to 111 boys, in the first quarter of 2023, it further rose to 112 boys for every 100 girls.⁷⁰

These numbers represent averages – they do not capture the significant regional differences. Generally, sex ratio at birth is much closer to balance in the central provinces than it is in the eastern provinces bordering Azerbaijan, and the western provinces bordering Turkey. In 2021, four provinces reached a sex ratio at birth of 115-119 boys for every 100 girls: Syunik, the southernmost province bordering Azerbaijan to the East and Iran to the south, Armavir bordering Turkey to the West, Shirak, bordering Turkey to the West and Georgia to the North, as well as Lori, bordering Turkey to the North. In the other regions, sex ratio at birth ranged between 105 and 109 boys for every 100 girls.⁷¹

Data on the number of families making use of the fourth child provision was not available to this evaluation. However, interviews of stakeholders, including National Assembly members, suggest that the total number is very low, i.e. perhaps even in single figures and certainly not in the dozens.

Project activities

The PHRiB project has supported the removal of the fourth child provision by providing the relevant stakeholders with background information on the matter. Prior to the 2021 amendment of the law on "Reproductive Health and Rights to Reproduction" the project team received a first request from the Ministry of Health asking for EU and Council of Europe standards and Member States' best practices in the field of reproductive health. Following that request, the team approached its local and international experts and asked them to write a first set of recommendations and best practices.

After the 2021 amendment, the team received a second request, this time, from the National Assembly, asking again for best practices and, this time, also for an explanation of the amendment's incompatibilities with the Oviedo Convention. In response to that second request, the team provided a detailed concept note including best practices, and a detailed explanation of Article 14 of the Oviedo Convention. This concept note was finalised by the end of 2022. The team sent it to the National Assembly and the Standing Committees of the National Assembly, and all other national stakeholders, including the Ministry of Health, the Ministry of Justice, and the Human Rights Defenders Office. To increase visibility, the Council of Europe also published the concept note on its website.

The project has also facilitated expert-led training sessions for members of the National Assembly and the Ministry of Health. In these discussions, the experts explained the nature of the Oviedo Convention to Assembly Members and showed how the fourth child provision deviated from it.

Effects

Consultations of stakeholders suggest that the support offered by the project has been effective in supporting the case for legislative revision or repeal of the fourth child provision. The measures taken by the project have facilitated a broad discussion about sex-selective abortions through the lens of human rights. An external expert and trainer stressed the importance of the project work and, consequently, the signature of the Oviedo Convention in starting a high-level discussion about human

⁶⁸ UNWOMEN "[Republic of Armenia. Review of the Implementation of the Beijing Declaration and Platform for Action Beijing+25](#)", p.5.

⁶⁹ Low, Florence. "[Law to cut sex-selective abortions in Armenia 'putting lives at risk'](#)" The Guardian, 21 October 2016.

⁷⁰ UNFPA Armenia. 2023. "[Fact Sheet Armenia. Every Girl Counts. Son Preference and Daughter Aversion](#)", p.8.

⁷¹ UNFPA Armenia. 2023. "[Fact Sheet Armenia. Every Girl Counts. Son Preference and Daughter Aversion](#)", p.8.

rights in healthcare. Legislators and policymakers, when interviewed, suggested that political support for removing the provision was growing and thus a legislative revision might be possible in the coming years.

However, some stakeholders consulted for this evaluation were unsure about the political will of some Assembly Members, in particular those representing rural areas where sex-selective abortion is more common. For instance, the above-mentioned external expert who promoted the case for a legislative amendment reported that some Assembly Members justified their support for the fourth child provision on the basis that there is a need to give birth to more boys to compensate for men lost as a result of the military conflict with Azerbaijan. Others appeared to fear the workload associated with amendments, worrying that the removal of one amendment will necessitate more action. However, two Assembly Members consulted for this evaluation, from different parties, agreed that overall, there is sufficient support and political will to scrap the fourth child provision.

It should be noted that the project activities to address the fourth child provision were relatively low-cost. The focus on high-quality content, written by authoritative authors with years of experience in government and in international organisations in Armenia and internationally illustrates an effective use of a small budget. Individual meetings were needed to raise awareness of the issue and encourage Assembly Members to act. Both the consultants themselves and the project team reported that the fees for these activities were adequate. The fact that the concept note was sent to all stakeholders and, additionally, published online further testifies to the team's effort to maximise the reach of this information while minimising costs.

Looking ahead, the fourth child provision remains the one clear incompatibility between national legislation and the provisions of the Oviedo Convention. It is also the only reservation made by Armenia at the timing of signing the Convention. Whilst the project activities have raised awareness, informed key stakeholders and helped support the political case for amendment, further efforts will be required in the coming months and years, if momentum is not to be lost.

