



Andalusian Agency for Healthcare Quality Independent Assessment Body

Healthcare Provider's Draft Assessment Report

University General HospitalL ATTIKON

Network: EuroBloodNet

This report has been developed in the framework of the service contract signed between ACSA as contractor and Chafea as contracting authority. The opinions expressed in this document are those of the contractor only and do not represent European Commission or Consumers, Health, Agriculture and Food Executive Agency official position.

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Confidentiality Statement

The results of the assessment of University General HospitalL ATTIKON are documented in the attached report which was prepared by the Independent Assessment Body.

This report is based on information obtained from the Healthcare Provider through the application forms, self-assessments, the Opinion of the Board of Networks and supporting documentation. The Independent Assessment Body relies on the accuracy of this information to prepare the report.

This confidential report is intended for the Network and Healthcare Providers, the European Commission, and the Board of Member States. Any alteration of this report is strictly prohibited.

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1. Introduction

The assessment model for the European Reference Networks (ERNs) is a voluntary process that fosters a culture of quality improvement and offers a peer review assessment of highly specialised healthcare providers. The assessment process provides a standardised method for forming and evaluating ERNs under the regulatory framework of the Commission Delegated and Implementing Decisions of 10 March 2014 and amendment of the Implementing Decision of 19 July 2019. It includes a comprehensive assessment of the Applicant through documentation review (application forms, self-assessments, the opinion of the Board of Networks and supporting documentation), and online audits.

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2. Assessment Summary

University General HospitalL ATTIKON

Network

EuroBloodNet

Representative

Evangelia Papadavid

Sub-representative

Vassiliki Pappa

Assessor Team

The following assessor team completed the technical assessment:

- Dr. Juan Manuel Torres Canizales. Hospital Clínic de Barcelona. (Spain) (*)
- Prof. Helmut Brand. Maastricht University. (Netherlands)

(*) Team Leader.

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3. Results Overview

3. 1. Assessor's Commentary

Main discrepancies between the self-scoring of the applicant and the assessor team judgement

Only minor discrepancies have been detected between the self-scoring of the Applicant and the Assessor team's scores.

Board of the Network (BoN) opinion

Favourable. There are no further comments.

Comments on the Board of the Network (BoN)

The Assessors' team agrees with the opinion of the Board of the Network and doesn't have further comments.

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3. 2. Overall Compliance with the Operational Criteria

Based on the assessment of compliance against the Operational Criteria, the following graph represents the overall distribution of the ratings for the Healthcare Provider. Please, see Appendix A for more information on the rating scale used by the assessors.

