18. SPECIFIC TERMS OF REFERENCE FOR THE NRC FOR HEPATITIS A, B, C, D, E VIRUSES

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 perform the diagnosis by serology and molecular techniques.
2. To participate in surveillance of antiviral resistance of circulating strains.
3. To participate in the assessment of vaccine impact for HBV.
4. To collaborate with existing networks.
5. 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.
6. 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)

HEPATITIS A

1. Confirm the presence of specific antibodies.
2. Validate and perform a fast diagnostic test for clinical samples.
3. Detect the presence of viral genome by molecular techniques.
4. Genotype and subtype the isolates.
5. Perform fast diagnostic tests in non-invasive samples (oral fluid, …) in the frame of outbreak investigations.
6. Have access to whole genome sequencing and expertise in species specific bioinformatics analysis.

HEPATITIS B

1. Confirm the presence of specific antibodies and antigens.
2. Validate and perform a fast diagnostic test for clinical samples.
3. Detect the presence of viral genome by molecular techniques.
4. Genotype the isolates.
5. Perform HBV genome sequencing to detect recombinant HBV strains and to detect mutant variants.
6. Perform resistance genotyping (to detect mutations that convey resistance to HBV antivirals.
7. Have access to whole genome sequencing and expertise in species specific bioinformatics analysis.

HEPATITIS C

1. Detect HCV RNA in clinical samples by molecular techniques.
2. Confirm the presence of anti-HCV antibodies in clinical samples.
3. Validate and perform a fast diagnostic test for clinical samples.
4. Genotype the isolates.
5. Further characterise HCV strains for detection of drug-resistance mutations in protease, NS5A and NS5B-polymerase genes by NGS.
6. Have access to whole genome sequencing and expertise in species specific bioinformatics analysis.

HEPATITIS D

1. Detect and confirm the presence of anti-delta antibodies.
2. Detect HDV RNA in serum.
3. Have access to whole genome sequencing and expertise in species specific bioinformatics analysis.

HEPATITIS E

1. Detect and confirm the presence of anti-HEV antibodies.
2. Detect HEV RNA in serum and faeces.
3. Be able to genotype and subtype HEV strains.
4. Have access to whole genome sequencing and expertise in species specific bioinformatics analysis.

TASKS THAT WILL BE ASKED IN A PARTICULAR CONTEXT

1. To perform the HDV and HEV diagnosis in clinically and laboratory suspected cases.
2. To characterize HBV (mutant variants, drug resistance).
3. To characterize HCV (mutant variants, drug resistance).
4. To collaborate with blood safety control laboratories, i.e. Red Cross, Biological Standardisation of Sciensano.
5. To collaborate with veterinary and food microbiology centres to compare HEV strains between humans, animals and food in a One Health approach.
6. To participate to seroprevalence studies when requested.
7. To perform genome sequencing and phylogenic analysis in case of nosocomial HBV or HCV outbreak.
8. To perform the verification by laboratory testing, of the claimed performances and conformity of IVD devices, for HBV, HCV and HDV, within the Belgian EURL (European Union Reference Laboratory Network) after its designation by the European commission under Regulation (EU) 2017/746. (http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2017:117:TOC)