Annex 6: Case study 2. Ethics Committee for Healthcare Professionals

Introduction

The Ethics Committee for Healthcare Professionals (hereafter ‘the Ethics Committee’) was created as a response to an identified gap in the enforcement of ethical standards in healthcare and a perceived need to build greater trust between patients and healthcare professionals. It was established in July 2023, following the 2020 amendment of the 1996 Law on “Medical Care and Assistance to the Population” in which the National Assembly decided (among other things) to establish rules of professional ethics and a committee to ensure compliance with them.

The rules of professional ethics

The rules of professional ethics, a concise, two-page document adopted by the Armenian Government in February 2022 aim to improve the quality of medical care in Armenia. They include general rules of ethics, rules on healthcare professionals’ conduct toward patients, other medical professionals, and third parties, as well as provisions on protecting public health in emergency situations.⁷²

For instance, the rules require medical professionals to act on the basis of the principles of evidence-based medicine, to treat patients’ families with respect, to take appropriate measures to improve the quality of their care, and to stay informed about scientific and technical progress.⁷³

Healthcare professionals are to respect their patients’ dignity, their right to privacy, their religion, their worldview, and their political or other views. They are to care for their patients with a view to strengthening or restoring their health, and they are to refrain from discriminatory behaviour, torture, cruel, inhumane or humiliating behaviour.⁷⁴ Healthcare professionals are to treat fellow healthcare professionals with respect, and in a cooperative manner.⁷⁵

To protect public health, and to prevent the outbreak of diseases or epidemics they are to cooperate with the competent authorities, inform them of any cases of threatening diseases, and follow the relevant orders of the competent authorities. In the case of military or other emergencies, healthcare professionals are to provide medical assistance at the request of the competent authorities in addition to caring for their patients.⁷⁶

Healthcare professionals are not to accept gifts from any actors in the field of health care, in particular, drugs or medical products, if those gifts are understood to be related to the performance of their professional duties.⁷⁷ Finally, healthcare professionals are to avoid entering into conflicts of interest, i.e. situations where relationships with family members or third parties could prevent them from acting in the best interest of their patient.⁷⁸

Establishment of the Ethics Committee

The Ethics Committee for Healthcare Professionals is an independent body under the Armenian Ministry of Health. It is comprised of seven members with professional backgrounds in law,

⁷² Government of the Republic of Armenia. N 182 of 17 Feb 2022. [Republic of Armenia’s decision on approving the rules of professional ethics for healthcare professionals.](#)

⁷³ Ibid, article 1.

⁷⁴ Ibid, article 2.

⁷⁵ Ibid, article 3.

⁷⁶ Ibid, article 4.

⁷⁷ Ibid, article 5.

⁷⁸ Ibid, article 6.

medicine, psychology, and medical patients' protection. The members work pro bono, carrying out their duties alongside their regular jobs.

The Ethics Committee was established through a competitive process in July 2023. The members were selected by a selection committee of representatives of the Prime Minister's Office, the Ministry of Health, the Ministry of Social of Labour and Social Affairs, and educational institutions.

The Ethics Committee started receiving the first cases in 2024. Examples of cases include refusal to prescribe painkillers to alleviate pain, refusal to interact with patients' families, or avoiding in-person contact with patients and instead giving serious diagnoses over the phone.

The Ethics Committee follows a strict procedure to deal with cases they receive. After they are notified of an alleged violation of the rules of professional ethics, they consider (or investigate) the case. The seven members meet to hear the case. Each member shares their views. Next, the Committee writes up a decision (or opinion), in which they explain the nature of the violation. The opinion refers to legal documentation, as well as scientific literature in the field of medical ethics, and precedents from Armenia and other countries. The opinion is sent to the relevant parties, i.e. to the health facility where the respective health care provider works at and to the Ministry of Health.

At present, the opinion is not legally binding, meaning that employers can but are not required to take disciplinary action against doctors or nurses who have been found to have infringed the rules of professional ethics. This is due to the fact that under Armenian Labour Law employers have a right, but no obligation to take disciplinary action. However, this legal loophole, which Members of the Committee describe as problematic, will be closed in two years' time, when an amendment of the 1996 "Law On Medical Aid and Service of the Population" and a new law on individual licencing for medical professionals comes into effect.

Once that law comes into effect, the Ethics Committee's opinions will be sent to a new licencing Committee at the Ministry of Health. Then, a first infringement will lead to a one-month suspension of the respective healthcare professional's medical licence; the second infringement will lead to a three-month suspension. Members of the Ethics Committee expect the new law to boost the relevance and effectiveness of their work.

The rules of professional ethics were adopted with the support of an expert group of the Council of Europe's project on the 'Protection of Human Rights in Biomedicine' in Armenia.⁷⁹

Project support for the Ethics Committee

The Council of Europe played a key role in the establishment of the rules of professional ethics and the Ethics Committee. In 2020, when the Law on Medical Care and Assistance to the Population was amended, the Yerevan Office first received a request to support the Ministry of Health in developing the rules of ethics and the Ethics Committee.