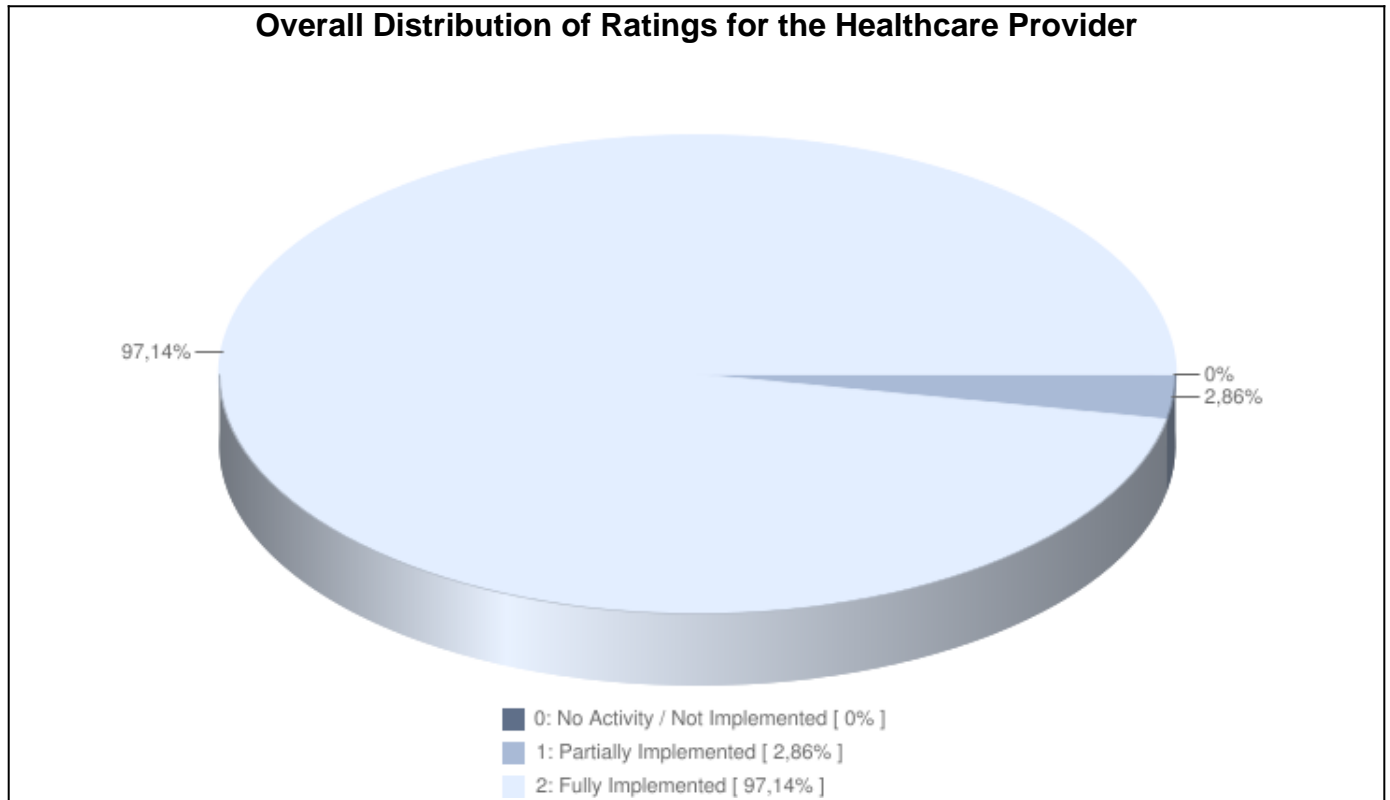


Chart 1

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3. 3. Overview by Themes

The Operational Criteria for the Healthcare Providers are grouped into the following 9 themes:

General Criteria and Conditions:

1. Patient Empowerment and Patient Centred Care
2. Organisation, Management and Business Continuity
3. Research, Education and Training
4. Expertise, Information Systems and e-Health Tools
5. Quality and Safety

Specific Criteria and Conditions:

6. Competence, Experience and Outcomes of Care
7. Human Resources
8. Organization of Patient Care
9. Facilities and Equipment

Each theme consists of one or more criteria with measures in line with the Commission Delegated Decision. The following graph represents the Healthcare Provider's overall compliance with the Operational Criteria by theme.

