Second Online ERN Stakeholder Meeting AMEQUIS

26 & 27th of October 2021, by Zoom

European Reference Networks

AVEDIS DONABEDIAN INSTITUTO UNIVERSITARIO-UAB

NIVEL Kennis voor betere zorg

Partners presentation

FAD

Avedis Donabedian Research Institute (UAB)- non profit.

Supporting governments, health and social care organizations, professionals and patients in improving quality of care

- **Design and apply accreditation /certification/external evaluation models**
- **Supporting patients to include their perspective (myeloma, cancer …)**
- **Support organizations in implementing quality strategies (hundreds)**
- **Extensive experience in EU policy projects and EU research (implementation)**

Nivel

Netherlands institute for Health Services Research - independent

- **Striving for high quality research with impact upon society.**
- **Research focus on quality & effectiveness of health and social care.**
- **Integration of patient, professionals and system perspective.**
- **Extensive experience in development, implementation and evaluation of quality systems.**

Close collaboration with universities and policy makers.

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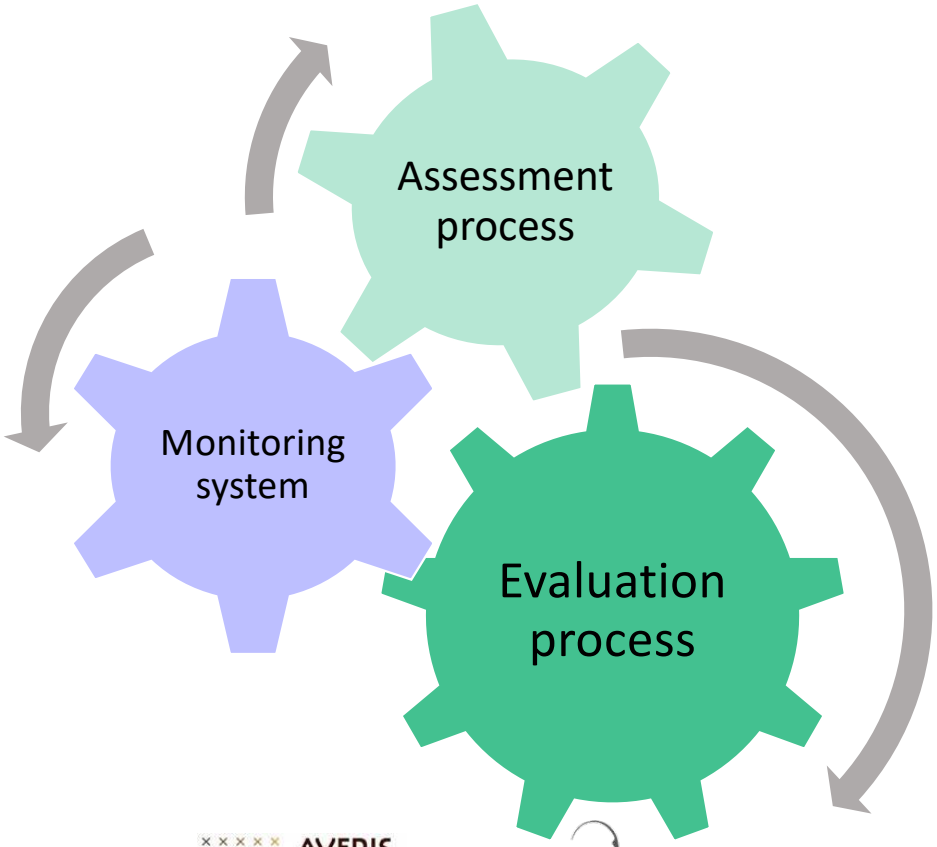
General Objective

- To develop an integrated assessment, monitoring, evaluation and quality improvement system (AMEQUIS) of the ERNs, in order to:
  i. assess any new ERN or HCP application;
  ii. monitor the activities carried out and the produced deliverables developed by the approved ERNs and their members;
  iii. evaluate the ERNs; and
  iv. improve the ERN system on the basis of a continuous quality improvement system approach (PDCA) and develop an integrated AMEQUIS model.

What has been done so far?



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What has been done so far?

Literature review of the three phases

Stakeholders' consultation

Online Surveys

- ✓ ERN coordinators & members (24 ERN)
- ✓ Patient representatives (24 ERN)
- ✓ The Board of Member States
- ✓ Member of the ERN monitoring working group

Interviews and group discussions

- ✓ Independent Assessment Bodies

Group discussions or meetings

- ✓ European Commission
- ✓ Working Monitoring Group
- ✓ e-Pag representatives

\+ **Online ERN stakeholder meeting**

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Objectives for the conference

- To obtain participant's inputs on the updated proposal for the assessment and monitoring system and for the design of the evaluation scheme.
  - Agreement- disagreement to our proposal
  - Barriers or facilitators to increase the impact of the proposed measures
  - What it is missing

This is not a closed proposal, your suggestions and comments are crucial!

Proposal for the updated assessment and monitoring process, and draft design for the evaluation process

Section 1:
Assessment process: proposed update

Section 1 outline: Assessment process: proposed update

Assessment process: Process to integrate new HCPs to the ERN or new Networks

1. Sources of information
2. Main improvement suggestions from the stakeholders
3. Proposal of the most important changes suggested for the assessment process of the ERNs/HCPs

These proposals are open for debate and further suggestions. Your participation is very important.

1. Sources of information

Sources of information	
Literature review assessment	1779 screened , 22 papers (PubMed, grey literature)
Interviews with IAB	10 representatives
Survey among ERN coordinators and HCPs	309 invited, 111 responses
Survey among patient representatives	120 invited, 82 responses
Survey among members of the BoMS	28 invited, 11 responses
Stakeholder conference	105 participants: ERN's, patient reps., BoMS, EC/HaDEA
Group discussion with EC / HaDEA	8 representatives
Group discussions with IAB (02)	9 representatives
Interviews with 2019 applicants	4 representatives

2. Main improvement suggestions from the stakeholders

- In general: positive about 2016 assessment process, although application tool and manuals could be further improved
- Heterogeneity in endorsement processes by Member States
- Majority of operational criteria for ERNs and HCPs are considered highly relevant by all stakeholders, although not always sufficiently clear how to fulfil / provide proof of compliance (clarity on measures)
- Patient involvement in the assessment process is largely missing and could be further strengthened

Surveys

- Find efficiencies within the process to lower the workload for ERNs and HCPs
- Review and update of the operational criteria for ERNs and HCPs
- Standardisation across ERNs
- Inactive HCPs
- Improve validity of the application (as the IAB is not able to check the validity)
- No clear procedure for the endorsement by the Member States

Conference

3. Proposal of the most important changes suggested for the assessment process of the ERNs/HCPs

4 themes for improvement:

1. Simplification (3 proposals)
2. Standardization & clarification (5 proposals)
3. Quality improvement (1 proposal)
4. Patient engagement (3 proposals)

Proposals for improvement: simplification

1. **Simplify application process**

2. Support applicants with IT and with helpdesk / webinar

3. **Removal of redundant operational criteria and reduction of overlap between criteria**

Simplification – Proposal 1

Simplify application process

Based on feedback from: Surveys, stakeholders conference, interviews with applicants and EC expectations

Adjustments:

- specific guidance
- integrate application form and self-assessment
- integrate supporting information and documentation from application form and self-assessment

Simplification – Proposal 3 (1)

Remove less relevant criteria and reduce overlap between criteria

Based on feedback from: Surveys, interviews with IAB and literature review

Adjustments:

1. Reduce overlap

- HCPs: Measure 4.4.2 *The Healthcare Provider has procedures in place to monitor and maintain data quality* (overlap with other measure of different theme)
- Networks: Measure 6.1.1 *The Network gathers, exchanges, and disseminates knowledge, best practice evidence, and clinical expertise within and outside of the Network* (overlap with other measure)

Simplification – Proposal 3 (2)

2. Remove Measure 3.2.7

3.2.1	The Healthcare Provider provides evidence that adequate resources are available, i.e. human, technical, or physical structure, to support research activities.
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.
3.2.3	The Healthcare Provider follows a set of Standard Operating Procedures (SOPs) that govern research activities.
3.2.4	There is a procedure to review the ethical implications of research activities.
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.
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.
3.2.7	The Healthcare Provider evaluates the effectiveness of research activities.

