ALERRT

African coaLition for Epidemic Research, Response and Training

FACILITATING RAPID ETHICS REVIEW OF PROTOCOLS DURING OUTBREAKS

Reaching Out (PREPARE & GLOPID-R Meeting)
Brussels, September 21, 2018

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EDCTP

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African CoLition for Epidemic Research, Response and Training (ALERRT) Overview

- EDCTP-funded Programme (10M Euros, 5 years) to build a patient-centred clinical research network to respond to epidemics across sub-Saharan Africa
- Multidisciplinary consortium of 21 partner organizations from 13 countries (9 African, 4 European)
- Work Packages
  1. Clinical research network
  2. Lab network to support clinical research
  3. Data management/ICT infrastructure
  4. Response framework to facilitate rapid implementation of clinical research
  5. Training and capacity development
  6. Social sciences support for community engagement and evidence-based policy change
  7. Governance

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ALERRT & WHO Ethics Workshop

- "Ethics preparedness: Facilitating Ethics Review During Outbreaks"
- Dakar, 20-21 March, 2018 (before the Global Summit of National Ethics/Bioethics Committees)
- Objective: to identify practical processes and procedures related to ethics review that support national and international outbreak preparedness and response, and facilitate the timely implementation of research.
- Participants
  - National Research Ethics Committee ((N)RECs), National Bioethics Committees or other concerned institutions from 29 countries
  - WHO Global Health Ethics Team; Research, Ethics and Knowledge Management Unit
  - ALERRT Consortium

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Dakar Ethics Workshop – Format

- Discussed 6 topics for action to facilitate rapid & sound ethics review during outbreaks
  1. Preparing (N)RECs for outbreak response
  2. Pre-approval of protocols
  3. Multi-country review
  4. Interaction/Coordination between (N)RECs and other research oversight bodies & public health authorities
  5. Data sharing
  6. Preparedness for export of samples to third countries
- Produced observations, recommendations & action items for each topic

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1. Preparing (N)RECs for Outbreak Response

- **Observation:** Rapid review of research should not involve reduced quality of ethics review or rushed decision-making. Rapid review rather means being prepared for emergencies, and having clear procedures in place prior to an event.
- **Recommendation: A national standard operating procedure (SOP), or a framework for emergency response ethical review** should be developed and adopted by (N)RECs and/or countries' competent authorities.
- **Action Item:** Regional workshops will be held with the aim of drafting a "model SOP" for emergency response ethical review for adaptation and adoption at country level or through sub-regional mechanisms.
- ***Status:*** *WHO will follow up, in collaboration with partners. Note: R&D Blueprint is an important stakeholder.*

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2. Pre-review of Protocols

- **Observations:** Term “pre-approval” seems too rigid; “pre-review” is generally preferred. This process should entail review of full or partial protocols prior to outbreaks so the (N)REC may provide advice. Once the context of a specific outbreak is known, the final protocol should undergo rapid review, which should be accelerated since key ethical issues would have been considered during pre-review, and the (N)REC is already familiar with the protocol.
- **Recommendation: Clarify the terminology and expectations of pre-review, pre-approval, generic protocols etc., and propose specific terminology** to be agreed upon (in multiple languages as appropriate; at a minimum in English, French and Spanish).
- **Action Item:** Draft a white paper that explores and clarifies the terminology and expectations of pre-review, and proposes specific terminology.
- ***Status:*** *ALERRT and WHO will identify someone to take the lead on drafting this paper*

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3. Multi-country Review

- **Observations:** Multiple ethical reviews can present different/complementary perspectives, but can also introduce delays or contradictions. For multi-country protocols, the sovereignty of national reviews must be respected, while avoiding unnecessary duplication of effort.
- **Recommendations:** (a) Mechanisms should be explored for **regional, multi-country emergency ethical consultation** to support rapid review at the country level. (b) The **role of WHO in multi-country ethical review** in Public Health Emergencies of International Concern (PHEICs) and "other similar emergencies" should be clarified.
- **Action Items:** (a) WHO should lead a process for consultation on "multi-country rapid ethics review," involving sub-regional mechanisms as appropriate. (b) WHO should define the scope of "other similar emergencies" and conduct regional consultations on WHO-supported review of multi-country research protocols during PHEICs and "other similar emergencies."
- ***Status:*** *WHO will follow up*

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4. Interaction/Coordination between (N)RECs, Other Research Oversight Bodies & Public Health Authorities

- **Observation:** In emergencies there is a need for sound and rapid decision-making and action, and to align research activities with regulatory and public health decision-making.
- **Recommendation:** Emergency SOPs should include procedures for communications between (N)RECs and other key national stakeholders, e.g. national regulatory authorities, public health authorities, and relevant research stakeholders.
- **Action Item:** Procedures for communications between (N)RECs and other key stakeholders should be specified in the "model SOP" in Action Item 1
- ***Status:*** *See Action Item 1 (WHO will follow up, in collaboration with partners. Note: R&D Blueprint is an important stakeholder)*