With the support of the Human Rights and Biomedicine division, the Yerevan team hired both national and international experts with experience in the field, including a member of the UNESCO International Bioethics Committee. These experts drafted the rules of professional ethics and, in parallel, started developing a concept for the new Ethics Committee. The government adopted the final version of the rules of professional ethics in February 2022.

In parallel, the Council of Europe started training sessions, capacity-building, and awareness raising activities. To that end, the Council of Europe invested in the development of a wide range of materials including leaflets, brochures, posters, and a short video explaining the rules of professional ethics for

⁷⁹ Council of Europe. 17 Feb 2022. "[The Government of the Republic of Armenia has approved the rules of professional ethics for the healthcare professionals](#)".

healthcare professionals. These materials were developed in cooperation with public relations specialists.

Links to the video were shared widely; both the Yerevan and the Strasbourg Office and the Ministry of Health shared the link on their website; additionally, individuals within the Council of Europe posted it on social media, increasing its reach. The posters were disseminated to medical centres across the country, and were put up in prominent places. The Council of Europe's office asked the medical centres to take photos of these posters, allowing them to collect evidence of the dissemination of information about the rules of professional ethics and the Ethics Committee.

In addition, the Council of Europe organised a series of capacity-building events inviting a broad range of stakeholders, including healthcare professionals, administrative staff and public relations specialists from healthcare institutions, such as public hospitals, or private medical centres, or medical universities. During these events, the Council of Europe, as well as members of the Ethics Committee, and other stakeholders explain the nature of the ethical rules for healthcare professionals and the functioning of the Ethics Committee.

Impacts

The establishment of the Ethics Committee can be seen as one of the key achievements of the project. The Council of Europe, which was described by one of our interviewees as “the founding father” of the Ethics Committee, has brought together the experts who first designed the rules and the set-up of the committee, and has been so successful in raising awareness that less than a year into its first term the Ethics Committee is operating at capacity, answering questions about medical misconduct, investigating three cases, and writing legal opinions. Because the rules of professional ethics for healthcare professionals were not a standalone legal development but were accompanied by the establishment of an enforcement mechanism, they are very likely to have a long-term impact. In this way, the adoption of the rules of professional ethics and the establishment of an Ethics Committee to enforce these rules directly responds to the need of Armenia to improve ethical conduct in the healthcare sector and empower patients to challenge ethical misconduct. They represent the first set of ethical rules for medical professionals – before their adoption, there were no codified ethical rules, and patients had no legal basis to appeal medical malpractice. As one interview partner put it, ‘doctors were always right’.

The Council of Europe's activities supporting the codification of the rules of professional ethics was necessary to turn infringements of norms into infringements of laws and to promote broader change in attitudes. Its support in raising awareness of these new rules is necessary to ensure both healthcare professionals and patients know their rights and responsibilities, and its support in setting up the Ethics Committee was a necessary first step to establish the institutional structures required to enforce any new set of rules.

The large-scale information campaign following the establishment of the rules in 2022 has raised awareness among healthcare professionals, and among patients and their families. This awareness manifests itself in various ways, including patients, healthcare professionals, and members of the public approaching individual members of the Ethics Committee to ask questions about, for instance, how to file a complaint.

This awareness also manifests itself in the first cases being filed – a few months into the Ethics Committee's first term, the seven members have already worked on three cases of medical misconduct. This number does not include the many inquiries and applications the members receive but do not investigate due to legal concerns. Many of these concern ethical issues, or complaints about medical conduct that is perceived to be unethical, but is not clearly prohibited under the rules.

Most importantly, stakeholders consulted for this evaluation see early signs of a changing attitude: Members of the Ethics Committee, HELP course trainers, and representatives of the Ministry of Health

all reported witnessing a changing attitude, or mentality among healthcare professionals. Members of the Committee reported that this change in attitude manifested itself in a recognition that compliance with ethical rules would no longer be a matter of choice and in greater respect being shown for those tasked with monitoring and enforcing standards.

A HELP trainer interviewed for this evaluation reported signs of awareness and interest in the new rules snowballing to new professional circles: complaints about ethical misconduct that are brought before the Ethics Committee increase demand for lawyers to represent the respective healthcare professional. That, in turn, increases lawyers' interest in the subject.

Challenges

A first challenge is the high workload for an unpaid committee. At the moment, the seven members, who, according to reports by the Chair, are highly professional and highly dedicated to the task are investigating cases in their spare time.. However, the time commitment is significant. For example, one member, reported spending at least an hour every evening, sometimes much longer, working for the Ethics Committee, in addition to a full-time job. Even though this member was fully committed to the cause, they reported the time commitment was 'too much'. Moreover, members lack a budget to cover administrative costs such as postage, which they must pay for themselves.