Guideline Measure 3.2.7: Monitoring of research production, performance of research projects, and overall return on investment such as the outcomes of research activities over the last three years

Rationale to remove Measure 3.2.7:

- Considered less relevant (surveys & literature review)
- Could be sufficient to evaluate *effectiveness* at ERN level (research *activities* are already captured in Measure 3.2.2)

2. Standardisation & clarification - Proposals

1. Manage expectations of applicants upfront
2. **Adapt process scheme**
3. **Harmonise manuals and toolboxes into 1 master manual**
4. **Update the scoring guidelines**
5. **Update and clarify measures of operational criteria**

2. Standardisation & clarification – Proposal 2

Adapt process scheme

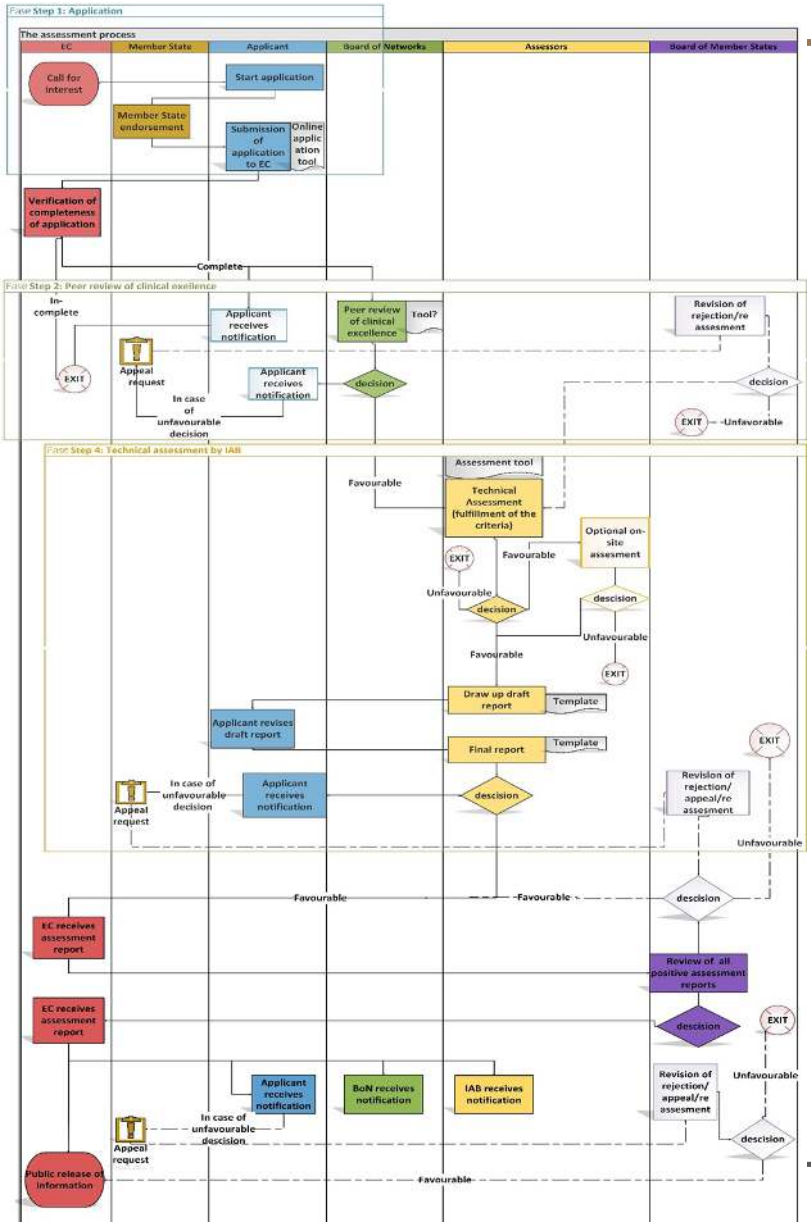
Based on feedback from: European Commission

Adjustments:

- harmonise the process steps, process schemes and the flowchart,
- alignment with the procedure, decisions and criteria in the Implementing Decisions
- updated and revised assessment process and assessment process scheme

Adapted process scheme

STEP	OLD assessment process scheme	NEW assessment process scheme
1		Call for interest
2		Member State endorsement of application of their Health Care Providers
3	Complete & submit Application	Submission of application to the European Commission
4	EC Eligibility Check	Verification of completeness of application by the European Commission
5a	ERN Review - review initial & revised HCP application & provide Draft & Final Opinion (ERN)	Peer review of clinical excellence by each Board of the Network (Fulfilment of the specific criteria)
5b	IAB Review – review Completed-HCP- Fav. Application & prepare Draft Assessment Report (IAB)	Technical Assessment by Independent Assessment Body (Application form, fulfilment of the criteria)
6	IAB Review- prepare Final Assessment Report	Communication of assessment outcomes
7	BoMS Approval - approve Applications	Approval by Board of Member States
8		Publication of list of established Network and their Members



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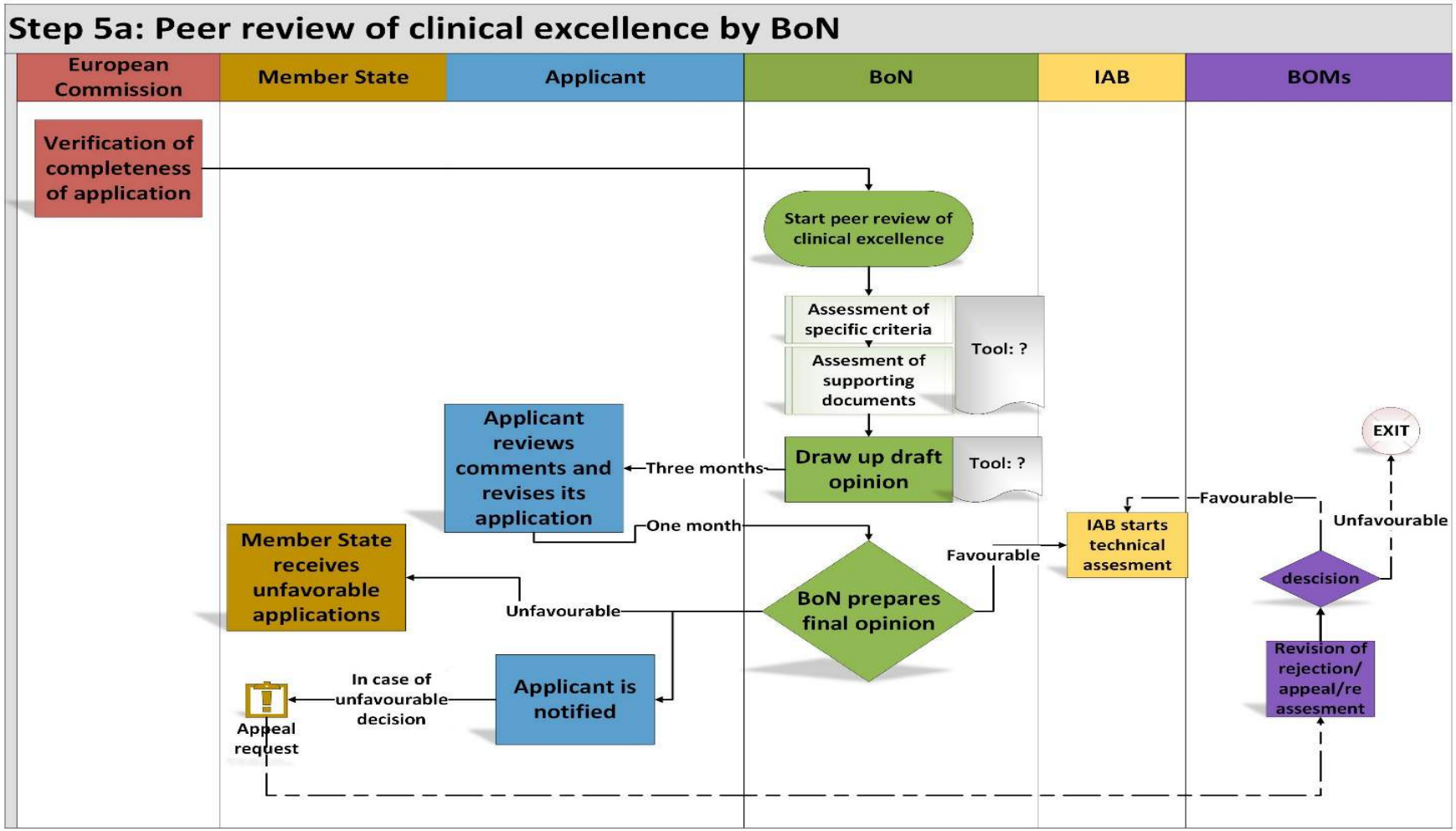
Step 5a: Peer review of clinical excellence by BoN



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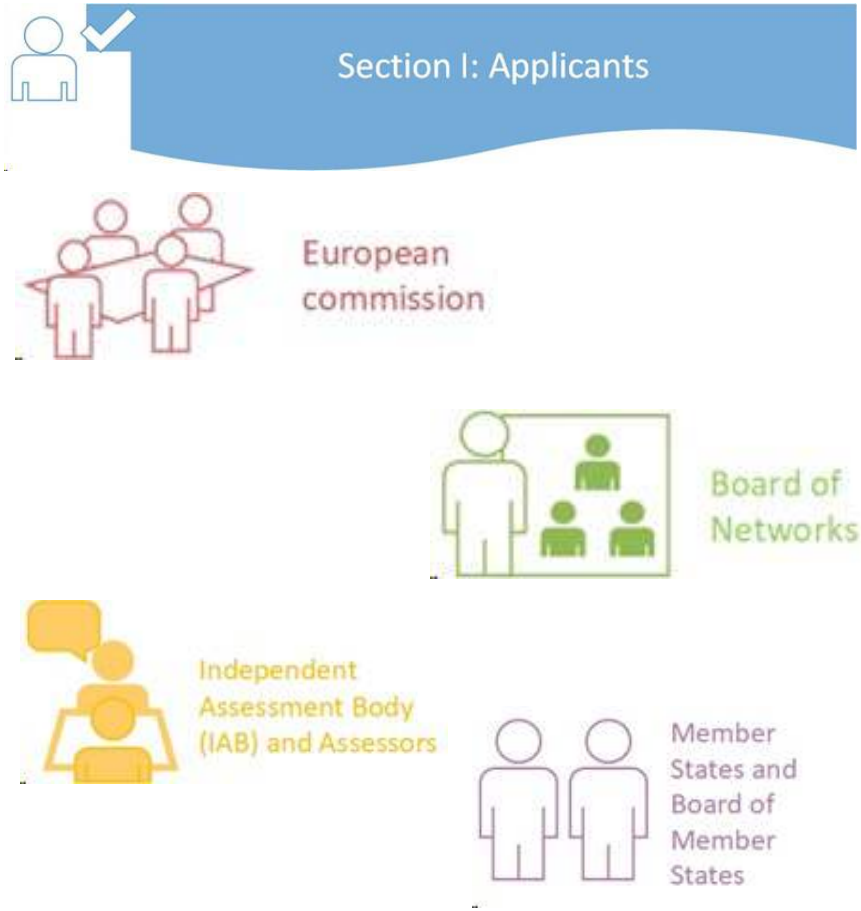
2. Standardisation & clarification – Proposal 3