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5. Data & Benefit Sharing

- **Observations:** Rapid sharing of research results has the potential to influence decision-making in ongoing and future outbreaks. Early in an outbreak response, it is not always possible to have a complete understanding of data and samples that will be available and how they might be shared. (N)RECs should distinguish between sharing underlying (raw) datasets, and sharing the results of research (i.e., analysis & interpretation of data).
- **Recommendations:** (a) (N)RECs should request a **preliminary data & sample sharing plan** that outlines how the results of research and the samples will be made available for public health and other purposes, particularly for the benefit of the affected population/country. (b) A **full data & sample sharing plan** should be submitted to (N)RECs within a defined period.
- **Action Item:** The requirement for submission of preliminary and full data and sample sharing plans should be specified in the "model SOP" in Action Item 1.
- ***Status:*** *See Action Item 1*

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6. Preparedness for Export of Samples to Third Countries

- **Observation:** Protocols should define the conditions under which biological samples will be collected, stored, shared and used. Some (N)RECs or in-country entities may have a model Material Transfer Agreement (MTA).
- **Recommendation:** (N)RECs should engage with relevant national authorities (MOH, environmental e.g. Nagoya protocol, legal experts etc.) to ensure that MTAs are ethically sound.
- **Action Item:** An inventory should be conducted of resources used by (N)RECs related to MTAs.
- ***Status:*** *R&D Blueprint may wish to follow up on this*

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Existing WHO Tools

- Facilitate rapid and sound ethics review during outbreaks, including practical considerations of
  - Various clinical dilemmas
  - Determining the boundary between what constitutes human subjects research, and what does not (i.e. outbreak response)
- WHO developed a platform to help stakeholders integrate ethics in all aspects of outbreak response
  - “Integrating ethics in infectious disease outbreaks”
  - https://extranet.who.int/ethics/

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Luebo, DRC 2007

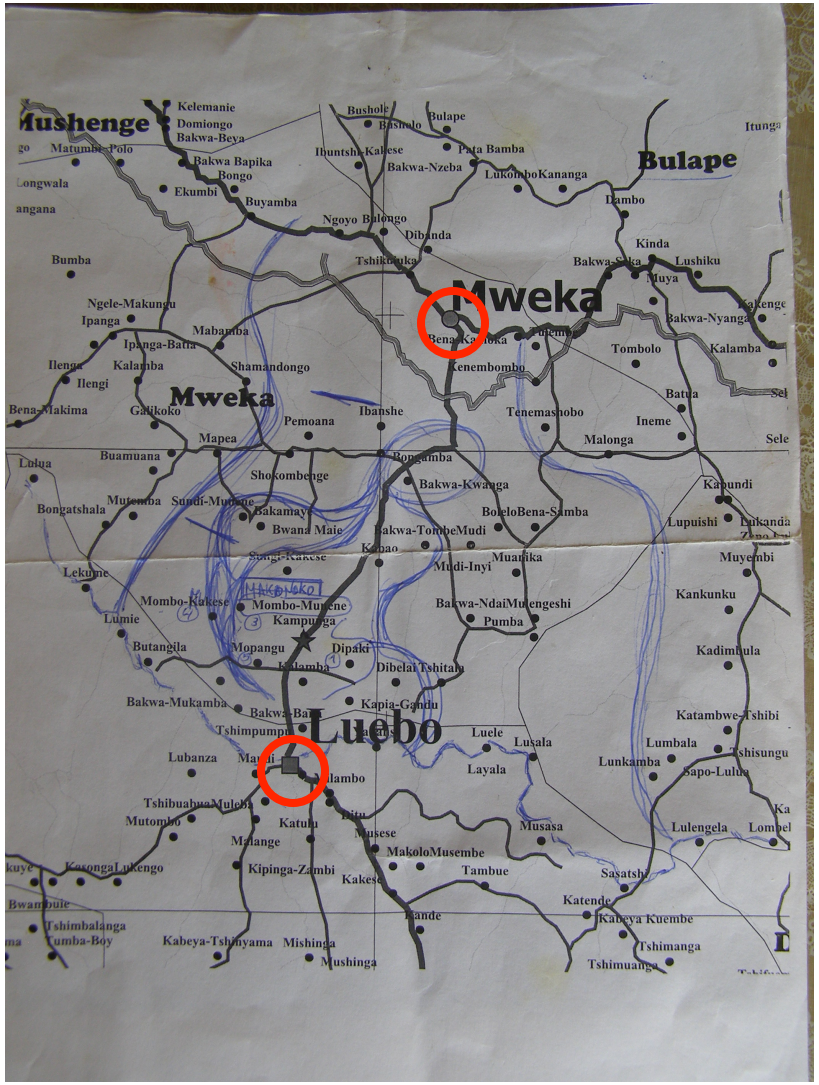
Participants

- Ministry of Health, DRC
- WHO/GOARN
  - WHO-Geneva
  - WHO-AFRO
  - Centre International de Recherches Médicales de Franceville, Gabon (CIRMF)
  - Health Canada
- Medecins sans Frontiers (MSF)
- Red Cross
- CDC

