

2. Operational Criteria for Healthcare Providers

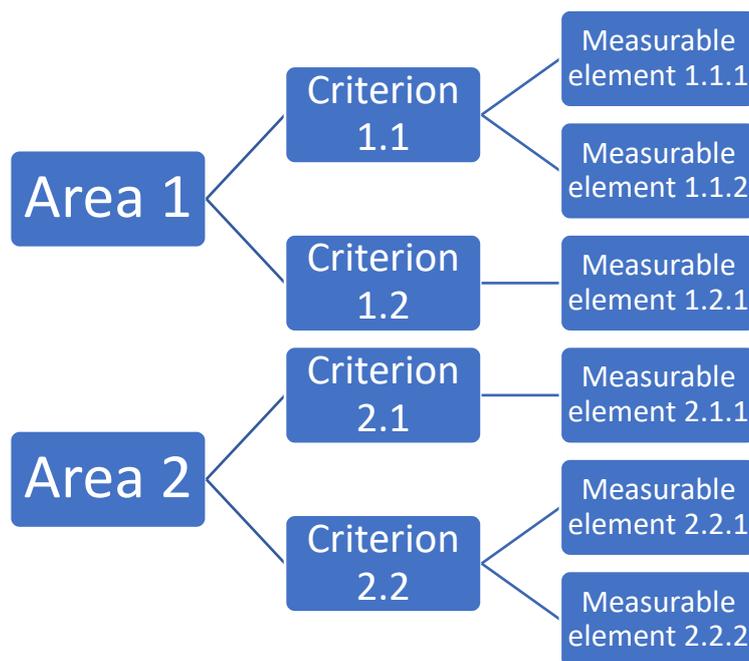
INTRODUCTION

The evaluation of the European Reference Networks (ERNs) is based on verifying to which extent the ERNs and their Members (Healthcare Providers, HCPs) meet those quality requirements relevant to the achievement of the objectives for which they were constituted.

Quality requirements are formulated as criteria, which describe an "enhanced practice" which is both aspirational and achievable.

The Measurable Elements (ME) are used to assess the aspect or level of performance specified in each criterion.

The criteria are classified in several dimensions or thematic areas related to the different goals and objectives included in the evaluation:



Some of the measurable elements are considered as "core" and should have been accomplished or implemented at the time of evaluation. The remainder measurable elements refer to important areas in which Networks or their Members should work on and whose level of development can serve as an indicator of their maturity status.

Two sets of criteria have been elaborated, one for the evaluation of the Networks and the other for the evaluation of the HCP teams. Each criterion has been made "operational" through one or several MEs. Therefore, an operational criterion includes the criterion and the MEs.

This document presents the operational criteria for HCPs and specific guidance to score the level of performance or achievement of the practices described in them.

OVERVIEW

A total of 24 operational criteria with 64 measurable elements classified in 7 areas have been developed:

EVALUATION CRITERIA FOR THE HCP TEAM			
AREA	Number of Criteria	Total number of ME	Total number of core ME
1. Patient centred care	9	19	8
2. Organisation and management	5	10	4
3. Research, education, and training	2	11	6
4. Exchange of expertise, Information systems and e-Health	3	7	3
5. Quality and safety	2	9	2
6. Competence, experience, and outcomes of care	1	4	4
7. Human resources	2	4	2
TOTAL	24	64	29

Some of the measurable elements are considered as “core” and should have been accomplished or implemented at the time of the evaluation. The remainder measurable elements (“extended” ME) refer to important areas in which the Networks should work and whose level of development can serve as an indicator of their maturity status.

As shown in the table above, each criterion may include core and extended ME.

Each Operational Criterion is presented in the Manual with the following structure:

- Thematic area to which the criterion belongs
- Guidelines: intention and rationale for the criterion
- Measurable elements that compose it and suggested evidence that the HCP can provide in each case and that will serve the evaluator to score the ME
 - The Scoring guide provides specific indications to rate each ME

Symbols included in the description of the operational criteria



Core measurable element



Measurable element to be evaluated during the onsite audit



Measurable element that identifies the HCP team contribution to the mission of the Network

Scoring

The degree of compliance with each ME is scored using a 3-point scale (0, 1 and 2). To minimize the variability between the evaluators, a tool is provided for the assignment of each of the categories.

Rating	Guidelines
0: No activity / Not developed	<p>All Criteria: this rating is used if the answer is “scarcely” or “none” to the specific measure and/or when there are no actions in place or there is insufficient evidence to support compliance.</p> <p><u>Considerations:</u></p> <ul style="list-style-type: none"> • Evidence of compliance is not appropriate for the purpose or not complete. • Actions have been described but they are not implemented. • When there are multiple requirements in one measure, less than 50% are present.
1: Partially developed	<p>All Criteria: this rating is used if the answer is “incomplete” or “partway” to the specific measure and/or when there are some actions in place or there is some evidence to support compliance.</p> <p><u>Considerations:</u></p> <ul style="list-style-type: none"> • Evidence of compliance does not cover the whole period of time in which the requirement is applicable. • Not all actions required have been implemented. • When there are multiple requirements in one measure, at least half (50%) are present.
2: Fully developed	<p>All Criteria: this rating is used if the answer is “totally” or “completely” to the specific measure and/or when there is sufficient evidence to support compliance.</p> <p><u>Considerations:</u></p> <ul style="list-style-type: none"> • Evidence of compliance covers the whole period of time in which the requirement is applicable • All actions required have been implemented or are underway • When there are multiple requirements in one measure, all are present.

1. PATIENT CENTRED CARE

1.1. The HCP team has implemented strategies to ensure that care is patient-centred, and that patients' rights, and preferences are respected.

Guidelines

Patient-centred care is considered one of the central dimensions of quality in hospital services. It is defined as care that establishes a collaboration between professionals, patients, and their families to ensure that decisions respect the patient needs and preferences and that patients have the education and support they need to make decisions and participate in their care.

Patient and family³ centred care is a necessity to obtain effective, efficient, and sustainable care in the long term. An intrinsic part of patient-centred care is that patients are aware of their rights and responsibilities and that they receive information that is understandable.

For the care process to be patient-centred, patients have to know the characteristics of the facilities and the organizational aspects that they will follow in order to be cared for.