The challenge is aggravated by the fact that the workload is expected to increase in the future. As patients become more aware of their rights, and as the first cases of suspensions of medical licences due to non-adherence to the rules of professional ethics for healthcare providers make the news, the number of cases is likely to increase. Without any adjustments, even a small rise in the number of cases is likely to lead to longer wait times, which may threaten the public image of the Committee. A more significant rise in the number of cases may lead to resignations due to workload, or a necessity to prioritise, and not process all incoming cases.

To ensure the continued work of the Ethics Committee it may be necessary to pay the members, as originally recommended by the Council of Europe. This would require an amendment of the Law on Medical Care and Assistance, which currently states that the Ethics Committee is unpaid.

The second challenge concerns the need to build trust in a new, still largely unknown body. Doctors and civil society organisations, often speaking at capacity-building events, have raised doubts as to the effectiveness of the Ethics Committee. Members of the public, often posting on social media, have raised doubts as to the independence of the Ethics Committee.

The most pressing misperception concerns the Ethics Committee's independence, or suggestions that it is part of the Ministry of Health. Due to the fact that the Ethics Committee does not have an office, it receives technical assistance from the Ministry, and it receives its cases through the Ministry. It also sends its opinions to the Ministry. However, its work is entirely independent of the Ministry. Action is being taken to address this misconception, including capacity-building activities and the creation of a dedicated website for the Committee (for which a tender has been launched). There may also be a need for the Committee to receive staff resource to support its work and to counter misinformation and perhaps also for Committee to receive payment. However, members of the Committee stress that any future payments must not compromise the independence of the Committee. In particular, the Committee must not accept any money from the Ministry of Health, so as to guard its independence.

Lessons learned

A first lesson concerns the need for effective enforcement mechanisms. Having ethical rules in place is a first step in the right direction but, by itself, is insufficient to change actual conduct. To that end, it is crucial that both patients and doctors are aware of the rules, and that the rules are enforced. An institution such as the Ethics Committee is needed to enforce them. Here, the example of the

Committee will inform other aspects of the Convention, as other rules or legislation are introduced to raise ethical standards.

A second lesson concerns the need for decisions of the Committee to be legally-binding. At the moment, healthcare providers are not legally required to act upon such decisions. This will change in two years, when an amendment comes into effect making the Committee's decisions legally binding and requiring hospitals or medical practices to sanction healthcare professionals who have been found to have violated the rules of professional ethics. The impact of the Committee's work in sanctioning individual cases of ethical misconduct, deterring misconduct and empowering patients to stand up for their rights can be expected to increase as and when its decisions become legally binding.

A third lesson concerns the payment of the Committee. At present, members of the Ethics Committee are not paid. Given that the current workload is already unsustainably high and expected to rise in the next few months and years it is essential that the Committee be paid. In the long run, a failure to create paid positions for lawyers to investigate cases of medical misconduct risks destabilising the progress made to date. It is very unlikely that individuals working pro bono will be able to fulfil the mandate of the Committee in the long run.

A first step toward a sustainable, paid Ethics Committee could be the creation of a paid secretariat. A budget to pay for administrative expenses, and paid administrative support would allow Committee members to focus on legal case work. There is also an argument that the Committee Members need to be paid in order to continue to carry out their duties effectively.

A final lesson concerns the complementarity of the various project activities that jointly led to a well-functioning Ethics Committee. The PHRiB project supported Armenia in i. developing the rules of professional ethics for healthcare providers, ii. establishing the Ethics Committee, iii. training the Members of the Committee (both in terms of their actual mandate and in terms of the soft skills required to fulfil it, e.g. public speaking) and iv. creating awareness among healthcare professionals and the general public. These different types of support were complementary: each activity was needed to establish the Committee and help it undertake its work. A lesson to be learned is that the approach of focusing on one (or a few) tangible outputs and then investing in the legal framework, the institutional set-up, the human resources, and the communication can be an effective approach to work toward a broader goal, such as raising ethical standards in the healthcare sector.

Annex 7: Case study 3. HELP training for medical and legal professionals

Background

The European Programme Human Rights Education for Legal Professionals (HELP) is a broader CoE programme to support CoE member states in implementing the European Convention on Human Rights (ECHR) at the national level. It builds the capacity of judges, lawyers and prosecutors in all 46 member states to apply the ECHR in their daily work.⁸⁰ The rationale for HELP is that legal professionals must benefit from high-quality training given their role at the forefront of the protection of human rights. HELP courses are tailored to the needs of different countries, institutions and professionals. Since 2015, HELP has increasingly been provided for other professionals are increasingly, including medical practitioners.