Objectives

- Stop transmission
  - Active surveillance, isolation & treatment, laboratory confirmation
  - Support community education
- Describe the outbreak
  - Case definition: suspected, probable, confirmed
  - Line listing of cases and contacts
  - Chains of transmission
    - Identify contacts to follow
    - Index case/village
- Plan studies to test hypotheses

Two Laboratories – CDC, Health Canada

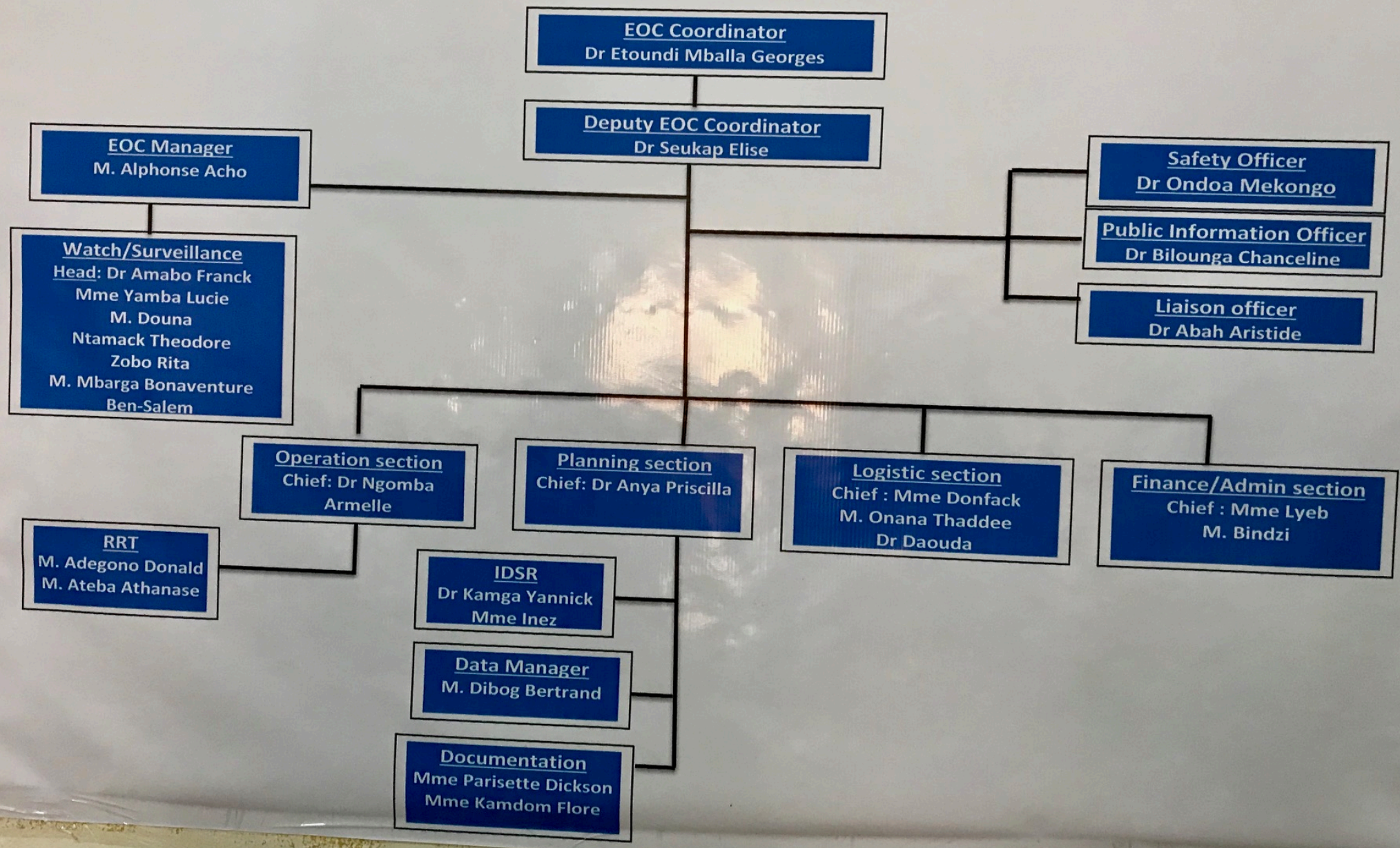


Coordination

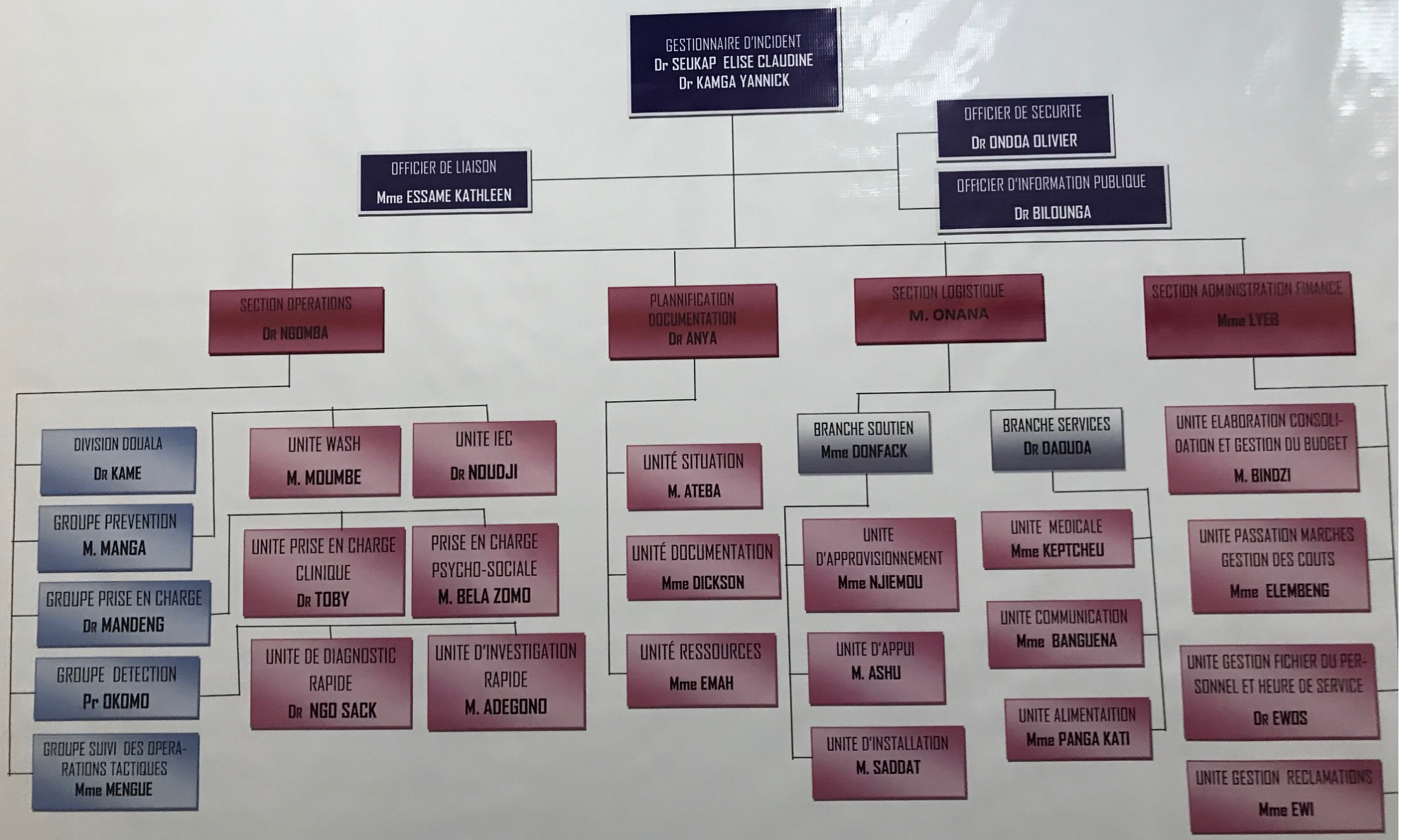
Preparation

Practice

Emergency Operations Center (EOC)



ORGANIGRAMME DU SYSTÈME DE GESTION DE L'EPIDEMIE DE CHOLERA



Strengthen (N)RECs to Facilitate Review of Research Protocols during Outbreaks

- Applied Public Health Research
  - Epidemiological – serosurveys, household transmission studies, case-control studies, descriptive clinical-epidemiological studies, effectiveness of public health interventions
  - Social sciences
  - Ecological
- Clinical intervention studies
  - Clinical research
- Spectrum of research – outbreak response to full research protocols
- (N)REC reviews protocols, may exempt if outbreak response
  - Strengthen capacity, integrate in coordination of outbreak response
  - EOC – Research Pillar, other arms of Operations
  - Context depends on country, principles remain the same – coordinate, plan, practice

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Merci! Thank you!

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