Measurable Elements

1.1.1. The HCP team provides patients and/or their families with written information about the facility, the organisation, and its specific area of expertise.



<p>Evidence</p>	<p>Specific written information provided to the patients.</p> <p>Verify during the visit (online/onsite) in the session with discharged patients and outpatients.</p> 
<p>Scoring guide</p>	<p>0: The HCP team does not provide evidence about the information it provides.</p> <p>1: The HCP team provides evidence, but 1 or 2 of the required elements are missing (facility, organisation, or specific area of expertise).</p> <p>2: The HCP team provides evidence, and it contains the 3 required elements (facility, organisation or specific area and expertise).</p>

³ Family: the person(s) with a significant role in the patient's life. This may include a person(s) not legally related to the patient. This person(s) is often referred to as a surrogate decision maker if authorized to make care decisions for a patient if the patient loses decision-making ability.

1.1.2. The HCP team gives patients and/or their families written information about their rights and responsibilities in a language they can understand.

Evidence	Verify during the visit (online/onsite) in the session of patients. 
Scoring guide	<p>0: Less than 50% of the patients present in the session claim to have received the information.</p> <p>1: Between 50% -80% of the patients present in the session claim to have received the information.</p> <p>2: More than 80% of the patients present in the session claim to have received the information.</p>

1.2. The HCP team provides educational activities for patients and their families with the aim of improving knowledge of the disease and the capacity for self-management to face the different aspects of their disease.

Guidelines

The impact of patient care can be enhanced when patients and families are better acquainted with their health process, allowing for greater participation in decision-making.

Identifying patients’ educational needs and implementing educational activities based on those needs is key to providing high quality care.

To guarantee the continuity of care and knowledge of these activities by the multidisciplinary team, they must be recorded in the clinical history.

Measurable Elements

1.2.1. Patient and family educational needs are addressed in a defined process.	
Evidence	Indicate the process for identifying educational needs in patients and family members, and the potential barriers to education. 
Scoring guide	<p>0: It does not provide evidence of the process to identify educational needs and the identification of barriers.</p> <p>1: It provides evidence of the process to identify needs, but not on the process to identify barriers.</p> <p>2: It provides evidence of the process to identify needs and barriers.</p>

1.2.2. Education activities are recorded in the medical record	
Evidence	Verify during the onsite visit using a sample of 3 clinical records in given patients who have required educational activities on medication, medical devices, pain management or rehabilitation. 
Scoring guide	<p>0: None of the 3 medical records reviewed have recorded the completion of the education activities.</p> <p>1: 1 or 2 of the 3 medical records reviewed have recorded the completion of the education activities.</p> <p>2: All of the 3 medical records reviewed have recorded the completion of the education activities.</p>

1.3. The HCP team provides patients with clear and transparent information about the complaints' procedures and remedies and ways of redress available for both domestic and foreign patients.

Guidelines

The possibility of making a complaint is a right of patients, as well as that they have an answer adapted to their needs and knowledge in a set time. Furthermore, complaints are also a source of information that can be useful for quality management and for establishing improvement strategies.

Measurable Elements

1.3.1. The information about complaints, violation of the rights, and concern of the care and/or safety of patients and their families is periodically analysed and integrated into a continuous quality improvement process. An annual report is made on the complaints and the improvement actions carried out.

Evidence	Attach last year's report and proposed improvement actions if applicable.
Scoring guide	<p>0: It does not provide a report for the last year on the improvement actions taken based on the evaluation of patients' complaints.</p> <p>1: It provides the last year's report with the proposed improvements, but these have not yet been implemented.</p> <p>2: It provides the last year's report with the proposed improvements, and these have been implemented or are in the process of being implemented.</p> <p>NA: There were no claims over the previous year</p>

1.4. The HCP team regularly collects information on patient care experience or satisfaction within the ERN’s area of expertise and uses this information to make ongoing improvements.

Guidelines

Patient experience is an important component of patient-centred care and collecting and analysing it periodically enables the HCP team to give patients a voice in a structured way. This information is essential to introduce improvements from the patient's perspective that, on occasions, are not sufficiently perceived by the team.

A satisfaction evaluation also allows us to capture the vision of patients about the services received.

Whereas patient satisfaction is a subjective measure (of perception), patient experience is a more objective measure. In measuring satisfaction, we can ask patients or relatives how they have perceived the treatment of professionals, and in the measurement of experience we will ask more objective questions, such as, for example, if the professional who has cared for the patient has presented himself.

The HCP team can use one of the methodologies or both depending on its priorities.

Measurable Elements

1.4.1. The HCP team routinely measures patient and family satisfaction using the ERN common tool.



Evidence	Attach the results of the latest patient satisfaction assessment and the identified improvement actions if applicable.
Scoring guide	<p>0: It does not provide results from the latest evaluation on satisfaction of patients and families.</p> <p>1: It provides results from the latest evaluation on the satisfaction of patients, but not families (surveys or other methodologies).</p> <p>2: It provides results from the latest evaluation on the satisfaction of patients and families (surveys or other methodologies).</p>

1.5. The HCP team obtains the patient’s informed consent to provide clinical risk treatments and procedures.

Guidelines

Informed consent to medical treatment is an important patient right: patients have the right to receive information and ask questions about recommended treatments. It can also be one of the most effective ways to foster patient participation in decisions that affect their health care process. The patient must comprehend the benefits, risks, and alternatives to diagnostic and therapeutic procedures. The consent document should be easy to understand and written in a language known by the patient.

Normally, surgical procedures, anaesthesia and the use of blood and blood products will require informed consent. The HCP team will decide which procedures require consent and will provide the consent form to the patient or they family member when appropriate.

When conducting research with patients, obtaining informed consent is also required and patients should also be informed about the benefits, risks, and alternatives. The process of obtaining informed consent is central to patient safety and quality of care, and the patient always has the right to waive her participation. For the adequate follow-up of the patients by those who carry out the research and by other professionals who may intervene, consent must be documented in the clinical record.

Measurable Elements

1.5.1. The Informed Consent (IC) is documented in the patient’s medical record, including the risks, benefits, and alternatives to the procedure to be performed, and must be understandable to patients.