Harmonise manuals and toolboxes in 1 master manual

Based on feedback from: Interviews with the IABs, surveys and aligned with the EC

Adjustments:

- combine different manuals
- combine toolbox with manual



Section I for Applicants

- Process and Procedures
- Technical toolbox

Section II for European Commission

- Process and Procedures
- Technical toolbox

Section III for Board of the Network / Network Coordinator

- Process and Procedures
- Technical toolbox

Section IV for Independent Assessment Body

- Process and Procedures
- Technical toolbox

Section V for Board of Member States and Member States

- Process and Procedures
- Technical Toolbox

2. Standardisation & clarification - Proposal 4

Update scoring guidelines

Rationale: interviews with IAB, literature, the AMEQUIS consortium partners' opinion

Adjustments:

- more details and equipped with considerations:
  - also rated based on frequency of occurrence
  - equipped with considerations, whether a particular score is indeed applicable.
  - mandatory comment fields

2. Standardisation & clarification – Proposal 5 (1)

Update and clarify measures of operational criteria

Based on feedback from: stakeholder conference, surveys, interviews with IAB, interviews with applicants, literature review

Adjustments: 1. Clarify/rewrite guidelines for:

- Criterion 2.3 *The Healthcare Provider has a business continuity plan* (relevance was not clear to stakeholders)
- Measure 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 e-health agreed to standards and recommendations*
  - List of available tools required for self-assessment instead of application form (clarification)

2. Standardisation & clarification – Proposal 5 (2)

2. Adjust Measures for Operational Criteria HCPs

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.*

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.*

Proposal: use relative minimum numbers, related to the size of a Member State.

Rationale to adjust Measures: the minimum patient and procedure numbers may be more difficult to achieve for HCPs from smaller countries

3. Quality improvement – Proposal 1

Independent sampling methodology of onsite audits based on multiple sources

Based on feedback from: Interviews with IAB

Adjustments: A selection system (25% at random, 75% purposeful) that targets specific HCPs based on:

- the feedback from the peer reviewers (BoN) and assessors (IABs)
- geographical dispersion of the ERN members
- HCPs acting as the Coordinating Member of a Network

4. Patient engagement - Proposals

1. **Include patient representatives in the document review process of patient material**
2. Ensure that actions are taken upon unmet patients needs at the ERN level
3. **Include a role for patients in governance of ERNs**

4. Patient engagement – Proposal 1

Include patient representatives in the document review process of patient material

Based on feedback from: stakeholder conference

Adjustments: a role for patients /patients' associations in co-assessing and reviewing patient-related measures or patient material

4. Patient engagement – Proposal 3

Include a role for patients in the governance of ERNs

Based on feedback from*:* Stakeholders conference, surveys, interviews with IAB, meeting with E-PAG

Adjustments:
In operational criteria for Networks: **replace** measure 3.1.5 *The Board has established mechanisms to hear from and incorporate the voice and opinion of patients and families*
with
The Networks allows patient representatives and/or patients organisations to be involved in the overall governance of the ERN (for example through a Patient Advisory Board)

Section 2:
Monitoring system: proposed update

Section 2 outline:
Monitoring system: proposed update

Monitoring system: Process to continuously monitor the progress of the ERNs using key performance indicators

- Sources of information
- Main improvement suggestions from the stakeholders
- Proposal of the main changes suggested for the monitoring system

Stakeholder's activities and literature review

Sources of information	
Literature review monitoring	Scientific literature: 1779 screened , 45 papers included Grey literature across 12 countries worldwide, 19 web resources explored
Survey among ERN coordinators and HCPs	309 invited, 111 responses
Survey among patient representatives	120 invited, 82 responses
Survey among members of the BoMS	28 invited, 11 responses
First stakeholder conference	105 participants: ERNs, patient reps., BoMS, EC/HaDEA
Group discussion with EC / HaDEA	8 representatives
Group discussion with ePAG/EURORDIS	20-30 representatives
Group discussion with MWG	11 MWG members

Main inputs collected from the stakeholders' activities

- Review current indicators and consider adding/removing indicators as needed
- Short-term and long-term indicators related to patient experience and perspective are needed
- Increase patient involvement in all aspects of the monitoring process
- Streamline the implementation of the monitoring process to improve the quality of care

Surveys

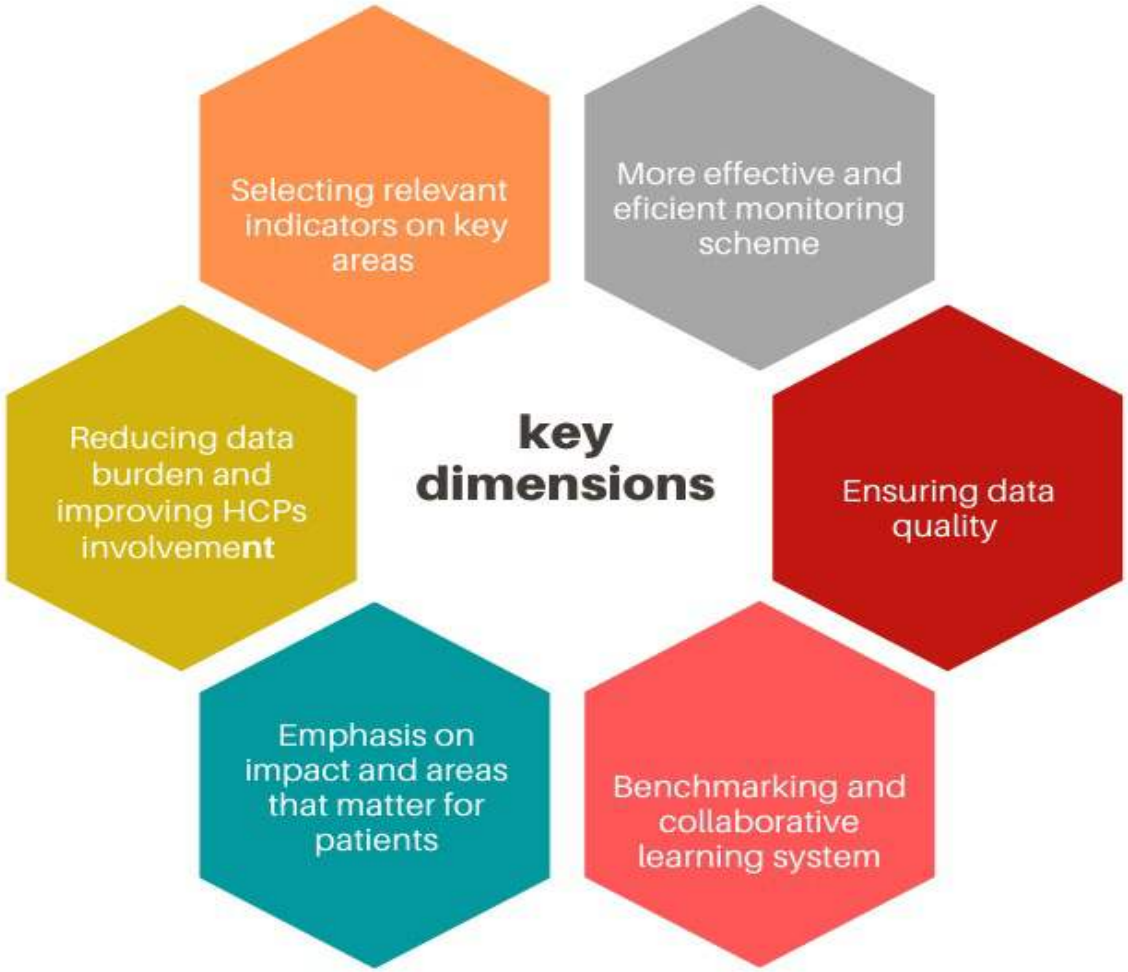
- Lack of clinical outcomes or specific indicators per ERN
- Consider reviewing and extending the list of the current set of indicators (not all are relevant, additional indicators are needed)
- Issues & challenges regarding data collection, validity and reporting at HCP level
- Lack of patient representation in the monitoring system (design, selection and analysis of results)
- Lack of incentives for the HCPs to provide data
- Improvement of the CPMS and patient registries (as causes or low performance)
- ERNs/HCPs interested in receiving feedback based on the monitoring data

