



Translating Evidence Into Recommendations In The Context Of Rapidly Evolving Evidence And Urgency: Ebola Rapid Advice Guidelines

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www.uwoanesthesia.ca

LHSC (UH-VH) \$1.1 Billion

SJHC London \$480 Millions

**42 OR (3-4 Cardiac OR/d,
1,350 cardiac surgery/yr)**

68 ICU beds (14 CSRU)

88 Anesthesia Faculty

20 Fellows

47 Residents



DISCLOSURE

- **No Industries Conflict of Interests**
- **Ministry of Health and Long-Term Care AFP Innovation Fund (MOHLTC)**
- **Canadian Institutes of Health Research**

- **Co-Chair ISMICS Consensus Conferences**
- **Co-Chair ECTS Consensus Conference**
- **Guideline Committee - AHA, WHO**
- **MOHLTC OBAC (Chair)**

Acknowledgements

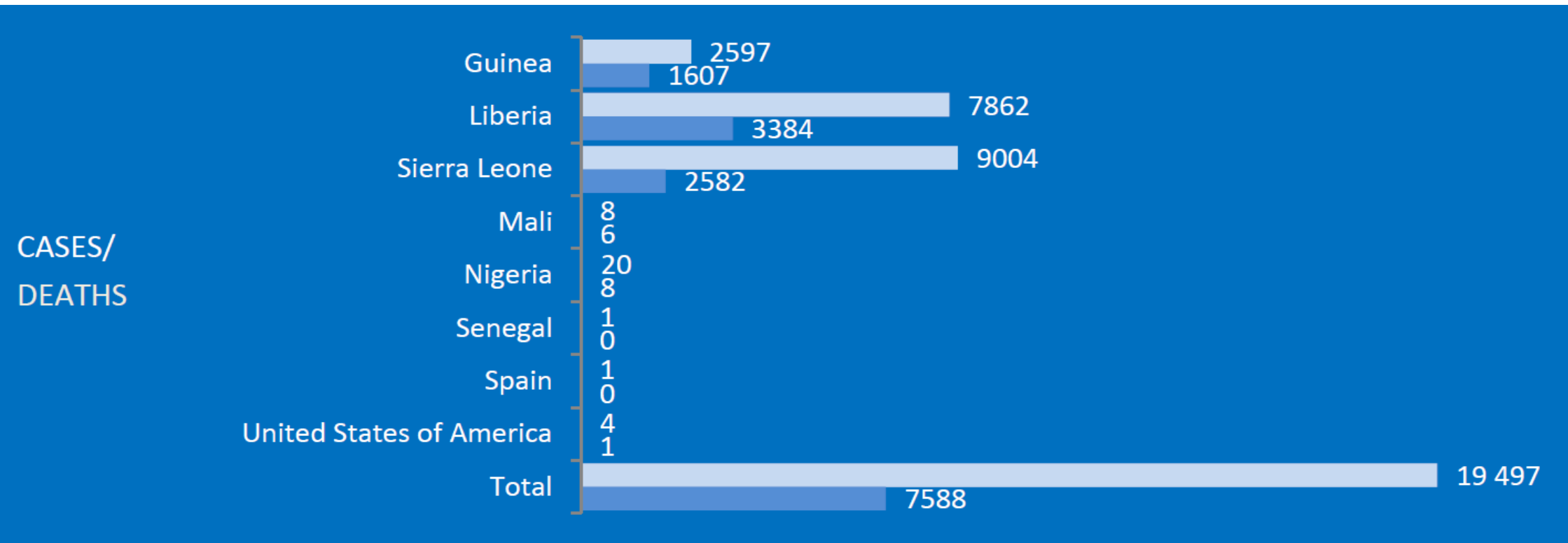
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OBJECTIVES

1. **EVD Rapid Guideline Development**
2. **To reflect on our experience to produce rapid advice globally-relevant guidelines in the context of complex evidence, changing dynamics of disease, and contextual issues not related to evidence.**
3. **Lessons learned in the context of high-stakes decision-making with rapidly evolving evidence.**