<p>Evidence</p>	<p>Verify during the onsite visit in a sample of 3 medical records of patients who have undergone a risky procedure.</p>	
<p>Scoring guide</p>	<p>0: None of the 3 patients' medical records who have undergone a risk procedure have the IC in their documentation.</p> <p>1: 1 or 2 of the 3 patients' medical records who have undergone a risk procedure have the IC in their documentation with the elements required by the ME.</p> <p>2: The 3 patients' medical records who have undergone a risk procedure have the IC in their documentation with the elements required by the ME.</p>	

1.5.2. The document to obtain IC for research must contain information on the risks, benefits, and alternatives to the procedure to be performed, and conflicts of interest (financial or non-financial).



Evidence	Attach the IC document template for patients included in research studies.
Scoring guide	<p>0: It does not provide the IC model for research.</p> <p>1: It provides the IC model, but does not have all the sections that are specified in the ME.</p> <p>2: Provides the IC model and has the requirements specified in the ME.</p>

1.5.3. The patients' medical records included in a clinical trial contain information about their participation in it.

Evidence	Verify during the onsite visit in a sample of 3 medical records from patients included in a clinical trial. 
Scoring guide	<p>0: None of the 3 patients' medical records included in a clinical trial contain information of their inclusion in a clinical trial.</p> <p>1: 1 or 2 of the 3 patients' medical records included in a clinical trial contain information of their inclusion in a clinical trial.</p> <p>2: The 3 patients' medical records included in a clinical trial contain information of their inclusion in a clinical trial.</p>

1.6. The HCP team maintains transparency by providing information to patients about clinical outcomes, treatment options, and quality and safety standards that are in place.

Guidelines

The HCP teams have to provide information about the patient's journey throughout the care process in the different languages of the population served, including: the steps they have to take for the diagnosis and treatment, and the coordination systems with other levels of care where the patients are going to be cared for. This information is documented in the medical record.

Measurable Elements

1.6.1. The HCP team provides comprehensive diagnostic and treatment information.	
Evidence	Verify during the visit (online/onsite) in the patient session. 
Scoring guide	<p>0: Less than 50% of the patients present at the session claim to have received comprehensive information about their diagnosis and treatment.</p> <p>1: Between 50% -80% of the patients present at the session claim to have received comprehensive information about their diagnosis and treatment.</p> <p>2: More than 80% of the patients present at the session claim to have received comprehensive information about their diagnosis and treatment.</p>

1.6.2. Information is provided in the language of the different populations served.	
Evidence	Verify during the visit (online/onsite) in the session with the professionals. 
Scoring guide	<p>0: Information is only provided in the main official language of the country.</p> <p>1: Information is provided in the official language of the country and can also be provided in English.</p> <p>2: Information is provided in the official language of the country and means are available to provide it in the patient's and family's own language.</p> <p>NA: No patient from another country with a different language has been treated.</p>

1.6.3. The information necessary for the follow-up of the patient after the treatment is provided



Evidence	<p>a) Provide some examples of the information provided to three patients for the follow-up after treatment.</p> <p>b) Verify during the visit (online/onsite) in the patient session. </p>
Scoring guide	<p>0: a) No examples are provided. b) Less than 50% of the patients present in the session claim to have received information about the follow up.</p> <p>1: a) Only 1 or 2 examples are provided. b) Between 50% -80% of the patients present in the session claim to have received information about the follow up.</p> <p>2: a) 3 examples are provided. b) More than 80% of the patients present in the session claim to have received information about the follow up.</p>

1.6.4. The HCP team provides information on coordinating care with other levels of care.

Evidence	<p>Verify during the visit (online/onsite) in the interview with the professionals. </p>
Scoring guide	<p>0: They do not provide information on how to coordinate with other levels of care.</p> <p>1: They provide information on coordination but do not include all the levels of care to which you can refer your patients (primary care, other hospitals, rehabilitation services, etc.).</p> <p>2: They provide information on coordination with all the levels of care to which you can refer your patients.</p>

1.6.5. The information provided to the patient and the family on the follow up and coordinating care with other levels of care is included in the clinical record.

Evidence	<p>Verify during the onsite visit in a sample of 3 HC from discharged patients and outpatients. </p>
Scoring guide	<p>0: None of the 3 medical records reviewed contains details on the information provided on the follow up and coordinating care.</p>

	<p>1: 1 or 2 of the 3 medical records reviewed contain details on the information provided on follow up and coordinating care.</p> <p>2: The 3 medical records reviewed contain details on the information provided on follow up and coordinating care.</p>
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1.6.6. Unanticipated outcomes and complications are disclosed to patients and their families as established in the HCP policy/procedure 	
Evidence	Provide the HCP policy/procedure and an example of disclosure to patients performed
Scoring guide	<p>0: No policy or example is provided.</p> <p>1: Either the policy or an example is provided, but not both.</p> <p>2: Both the policy and an example are provided</p>

1.7. The HCP implements a pain identification and management protocol.

Guidelines

In many patients, pain is part of their experience and can have negative physical and psychological effects. In hospitalized patients this becomes more evident when surgical or invasive procedures are performed. It is in these patients where it is expected that there will be procedures in place to detect the presence of pain, such as scales adapted to the characteristics of the patients, especially for younger patients and for those with cognitive or sensory difficulties.

Pain identification has to lead to pain management with the measures that have been established in the protocol.

Measurable Elements

1.7.1. In hospitalised patients with rare diseases or complex patients, pain is regularly identified with a standardised scale as established in the hospital's protocol.

Evidence	Verify during the onsite visit in a sample of 3 HC from discharged patients. 
Scoring guide	<p>0: None of the 3 medical records has a pain assessment registered 3 times a day throughout their stay.</p> <p>1: In 1 or 2 of the 3 medical records, the pain assessment is registered 3 times a day throughout their stay.</p> <p>2: The 3 medical records have registered the pain assessment 3 times a day throughout their stay.</p> <p>N.A: all patients receive care in an outpatient department</p>

1.8. A policy is implemented to encourage patient and family involvement.

Guidelines

Patient involvement can lead to better health outcomes and can improve quality of care and patient safety. The HCP team has to encourage patient engagement in healthcare decisions, in healthcare services organizations and in health research.

To achieve patient participation, it is essential to provide complete information about the disease and the treatment alternatives and take into account the preferences and values of the patients. The HCP team facilitates the decision-making process for patients and families, taking these elements into account.

Measurable Elements

1.8.1. Professionals encourage the participation of the patient and their family, based on their interests, in the care process and in decision-making.