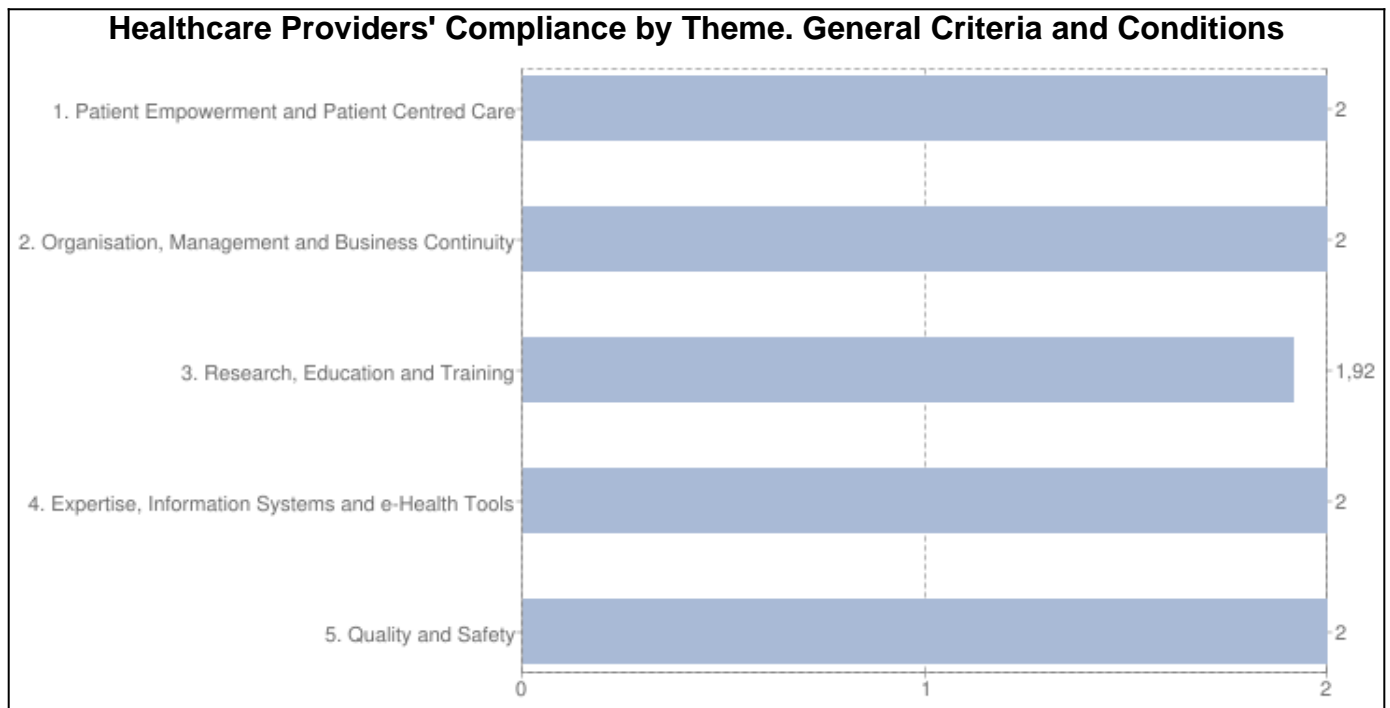


Chart 2

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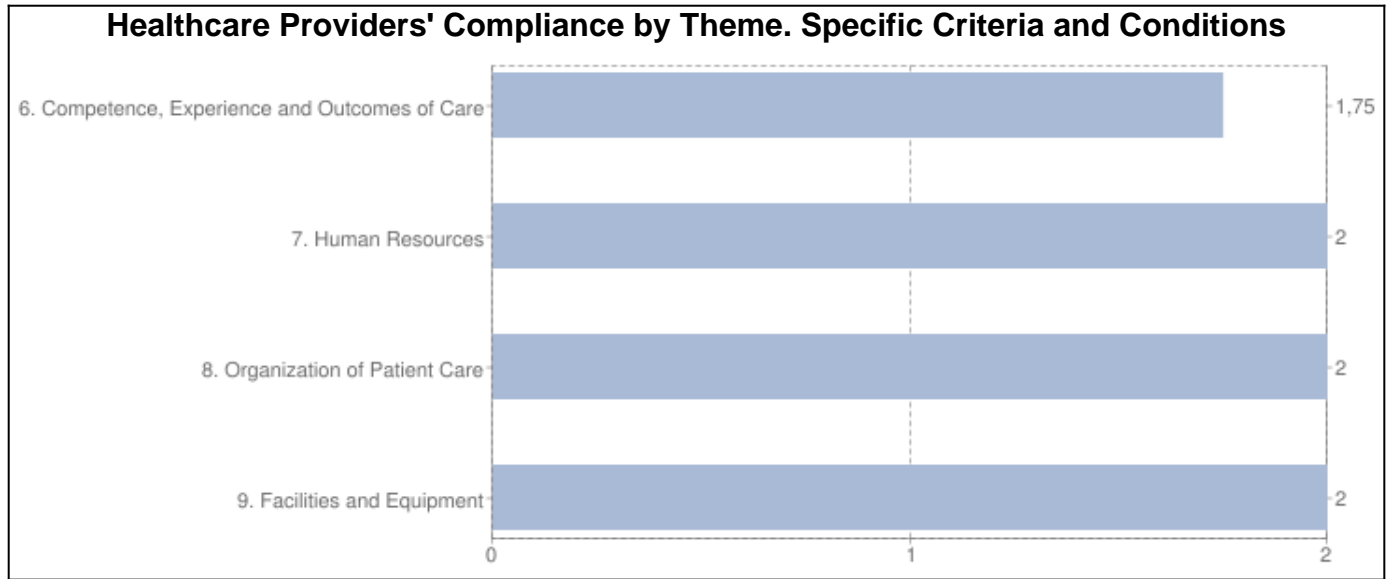