HELP courses are offered as an interactive, virtual, free learning tool. Each of the courses covers a specific human rights-related subject relevant to the remit of the ECHR. In total, through its virtual platform, the CoE offers courses covering more than 50 subjects. While HELP courses are available on-line as a self-education tool, they are also provided by the CoE in a tutored format, for example, as part of broader technical cooperation projects between the CoE and member states.

HELP features three components:

- HELP Network of national training institutions for judges, prosecutors and lawyers in the 46 CoE member States (and beyond);
- HELP Human rights online courses for self-study in the HELP e-learning platform;⁸¹
- Human rights training methodology to develop HELP courses that can be taken in two formats: self-study (free access in the HELP platform); or tutored in groups organised in co-operation with national training institutions or universities.

Since June 2018, the CoE has made available a customised HELP course on “Key Human Rights Principles in Biomedicine”.⁸² The course assists legal and health professionals to understand key human rights principles in biomedicine. It covers binding legal instruments, notably the Oviedo Convention, relevant case-law of the European Court of Human Rights, and non-binding instruments adopted by the Council of Europe Committee on Bioethics.⁸³ The course has eight modules:

- Introduction
- Free and informed consent
- Medical confidentiality and protection of health related data
- Protection of the embryo and procreation
- End of life
- Genetic testing
- Biomedical research
- Transplantation of human organs and tissues.

⁸⁰ <https://www.coe.int/en/web/help/about-help>

⁸¹ <https://help.elearning.ext.coe.int/>

⁸² <https://www.coe.int/en/web/bioethics/-/the-help-course-on-key-human-rights-principles-in-biomedicine-launched-on-the-help-platform-1>

⁸³ Council of Europe, nd., HELP Online Training, Human Rights and Biomedicine, [HELP Online Training - Human Rights and Biomedicine \(coe.int\)](https://www.coe.int/en/web/help/online-training-human-rights-and-biomedicine).

As of December 2022, the tutored format of the course had been launched 44 times in 11 countries and also for the whole European Union. The total number of participants exceeded 1,110.⁸⁴ The courses are available via the online platform maintained centrally from Strasbourg, which limits costs for national co-operation projects, such as the PHRiB.

Project activities

Development of the course

As part of the PHRiB project in Armenia, it was considered beneficial to introduce a customised version of the HELP course to address needs in the country and raise ethical standards in medical practice. As noted in section 3.2.2, Armenia faced various challenges, including weaknesses in the legislative framework, a need to raise ethical standards in medical practice and insufficient levels of expertise and knowledge of ethical standards and the relevant legal framework among medical and legal professionals. It also necessary to help professionals adapt to legislative revisions, not least the introduction of the Ethical Rules for Medical Professionals and the corresponding establishment of the Ethics Committee for Medical Professionals

Through the PHRiB project, the HELP course on biomedicine was updated, tailored to the Armenian context and translated into Armenian. The updated course covers the eight modules listed above.⁸⁵ Participants in the HELP courses were also provided with supporting materials, including relevant national legislation, the text of the Oviedo Convention (translated into Armenian), publications of the project (see section 4.3), other publications of the CoE and other materials available via the HELP on-line platform.

In January 2021, the project carried out the Training of Trainers (ToT) for 17 participants, including staff of the Ministry of Health, Human Rights' Defender's Office, the National Institute of Health and the National Assembly, as well as judges, academics and representatives.

Level of participation and completion

The first pilot course was then launched in January 2021. There were 15 groups tutored in Phase I, covering about 280 medical and legal professionals. Phase II featured a further 6 roll-outs, bringing the total number of launches to 21, to date. Under one group, each trainer convened tutoring for 16 participants on average. In the tutoring process, the course's contents were further adjusted by the tutors to respond to specific needs identified in Armenia, in line with participants' professional background, and according to participants' suggestions. For instance, one tutor reported that they discussed the issue of obligatory vaccinations in the context of Oviedo Convention principles, as such was the request of the tutored group.

By the end of December 2022, Armenia had featured more iterations of the tutored course and more participants than any other country. As shown in the table below, the first 20 iterations featured 326 participants. This suggests that the PHRiB project has been the key driver, given that it is the only technical co-operation project in the area of biomedicine implemented by the CoE. Of the 326 participants only 212 (65%) completed the course and received the certificate, which is only slightly below the average across all countries (68%) but the lowest rate of any country, aside from Ukraine (where completion may have been affected by the current war).⁸⁶

⁸⁴ Council of Europe (2023) Report Human Rights Education for Legal Professionals Data and Information For 2015-2022, 1680ab591b (coe.int), p. 48

⁸⁵ Council of Europe n.d. "[HELP Online Training](#)".