Evidence	Indicate the process followed for patients' involvement.
Scoring guide	<p>0: It does not provide any evidence on how the process is carried out to encourage participation and decision making.</p> <p>1: It provides evidence about participation in the care process OR in decision making.</p> <p>2: It provides evidence about participation in the care process AND in decision making.</p>

1.9. The HCP team collaborates and carries out activities with patient associations.

Guidelines

Informing, defending the rights of patients, improving the professional-patient relationship, facilitating access to care ... are some of the objectives pursued by patient associations and other community resources.

The HCP team provides information on community resources and associations of pathologies that are attended by the team that allow patients to access educational consultations, counselling services and psychological care and other services that help patients improve their autonomy and biopsychosocial care.

Measurable Elements

1.9.1. The HCP team provides information on patients' associations and that can support the patient and their family.



Evidence	Specific information provided about patients' associations (examples) Verify during the visit in the session with professionals.
Scoring guide	0: Professionals do not show evidence of the information provided to patients and their families about patients' associations. 1: Professionals show evidence of the information provided about patients' associations. 2: Professionals show evidence of the information provided about patients' associations.



1.9.2. The HCP team collaborates and carries out activities with patients' associations.



Evidence	List the associations you work with, and the main activities carried out in the period. <i>Monitoring indicator number 1.4.</i>
Scoring guide	0: The list of patients' associations with which collaborative activities have been maintained during the 2019-2021 period is not provided. 2: The list of patients' associations with which collaborative activities have been maintained during the 2019-2021 period is provided.

2. ORGANISATION AND MANAGEMENT

2.1. The HCP team follows policies and procedures to manage the services offered to cross-border patients, including easy access to information regarding any tariffs that may be in place.

Guidelines

The healthcare provider team should follow the set cross border policies and procedures established by the Network and the national authorities. It is very important for the patient and the family to have complete information about cross border care and the implications it has in services provided and expected benefits, as well as from an economic perspective about any tariffs that may be in place for the reimbursement of care.

Policies and procedures should be in accordance with those set out in the legislation of the Member State of treatment and as described in the Directive 2011/24 and Social Security Regulation 883.

The HCP team informs and facilitates the care of cross border patients to the affiliated centres and carries out training and dissemination activities among the professionals and patients of these centres.

Measurable Elements

2.1.1. The HCP team establishes collaboration with affiliated centres in neighbouring countries for cross-border care or for training / dissemination of information for professionals and patients.



Evidence	List the HCP's affiliated centres in neighbouring countries for cross-border care.
Scoring guide	<p>0: It does not provide the list of its affiliated centres for cross border patients, nor the list of centres or professionals to which it disseminates the information generated in the Network.</p> <p>1: It provides the list of affiliated centres, but not that of centres or professionals to which the information generated on the network is disseminated.</p> <p>2: It provides the list of its affiliated centres and the list of other centres or professionals to which it disseminates the information generated in the Network.</p> <p>NA: It is not possible to have affiliates.</p>

2.1.2. The HCP team establishes and maintains a set of policies and procedures addressing aspects for the management and health care services of cross border patients.

Evidence	List the policies and the procedures established for cross border patients.
Scoring guide	0: It does not provide the policies and the procedures established for cross border patients. 2: It lists the policies AND procedures.

2.1.3. The HCP team shares information with patients and their families about any tariffs that may be in place for the reimbursement of care, as well as services provided and expected benefits.

Evidence	Include examples of the information provided to patients and their families.
Scoring guide	0: It does not include any example. 1: It includes 1 example. 2: It includes more than 1 example. N.A: tariffs do not apply at the point of healthcare delivery

2.2. The HCP team implements procedures and/or inter-agency or shared care agreements to support ease of access and coordination with other resources, specific units, or services necessary for managing patients.

Guidelines

In some cases where part of the care cannot be performed by the team itself, the HCP team has to refer patients to other centres that have the necessary technology or training for diagnosing and managing patients.

The HCP team must agree with these centres on the details of the procedure for the referral of patients, especially the clinical data to be included in the reports. For the follow-up of the patient, the information about the referral must be included in the medical record.

Measurable Elements

2.2.1. When necessary, the HCP team has easy access to other centres or highly specialised units outside its own facilities necessary for diagnosis, treatment, and delivery of care to patients.



Evidence	<p>a) Indicate the external centres or highly specialized units to which you can refer patients and if it is for diagnosis, treatment, or delivery of care.</p> <p>Comment if, in your opinion, you have been able to refer the patients with this need.</p>
Scoring guide	<p>0: It does not provide the list of external units to which it refers patients.</p> <p>1: It provides the list of external units, but without specifying if it is for diagnosis, treatment, or delivery of care.</p> <p>2: It provides the list of external units specifying the purpose for each of them (diagnosis, treatment, or delivery of care).</p> <p>NA: It has all the necessary services in their HCP.</p>

2.2.2. The HCP team sends the receiving organization a written summary about the patient's clinical condition and the interventions carried out in the hospital from which he/she is referred. The process is recorded in the medical record.

Evidence	<p>Verify during the onsite visit by reviewing a sample of 3 HC of patients who have been transferred to another organisation.</p>
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Scoring guide	<p>0: None of the 3 medical records reviewed has the transfer document with all the items required in the ME.</p> <p>1: 1 or 2 of the 3 medical records reviewed have the transfer document with all the items required in the ME.</p> <p>2: The 3 medical records reviewed have the transfer document with all the items required in the ME.</p>
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2.3. The HCP team has policies and procedures implemented to communicate post discharge with clinicians, including cross border.

Guidelines

The patient’s discharge document is an essential instrument for coordination with other levels of care that provides relevant clinical information for the continuity of patient journey.

Clinicians in local hospitals, general practitioners and/or primary care providers must receive this information.

Patient discharge also addresses patient and family education and training related to the patient's needs for ongoing care and services.

Measurable Elements

2.3.1. Discharge reports contain at a minimum: diagnoses; significant physical findings; diagnostic, surgical and medical procedures performed; medication received at discharge; and follow-up instructions.