Chart 3

Legend	
0:	No Activity / Not Implemented
1:	Partially Implemented
2:	Fully Implemented

Table 1

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The following tables show the Healthcare Provider's compliance with the measures in each theme.

Patient Empowerment and Patient Centred Care	Assessor Rating
1.1.1 The Healthcare Provider's commitment to patient-centred care is formally and consistently communicated with patients and their families.	2
1.1.2 Processes are in place to assist patients and their families in knowing who is providing their care, and the role of each person on the multidisciplinary care team.	2
1.1.3 Patient education materials appropriate for readers of varying literacy levels and for speakers of different native languages are available.	2
1.1.4 The Healthcare Provider provides patients and their families with written information about the facility, the organization, and its specific area of expertise.	2
1.1.5 The Healthcare Provider gives patients and their families written information about their rights and responsibilities.	2
1.1.6 There is a policy and procedure in place to disclose unanticipated outcomes and complications to patients and their families, as appropriate.	2
1.2.1 Patients and their families are given information about how to file a complaint, report violations of their rights, and raise concerns about their care and/or safety.	2
1.3.1 The Healthcare Provider routinely measures or facilitates the measurement of patient and family experience using a standardised validated questionnaire. This information is periodically reported to all healthcare professionals and managers involved in delivering care, patients and families, and the general public.	2
1.4.1 The Healthcare Provider ensures access to medical records and clinical information is in compliance with EU data protection provisions and national implementing measures, in particular, Directive 95/46/EC.	2
1.5.1 If patient personal health information is exchanged, patients are informed of their rights under the applicable data protection rules and informed consent is obtained. The Healthcare Provider has a policy and standard procedure for obtaining informed consent. The Informed consent is documented in the patient's medical record.	2
1.6.1 The Healthcare Provider presents patients and their families with reliable information on clinical outcomes in a form that is useful to them.	2
1.6.2 All relevant information must be provided to patients in an anonymized format, including claims data, patient registry data, clinical data, and patient-reported outcomes.	2
1.6.3 Every patient is provided with a full description of the available alternatives for tests and treatments, as well as the pros and cons for each, and the potential risks and benefits.	2
1.6.4 The Healthcare Provider disseminates information to patients and their families on patient safety standards and safety measures to reduce or prevent errors.	2
1.7.1 The Healthcare Provider ensures disclosure of all financial and non-financial conflicts of interest related to treatment and/or research activities.	2
Average Rating	2

