



Towards EU guidelines on prudent use of antimicrobials in human health

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Background



- COMMISSION NOTICE. Guidelines for the prudent use of antimicrobials in <u>veterinary medicine</u> (2015/C 299/04)
- Request from DG SANTE to ECDC to draft EU guidelines for the prudent use of antimicrobials in <u>human medicine</u>: 21 March 2016
- Aim: To provide generic elements of good practice on prudent and appropriate use of antimicrobials for all the main spects of human medicine in the EU
- Final draft to be delivered by ECDC to DG SANTE:
 31 October 2016

Purpose of EU guidelines on prudent use of antimicrobials in human medicine



 To provide generic elements of good practice on prudent and appropriate use of antimicrobials for all the main aspects of human medicine



Scope of the guidelines



- Principles of prudent and appropriate use of antimicrobials
- Take into account:
 - Council recommendations on the prudent use of antimicrobial agents in human medicine (2002/77/EC)
 - "One Health" approach
 - Existing EU policy on antimicrobial resistance
 - Commission guidelines for the prudent use of antimcirobails in veterinary medicine (2015/C 299/04)
- Two parts:
 - Clinical practice
 - Resources, systems and processes that EU health systems should provide
- Constructed in such a way that implementation of teh guidelines can be evaluated in a straightforward manner

Principles for guideline development



Transparency and management of conflicts of interest

Evidence-based approach

- Systematic review and appraisal of existing evidence
- Existing relevant guidelines
- Expert opinion

Broad involvement of stakeholders

- Member states
- EMA
- Professional associations
- Public, patients, consumers

Public consultation

Evaluation and monitoring – indicators, auditing

Challenges



- Address all key actors
- Evaluate generalisability of recommendations
- Account for behavioural, cultural, organisational and legal variability in Europe
- Encourage adaptability
- Ensure endorsement by the target audience(s)
- Facilitate implementation
- Short deadline



Methods, roles and timeline

Definitions and elaboration of scope



- Ensure consistent definition of antimicrobials
- Define prudent and appropriate use

Review of evidence



 Review of available systematic reviews on antimicrobial prescribing

Cochrane database of systematic reviews

Pubmed

EMBASE

Review of available relevant guidelines
 National guidelines (Member States, USA, others)

Other sources

Council recommendation

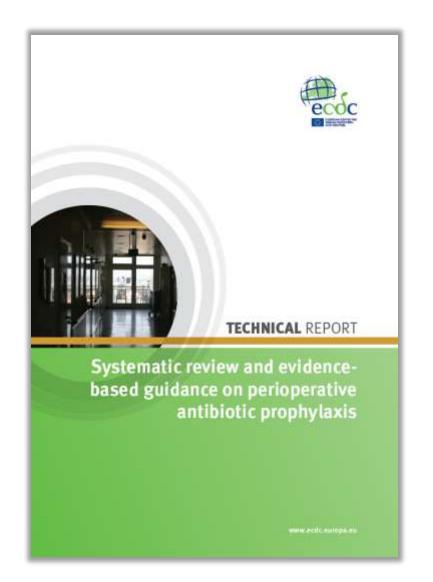
National action plans on antimicrobial resistance

Other grey literature sources

Evaluation with use of assessment tools (PRISMA, AGREE)

ECDC guidelines







Transatlantic Taskforce on Antimicrobial Resistance (TATFAR)

Summary the modified Delphi process for common structure and process indicators for hospital antimicrobial stewardship programs

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> > June 12, 2015

Content (first draft)



- Definitions
- Scope and purpose
- General principles
- Responsibilities (see next slides)
- Awareness raising
- Education
- Surveillance and monitoring
- Research

Responsibilities (1)



- International
- National / regional
- Healthcare facilities (resources, systems and processes)

Responsibilities (2)



Prescribers

- General
- Community prescribers / General practitioners / Family medicine
- Hospital prescribers (incl. prescribing nurses)
- Long-term care facilities

Non-prescribers

- Pharmacists
- Nurses
- Microbiologists
- Infection control practitioners
- Others
- Patients / Public
- Educators / Academics
- Pharmaceutical industry

For each recommended measure:



- Description [incl. reference]
- Possible adaptation to suit different settings
- Indicators
 - Structure
 - Process
 - Outcome (would need adjustment)
- Enabling factors / Examples of good practice [incl. reference]

Next steps



- 9-10 June 2016 (ECDC): Expert meeting
 - 10 experts with research and experience in antibiotic use policies and development of guidelines
 - Review of early draft of guidelines
- July-August: Public consultation (web)
- 12-14 September (ECDC): Advisory Forum
- 16 September (ECDC): Stakeholder meeting
 - professional associations
 - scientific societies
 - o patients' (users', consumers') associations
- 31 October 2016: Final draft delivered to DG SANTE