<p>Evidence</p>	<p>Present 3 discharge reports (anonymized copies).</p> <p>Verify during the onsite visit 3 medical records of discharged patients.</p> 
<p>Scoring guide</p>	<p>0: None of the 3 medical records reviewed have ALL the items required in the ME.</p> <p>1: 1 or 2 of the 3 medical records reviewed DO NOT have ALL the items required in the ME.</p> <p>2: The 3 medical records reviewed have ALL the items required in the ME.</p>

2.3.2. The HCP team provides clinicians post discharge with complete discharge summaries in English for all cross-border patients.

<p>Evidence</p>	<p>Verify during the onsite visit 3 discharge reports of discharged cross border patients.</p> 
<p>Scoring guide</p>	<p>0: None of the 3 discharge reports reviewed are in English.</p> <p>1: 1 or 2 of the revised discharge reports are in English.</p> <p>2: The 3 revised discharge reports are in English.</p> <p>NA: no cross-border patient has been seen in the last 5 years.</p>

2.4. The HCP team is integrated into national networks.

Guidelines

One of the relevant objectives of integration with national networks is strengthening dissemination of information on ERNs, national care pathways, referral systems and health system organization for rare and complex diseases among medical, nursing, and allied health professionals according to the needs of the MS.

The HCP team collaborates with national centres in the dissemination and training on the diseases that are treated within the framework of the ERN at the national level.

Measurable Elements

2.4.1. The HCP team collaborates in training or dissemination activities with centres which are not members of the ERN.



Evidence	Indicate the activities carried out at national level.
Scoring guide	<p>0: It does not provide information on training or dissemination activities to other centres in its country on topics specific to its Network.</p> <p>2: It provides information on training or dissemination activities to other centres in its country on topics specific to its Network.</p>

2.5. The HCP team uses CPMS and includes all the information required.

Guidelines

The use of CPMS facilitates the improvement of the diagnosis and treatment of ERN patients and multidisciplinary work through communication between healthcare professionals. The CPMS must contain at least the detection of physical, psychological, and social needs of the patients, and the treatment plan and the completed sign off.

Measurable Elements

2.5.1. The HCP team shares patient information or participates in panels of complex cases through the CPMS with other members of the ERN.



Evidence	Indicate the number of patients entered into CPMS.
Scoring guide	<p>0: It has not contributed any patients to CPMS in 2019, 2020 and 2021.</p> <p>1: It has contributed some patients to the CPMS, but not in each of the following years: 2019, 2020 and 2021.</p> <p>2: It has contributed patients to the CPMS, in each of the following years: 2019, 2020 and 2021.</p>

2.5.2. The CPMS of each patient includes:

- a) physical needs
- b) social needs
- c) psychological needs
- d) treatment and care plan
- e) sign off completed

Evidence	Verify during the onsite visit on a sample of 3 medical records of patients included in the CPMS.
Scoring guide	<p>0: None of the registries of the lasts three years has all the information ("a" to "e")</p> <p>2: 80% registries of the last three years have all the information ("a" to "e")</p>



3. RESEARCH, EDUCATION AND TRAINING

3.1. The HCP team participates in education and training activities, such as continuing medical education and distance learning, aimed at staff, students, and other care professionals.

Guidelines

Education and training are key to guarantee the continuous development of knowledge and skills of professionals for both patient care and research.

The HCP teams annually define objectives and educational activities related to the type of patients represented by the ERN and the objectives are aligned with those of the ERN. They must also participate actively in the activities organized by the ERN.

The HCP identifies educational needs for each professional. The process of identifying individualized needs makes their approach more effective in achieving the training objectives.

Training activities must be carried out both within the HCP team and should be provided to other external actors that play a role in the care of patients with rare diseases.

Measurable Elements

3.1.1. The HCP team has a defined set of objectives for its education and training activities aligned with the ERN.



Evidence	State the HCP's educational and training goals.
Scoring guide	<p>0: It does not provide information on objectives for its education and training activities aligned with the ERN, intended for staff and other care professionals</p> <p>2: It provides information on objectives for its education and training activities aligned with the ERN, addressed to staff</p>

3.1.2. The HCP team regularly detects the training needs of the staff members.

Evidence	Indicate what process the HCP team has followed to identify training needs.
Scoring guide	<p>0: It does not report the process.</p> <p>2: It reports the process followed.</p>

3.1.3. Education and training activities are delivered to providers involved in the same chain of care within and outside the HCP's facility.

Evidence	<p>Indicate the training activities carried out in the period, with and without credits.</p> <p>Monitoring indicator number 4.1 and 4.2.</p>
Scoring guide	<p>0: It does not provide the activities carried out</p> <p>2: It provides a list of the activities carried out</p>

3.1.4. The HCP team participates in the training activities organised by the ERN.



Evidence	<p>Indicate the training activities organised by the Network in which you have participated.</p>
Scoring guide	<p>0: It does not provide information or has not participated in any training activity of the Network</p> <p>2: It provides information on the activities in which it has participated.</p>

3.2. The HCP team has the capacity to carry out research activities and demonstrated research experience in the framework of the ERN.

Guidelines

An essential facet of HCP teams is research on the diseases they care. The HCP team must ensure that those conducting research in the organization satisfy the qualifications established to do so.

The degree of contribution of the HCP team in the research and the information provided to patients for their participation in clinical trials and observational studies will be evaluated.

The results of the studies should be disseminated in the scientific community so that others can benefit from the advances achieved. The team shares the results with patient associations and other community-based organisations in a lay language.

Registries are key in rare disease research and the HCP team must share the data of the patients it cares for with existing registries or databases for research.

Measurable Elements

3.2.1. The HCP team leads and/or participates in research activities and clinical trials, at both national and international level, within the ERN's area of expertise.



Evidence	List the research activities of the Network in which the HCP team has participated (i.e., clinical trials and observational prospective studies). Include your answer in table 11 of the application form.
Scoring guide	0: There is no participation in any of the Network's research activities 2: There is participation in clinical trials or observational prospective studies

3.2.2. The HCP team ensures that records from research activities and clinical trials are safely stored.

Evidence	Verify during the onsite visit in a sample of 3 medical records of patients included in clinical trials. 
Scoring guide	0: None of the 3 medical records of clinical trial are safely stored. 1: 1 or 2 of the 3 medical records of clinical trials are safely stored. 2: All 3 medical records of clinical trials are safely stored.

3.2.3. The HCP team involves patients and / or their representatives in the most relevant aspects of the research process.



