



"ERNs in action"

Parallel Session 7

Clinical Patient Guidelines and other Clinical Decision Support Tools

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Cornerstone of the ERNs system

- Knowledge generation and production of **clinical practice guidelines and patient pathways**

CLINICAL PRACTICE GUIDELINES





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Clinical Practice Guidelines

- "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options" (IOM)

Clinical Decision Support Tools

Aim: to support healthcare providers' decision-making **when the amount and/or quality of available evidence prevent to develop a CPG.**

- **A position paper** designates a detailed policy report that usually explains, justifies, or suggests a particular course of action.
- **A consensus statement** is the product developed by an independent panel of experts, usually multidisciplinary, convened to review the research literature for the purpose of advancing the understanding of an issue, procedure, or method.
- **A scientific statement** represents the collective opinions of the convened expert panel.
- **Etc...**



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CPG are addressing:

- Complex diagnostic or therapeutic strategies
- Several possible interventions
- Comparison between interventions for efficacy, effectiveness, efficiency (optional), side effects, quality of life, acceptability, benefits/risks ratio.

Common Diseases

- Well and standardised established and recognised methodology
- Principles of evidence-based-medicine

Rare Diseases

- Challenge for the development of CPG
- lack of sound evidence, scientific publications, clinical trials etc.

Kremp O, Dosquet P, Rath A. Professional clinical guidelines for rare diseases: methodology. *Orphanet J Rare Dis.* 2012;7(Suppl 2):A12. Published 2012 Nov 22. doi:10.1186/1750-1172-7-S2-A12

Guidelines for Rare Diseases



- “.....guidelines specific to RDs **are difficult to find** amongst the mass of recommendations available for more frequent diseases.”

- Pavan S, Rommel K, Mateo Marquina ME, Höhn S, Lanneau V, Rath A. Clinical Practice Guidelines for Rare Diseases: The Orphanet Database. *PLoS One*. 2017;12(1):e0170365. Published 2017 Jan 18. doi:10.1371/journal.pone.0170365

- **lack** of systematic reviews and strong evidence
- CPG are **substituted by** other types of Clinical Decision Support Tools (**CDST**) based in **opinions and expertise** of healthcare professionals
- CDST are very valuable but **heterogeneous** in terms of **nomenclature, quality and methodology** and should **not be confused with the evidence based CPGs**.
- Need of a **well-defined methodology** for the development of **CDSTs**
- **CDSTs** will represent the **best available knowledge** in the absence of CPGs.

- Most ERNs **actively working** in the development of CPGs
- **Different levels** of maturity or organisational approaches:
 - Some ERN in the **phase of implementation** or adaptation
 - Others **starting to set-up** their plans and priorities.
- Important differences between ERNs on **the n° of available CPGs or CDSTs**
- Some ERNs using CPGs produced by National/International organisations and/or the **support of Professional Societies or Academic Institutions**





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Dimensions and criteria to be fulfilled by the ERNs related with Clinical Practice Guidelines and Patient Pathways

- 4.- Patient Care
- 5.- Multi-disciplinary approach
- 6.- Good practice, outcome measures, and quality control

Clinical guidelines and patient pathways are the corner stone of the ERNs





4.1 CRITERIA

The Network promotes good quality and safe patient care by fostering timely and pertinent diagnosis, treatment, follow-up and management across the Network.

4.1.5 MEASURE

The Network implements guidelines and/or protocols to support transition and continuity of care from childhood, through adolescence, and into adulthood, where applicable.

The Network collaborates with its Members, Affiliated Partners, and patient organizations to develop, disseminate, and implement these guidelines and protocols. The Network identifies and monitors a quality indicator for transitions of care.

6.3 CRITERIA

The Network develops and/or implements clinical guidelines and cross border patient pathways.



6.3.1 MEASURE

The Network has a formal process for developing or selecting and disseminating clinical guidelines.

CPG comprise recommendations on the care of patients with specific conditions, based on the best available research, evidence, and practice/experience.

The process for developing or selecting clinical guidelines may include using content experts; a consensus panel; Grades of Recommendation Assessment, Development and Evaluation (GRADE); or the Appraisal of Guidelines Research and Evaluation (AGREE) II instrument,

When developing and/or selecting clinical guidelines, the Network obtains patient and family input.

6.3.2 MEASURE

The Network adheres to ethical criteria, is transparent, and avoids any conflict of interest when developing and implementing clinical guidelines, patient pathways, and other clinical decision making tools.

The Network Board should define specific rules and procedures to ensure transparency and adherence to ethics requirements.

6.3.4 MEASURE

The Network monitors implementation of established clinical guidelines and patient pathways to encourage consistent use across its Members and monitor their appropriateness. Information is used to make ongoing quality improvements.

The Network should establish both process and clinical outcome measures before implementing any clinical guideline or pathway.



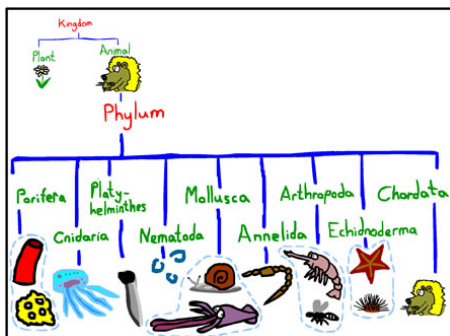
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Ongoing activities to support ERNs in the development of Clinical Practice Guidelines

- ✓ Contract on Taxonomy
- ✓ Tender on Clinical Practice Guidelines





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Tender: European Reference Network: Clinical Practice Guidelines (CPG) and other Clinical Decision Support Tools (CDSTs)

- The overall purpose of the call for tender is to provide **assistance to the commission to support the ERNs and their healthcare providers** in the process of development, appraisal and implementation of Clinical Practice Guidelines (CPG) and other Clinical Decision Support Tools (CDSTs)

This site is a part of 



Ted·eTendering

Calls for tenders from the European institutions

<https://etendering.ted.europa.eu/cft/cft-display.html?cftId=3788>

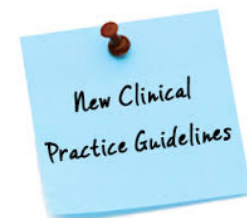


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Tender on Clinical Guidelines (Public Health Programme WP 2018)

Areas and actions to be addressed

- 1. Creation of and support to the bodies, task forces and panels** involved in the Clinical Practice Guidelines (CPGs and Clinical Decision Support Tools (CDSTs)),
- 2. Methodology:** Review tools and state of art and adapt/develop a standardized methodology for the ERNs Clinical Decision Support Tools development
- 3. Training & capacity building:** different audiences and level of training
- 4. Clinical Guidelines development:** At least **48 new CPG & 120 adaptation** of existing CPG
- 5. Dissemination, evaluation and quality control**



For and with the ERNs and patients

- “....For the performance of the tasks defined in this tender, the contractor **will work in constant collaboration and consultation with the ERN Coordinators** and other designated representatives of the Networks in charge of CPGs including **healthcare professionals, experts and patient representatives**.
- Consultation with the Members of the **ERN Board of Member States** will take place as well. Other stakeholders would also be consulted upon request of DG SANTE.



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Tender characteristics

- **Estimated total value:** 4 mill EUR
- **Deadline for proposals:** 15/02/2019
- **Duration of the contract:** 48 months:

“....it may be decided by the Contracting Authority **to award, to the same Contractor, an additional contract** for developing additional clinical guidelines if needed, using a negotiated procedure without prior publication of a contract notice.



Thank you for your attention



Further information:
http://ec.europa.eu/health/ern/policy/index_en.htm