⁸⁶ Council of Europe (2023) Report Human Rights Education for Legal Professionals Data and Information For 2015-2022, 1680ab591b (coe.int), p. 48

Table 5 Enrolment and certification in tutored HELP courses

Country	Number of course iterations	Participants enrolled	Completion rate
Armenia	20	326	65%
Italy	1	179	73%
Ukraine	6	175	14%
Northern Macedonia	1	146	71%
Moldova	1	80	71%
EU	1	60	82%
Spain	2	45	73%
Poland	1	33	73%
Greece	1	29	66%
Latvia	5	29	72%
Belarus	1	24	88%
Portugal	1	15	67%
TOTAL		1141	68%

Source: Council of Europe (2023) Report Human Rights Education for Legal Professionals Data and Information For 2015-2022, 1680ab591b (coe.int), p. 48

The Armenian version of the course was also made available online for self-study and attracted 53 enrolments, of which 3 (6%) completed the course and received the certificate, i.e. they completed the course and generated their electronic statement of accomplishment. This rate of completion is relatively low compared with the total in all languages (14%), as shown in the table below.

Table 6 Enrolment and certification in self-learning HELP courses

Language of delivery	Users enrolled	Users enrolled and certified
English	1678	209
Italian	991	133
Russian	717	136
Spanish	567	105
French	274	27
Ukrainian	221	42
Romanian	93	10
Latvian (2022 only)	69	4
Armenian	53	3
German	53	3
Polish	24	4
Macedonian	19	1
Czech (2022 only)	8	0
TOTAL	4767	677
%	100%	14%

Source: Council of Europe (2023) Report Human Rights Education for Legal Professionals Data and Information For 2015-2022, 1680ab591b (coe.int), p. 47

Professional background of participants

Course groups were mixed in terms of participants' professional background. For the six groups covered by the tutor reports provided to this evaluation, one group was constituted entirely by the students of the Russian-Armenian University (Institute of Law and Politics), while the remaining five included medical professionals (doctors and non-clinicians) and legal professionals. Medical professionals and legal professionals each constituted roughly 50% of the participants for those five groups taken together. None of the tutor reports highlighted participation of prosecutors or judges, even though such professional groups were suggested in the tutor reports as possible target groups. The course was also customised for provision to journalists in order to increase their capacity to report on human rights issues in biomedicine.

The balance varied between groups with some covering mostly medical professionals, others mostly legal professionals and others more or less balanced. Some professionals worked as subject-experts and academics, hence, expanding the outreach of the course beyond clinical medicine. While delivering to mixed groups, tutors attempted to cater to needs of all the participants. For instance, in groups with doctors and lawyers involved, separate fora were opened for each sub-group of participants in the digital platform, so that participants could make the best use of the shared material, applying it to their and their peers' every-day work practice. While the diversity of professional backgrounds among participants was initially seen as a concern, the tutors reported that medical and legal professionals could learn from each other's experience and that discussions between them could be animated. Tutors also reported that doctors faced a relatively steeper learning curve than legal professionals when it came to comprehending of the legislation.

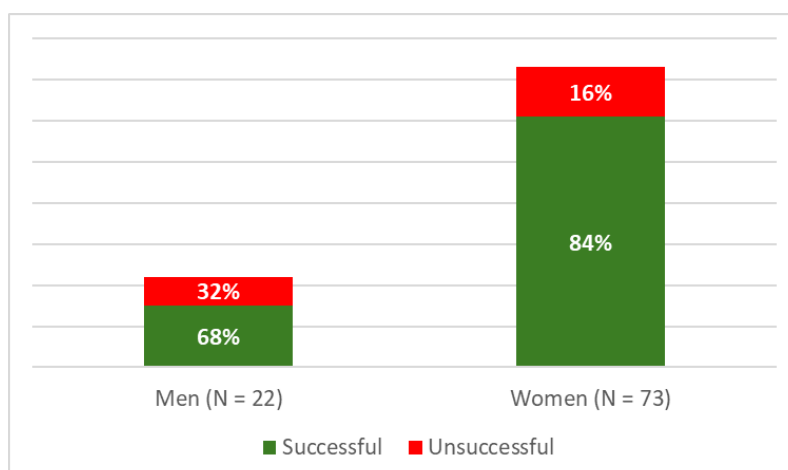
Some interviewees suggested that it would be beneficial for the HELP course on biomedical ethics to be incorporated into degree courses for students on degree courses in medicine or law. While one pilot course was operated specifically for university students, the suggestion was that the mainstreaming of HELP into degree courses in this way would ensure greater long-term impact and by making prospective professionals aware of the Oviedo Convention principles before they embark on their careers.