Evidence	Indicate the process followed to involve patients and families included in research studies.
Scoring guide	<p>0: It does not provide any evidence on how the process to involve the patient and their family in research studies carried out (clinical trials and observational prospective studies)</p> <p>2: It provides information on how the process is carried out to involve the patient and their family in research studies (clinical trials and observational prospective studies)</p>

3.2.4. The HCP team shares the results, in a timely manner, from its research activities and clinical trials through scientific publications.



Evidence	List the peer reviewed publications in scientific journals within the knowledge framework of the Network in which you have participated.
Scoring guide	<p>0: No publication has been produced within the framework of the Network in the last 5 years</p> <p>2: 1 or more publications have been produced within the framework of the Network in the last 5 years (attach the link or reference of the publication/s)</p>

3.2.5. The results should be disseminated to patient associations in lay language.



Evidence	Indicate the publications/results of research within the framework of the Network that have been sent to patients' associations, adapted for clear understanding.
Scoring guide	<p>0: Publications/results were not sent to patient associations</p> <p>1: Some publications/results were sent (attach email reference)</p> <p>2: All publications/results were sent (attach email reference)</p> <p>N.A: there is no patient associations for some specific diseases or conditions</p>

3.2.6. The HCP team provides patients' information for the registries or databases promoted by the ERN.



Evidence	Indicate how many patients you have incorporated into the registries or databases of the Network.
Scoring guide	0: No patients were added to the registries or databases developed by the Network 2: 1 or more patients were added to the registries or databases developed by the Network

3.2.7. The HCP team is contributing to disseminate the ERN activities.



Evidence	Indicate what your contribution has been. For example, in social media, website, flyers and materials, attendances to congresses and conferences disclosing the ERN, etc.
Scoring guide	0: It does not provide information. 1: It provides information, but it has only used 1 channel for dissemination 2. It provides information and contribution to dissemination is made in several ways.

4. EXCHANGE OF EXPERTISE, INFORMATION SYSTEMS AND e-HEALTH

4.1. The HCP team is able to exchange expertise with other providers and provide support to them.

Guidelines

A broad and deep knowledge about the rare or complex disease(s) or condition(s) should be maintained and used to provide health care professionals the information about the disease or condition they demand. Health care professionals may include clinicians at local hospitals, local referring physicians and general practitioners, other specialist centres, etc.

Measurable Elements

4.1.1. The HCP team offers an advisory service to exchange expertise with other professionals and caregivers involved in the patients' treatment.



Evidence	Attach the list of other professionals and caregivers or healthcare facilities with whom you maintain an advisory service.
Scoring guide	<p>0: It does not provide the list of other professionals and caregivers with whom it maintains an advisory service.</p> <p>2: It provides a list of other professionals and caregivers with whom it maintains an advisory service.</p>

4.2. The HCP team fosters the use of telemedicine and other e-health tools within and outside its facility.

Guidelines

Telemedicine and e-health tools are very useful in health care and, particularly, in the activities of the HCP due to the location of the patients, which, on occasions, can be far from the place where the HCP team is located.

Not all professionals are familiar with these tools, so it is essential to establish a protocol of good practices that allows homogenizing their use and improving quality.

Similarly, not all patients can connect through these tools and the criteria of those who are candidates to use them must be defined. The criteria must take into account the health literacy, technological, cognitive, or sensory barriers of the patients.

Patients must be guaranteed that these tools will respect the confidentiality of the information.

The minimum interoperability requirements include the technical specifications to support: transmission speed and bandwidth; image storage, retrieval, and transmission; physical location of the equipment and room requirements.

Measurable Elements

4.2.1. The HCP team uses telemedicine and other e-health tools.



Evidence	<ul style="list-style-type: none"> a) Indicate the procedures in which telemedicine can be used. b) Indicate the e-health tools you use.
Scoring guide	<p>0: It does not provide the list of Telemedicine procedures or the e-health tools it uses.</p> <p>1: It contributes only one of the 2 lists.</p> <p>2: It provides the 2 lists.</p>

4.2.2. Professional telemedicine guidelines available are used to guarantee the homogeneity of its use.



Evidence	<p>Provide the guidelines used.</p> <p>Verify during the visit (online/onsite) in the interview with the professionals.</p>
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Scoring guide	0: There are no guidelines for procedures performed with telemedicine. 2: Guidelines are available for procedures performed with telemedicine.
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4.2.3. The HCP team should identify inclusion and exclusion criteria for potential telehealth patients.

Evidence	Indicate the criteria that apply.
Scoring guide	0: There are no inclusion and exclusion criteria for potential telehealth patients. 2: There are criteria for inclusion and exclusion of potential telehealth patients.

4.2.4. Patients and family members who access telehealth have the right to have their privacy guaranteed.

Evidence	Verify during the visit (online/onsite) in the interview with the professionals. 
Scoring guide	0: Professionals do not clearly specify the mechanisms used to guarantee privacy. 2: Professionals explain the mechanisms used to guarantee privacy.

4.2.5. When surveying patient and family satisfaction, satisfaction with the services provided by telehealth should be included, when appropriate.

Evidence	Survey content. 
Scoring guide	0: The satisfaction surveys do not evaluate satisfaction with telemedicine procedures and other e-health tools. 2: The satisfaction surveys evaluate satisfaction with telemedicine procedures and other e-health tools.

4.3. The HCP team codes the information, and the information system is aligned with nationally and internationally recognised systems when appropriate in the framework of the ERN.

Guidelines

This coding system is in line with nationally and internationally recognised systems, when appropriate. This may include the International Classification of Diseases and Complementary Codes and/or Orphanet Classification.

Measurable Elements

4.3.1. The HCP team uses a standardised information and coding system for rare or low prevalence complex disease(s) or conditions(s), agreed within the ERN.



Evidence	Explain if you use the coding system agreed in the Network.
Scoring guide	<p>0: The diagnostic coding system agreed in the Network is not used.</p> <p>1: Not all diagnoses are coded with the coding system agreed upon in the Network.</p> <p>2: All diagnostics are coded with the coding system agreed upon in the Network.</p>

5. QUALITY AND SAFETY

5.1. The HCP team regularly monitors and improves the quality and safety of the care provided to patients with rare or low prevalence complex diseases or conditions.