Organisation, Management and Business Continuity	Assessor Rating
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2.1.1 Management and staff and/or clinician roles and responsibilities specific to the area of expertise are clearly defined in an organization chart.	2
2.1.2 The Healthcare Provider establishes and maintains a set of policies and procedures addressing aspects of management and activities or services within the Network's area of expertise.	2
2.1.3 There are policies and procedures for managing cross border patients within the Network's area of expertise.	2
2.2.1 The Healthcare Provider provides patients and their families with easy access to information regarding any tariffs that may be in place, services, and benefits.	2
2.3.1 The plan includes the provision of essential medical care in the case of unexpected resource failure, or referral to alternative resources, if necessary; and maintaining stability, technical capacity and expertise of the provider, such as a plan for human resources and updating technology.	2
2.4.1 There are procedures for emergencies and patients presenting outside normal working hours. Patients within the Network's area of expertise can be admitted without delay to a suitable hospital ward service area, where necessary.	2
2.4.2 When necessary, the Healthcare Provider has easy access to other centres or highly specialised units outside its own facilities necessary for diagnosis, treatment, and delivery of care to patients.	2
2.5.1 Treatment of patients takes place in dedicated clinical areas that are easily accessible, clean, comfortable, quiet and appropriately equipped.	2
2.6.1 The Healthcare Provider provides local clinicians with complete discharge summaries post discharge for all patients.	2
2.6.2 Where possible, the Healthcare Provider uses information and communication technologies, such as eHealth tools, telemedicine/tele-expertise, and case management tools to follow-up post discharge.	2
Average Rating	2

Research, Education and Training	Assessor Rating
3.1.1 The Healthcare Provider delivers university, post-graduate, or specialised level of education and training in the Network's area of expertise.	2
3.1.2 The Healthcare Provider has a defined set of objectives for its education and training activities.	2
3.1.3 The Healthcare Provider provides evidence that resources are available, i.e. human, technical, or physical structure, to support education and training activities.	2
3.1.4 Education and training activities are delivered to providers involved in the same chain of care within and outside the Healthcare Provider facility.	2
3.1.5 The Healthcare Provider evaluates the effectiveness of its education and training activities on an annual basis.	2
3.2.1 The Healthcare Provider provides evidence that adequate resources are available, i.e. human, technical, or physical structure, to support research activities.	2
3.2.2 The Healthcare Provider leads and/or participates in research activities and clinical trials, at both a national and international level, within the Network's area of expertise.	2
3.2.3 The Healthcare Provider follows a set of Standard Operating Procedures (SOPs) that govern research activities.	2

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3.2.4 There is a procedure to review the ethical implications of research activities.	2
3.2.5 The Healthcare Provider maintains and manages records of research activities and clinical trials in accordance with institutional policies and set laws and regulations.	2
3.2.6 The Healthcare Provider shares the results of its research activities and clinical trials through scientific publications. The results should be disseminated to other centres and professional and patient associations.	2
3.2.7 The Healthcare Provider evaluates the effectiveness of research activities.	1

Comments:

The HCP has a procedure for verification of a scientific project, design is defined as acceptance by the scientific community of the scientific project. However, there is no documental evidence that supported the measures or performance made in the last three years. Based on this information, the measure is considered partially implemented.

Average Rating	1,92
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Expertise, Information Systems and e-Health Tools

**Assessor
Rating**

4.1.1 The Healthcare Provider offers an advisory service to exchange expertise with other professionals and caregivers involved in the patients' treatment.	2
4.1.2 The Healthcare Provider maintains an accurate database of patients under its care within the Network's area of expertise.	2
4.2.1 The Healthcare Provider follows established procedures to manage, safeguard, and exchange medical data. These procedures are in accordance with the EU data protection legislation, in particular, with Directive 95/46/EC and with Article 2 (e) of the Delegated Decision 2014/286/EU.	2
4.3.1 To support the use of telemedicine and other e-health tools, the Healthcare Provider fulfils the minimum interoperability requirements and when possible, uses agreed to standards and recommendations.	2
4.4.1 The Healthcare Provider uses a standardised information and coding system for rare or low prevalence complex disease(s) or conditions(s).	2
4.4.2 The Healthcare Provider has procedures in place to monitor and maintain data quality.	2