Conference

- Simplify the system / reduce the burden of the monitoring process
- Facilitate communication within the ERNs/with stakeholders
- Better integrate the monitoring process with the overall system
- Highlight how ERNs are adding value via the monitoring outcomes
- ERNs should be viewed as a learning system, benchmarking within each ERN

Other sources

Monitoring system



Quality Indicators

- Useful to monitor improvement efforts
- Importance, reliability, validity
- Easy to read and understand
- Available in a timely fashion
- Comparable across members and, as much as possible, with other countries/other ERN
- Selected from reliable sources
- Co-designed in dedicated working groups
- Reached by consensus among different stakeholders
- Integrated with the patients' care pathways

Reducing data burden and improving HCPs involvement

1. Consider data reporting at HCP level *(validated by the ERN coordinator after their inclusion into the reporting system)*
   a) Higher involvement and accountability for HCPs
   b) More accurate data collection (data entry validation)
   c) Possibility for benchmarking exercises within the ERN
   d) Reducing variability among HCPs - ERNs
2. Consider reducing or adjusting the frequency of the reporting: once a year (depending on data quality)
3. Consider including the Hospitals CEO's commitment of facilitating resources for data collection in the support letter of the assessment process
4. Consider to evaluate the availability of resources for data management and collection at HCP level into the evaluation system
5. Consider updating the reporting system to include the features previously mentioned

Ensuring data quality

Improving the current indicators' definition and updating guidelines for data entry and data collection

1. Indicator description sheet sections (for each of the final indicators included):
   a) Relevant area
   b) Definition
   c) Clarification
   d) Rationale
   e) Dimension
   f) Structure-Process-Outcome
   g) Formula
   h) Source
   i) Frequency
   j) Examples
   k) Comments
   l) References
2. Provide recommendations for data entry systems that facilitate accurate data entry and pre-processing.
3. Provide recommendations to automate data collection

More effective and efficient monitoring system

1. **Ongoing data collection and reporting system:** Users can enter data at any time instead of having to wait until the reporting period
2. **Propose target values, thresholds or improvement objectives**: to promote improvement efforts

Emphasis on impact and areas that matter for patients

1. Involve patients in the different phases of the monitoring process (including selection of clinical indicators that are relevant for patients)
2. Considering involving patients representatives in the Monitoring Working Group
3. Prepare data analysis report addressed to patients and other stakeholders
4. Use the monitoring system to estimate and link with the impact of the European Reference Networks
5. Transparency on data results

Benchmarking and collaborative learning system

1. Establish **periodicity for data feedback** (quantitative and qualitative)
2. Provide **recommendations to interconnect the monitoring system** with the evaluation and the assessment process
3. Place emphasis on the **learning process among ERNs** (e.g., Learning webinars among ERN coordinators or ERN data managers)
4. **Learning activities at country level** (among HCPs belonging to the ERNs)

Selection of indicators covering relevant areas

1. **Modification/refinement of the current indicators (to be included in the reporting exercise of 2022)**

2. **Consider adding at least two new indicators in the reporting exercise of 2022**

3. **To be introduced in the future (progressive inclusion, as a quality improvement process and plan)**

Modification / refinement of current indicators

- **Better exploitation of the existing indicators:**
  - If the reporting is done by HCPs, the system will allow to build sub-set of indicators better representing the involvement of the HCPs
  - Adding qualitative content to identify causes of lower performance (quality improvement)

Example:

- **Total number of new patients referred to the HCPs participating in the ERN with the diagnosis of a disease / condition that fall within the scope of the ERN**
  - **% of HCPs that have equal or more than xx new patients within the reporting period**
  - **Add qualitative content: e.g., Main causes for HCPs reporting "0" new patients**
- **Total number of patients entered into the CPMS**
  - **% of HCPs that have equal or more than one new patient entered into CPMS**
  - **Add qualitative content: e.g., Main causes for HCPs with "0" new patients**

Modification / refinement of current indicators

- **Improve accuracy:**

  Patient representation

  it could be improved by better definition and focusing on specific activities that are more relevant for patients.

- **Removal:**

  Number of individual ERN website hits

  There are other standard metrics for reporting or comparing web traffic

  Training, conferences and papers are better metrics to identify knowledge spread

Potential indicators to monitor national integration

Indicators	Reported by
Number of HCPs participating as national or regional centres of expertise on RD	ERN/HCP
Amount of funds received from a National Public Program	ERN/HCP
Nº ERN Coordinators and/or ERN Members/ Affiliated Partners included into national policy-making bodies	ERN/HCP
Existence of a procedural organization and/ or legal definition of other ERN integration-related procedures	ERN/HCP
Existence of a referral system to the ERN (including the Alignment of national care pathways with ERN referral systems to ensure ERN accessibility according to the needs of MS)	BOMS
Existence of RD national/regional research programmes	BoMS
Existence of a governmental Compassionate Use Program for rare diseases	BoMS
Existence of a national/regional official directory of social resources for patients with disabilities	BoMS
Existence of national schemes promoting access to Respite Care services for RD patients and their families	BoMS
Existence of national public schemes supporting Therapeutic Recreational Programmes	BoMS
Existence of programmes to support rehabilitation of RD patients	BoMS
Existing policy/decision to ensure long-term sustainability of the RD plan / strategy	BoMS
Amount of funds allocated for ensuring RD plan / strategy sustainability	BoMS
Number of rare diseases screened for newborns at national level	BOMs
Number of national disease-specific registries for rare diseases	BOMs

Potential indicators to capture patient's experience and involvement

Indicators	Reported by	Source
Perceptions or level of satisfaction on how ePAG advocates and clinicians are working together as a team to advance the ERN goals	ePAG	e-PAG
Listed as co-authors of consensus statements and Clinical Practice Guidelines	ERN	e-PAG
Percentage of ERN WGs with ePAG advocates participating as members	ePAG	e-PAG
Patient representatives are members of the ERN Registry governance structure and/or ERN Registry Working Group (Yes/No)	ePAG	e-PAG
Number of patient journeys or surveys to capture patients' needs that have been discussed with ERN clinicians	ePAG	e-PAG
Percentage of sub-thematic areas where patient needs have been captured through a Patient Journey (or a survey on patients') and results have been discussed with ERN clinicians	ePAG	e-PAG
Percentage of outcome measures identified with the input of ePAG advocates	ePAG	e-PAG
Nº of patients' organizations in the development of RD research strategies	ERN	Consortium
Patient satisfaction regarding their involvement in ERN activities	ePAG	Consortium
Patients perceived degree of benefit from the participation in CPMS	Patients/ ERN	Consortium
Patient perceived degree of benefit from the care provided by the HCPs	Patients/ ERN-HCPs	Consortium

Other indicators to be included in the future

Indicators
Specific clinical indicators at ERN level
Healthcare provider compliance to clinical guidelines
Sustainability indicator to measure the organisational and economic efficiency
PROMs (i.e. Quality of life)
Resources (funding) provided for supporting the activities performed by patient organisations

Section 3
Scheme of the evaluation process: proposed design

Section 3 outline:
Scheme of the evaluation process

Scheme of the evaluation process: to estimate the added value of the ERNs after 5 years of performance.

- Sources of information
- Main improvement suggestions from the stakeholders
- Draft proposal for the scheme of the evaluation process:
  - Workflow of the proposed process
  - Documentation to review
  - Operational criteria for ERN and HCP (Core and extended)

These proposals are open for debate and further suggestions.
Your participation is very important.