Gender balance among participants

The original intention was to aim for a gender balance in each group and a requirement to that effect was placed on the trainers when recruiting participants. However, in some cases it was not feasible to enrol a sufficient number of men to ensure a gender parity. As a result, such a requirement was repealed by the project team in order to ensure that the course groups would be formed. Based on the analysis of the sample of 6 tutor reports, women constituted 77% of 95 participants in those groups. This rate of female participation may be related to the wider gender balance amongst healthcare professions; according to the WHO, women account for 67% of the global health and social care workforce.⁸⁷

Based on the 6 tutor reports provided to this evaluation team, there was a much higher rate of completion amongst female participants (84%) than amongst male participants (68%). This finding corresponds with the opinion stated by one of the Council of Europe stakeholders who suggested that in the HELP courses internationally, females are more likely to succeed, while males tend to disengage faster and drop out more frequently.

⁸⁷ <https://www.who.int/activities/value-gender-and-equity-in-the-global-health-workforce>

Figure 1 HELP course completion rates

Source: Own elaboration based on 6 HELP tutor reports.

Recruitment of participants

The promotion of HELP courses is carried out at different levels. The relevant CoE field office is responsible for the promotion of courses in their own country. At the same time, the Strasbourg CoE unit in charge of HELP maintains the HELP platform and liaises with other countries that could be interested in a given course.

In Armenia, the recruitment for courses mostly was carried out by the tutors themselves (e.g., via social media groups, via email, via personal acquaintances), based on their private contacts and knowledge of the relevant professional and social circles in Armenia. Given the small scale of the courses, and a relatively small size of Armenia as a country, such a strategy was feasible and proved effective in attracting sufficient participants.

Evidence from the interviews confirms that word of mouth-based recruitment played a significant role in ensuring sufficient enrolment. There were numerous examples of participants who became interested in taking part in the course after their colleagues had shared their positive experience from their prior course participation. One tutor reported being approached with questions about possibilities of future enrolment soon after completing delivery with one group. Another shared in their tutor's report to the CoE:

“Most of the members of the group were informed about the current course by the participants of the previous groups, who shared their experience, and this served as an incentive to express their desire to join the new group. Perhaps this is the best assessment of the course and the best promotional tool.”

One factor that stimulated interest in the course was the new legal obligation for medical professionals to enrol in self-education courses and collect credits as a condition of renewing their professional licence. In this context, the inclusion of the HELP course in the list of government-accredited, credit-rewarded courses, significantly contributed to uptake. Notably, the government amends the list based on changing needs, hence, ensuring uptake of the knowledge most relevant to the needs identified on the ground.

Role of tutors

The interviewed stakeholders stressed the role of course tutors in effective implementation of courses. Indeed, tutors' engagement, skilful delivery of teaching and personal commitment was a key factor that stimulated engagement among participants. Moreover, the role of tutors in adjusting

course contents to the local context (e.g., referring to specific cases proceeded in Armenia) was emphasised. In doing so, the tutors can ensure that participants find the content to be directly relevant to their everyday work. However, one challenge has been that the illustrative examples of good practice have tended to come from other countries, given that Armenia has only recently committed itself to addressing human rights issues in biomedicine.

The interviewed trainers highlighted several factors that allowed them to ensure participants' engagement. First, allowing participants to meet in person before switching to online teaching tends to increase their confidence to actively contribute during online meetings. Second, discussing Oviedo Convention provisions in direct reference to participants' everyday work and their own experiences effectively invites them to make their contributions during online sessions. Third, the distribution of subject-specific materials in Armenian developed by the CoE helped to keep participants engaged.

Effects

Experiences of participants

Based on the feedback received by the tutors and by the evaluation team, the participants had a positive view on how the course was designed, organised, and delivered, while its contents were seen as very interesting and relevant to the every-day work of the trainees. For example, evidence from the feedback surveys undertaken at the end of each iteration showed that 50/52 (96%) participants reported the course as "excellent", "very good" or "good", whilst 1 (2%) reported it as "satisfactory" and only 1 (2%) as "bad".⁸⁸ Specifically, the course contents were seen as attractive and comprehensive, and its delivery dynamic and easy to understand. The participants received practical knowledge and were sufficiently supported in digesting the new information. The selection of the subjects for the course was seen as appropriate, while presentation of applicable good practices made it more feasible and likely for the attendees to apply the knowledge in their ongoing work.

The participants appreciated that the course's delivery mode allowed them to access the materials whenever they wanted to. Such a flexible delivery mode, then, allowed them to manage their time commitment while at the same time delivering their regular, professional work.

An individual, one-to-one communication-based approach of the trainers greatly facilitated learning for the participants. Indeed, the commitment of trainers to teaching about the Oviedo Convention and their eagerness to support the trainees enabled participants to individually discuss their concerns and received advice on the subjects where they needed further explanations.

The interviewed trainers reported that they were repeatedly approached with follow-up questions relevant to Oviedo Convention standards, sometimes even by such individuals who had not partaken in the courses. This proves that, firstly, there was a significant interest in the courses' subject among the relevant professional groups in Armenia, and secondly, that the tutors were seen as approachable, and their guidance as reliable and useful.