Guidelines

Quality and safety are rooted in the daily work of all staff in the HCP team. Developing quality improvement and patient safety strategies includes data aggregation and analysis to support patient care and HCP team management. Indicators can provide information on the functioning of the relevant areas of the HCP team for quality and safety improvement strategies.

The strategies should include measurable quality and safety objectives aligned with the ERN and the display of the activities necessary to achieve the objectives. The description of the staff components responsible for the objectives is recommended.

Safety strategies should include the most common preventive actions in risk management such as: hand hygiene, prevention and control of healthcare related infection, prevention of medication errors (completed medical orders, process of administration, identified high-risk medications), ensuring safe surgery (verification, time out and sign out), and unequivocal identification of patients, etc.

One of the safety improvement strategies is learning to analyse adverse events. The HCP can analyse adverse events and complications to make process improvements that minimize their occurrence. For the learning to be effective, the results will be shared with the team.

There may be a structured reporting system for all the services of a centre which the HCP team may be able to use, but even if there is not or if there are difficulties in using the centre's system, the HCP should investigate the root cause of all critical incidents or adverse events and implement corrective or preventive actions.

Measurable Elements

5.1.1. The HCP team applies a strategy of quality and safety improvement, which includes specific objectives and recommended activities for the achievement of the objectives



Evidence

Attach the quality and safety strategy, it should describe: 1) concrete and measurable objectives of quality and safety, and 2) the actions for each objective.

The objectives and activities must contemplate those established in the Network's strategy.

Scoring guide	<p>0: It does not provide the quality and safety improvement strategy and its alignment with the Network strategy.</p> <p>1: It provides the quality and safety improvement strategy but does not follow the objectives established by the Network and the actions to implement these objectives.</p> <p>2: It provides the quality and safety improvement strategy with the objectives and actions established by the Network.</p>
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5.1.2. The main objectives of the strategy on quality and safety improvement include:

- a) Hand hygiene
- b) Prevention and control of healthcare related infections
- c) Prevention of medication errors (completed medical orders, process of administration, identified high-risk medications)
- d) Ensure safe surgery (verification, time out and sign out)
- e) Unequivocal identification of patients

Evidence	Assess during the visit (online/onsite) in the interview with professionals. 
Scoring guide	<p>0: Professionals know the protocols of the 5 procedures, but do not explain how they are implemented.</p> <p>1: Professionals know the protocols of the 5 procedures, but do not clearly explain (with examples) how each of them are implemented.</p> <p>2: Professionals know the protocols of the 5 procedures and clearly explain (with examples) their application.</p>

5.1.3. The quality and safety strategies are implemented, and the results obtained are evaluated.

Evidence	Attach the result of the evaluation of the quality strategies from last year.
Scoring guide	<p>0: It does not provide information on the results of the quality and safety strategies for the last year.</p> <p>1: It delivers results for some but not all of the last year goals.</p> <p>2: It provides results for all of the last year goals.</p>

5.1.4. There is a procedure in place to report, document, investigate, and learn from adverse events and complications.



Evidence	<p>a) Do you have access to an adverse event reporting system?</p> <p>b) How many events related to the diseases that you care for in the framework of the Network have you reported in the last 5 years?</p> <p>c) Is a comprehensive analysis of all serious adverse events carried out?</p>
Scoring guide	<p>0: It does not provide information regarding the management of adverse events by the HCP member.</p> <p>1: It describes the adverse event management system but does not indicate the number of incidents reported in the last 5 years, or if it has carried out an analysis in any case.</p> <p>2: It describes the adverse event management system, indicates the number of incidents reported made in the last 5 years and when an analysis has been carried out on all of them.</p> <p>NA: There were no adverse events in the last 5 years.</p>

5.1.5. The HCP team uses this information to make ongoing improvements.

Evidence	<p>Indicate whether you have identified and implemented improvement actions after analysing the reported adverse events. List the improvement actions identified and specify whether they have been implemented, if any.</p>
Scoring guide	<p>0: No improvement actions have been defined.</p> <p>1: Improvement actions have been defined, but they have not been implemented.</p> <p>2: Improvement actions have been identified and implemented.</p>

5.1.6. All healthcare personnel are familiar with the system for reporting safety incidents and adverse events.

Evidence	<p>Assess during the visit (online/onsite) in the interview with professionals.</p>
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Scoring guide	<p>0: Professionals do not know the system used in their organization to report adverse events.</p> <p>1: Professionals know the system used in their organization to report adverse events, but they have not reported any adverse events during 2019, 2021 and 2021.</p> <p>2: All of the professionals in the team know the system used in their organization to report adverse events and use it.</p>
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5.1.7. A procedure is implemented to provide information on adverse events with patient damage to patients and their families.

Evidence	<p>Assess during the visit (online/onsite) in the interview with professionals.</p> 
Scoring guide	<p>0: The HCP member does not have or explain the process to communicate adverse events to patients and families.</p> <p>2: The HCP member arranges and explains the process for communicating adverse events to patients and families.</p>

5.2. The HCP team adopts and uses clinical practice guidelines in their area of expertise.

Guidelines

To improve clinical care, clinical practice guidelines represent an essential instrument that will contribute to the standardization of care processes, the risk reduction, the provision of clinical care in a timely manner, the efficient use of resources and the provision of consistently high-quality care using evidence-based practices.

An assessment of compliance with clinical practice guidelines should be carried out because it represents essential information for the proper management of patients treated by the HCP team. Their better compliance will increase the likelihood that the care will be of higher quality and safety.

The Healthcare team obtains and considers patient and family input when developing / adopting and/or selecting guidelines. Patients and families are consulted to determine whether the method of adopting guidelines follows a patient-centred approach. Patient and family input is used to select guidelines that are appropriately linked to improved patient experience.

Measurable Elements

5.2.1. The HCP team adopts and implements clinical practice guidelines and decision-making tools developed or adapted by the ERN.



<p>Evidence</p>	<p>Indicate which clinical guidelines and decision-making tools developed or adapted by the ERN, and their respective updates have been implemented in your patients, as well as other good practices recommended by the Network.</p>
<p>Scoring guide</p>	<p>0: It has not implemented any of the clinical guidelines and decision-making tools developed or adapted by the ERN</p> <p>1: It has implemented some guidelines and decision-making tools, but not all those that correspond to its area of expertise.</p> <p>2: It has implemented all the clinical guidelines and decision-making tools developed or adapted by the ERN and that correspond to their area of expertise.</p> <p>N.A: the ERN has not developed or adapted any clinical guideline or clinical decision-making tool</p>

5.2.2. An annual evaluation on adequate compliance of the clinical practice guidelines is carried out using the indicators agreed in the ERN.



