# EUCERD Recommendations
# Quality Criteria for Centres of Expertise for Rare Diseases in Member States

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EUCERD
European Union Committee of Experts on Rare Diseases

# CENTRES OF EXPERTISE FOR RARE DISEASES IN EUROPE:

# THE CONTEXT

# Specificities of CEs

- To provide multi-disciplinary healthcare services (high quality and cost-effective care) to patients with conditions requiring a particular concentration of resources or expertise
- To act as focal points for medical training, research and information dissemination

# European context

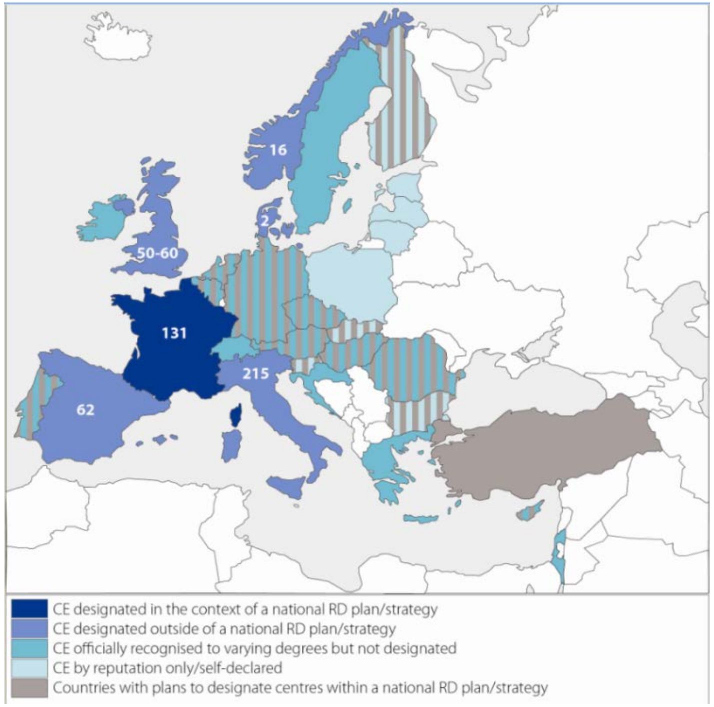
- Development of CE in the field of rare RD encouraged explicitly in:
  - Council Recommendation on an Action in the Field of RD (2009/C 151/02) (8 June 2009)
  - Directive on the application of patients' rights in cross-border healthcare (2011/24/EU) (9 March 2011)

# Countries with designated CE

A few countries have designated centres either at national or regional level:

| | |
|---|---|
| **1990 UK** | **(50-60 centres)** |
| **2001 Denmark** | **(2 centres)** |
| **2001 Italy** | **(215 regional centres)** |
| **2006 France** | **(131 centres)** |
| **2006 Spain** | **(62 centres)** |

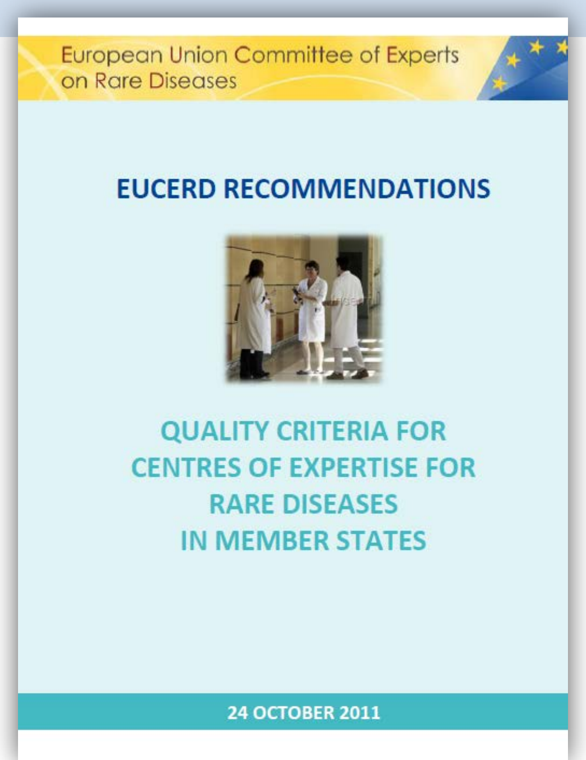
**Norway (16 centres)**



# Heterogenous designation processes

- Processes for designation in these countries differ greatly from one country to another:
- **In form**
  - Reflecting heterogeneity of national health care systems
  - Depending on budget allocation
- **In focus**
  - Specialised centres vs general centres
  - Clinical only vs clinical research
  - Focus on technology / expert intervention
- **In designation process**
  - Specific policy regarding RD or not
  - National vs regional approach

# EUCERD RECOMMENDATIONS



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EUCERD RECOMMENDATIONS

QUALITY CRITERIA FOR
CENTRES OF EXPERTISE FOR
RARE DISEASES
IN MEMBER STATES

24 OCTOBER 2011

# Scope of the Recommendations

**45 recommendations**

**4 main areas:**

- Mission and scope of CEs
- Criteria for designation
- Process for designation
- European dimension

# Recommendations: Definition of what is a CE

- CEs tackle diseases or conditions requiring **specific care** due to difficulty in establishing diagnosis, to prevent complications and/ or to set up treatments
- CEs are expert structures for the management and care of RD patients in a defined catchment area, **preferably national** and at international level if necessary