Stakeholders' activities and literature review

Sources of information	
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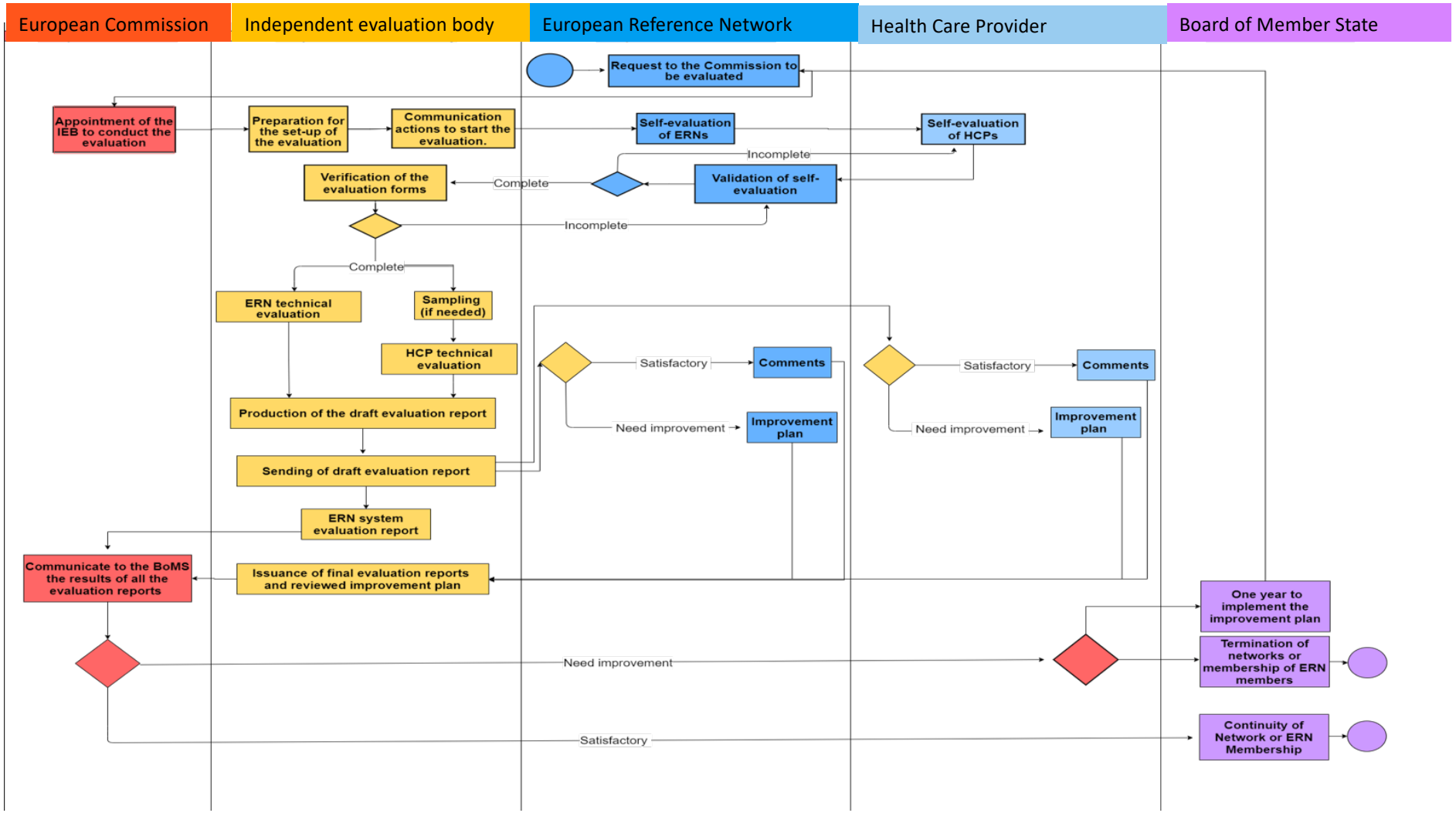
Main inputs collected from the stakeholders' activities From surveys:

- **ERN evaluation:**
  - To evaluate if patients' health outcomes have improved
  - Collaborative clinical activities among Network members
  - Indicators measured
  - Evaluation of patient experience
- **HCP evaluation:**
  - Active participation in the ERN (clinical, educational and research activities)
  - Patient reported outcomes
  - Collaboration with patient organisations
  - National networking
  - Clinical expertise

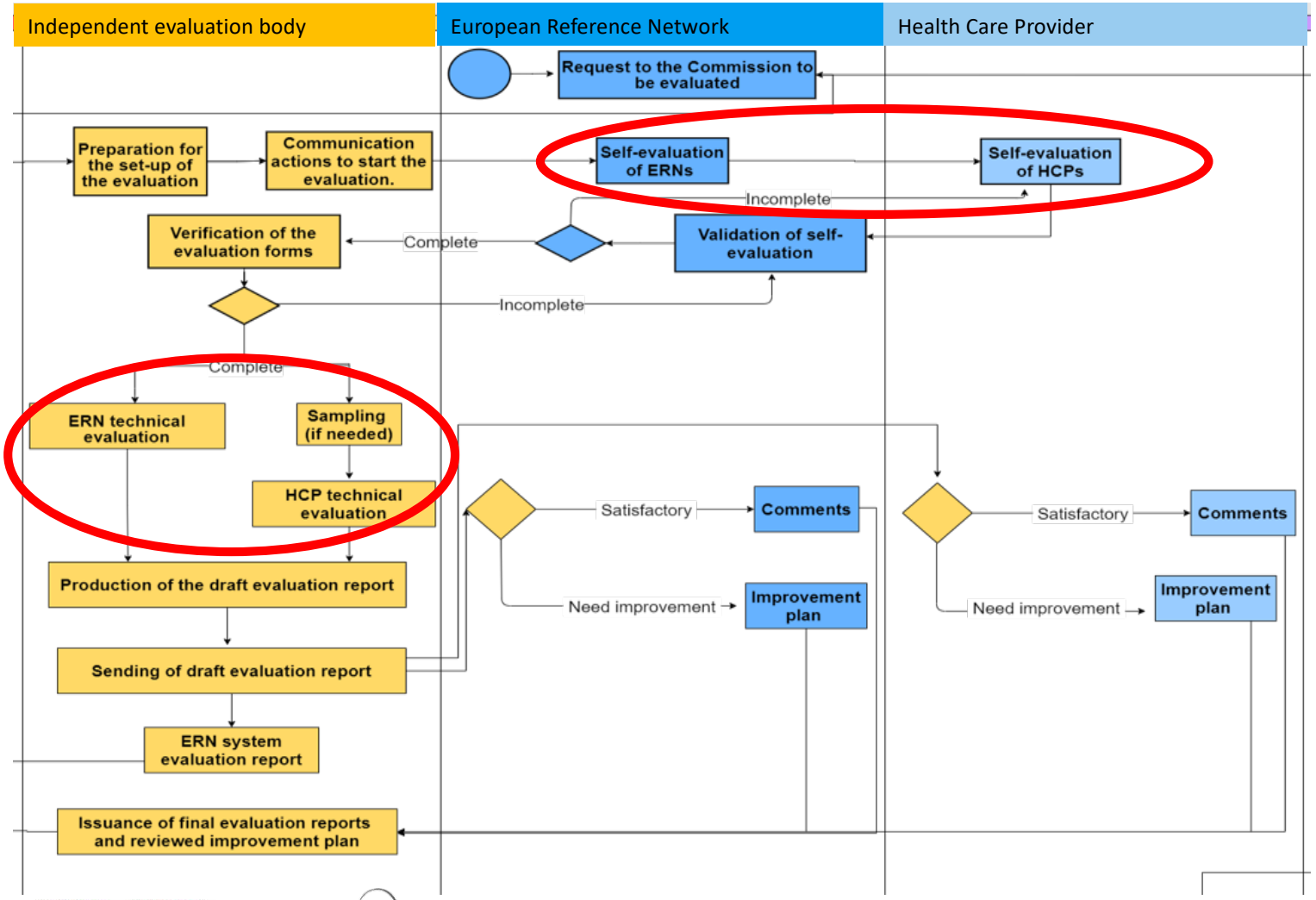
Main inputs collected from the stakeholders' activities From the previous conference:

- **ERN evaluation:**
  - Achievement of initial mission, aims and plans
  - ERN impact
  - ERN activities
- **HCP evaluation:**
  - HCP expertise
  - HCP contribution and participation within the ERN

Process of evaluation (proposal)



Process of evaluation (proposal)



Evaluation methodology (main activities)

Self evaluation

- By ERN and HCPs
- Overseen by ERN coordinator

Technical evaluation

- By IEB
- ERN evaluation: documentation review, interviews with ERN and WP leaders and patient representatives
- HCP evaluation: documentation review, on-site audit

Draft evaluation report

- By IEB
- Separate reports for each ERN and each HCP and for the ERN system as a whole: two months to send comments
- If not satisfactory, an improvement plan has to be elaborated by ERN/HCP and be reviewed by IEB

Final evaluation report

- By IEB
- Final separate reports for ERNs and each HCP (including reviewed improvement plans if they have been requested)
- Final ERN system evaluation report for EC
- In case of risk of termination, BoMS will receive the reports and the improvement plans and decide whether or not to offer one additional year to implement improvement plans

Documentation review:
A core part of the evaluation process

ERN evaluation:

ERN self-evaluation

Monitoring indicators

Grant reports

(objectives outlined, tasks performed by the work-packages, results achieved)

Sample of deliverables generated

(webs, reports, educational materials, research papers…)

Assessment application and report

(assessors' comments and recommendations)

Documentation review:
A core part of the evaluation process

HCP's evaluation:

HCP self-evaluation

Monitoring indicators

Specific evidence related to HCP expertise and quality of care

Specific evidence related to contribution and participation in the ERN

Assessment application and report

(assessors' comments and recommendations)

Development of operational criteria

Analysis & integration of different sources of information

- Objectives set out in **Article 12(2)** of Directive 2011/24/EU.
- Criteria and conditions for the Networks set out in **Delegated Decision 2014/286/EU.**
- Recommendations and suggestions obtained from the **consultation with the stakeholders** regarding the evaluation: surveys and conference.
- The **literature review** and mapping exercise regarding the evaluation.
- The **objectives** included in the **Framework Partnership Agreements** signed by the ERN coordinators.
- The current **assessment operational criteria.**