Average Rating	2
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Quality and Safety

**Assessor
Rating**

5.1.1 The Healthcare Provider has a quality assurance or management system in place that includes processes to regularly monitor the quality of its performance within the Network's area of expertise. The information it collects is used to make ongoing quality improvements.	2
5.1.2 The Healthcare Provider regularly collects and monitors process and outcome indicators.	2
5.1.3 The Healthcare Provider has a patient safety programme or plan in place adapted to the Network's	2

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area of expertise.	
5.1.4 There is a procedure in place to report, document, investigate, and learn from adverse events and complications. The Healthcare Provider uses this information to make ongoing improvements.	2
5.1.5 The Healthcare Provider contributes performance and outcome data to evaluate the Network, as a whole.	2
5.2.1 There is a process to periodically review and share best practices, review the results of clinical audits, review new evidence-based treatments and therapies, and discuss difficult cases.	2
5.3.1 The Healthcare Provider collaborates with other members of the Network or centres of expertise to develop and/or select clinical practice guidelines following a standard evidence-based procedure.	2
5.3.2 The Healthcare Provider implements, where possible, clinical practice guidelines agreed to or developed by the Network.	2
5.3.3 Clinical practice guidelines are regularly reviewed to ensure they reflect current research and best practice information.	2
Average Rating	2

Competence, Experience and Outcomes of Care

**Assessor
Rating**

6.1.1 The Healthcare Provider regularly monitors and documents its patient activity specific to the Network's area of expertise, disease or condition.	2
6.1.2 To maintain its competency and expertise, the Healthcare Provider serves the minimum/optimal number of patients and/or procedures per year as defined by the Network based on professional/technical standards or recommendations.	2
6.2.1 There is evidence that the treatments and advice offered are recognized by international medical science in terms of safety, value, and/or potential positive clinical outcome.	2
6.2.2 The Healthcare Provider shows evidence of good clinical care and outcomes according to available standards, indicators, and knowledge as defined by the Network.	1
<u>Comments:</u>	
Patients outcomes are monitored and collected in the PROCLIFI registry. All the procedures are written in SOPs. Routine publication of mortality, morbidity, survival rates, loss of function and quality of life measures are measured. There is no documentation about variations in the data which are routinely analysed. Based on this information, the measure is considered partially implemented.	
Average Rating	1,75

Human Resources

**Assessor
Rating**

7.1.1 The Healthcare Provider identifies and documents the skills and professional qualifications required for the staff performing activities critical to the quality of patient care.	2
7.1.2 There is a sufficient number of staff with the necessary qualifications to perform the specialized	2

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function.

7.1.3 Each core team member should undertake a minimum number of procedures and/or care for a minimum number of patients in a given year as defined by the Network. The multidisciplinary team should discuss a minimum number of patients per year.	2
7.1.4 The Healthcare Provider retains records of staff training, professional development, and maintenance of competencies. There is a process to routinely assess staff skill to ensure adequate performance of specialized tasks.	2
Average Rating	2

Organization of Patient Care

Assessor

Rating

8.1.1 The Healthcare Provider documents the characteristics of the multidisciplinary team.	2
8.1.2 There is a designated leader and chair of the multidisciplinary team.	2
8.1.3 There are documented procedures to support the organisation and functioning of the multidisciplinary care team.	2
8.1.4 There are regular structured meetings between multidisciplinary team members.	2
8.1.5 Patients receive a periodic clinical or multidisciplinary review. The timeframe is defined based on the area of expertise, disease or condition; and its severity.	2
8.1.6 The multidisciplinary team evaluates its performance on an annual basis.	2
Average Rating	2