# Recommendations: Coverage of CEs

- The combined scope of all CEs within a MS **covers all RD** patients' needs even if they cannot provide a full range of services with the same level of expertise for each RD
- The scope of diseases covered by each CE, or by a CE at a national level, will vary depending on the **size of the country** and the structure of the health care system
- CEs liaise with other CEs at National or European level as appropriate
- A **national directory of formally designated CEs** is compiled and made publically available, including on Orphanet

# Recommendations: Patient focus of CEs

- CEs collaborate with patient organisations to bring in **the patients' perspective**
- CEs respond to the needs of patients from different cultures and ethnic groups (ie have **cultural sensitivity**)
- According to national/ international ethical and legal frameworks, centres of expertise should ensure respect of non-discrimination and non-stigmatisation of RD patients across Europe, within their sphere of competencies

# Recommendations: Competencies of CEs

- CEs bring together or **co-ordinate** within the specialised healthcare sector **multidisciplinary competencies**/ skills including paramedical skills and social services in order to serve the specific medical, rehabilitation and palliative needs of RD patients
- CEs contribute to building healthcare **pathways** from primary care
- CEs have links with specialised laboratories and other **facilities**

# Recommendations: CEs' role in spreading information

- CEs contribute to the elaboration of **good practice guidelines** and to their dissemination
- CEs provide **education and training** to healthcare professionals from all disciplines, including paramedical specialists and of non-healthcare professionals (such as school teachers, personal/ homecare facilitators) whenever possible
- CEs contribute to and provide accessible **information** adapted to the specific needs of the patients and their families in collaboration with the **patient organisations** and with **Orphanet**

# Recommendations: CEs role in research

- CEs **contribute to research**, to improve the understanding of disease and to optimise diagnosis, care and treatment, including the clinical evaluation of long term effects of new treatments

# Criteria for designation of Ces: Leadership and credibility

- High level of **expertise and experience** documented for example by the annual volume of referrals and second opinions, and through peer reviewed publications, grants, positions, teaching and training activities
- **Contribution** to state of the art **research**

# Recommendations: Multidisciplinarity and inclusiveness

- Demonstration of a multidisciplinary approach when appropriate, integrating medical, paramedical, psychological and social needs (e.g. RD board)
- Appropriate capacity to manage RD patients and provide appropriate advice
- Organisation of collaborations to ensure continuity of care
  - Between childhood, adolescence and adulthood
  - Between all stages of the disease

# Criteria for designation of CEs : Capacity of CEs

- **Appropriate arrangements** to improve the delivery of care and especially to shorten the time taken to reach a diagnosis
- **Capacity** to produce and adhere to **good practice guidelines** for diagnosis and care
- Capacity to propose **quality of care indicators** in their area and implement outcome measures including patient satisfaction

# Criteria for designation of CEs : Capacity of CEs

- Capacity to participate in **data collection** for clinical research and public health purposes
- Capacity to participate in **clinical trials**, if applicable
- **Quality management** in place to assure quality of care, including national and European legal provisions, and participation in internal and external quality schemes when applicable
- Consideration of **E-Health** solutions

# Criteria for designation of Ces: Links and collaborations

- Links and collaborations with patient organisations where they exist
- Links and collaborations with other CE at national, European and international level
- Appropriate arrangements for referrals within individual MS from/ to other EU countries where applicable

# Recommendations

- **Mechanisms will need to be in place to capture measures of:**
  - Leadership and credibility
  - Capacity and quality assurance
  - Appropriate links and collaborations

# Process for designation of CEs: Core principles

- **MS take action** concerning the establishment and designation and evaluation of CEs and facilitate access to these centres
- MS establish a **procedure** to define and approve designation criteria and a transparent designation and evaluation process
- The designation process at MS level ensures that the designated CEs have the capacity and the resources to fulfill the obligations of designation

# Process for designation of CEs: Designation criteria

- The designation criteria defined by MS are **adapted** to the characteristics of the diseases or groups of diseases covered by the CE
- CEs may not fulfill some of the designation criteria defined by the MS so long as the absence of fulfillment of these criteria does not impact on the quality of care and as long as CEs have a strategy in place to attain designation criteria in a defined time period

# Process for designation of CEs: Duration of designation

- The designation of a CE is valid for a defined period of time
- CE are **re-evaluated** on a regular basis through a process incorporated into the designation process at MS level
- The designating authority at MS level may decide to withdraw the designation of a CE if one or more of the conditions that formed the basis for designation is no longer satisfied or if there is no longer a need to maintain the national service

# Process for Designation of CEs

- **MS** responsible for designation process based on recommended criteria but adapted according to the MS
- Designation is for a defined duration and subject to quality-based review

# European dimension : Sharing experience and indicators

- MS with established CEs share their experience and quality indicators with other MS and co-ordinate their efforts to identify CEs for all RD patients at EU level

- This is an important principle but requires the co-operation of national acreditating and quality assurance bodies

# European dimension : Cross-border considerations

- MS should provide adequate information to professionals, citizens and POs concerning the **possibilities and conditions of access** to health care at national and international level in the field of RD
- Cross-border healthcare is organised where appropriate with designated **CEs in neighbouring or other countries** where patients or biological samples can be referred

# European dimension : Networking

- Networking of CEs is a key element of their contribution to patient diagnosis and care, to ensure that expertise travels rather than patients where appropriate; exchange of data, biological samples, radiological images, other diagnostic materials and e-tools for tele expertise are promoted
- **Designated CEs at MS level are the key elements of the future European Reference Networks**

# Thank you for your attention!

**Be the advocates of these recommendations**

Which can be found at

www.eucerd.eu

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