Operational criteria for the evaluation of ERNs

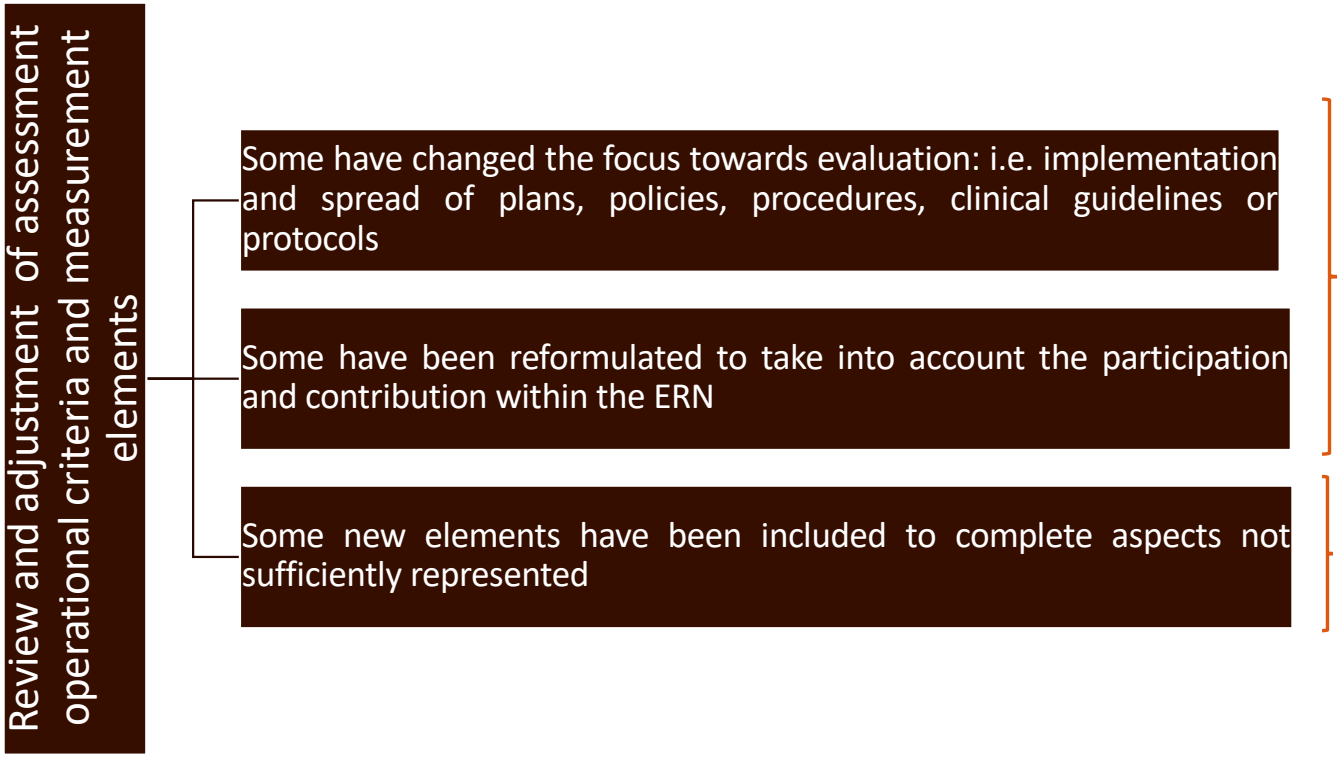
- A total of 27 operational criteria, classified in 8 areas have been developed

AREA	NUMBER OF CRITERIA
1. ERN strategy deployment (ERN grant reports evaluation)	4 criteria
2. Governance and coordination	4 criteria
3. Clinical care (guidelines, multidisciplinary teams, e-health)	4 criteria
4. Quality, patient safety and outcome measures	4 criteria
5. Patient centred care	3 criteria
6. Contribution to research	3 criteria
7. Continuous education, training, and development	2 criteria
8. Networking and collaboration	3 criteria

Examples of ERN operational criteria

2. GOVERNANCE AND COORDINATION		
2.1	**The ERN has established a clearly defined governance framework that ensures appropriate network coordination and oversight**	
Measurement Elements: functional mechanisms to facilitate governance		
	2.1.1	The structure and the implementation of the rules of procedure of the network's coordination board have facilitated the organization of tasks and the incorporation of new members.
	2.1.2	A professional functional management support for the Network is in place.
	2.1.3	Mechanisms to maintain the level of collaboration within the Network members as well as its affiliates have been put into practice.
	2.1.4	Healthcare Providers have been involved for specific tasks, sharing responsibilities among all the members of the Network.
2.2	**The ERN has developed regular evaluation and monitoring processes enabling the assessment of the Network's progress**	
Measurement Elements: monitoring of the activities of the ERN		
	2.2.1	An ERN dashboard or similar has been implemented to monitor the activity, outcomes, and initiatives of the Network and its Members
	2.2.2	There is an internal assessment of Healthcare Providers' participation
	2.2.3	HCP professionals' satisfaction with the performance of the ERN is periodically evaluated
	2.2.4	Key ERN outcomes can be demonstrated
	2.2.5	ERN activities encompass a wide geography and range of HCPs
2.3	**The ERN has established mechanisms for the integration of patient organizations in the strategical actions**	
Measurement Elements: involvement of patient representatives		
	2.3.1	Patient representatives have been included in the governance framework of the Network.
	2.3.2	The Board has incorporated the opinion of patients and families when outlining strategies.
	2.3.3	Patients and support groups are major stakeholders in ERN-related activities.
	2.3.4	The Networks measure and monitor the level of collaboration between ERNs/HCPs and patients in meetings, projects and working groups.
2.4	**The ERN has implemented actions to ensure the sustainability of the Network**	
Measurement Elements: planning for sustainability		
	2.4.1	The ERN has identified goals, opportunities and threats for the future.
	2.4.2	The ERN has evaluated the organizational and economic viability of the Network.
	2.4.3	The ERN has ensured its connection with other existing networks, authorities, health systems, etc. for the long-term sustainability.

Operational criteria for the evaluation of HCPs



Two levels suggested for the evaluation process:

CORE criteria and measurement elements

Extended criteria and measurement elements for this evaluation process (strategies for their accomplishment to be established in the next years)

Operational criteria for the evaluation of HCPs

- A total of 32 operational criteria, classified in 9 areas have been developed

AREA	NUMBER OF CRITERIA
1. Patient centred care	10 criteria
2. Organisation and management	7 criteria
3. Research and training	2 criteria
4. Exchange of expertise, information systems, and e-health tools	4 criteria
5. Quality and safety	3 criteria
6. Competence, experience and outcomes of care	3 criteria
7. Human resources	1 criterion
8. Organisation of patient care: multidisciplinary team	1 criterion
9. Facilities	1 criterion

Examples of HCP operational criteria

1. PATIENT EMPOWERMENT AND PATIENT CENTRED CARE (10 criteria)		
1.1	**The Healthcare Provider has implemented strategies to ensure that care is patient-centred, and that patients' rights and preferences are respected.**	
Measurement Elements		
	1.1.1	The Healthcare Provider's commitment to patient-centred care is formally and consistently communicated to patients and their families
	1.1.2	Processes are implemented to assist patients and their families in knowing who is providing their care, and the role of each person on the multidisciplinary care team.
	1.1.3	**Approach to education is multidisciplinary**
	1.1.4	**Patient and family educational needs are identified**
	1.1.5	**Barriers to learning are identified**
	1.1.6	**Education activities are recorded in the medical record**
	1.1.7	Patient education materials appropriate for readers of varying literacy levels and for speakers of different native languages are available and distributed.
	1.1.8	The Healthcare Provider provides patients and their families with written information about the facility, the organisation, and its specific area of expertise.
	1.1.9	The Healthcare Provider gives patients and their families written information about their rights and responsibilities.
	1.1.10	**The Healthcare provider implements a policy so that staff consider the preferences of patients (social, religious, cultural), when planning care.**
	1.1.11	A policy and procedure to disclose unanticipated outcomes and complications to patients and their families, as appropriate, are implemented.
1.8	**The Healthcare Provider implements a pain identification and management protocol**	
Measurement Elements		
	1.8.1	**In hospitalized patients, pain is identified with a standardized scale three times a day**
	1.8.2	**The scale is adapted to different ages and cognitive and sensorial situations of these patients.**

Dark bold: new criteria or measurement elements. *Orange: modifications in original criteria or measurement elements*

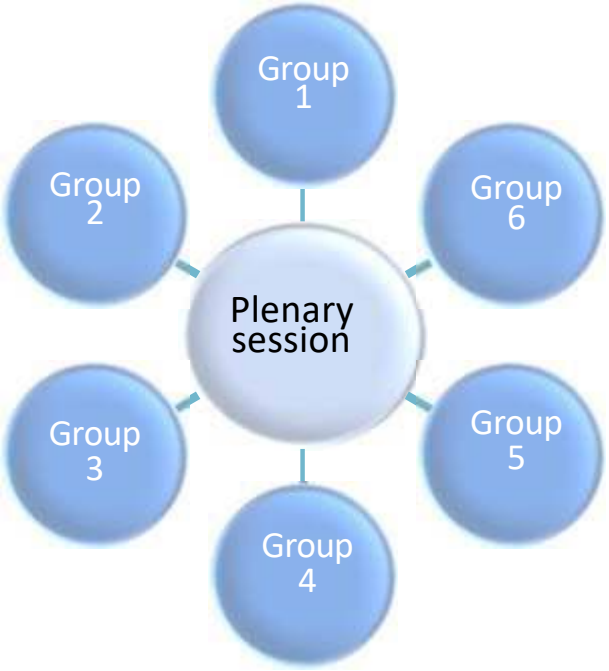
05

Conference methodology

What will we do today and tomorrow?

- Multiple 2-hour online sessions, spread over 2 days
- Mix of plenary sessions and break-out rooms
- Focussed on providing feeedback on the proposals developed

Your contribution in the break-out sessions is key!