Facilities and Equipment

Assessor

Rating

9.1.1 The Healthcare Provider has available within the centre or easy access to the necessary equipment and facilities to provide good quality patient care.	2
9.1.2 There is access to a specialised laboratory service capable of carrying out all tests required to diagnose the rare or low prevalence complex disease(s) or condition(s) as defined by the Network.	2
9.1.3 There is access to a range of diagnostic technologies as appropriate to the rare or low prevalence complex disease(s) or condition(s) as defined by the Network.	2
9.1.4 Based on the area of expertise, the Healthcare Provider has the capacity to process, manage, and exchange information and biomedical images, or clinical samples with external providers.	2
Average Rating	2

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4. Final Outcome of the Assessment

Scoring Table			
General Criteria			
Patient Empowerment and Patient Centred Care			
Total Score out of a Possible 30	30	Percent of Total	100%
Organisation, Management and Business Continuity			
Total Score out of a Possible 20	20	Percent of Total	100%
Research, Education and Training			
Total Score out of a Possible 24	23	Percent of Total	95,83%
Expertise, Information Systems and e-Health Tools			
Total Score out of a Possible 12	12	Percent of Total	100%
Quality and Safety			
Total Score out of a Possible 18	18	Percent of Total	100%
Sub score	103	Percent of Total	99,04%
Specific Criteria			
Competence, Experience and Outcomes of Care			
Total Score out of a Possible 8	7	Percent of Total	87,5%
Human Resources			
Total Score out of a Possible 8	8	Percent of Total	100%
Organization of Patient Care			
Total Score out of a Possible 12	12	Percent of Total	100%
Facilities and Equipment			
Total Score out of a Possible 8	8	Percent of Total	100%
Sub score	35	Percent of Total	97,22%
Overall			
Grand Total out of a Possible 140	138	Percent of Total	98,57%

Table 2

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Decision guideline	
✓	An overall compliance rate of 70% of the maximum score of the Healthcare Provider general and specific operational criteria.
✓	Each theme under the General Criteria must achieve 70% compliance against the maximum score.
✓	Each theme under the Specific Criteria must achieve 80% compliance against the maximum score.
✓	There should be no measurement elements under any theme rated as 0.
✓	A rating of 1 for any given measurement element may be accepted provided there is a clear action plan, defined accountabilities, and timeline in place.

Table 3

Based on the overall score and detailed findings in this report, the Healthcare Provider has achieved a:

- POSITIVE ASSESSMENT**
- NEGATIVE ASSESSMENT**

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5. Next Steps

Congratulations on reaching this important milestone in the assessment process for European Reference Networks (ERNs). Your ongoing efforts to incorporate the Operational Criteria into how you deliver patient care have been, and will continue to be, of great benefit to the Network, other Healthcare Providers, healthcare professionals, patients, and families.

The Healthcare Provider should take into account the comments included in this report, as appropriate. The following is a summary of the next steps:

- Review the assessment report and notify ACSA about any requests for amendments.
- The Board of Member States will issue the final approval for ERNs based on the assessment results.

If you have any questions, please contact ACSA through the Communication Area of the project in ERN - Assessment Tool.

Assessors Team Leader: Juan Manuel Torres Canizales

Assessment Coordinator: Patricia Moreno Martínez

José Ignacio del Río Maza de Lizana

ACSA Director

08 July 2021

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Appendix A: Rating Scale

The following rating scale is used by the assessors to assess compliance with the operational criteria for Network and Healthcare Providers. The same rating scale is used by the applicant for the self-assessments.

Rating	Guidelines
0: No Activity / Not Implemented	All Criteria: this rating is used when there is no action plan in place or there is insufficient evidence to support compliance. This rating may also be used when the practice is not implemented in any of the Healthcare Providers of the Network (if applicable).
1: Partially Implemented	All Criteria: this rating is used when there is an action plan in place or there is any evidence to support compliance. This rating may also be used when the practice is implemented by some of the Healthcare Providers of the Network (if applicable).
2: Fully Implemented	All Criteria: this rating is used when there is sufficient evidence to support compliance. This rating may also be used when the practice is implemented by all of the Healthcare Providers of the Network (if applicable).

Table 4

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