Meeting COVID protocol dd 19-3-2020

Present: 5.1.2e, 5.1.2e, 5.1.2e, 5.1.2e

Protocol overview:

1. Introduction and rationale
2. Objectives:
    a. Primary:
        i. correlation between (or superiority of) saliva vs standard NP and OP swabs
    b. Secondary:
        i. Comparison of viral load between these two
        ii. Viral and bacterial co-infections (related to (severity of) illness). Viral: standard respiratory viruses (included in Haarlem lab PCR, 5.1.2e is in charge). Bacterial: Pneumococcal/meningococcal (RIVM-IDS). Need storage/send to RIVM 5.1.2e).
        iii. (Also) aliquot and store for future immunology, microbiome and even mycobiome
        iv. Follow longitudinally along with questionnaires on symptoms (including household) -> plan: have people collect the samples themselves (to do: check publications on virus 'survival' with freezing at home at -20)
        v. transmission to household. -> only saliva samples (non-WMO)
3. Study design: cohort study, duration, setting (hospital + at home after discharge).
4. Study population: children and adults who present with respiratory symptoms (COVID symptoms) and are admitted to the hospital (+ members of their household). Sample size: need only 10 positive (10 kids, 10 adults, ideally) individuals needed for proof of principle.
5. Treatment of subjects: NA
6. Investigational product: NA
7. Non-investigational product: NA
8. Methods:
    a. Endpoints
    b. Procedures
    c. Storage -> Streeklab/RIVM? -> need to ask Streeklab if aliquoting + storage is feasible. -> 5.1.2e
        i. Samples should be used for microbiome, viruses, and antibodies -> which storage media are needed? Need to aliquot. How and where?
        ii. Freeze at -80
        iii. For antibodies: need EDTA probably (RNA protect?)
    d. Lab work
9. Safety reporting
10. Statistical analysis
11. Ethical considerations: need informed consent forms (IC) and patient information folder (PIF)
12. Administrative aspects, monitoring, publication
13. Structured risk analysis: NA

Task division:

Protocol:

laboratory work (except microbiota) ->5.1.2e and 5.1.2e: will look into storage media, etc. What's possible regarding transportation, freezing. -> virus needs to 'survive' in -20 freezer for prolonged time (days-weeks).

Study design, cohort description. 5.1.2e, 5.1.2e

Introduction & rationale. 5.1.2e

SOPs: pathogen detection (check); check with SG which SOPs are already in place (saliva collection, feces collection, also at home); need to adapt so that they comply with safety measures. Microbiome in saliva: check with 5.1.2e and 5.1.2e. 5.1.2e, 5.1.2e

PIF: 5.1.2e, 5.1.2e

IC: 5.1.2e, 5.1.2e

Plans for later

Later: Contact 5.1.2e later for input/view on added value ->5.1.2e and 5.1.2e through 5.1.2e and 5.1.2e

Potentially later on we can contact participants again to obtain serum for measuring IgG-levels (WMO-plichtig).