Participants invited

- 24 ERNs → 1 representative per ERN
- 24 Patient Representatives (via ERNs)
- 28 Board of Member States → 1 representative per MS
- 5 additional stakeholders
- European Commission
- HaDEA

Participants

- 18 ERNs members
- 10 Patient Representatives
- 10 Board of Member States
- 3 additional stakeholders
- 3 HaDEA representatives
- 3 DG SANTE representatives
- 1 DG RTD representative

Breakout sessions – multiple perspectives

- 3 break-out sessions

- 6 parallel breakout groups including a combination of participants:
  - 3 ERN representatives
  - 3 patients' representatives
  - 1-2 representatives of the Board of Member States
  - 1-2 European Commission
  - 1 HaDEA representative

  - 1 moderator
  - 1 notetaker
  - 1 observer (consortium team member)

Break-out sessions – every voice counts

- Large diversity in backgrounds and knowledge / experience of attendees
- Moderators will provide all participants with the opportunity to contribute
- Please don’t be shy to ask questions if unclear or voice your opinion
- At some point, you may be asked to express your opinion / preference explicitly (vote), as it helps us to prioritize the work to be done

Agenda meeting day 1

09.00 - 09.05 hrs **Plenary 1 Welcome and opening**
09.05 - 09.15 hrs Purpose of meeting
09.15 - 10.15 hrs Update of the assessment, monitoring and proposed design for the evaluation

1 link to Zoom of Tuesday

10.30 - 11.00 hrs Break

11.00 - 12.30 hrs **Break-out session 1** | Assessment session

12.30 - 13.00 hrs **Plenary session 2** | Feedback Assessment sessions

13.00 - 14.00 hrs Break

14.00 - 15.30 hrs **Break-out session 2** | Monitoring session
15.30 - 16.00 hrs **Plenary session 3** | Feedback Monitoring sessions

Agenda meeting day 2

09.00 - 10.30 hrs **Break-out session 3** | Evaluation session

10.30 - 11.00 hrs **Plenary session 4** | Feedback Evaluation sessions

11.00 - 14.00 hrs Break

1 link to zoom for Wednesday

14.00 - 16.00 hrs **Plenary session 5** |Sharing conclusions of group discussions
Closing + future steps
Evaluation poll

Reflection of participants on: recommended changes for the assessment

Assessment process update 1: Simplification

Simplification is key

Integration application form and self-assessment

- General agreement. Also **simplification in the form** is very important by providing examples for criteria, measurement elements and documentations; and useful to have pre-filled forms

Remove measure 3.2.7 for HCPs about effectiveness of research

- General agreement. Important aspects are already covered by other measures; evidence for this measure is too vague; 'effectiveness of research activities' is to vague

Other feedback:

- The communication process should be very clear
- ERNs would like to be informed about how the application is progressing
- Although simplification is key, make sure that expectations of new applicants are managed upfront
- Consider collecting information directly from the actor involved (e.g., national authorities vs increasing burden on clinicians)

Assessment process update 2: Standardisation and clarification

Absolute vs relative minimum numbers of patients

Proposal is rejected by all but 1 group: although equal opportunities are important, clinical expertise is not a relative thing and absolute numbers are needed to guarantee high quality & safety

- In case numbers can not be reached by smaller centers, one could be affiliated partner
- ERNs may need to review their thresholds

Master manual

General agreement

→ It should be as short and simple as possible with a clear structure: who, when, and how.

→ One tool, but very specific on the responsibilities of each stakeholder

Other feedback:

- use the information of HCPs already accredited on national level assessment process
- hospital managers could be involved in application process (active contribution, business continuity plan)

Assessment process update 3: Standardisation and clarification

Sampling based on documentation review by BoN and IAB

General agreement: a more structured proposal and conducting purposeful audits, with similarities to the 2019 procedure

Other feedback:

- Include findings of the BoNs into the IAB report that is approved by the BoMSs
- Avoid unnecessary onsite audits (e.g., well-known and well-performing provider), and conduct onsite audits on any questionable cases.
- Consider a combination of onsite and online audits. Based on prior experience, online audits have worked well and in some cases better than onsite audits.
- Include feedback of the ePAG
- Transparency of the sampling procedure is important
- Give enough time to the centres to prepare.
- Possibility to audit the same hospital for different networks simultaneously.

Assessment process update 4: Patient engagement

… in governance

General agreement

- Considerations: recognition their work and time commitment through reimbursement; language barriers
- Suggestions on how this may be achieved include:
  - a minimum standard could be 2 patient representatives in the ERN board **(**Patients may already be well represented in the board of various ERNs)
  - Patient advisory board / ePAG could be made mandatory
  - Clear governance rules on patient engagement
  - Mechanisms to assess the effectiveness of patient-clinician partnership
  - Review the Directive to make patients representatives full members of the ERN

…. as part of the team that reviews documentation of new applicants

General agreement, to (re-)check whether patients are included as active members in all ERN

Input of participants on sustainability of the assessment process (1)

Should the number of applicants be limited?

- Yes (3 groups): current growth rate not sustainable, coordinator resources are not limitless
- No (2): cannot refuse centres with high expertise that are relevant in their field, expertise may be spread out over different HCPs in one country
- Not sure (1): not sure if the number of applicants will be too high

If so, how to limit the number of applicants?

- Limited nr of centres per country
- Discourage overrepresented MS, encourage underrepresented MS
- Move towards national networks with the coordinator represented in the ERN (not all expert centres can be ERN members)
- Only allow HCPs that add to the geographical or disease-specific balance
- Terminate inactive HCPs so that other centres can join
- NOT limit based on a country's population size but consider the prevalence of the disease

Input of participants on sustainability of the assessment process (2)

Criteria to comply with:

- Required compliance with implementation of e-health tools
- Having a proper termination process
- HCPs should bring clear commitment to contribute to the ERN (e.g. participation in guideline group)

Who can play role?

- All actors should play a role
- Alignment between BoMS and ERNs could discuss and align on ERN-specific limitation of nr of applicants (but some level of standardisation between ERNs is needed)
- National responsibility
- Patient organisations could play a role in encouraging underrepresented MS

Considerations

- Have a balance between limiting the nr. of applicants and needing additional expertise, geographical coverage etc.
- MS should have a standardised list of criteria for endorsement

Reflection of participants on the recommended changes for the monitoring system

Proposed changes to the monitoring system (1)

- **Reducing data burden and improving HCPs involvement**
  - General **agreement** on reducing **frequency of the reporting**, obtaining support from the **hospitals' CEOs for data collection** (during assessment and the evaluation)
  - **Data reporting at HCP level**
    - **Benefits:** easier, potential to improve data quality, reducing diversity of tools and standardise how data are collected, can be used/developed by the ERN
    - **Disadvantages/barriers:** validation by the ERN could be difficult as not everything is possible to be validated, potential higher burden for HCPs, need to update the current reporting system
    - **Suggestions**: (1) Some indicators can be reported at HCP level and some by the ERN coordination team
      (2) Centralise the data collection in hospitals belonging to more than 1 ERN
- **Ensuring data quality (<u>key improvement!)</u>**
  - **Agreement** on better **definition of the indicators**; ensure each indicator is interpreted in the same way
  - **Agreement** on strategies for **data automation**
  - Consider **standardizing data** across ERNs and HCPs (when feasible)
    - **Suggestions:** Clarify if the data provided by the HCPs is for the whole rare disease group of interest or for a specific rare disease→ representative for each rare disease
- **More effective and efficient monitoring system**
  - General **agreement** on **ongoing data collection:** Can reduce the workload as the influx of data is distributed over time and not provided in bulk. Can only be successful if it is automated, well-explained, and if HCPs can enter the platform and data at any time
  - **Target values**: More qualitative rather than quantitative, **agreement on having a threshold for minimum activities**, but not sure if this relates to monitoring or assessment

Proposed changes to the monitoring system (2)

- **Emphasis on impact and areas that matter for patients**
  - Transparency of indicators is crucial
  - Need to involve patient representatives in the monitoring system: **this can be done now**

- **Benchmarking and collaborative learning system**
  - Agreement on the periodicity for feedback: it is crucial after the effort performed by the members
  - Important that data from ERNs becomes available to reflect upon and learn from
  - Very relevant to define the purpose of the benchmarking→ not to compare among HCPs
    - **Suggestion:** Project managers within ERNs can learn from each other

Proposal of indicators (1)

- **Modification or refinement**
  - **Different perspectives** regarding **building sub-set indicators**
  - **Agreement** on refining the indicator on "**patient representation**" (expressed in some groups)
  - **Agreement** on excluding the indicator "**Number of individual ERN website hits"** (expressed in some groups)
  - **Agreement** regarding a better definition for: Total number of **new patients referred to the HCPs** participating in the ERN with the diagnosis of a disease / condition that fall within the scope of the ERN

  - Indicator: "**Number of MS with HCPs as full members or affiliated partners in the ERN"**:
    - Relevant indicator, but not for an ERN to act upon (EC and BoMS). Could be good information to manage expansion of the Network and should be public.
  - Indicator: "**Total number of patients entered into the CPMS":**
    - **CPMS should be improved**, is not very user-friendly and data reflected there are not 100% reliable. There are other indicators that could be used when registries become available.

