

17. SPECIFIC TERMS OF REFERENCE FOR THE NRC FOR *HELICOBACTER PYLORI*

AIMS

- Each National Reference Centre (NRC) must meet both the general and the specific terms of reference.
- In the specific terms of reference, the NRC tasks dedicated to each selected pathogen or group of pathogens are described.
- These aim to guarantee the knowledge, the know-how and the epidemiological surveillance expertise of each NRC.
- The task list is not exhaustive and can be modified in function of the requirements and the evolution of knowledge and techniques.
- In the event a NRC is unable to perform a specific task, this can be subcontracted to preserve the knowledge in the NRC. If this is the case, quality of the subcontracted task has to be proven and assured.
- Each list of specific terms of reference is divided into three parts: 1) a reminder of the specific missions, 2) a description of the tasks that the NRC must be able to do including the competencies and 3) a list of the tasks that will be asked in a particular context.
- The type of analysis indicated for each specific pathogen in each particular situation (diagnosis or confirmation, typing, sensitivity to antimicrobial substances, virulence...) is defined.
- The collaboration with national and international surveillance systems (e.g. ECDC) and when relevant with other reference centres (European Medicines Agency, food safety reference centres, veterinary reference centres, ...) is also a priority.

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SPECIFIC MISSIONS

1. To confirm the clinical diagnosis by invasive (e.g.: culture, PCR) and by non-invasive diagnostic techniques (ELISA or *Helicobacter* antigen test) in clinically relevant contexts.
2. To study the resistance of *H. pylori* to antimicrobial agents and assess the level of primary antibiotic resistance of circulating strains.
3. To collaborate with existing networks (e.g. European *Helicobacter pylori* Study Group, other European *Helicobacter pylori* NRC, Belgian *Helicobacter pylori* Study Group,).
4. To participate in national surveillance, transfer microbiological data (through e-health reporting) and contribute to the presentation and interpretation of the results in a public health approach.
5. To interact with epidemiologists and other NRC's with the aim to sustain/adapt the use of the various outputs (with regards to quality of care, recommendations for control/prevention, ...).

THE NRC MUST BE ABLE TO (LEVEL OF COMPETENCES)

1. Confirm the clinical diagnosis by classical culture and/or molecular techniques.
2. Determine the antibiotic susceptibility and resistance by appropriate phenotypic testing methods.
3. Determine the presence of antibiotic resistance genes by molecular methods (i.e. 16S (R to tetracyclines) or 23S rRNA (R to macrolides), GyrA resistance mutations (R to quinolones),...).
4. Assist laboratories in implementing routine microbiological diagnostic techniques (culture, identification and antimicrobial susceptibility testing methods).
5. Detect the presence of specific antigen in stools.
6. Detect the presence of specific antibodies in serum.
7. Validate existing and new diagnostic tests and formulate recommendations for the implementation or optimization of classical diagnostic techniques in clinical laboratories.
8. Differentiate *Helicobacter pylori* from other (non *H. pylori*) *Helicobacter* spp. or non-*Helicobacter* species.
9. Manage a collection of representative strains. and organize external proficiency control tests (ring tests) for culture, identification and antimicrobial susceptibility testing of *H. pylori*.
10. Have access to whole genome sequencing and expertise in species specific bioinformatics analysis.

TASKS THAT WILL BE ASKED IN A PARTICULAR CONTEXT

1. To determine the antibiotic susceptibility/resistance pattern through a representative subset of strains.
2. To participate in the development of external quality control (EQA) of *H. pylori* culture and susceptibility testing in collaboration with other European NRCs and diagnostic companies and to stimulate the participation of clinical laboratories (in Belgium and in other countries).
3. To participate in collaboration with international organisation (QCMD) to the set up validation of EQA programmes for molecular diagnostics for *H. pylori* (PCR for detection of *H. pylori* and assessment of resistance mechanisms to macrolides).
4. To ensure a good representativeness for surveillance purposes, including geographical coverage when relevant.