Evidence	Indicate the results of the evaluation of adequate compliance with the clinical practice guidelines from last year.
Scoring guide	<p>0: It does not provide any information on the results of the evaluation indicators of the clinical practice guidelines evaluated from last year.</p> <p>1: Information is provided, but not on all the guidelines or all the indicators corresponding from last year.</p> <p>2: Information is provided on all the indicators of all the guidelines evaluated from last year.</p>

6. COMPETENCE, EXPERIENCE, AND OUTCOMES OF CARE

6.1. The HCP team maintains its clinical competence in the ERN's area of expertise.

Guidelines

The diagnostic and treatment capacity of patients may be conditioned by the volume of activities with a certain type of patient or procedures that are performed. The HCP team must demonstrate that it cares for a number of patients and performs a number of procedures that allows to maintain experience in professional practice.

To contribute to the knowledge of the clinical outcomes of the ERN, the HCP team should provide information on the results of the own monitoring indicators and the clinical indicators established by the Network.

Measurable Elements

6.1.1. To maintain its competency and expertise, the HCP team serves the minimum/optimal number of patients per year as defined by the ERN based on professional/technical standards or recommendations.



Evidence	<p>Attach the annual data (from the last 3 years), of the number of patients of the group of diseases you serve.</p> <p>Include the reference data agreed by the Network for each of the items.</p>
Scoring guide	<p>0: It does not provide the number of patients for the last three years.</p> <p>2: It provides the number of patients for the last three years and is equal to or greater than the reference value agreed by the Network.</p>

6.1.2. To maintain its competency and expertise, the HCP team serves the minimum/optimal number of procedures per year as defined by the ERN based on professional/technical standards or recommendations.



Evidence	<p>Attach the annual data (from the last 5 years), of the number of procedures of the group of diseases you serve.</p> <p>Include the reference data agreed by the Network for each of the items.</p>
Scoring guide	<p>0: It does not provide the number of procedures performed in 2019, 2020 and 2021.</p>

	<p>1: It provides the number of procedures performed in 2019, 2020 and 2021, but not the reference value agreed by the Network.</p> <p>2: It provides the number of procedures performed in 2019, 2020 and 2021, and the reference value agreed by the Network.</p>
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6.1.3. The HCP team regularly collects, and monitors process and outcome indicators as established in the ERN.



Evidence	a) Attach the result of the monitoring indicators reported periodically to the European Commission for the last 3 years
Scoring guide	<p>0: It does not provide information on the results of the monitoring indicators, established by the Network.</p> <p>2: It provides information on the monitoring indicators established by the Network for the last 3 years.</p>

6.1.4. The HCP team is actively involved in the activities organized for the development of the ERN.



Evidence	Attach the activities or working groups of the Network in which you have participated.
Scoring guide	<p>0: It does not provide information.</p> <p>1: It provides information, but it shows they participated in less than 3 activities or working groups.</p> <p>2: It provides information on their participation in more than 3 activities or working groups.</p>

7. HUMAN RESOURCES

7.1. The HCP has a team of trained professionals with the required competencies within the ERN's area of expertise.

Guidelines

If there have been changes in the staff of the HCP team since the assessment was carried out, documentation on the new staff should be included. Documentation includes type of professionals, number of professionals, specific qualifications, and skills. The required skills and competencies are defined by the Network and is consistent with the HCP team area of expertise.

Professional competencies are evaluated annually, and areas of improvement are identified for all components of the HCP team.

Measurable Elements

7.1.1. The HCP team identifies and documents the skills and professional qualifications required for the new staff in the multidisciplinary team performing activities critical to the quality of patient care.



Evidence	If there has been any change in the multidisciplinary team, with respect to those reported in the assessment, indicate their qualifications.
Scoring guide	<p>0: It does not provide information on the new professionals' qualifications.</p> <p>1: It provides information on the new staff but does not meet the requirements of the Network.</p> <p>2: It provides information on the new staff and complies with the requirements of the Network.</p> <p>NA: There has been no change in professionals since the assessment.</p>

7.1.2. There is a process to routinely assess staff skill to ensure adequate performance of specialized tasks.

Evidence	Verify during the visit (online / onsite) in the interview with professionals. See 3 examples. 
Scoring guide	<p>0: There is no process to ensure the maintenance of the necessary skills for the performance of their specialised tasks.</p> <p>1: There is a process, but it is not done routinely and systematically.</p> <p>2: There is a systematic process that is annually performed on all team members.</p>

7.2. The HCP team delivers a comprehensive care by a multidisciplinary and specialised team.

Guidelines

There are procedures in place to identify all patients where a multidisciplinary team discussion is needed, including undiagnosed/unclear cases. There are referral criteria in place that define when to send a case to the team for consideration. These include: the type of patients to be discussed; the clinical questions needed to be addressed; what information is required for the discussion; and when to refer the patient to another team, i.e., from a local team to a specialist team.

All team members have dedicated time included in their workload to attend team meetings. Core team members are present for all cases where their input is needed. Extended members and non- members may attend for those cases that are relevant to them. Decisions of the multidisciplinary clinical sessions on a determined patient are recorded in their medical record.

Measurable Elements

7.2.1. There are regular structured meetings between multidisciplinary team members.



Evidence	Indicate the number of sessions scheduled / year carried out by the multidisciplinary team (clinical, organisational, scientific sessions, etc.).
Scoring guide	0: It does not provide information about the regular meeting scheduling calendar. 2: It provides the regular meeting scheduling calendar.

7.2.2. The decisions of the multidisciplinary clinical sessions on a given patient are recorded in their medical record.

Evidence	Verify during the onsite visit in 3 HC of patients that they have been assessed by the team. 
Scoring guide	0: In none of the 3 medical records have the decisions of the multidisciplinary team meetings been recorded. 1: In 1 or 2 of the 3 medical records, the decisions of the multidisciplinary team meetings have been recorded. 2: The decisions of the multidisciplinary team meetings have been recorded in all 3 medical records.