- **Suggestions:**
  1. Formulating the recommendation on proving qualitative information in a positive way
  2. Consider the data processing burden when gathering qualitative data: predefined scales may be more helpful

Proposal of indicators (2)

Indicators for national integration: comments and suggestions

- All indicators seem to be important. Consider adding more than one indicator to measure national integration. However, the proposed indicators may not be relevant to measure the integration of the **specific ERN** in the Member State; they seem to be more general indicators for rare diseases.
- Considering including an indicator measuring the **level of social support**. This area is the most neglected in several countries.
- Regarding **feasibility**: ERNs have no legal means / influence over some of the proposed indicators
- National integration will also help to increase **patient involvement/perspective**
- The idea is very good but perhaps not the right indicators. Need a definition of what is integration for each country.

Preferred indicators:

- Existence of a procedural organization and/ or legal definition of other ERN integration-related procedures: clarify
- Existence of a referral system to the ERN (including the alignment of national care pathways with ERN referral systems to ensure ERN accessibility according to the needs of MS)
- Existence of RD national/regional research programmes
- ERN Coordinators and/or ERN Members/ Affiliated Partners included into national policy-making bodies
- Number of national disease-specific registries for rare diseases

Proposal of indicators (3)

Indicators to capture patient experience

- **Agreement** on including a **patient representative experience** indicator, but also "**clinicians' experience with patients**"
- Measuring **patient involvement in consensus statements** by whether or not they are listed as coauthors may not be sufficient
- Suggestion of **adding an indicator requesting a deliverable regarding patient involvement** (a more project-based approach)
- The indicators could be **reported by the patient committee** (to be more inclusive)
- It would be good to include some **indicators at patient level**
- Consider the **experience of patient associations** (also measure patient experience and satisfaction)
- **Disagreement** with including indicator on patient's perceived degree of benefit from the participation in **CPMS**. One group suggested to rephrase as 'perceived benefit of the case having been discussed through the CPMS'

Preferred indicators:

- Perceptions or level of satisfaction on how ePAG advocates and clinicians are working together as a team to advance the ERN goals
- Patient representatives are members of the ERN Registry governance structure and/or ERN Registry Working Group (Yes/No)
- Patient satisfaction regarding their involvement in ERN activities
- Some of these indicators have been developed by ePAG. A pilot exists in 4 Networks to use satisfaction as an indicator. Need to better understand the results.
- Percentage of ERN WGs with ePAG advocates participating as members
- Percentage of outcome measures identified with the input of ePAG advocates

Proposal of indicators (4)

Indicators for future reporting exercises:

- **Agreement** on the inclusion of **ERN-specific clinical indicators** (selected by each ERN) using a clinical approach (including PROMs and PREMs)
- **Agreement** on the inclusion of **PROMs**
- Include **indicators that are closely aligned to each ERN** to avoid a too "contractual approach" in the monitoring system.
- **Link between indicators and the objectives of each ERN** (3 objectives per ERN)

Reflection of participants on the proposal for the evaluation scheme

Evaluation scheme proposed

- **Steps proposed:**
  - Have a clear timeline to be able to prepare the evaluation
  - Evaluation should not as burdensome as the assessment process
  - Combine **on-site and on-line audits** (online audits increase participation, Include ERN coordinators on onsite audits)
  - **Improvement plan:** check if compliant prior to the 5 year evaluation and how should they be implemented and who is going to monitor it and time intervals.

- **Stakeholders:**
  - Directors/managers of the hospitals are important, should be included in the evaluation. How well has the ERN-mission 'landed' in the hospital?
  - The role of the MS have done to integrate themselves with the ERNs. **MS support** during the evaluation process as this may be a hindrance for the progress of some HCPs
  - Involve **patient representatives** throughout the evaluation process (e.g., online audits, interviews…)

- **Documents that should be taken into account**
  - Keep it lean!
  - The self-evaluation form and materials should be as simple and easy to use as possible
  - Some groups propose to use existing reports and deliverables to verify activities (and to avoid preparing ad-hoc documentation)
  - Clarify how to handle the availability to the documents from the monitoring and how and which to select (need to be recovered from the last 5 years)
  - Propose to develop (online) **templates** for some reports: list of e-health tools, other technology, etc.
  - Consider all possible sources of **patient experience measures** including patient satisfaction surveys collected by specific ERNs

Evaluation scheme proposed

- **Areas and criteria to be included**

ERN

- Evaluate the ERNs on what they could have possibly achieved in these past years; improvement in clinical outcomes are not feasible at this stage, but the long term added value of the ERNs should be the goal
- Generally areas defined for the ERN are already developed and covered in the grant and deliverables sent when the ERN justify the funding.
- Consider: SWOT analyses as part of the self-evaluation and relevant development in the ERN registries
- Consider financial criteria, which should involve MS support
- Take into account COVID pandemic in the first evaluation, activities that are recently funded thus less developed (ie. Registres), have a clear understanding of the nature of the network (funds the received, structure, scope etc.)

HCP

- The areas for HCP make sense.
- Should be focussed on what they can offer at a network level (using CPMS, performing webinars, distribute materials working packages, guideline development, etc.)
- Maybe human resources and multidisciplinary team have a low number of criteria
- Clarify that there are activities that are performed at ERN level that maybe are not needed at HCP level (ie. Evaluating patient needs or development guidelines)
- Focus on how is the acquired knowledge actually used to improve quality of care: adoption of documents/guidelines etc.

Participants would like to provide feedback on the specific criteria once they are drafted.

Evaluation scheme proposed

Barriers/challenges

- Worries about the bureaucratic and time-consuming process: simplicity is key
- Worries about the burden on the HCP. Potential lack of motivation to participate in the evaluation /ERN. So much time in controlling process.
- Lay language is key when patient representatives are involved

Facilitators

- Additional funding for HCP would be helpful, i.e: support of the local medical team: compensation for the work done by the coordinating centers
- The support from the Member States and European Commission is vital
- The BoN/coordinating team should be able to provide their view on the added value of specific HCPs in the network during the evaluation

Integration and sustainability

Elements to consider for the integration of the evaluation with assessment and monitoring

- Important to reflect on the initial assessment report and the goals and aims they had set at that stage
- Take advantage of the already collected monitoring data (no nee to input same data twice)
- Alignment between assessment and evaluation is good to evaluate the improvement of networks/HCPs. However, the evaluation should not only repeat the assessment process or the continuous monitoring process
- Important to demonstrate what is the added value of evaluation compared to assessment and monitoring

Activities to support the HCP/ERN before the evaluation period:

- Information (including the consequences of evaluation) and communication (formal announcement, ideally from the EC itself.)
- Help desk and communication process (including informative webinars)
- A clear definition of what is expected is important, so that doctors can understand. Provide examples
- A clear timeline and time to complete the form and prepare the process
- Good online tools, including template for documentation
- Requirements for audits should be received at least 1 month prior to the audit (In particular to prepare patient cases and avoid GDPR issues
- Strategies to encourage MS to provide coordination and administration support are needed.

Integration of the extended criteria into the assessment and the monitoring

- Agreement to track the progress over time

Future steps

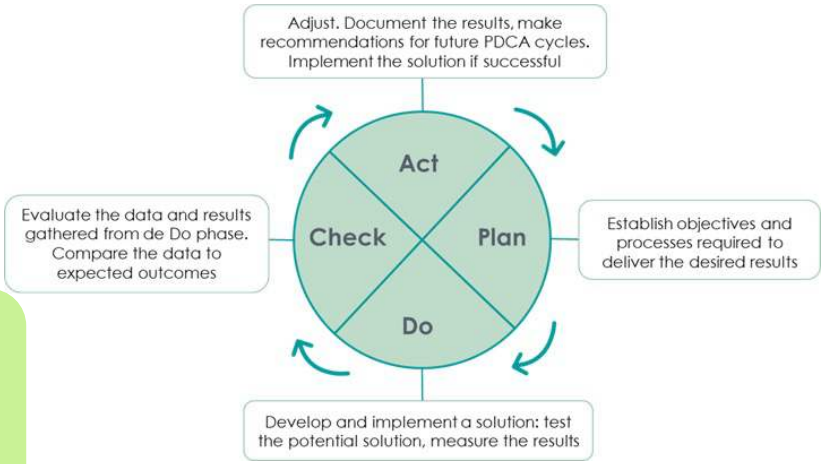
In the coming months, we will:

- ✓ Integrate findings from this conference into the work done for updating the assessment process and monitoring system
- ✓ Further develop the evaluation methodology, evaluation manual and toolbox with help of the findings from this conference
- ✓ Final version: January 2022

Your additional feedback is still very welcome in the coming 2 weeks!

Via email to amequis@fadq.org

Integrating all the knowledge



TASK 4 Development of an ERN **Quality Improvement System** and of the **AMEQUIS integrated model and toolbox**

Reviewing international standards

4 virtual meetings

Task 4.1

Developing an integrated ERNs' **Quality Improvement System** proposal

Task 4.2

Integrating, linking and structuring outcomes, conclusions, methods, tools and QIS, creating **AMEQUIS integrated model and toolbox**

The AMEQUIS model will consist of the PDCA quality improvement cycle

Thank you !

AVEDIS DONABEDIAN
INSTITUTO UNIVERSITARIO-UAB

NIVEL
Kennis voor betere zorg