ENOVAT

European Network for Optimization of Veterinary Antimicrobial Treatment

1 Purpose

The ENOVAT network aims to develop evidence-based veterinary practice guidelines to promote best practice for prevention, diagnosis and management of key infectious diseases in veterinary medicine. The guidelines will be developed following the AGREE II.

The aim of the present document is to describe the Operating Procedure (OP) that will be used by the drafting group (DG) chairs and members for guideline development.

2 Election of topics and commissioning of guidelines

The ENOVAT Guidelines Core Group is responsible for commissioning guidelines and managing the portfolio. Topics for guidelines can be proposed by any member of the ENOVAT.

Criteria for adopting proposals are: a) the amount and critical importance of antimicrobials used for treatment of the disease condition, b) the potential to impact animal and public health derived from such antimicrobial use, and c) lack of similar European guidelines.

3 Key persons and responsibilities

The ENOVAT Guidelines Core Group will appoint the chair and approve the composition of the DG. All members of the DG must complete a disclosure form concerning conflict of interest which will be evaluated by the DG chair and the chair of the ENOVAT core-group. The DG can include panel members for specific tasks, those members are named ancillary members and are not participating in making recommendations. The role of ancillary members should be stated in the manuscript.

The DG should be composed of 10 – 20 people and include experts in the narrow field under investigation and people with a wider perspective. The DG should include clinical experts, field

veterinarians/practitioners, microbiologists, pharmacologists and key opinion leaders. The DG should include panel members proficient in the methodology of systematic reviews, the GRADE approach and guideline development processes. Inclusion of animal owners (pet owners/farmers) in the panel is strongly encouraged and if left out, their opinion must be sought in a different way as described in section 6, Format of guidelines.

The DG should include at least one member from the Guidelines Core Group to take part in the guideline development process and assist the DG panel. DG members should be selected amongst ENOVAT members whenever possible; however, the required expertise may be sought outside ENOVAT. When composing the DG panel the balance in terms of gender and country should be sought.

4 Finances

The ENOVAT guidelines project is funded by Cost Action. Co-funding of activities from other sources is encouraged. Financial support from industry is not allowed.

5 Timeline

The expected time from appointment of the DG to the submission of the guidelines for ratification by ENOVAT is 12-18months after appointment of the DG panel.

6 Format of guidelines and assessment of evidence

Guidelines should address the key issues and questions should focus on antimicrobial management and interventions where a change in practice is desirable or where controversy exists.

Questions to be addressed in the guidelines are decided upon by the DG in a consensus process. Guidelines may contain background questions and foreground questions. Background questions

will typically provide information on prevalence and incidence of a disease and its forms. Background questions should not investigate standard information unless associated with uncertainty or controversy. Foreground questions typically concern management and interventions. They are the most important part of the guidelines and are prioritised over background questions.

All questions should be phrased as research questions. The PICO (Population Intervention Comparator Outcome) framework should be used when phrasing foreground questions that relate to comparative treatment questions. For diagnostic comparative questions the PIT (Patient group, Index test, Target condition) format should be used.For each PICO research question the evidence from the veterinary field should be assessed based on properly conducted systematic reviews (including the "a priori" development of protocols). In the absence of published systematic reviews, a systematic review must be conducted by the methodology panel members of the drafting group.Protocols must be approved by the ENOVAT methodology taskforce chair and registered at Syread.

Prior to the methodology members conducting the systematic review, all panel members must select outcomes and rate their importance in a consensus process.

For the purpose of selecting questions and outcomes the perspective of the end-users (farmers and animal owners) must be sought. This can be done in several different ways and the DG chair or his/hers delegate is responsible for organizing this. To exemplify, a survey addressing the importance of outcomes can be sent to a group of end users appointed by the DG members in the different countries.

The GRADE approach should be applied to assess and grade the available evidence and to grade the recommendations. The GRADE approach is described in detail elsewhere and all DG members

must familiarize themselves with the approach. An assembly of video tutorials on the GRADE approach from the McMaster University will made availbale to all panel members.

Evidence is assessed for each outcome across studies and may be categorized into good, moderate, low and very low. The latter two categories may be fused into one (very/low). The direction (for or against an intervention) and the strength of the recommendations (strong or weak) will be based on the quality of the evidence of available data taking into consideration also the balance of benefits and harms to the animal, aspects of public health, and resources.

Though the strength of a recommendation is not only based on the quality of the evidence, the latter is an important element to inform the decision, and the quality of the evidence supporting the recommendations must always be described in the document.

All considerations that determined the decisions and all challenges faced in making specific recommendations should be made explicit. Making recommendations based on sparse evidence does not preclude, and explicitly encourages, further relevant research.

The final recommendations will be subjected to a consensus vote. The level of agreement should be displayed and reasons for not agreeing should be listed in the final document. Consensus is defined as at least attaining 60% agreement for final recommendations.

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7 Internal ENOVAT & External review

ENOVAT guidelines shall undergo review by the ENOVAT network and by an external review group before submission for publication. Key veterinary organizations and national stakeholders may be involved for review and dissemination purposes.

The final draft shall be approved by the ENOVAT Guidelines core group prior to submission.

8 Dissemination Strategies

The ENOVAT aims to establish contact with a broad panel of veterinary organizations and agencies in order to promote dissemination and implementation of ENOVAT guidelines and position papers.

ENOVAT guidelines must be published in OPEN ACCESS veterinary journals. The most appropriate journal will be decided by the DG taking into consideration the audience targeted by the guidelines.

The published documents shall be available on the ENOVAT homepage.

9 Joint Guidelines and Liaison with external organizations

The ESCMID Study Group for Veterinary Medicine (ESGVM) is the preferred guidelines partner of ENOVAT. ENOVAT also encourages collaboration with other key veterinary organizations. The DG is expected to liaise with the relevant veterinary organizations in order to achieve official endorsement or publish joint guidelines. Both situations may require an internal review process by the veterinary organization(s) involved.