The courses' delivery was facilitated by participation of national and international experts, whose expertise and delivery was assessed very positively by the interviewees. In particular, facilitation of access to international expertise was praised by the project stakeholders as the key contribution to building of expert capacity in Armenia.

The tutors provided the participants with the Oviedo Convention text translated into Armenian, the relevant learning materials, and the library of the legal acts to be discussed during the implementation. The examples of materials provided to course participants included: the rules of

⁸⁸ Evidence from the feedback surveys was available in tutor reports for five iterations of the HELP course and thus does not cover all iterations. Feedback was provided only by participants who completed the course. The reports do not give a full disaggregation between those selecting "excellent", "very good" or "good".

professional ethics of medical workers, the procedure for competitive selection of ethics committee members, the work procedures of the ethics committee, the procedures for the ethics committee investigation of cases, the declaration form regarding the potential conflicts of interest, as well as various other reports, articles, legal acts and decisions of the relevant national authorities in Armenia, such as, the RA law on medical care and service of the population, RA Law on Reproductive health and reproductive health rights, or RA law on human organ and tissue transplantation.

The availability of the course contents in Armenian was much appreciated by course participants, as it enabled many of them to access the materials. Comparatively, materials in English prove less accessible, with one notable example of a project stakeholder who stressed that she could not access CoE courses on violence against women as neither of the three available HELP courses addressing this subject is available in Armenian.⁸⁹ The importance of translation of HELP courses to national languages is acknowledged by the CoE staff but the available resources do not allow the translation of all materials into all national languages covered by HELP. For that reason, a prioritisation process is carried out internally, where one of the decisive factors is the interest from national stakeholders in a given subject, and another one the identification of specific societal needs by the CoE. The latter prevails even if a given national government is not interested in working on a particular subject, hence, allowing the CoE to provide support to the civil society and a broader public regardless of the national political climate around specific, contentious issues.

One reported challenge was an insufficient level of digital skills among participants. The interviewed tutors highlighted that not all course participants had access to personal computers, and some struggled to handle even basic digital tasks, such as accessing one's own mailbox. Some also struggled to navigate access to digital contents of the HELP course, getting lost while trying to access the consecutive subjects of the course. This problem was reportedly most common among older participants. One of the interviewed CoE representatives acknowledged that such a challenge commonly occurs in the delivery of HELP courses. While the CoE cannot support cannot address participants' insufficient digital skills or directly facilitate their access to the online platform, it was explained that HELP tutors can contact the e-learning officer at the HELP Division of the CoE in Strasbourg and receive support if they face any problems delivering the trainings via the online platform.

To address this challenge, tutors invested much time in providing IT support to individual participants, explaining basic digital activities via phone calls, or during one-to-one meetings. Such additional support might result in the course participants retaining their new digital skills and use them to access further self-education materials in the future. However, during the course, it tended use time that could have otherwise been devoted to more substantive analyses and discussions on the course content.

Impacts on practice

The available evidence is insufficient to draw concrete conclusions about the impact on medical and legal practice. For example, follow-up surveys of participants are not undertaken to determine how they use what they have learned. However, the view of tutors is positive and some anecdotal evidence was provided to illustrate how the training is being translated by some course alumni into actual changes to their work. For example, individual course participants have reported doing the following:

- Incorporating HELP content into a course on health law taught by the participant at a university;
- advocates using the knowledge they gained in their every-day legal practice;
- using course knowledge to further develop an academic paper;

⁸⁹ See: Council of Europe, nd, HELP online courses on Violence against Women, [HELP online courses on Violence against Women](https://www.coe.int/en/web/help/online-courses-on-violence-against-women), [HELP online courses on Violence against Women - Istanbul Convention Action against violence against women and domestic violence \(coe.int\)](https://www.coe.int/en/web/help/online-courses-on-violence-against-women).

- incorporating learning from the course into academic research on the subject of surrogacy;
- incorporating the newly-acquired knowledge into a radio programme;
- integrating data confidentiality standards into the design of the medical digital services developed by the National Institute of Health.

A representative of the Human Rights' Defender's Office also reported observing evidence of impacts on practice during visitations by the Office's national prevention mechanism. The interviewee involved such visitations reported observing that medical professionals increasingly act in conformity with the principles of the Oviedo Convention, for example, by securing consent from the patients more often than in the past, and paying attention to the importance of explaining the relevant issues to patients, hence, obtaining informed consent as per its definition. The interviewee stressed that the HELP course participants were provided with the digital copies of the Oviedo Convention and, based on the knowledge from the visitations, some of them keep a physical copy on their desks.

Training of Trainers among Armenian subject experts offers the potential for sustained impact. Given that trainers were recruited from the main bodies with a remit relevant to human rights in biomedicine, there is potential for them to promote knowledge of application of the principles of the Convention throughout their organisations.