WHO EVD RESPONSE ROADMAP SITUATION REPORT 24 DEC 2014

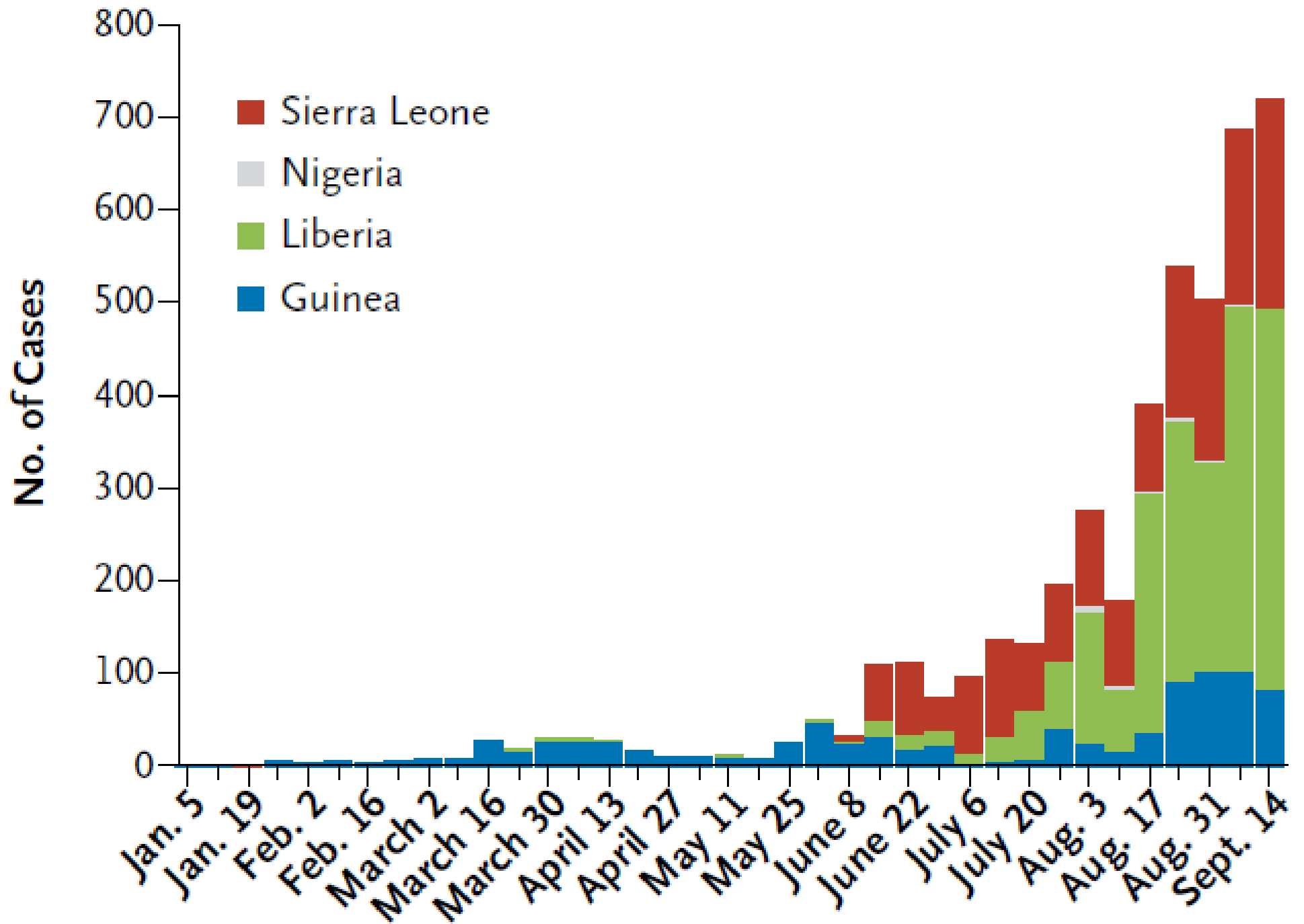
- 'Patient Zero' 2-yr old boy (28 Dec 2013), Guéckédou in Guinea (borders of Sierra Leone and Liberia)

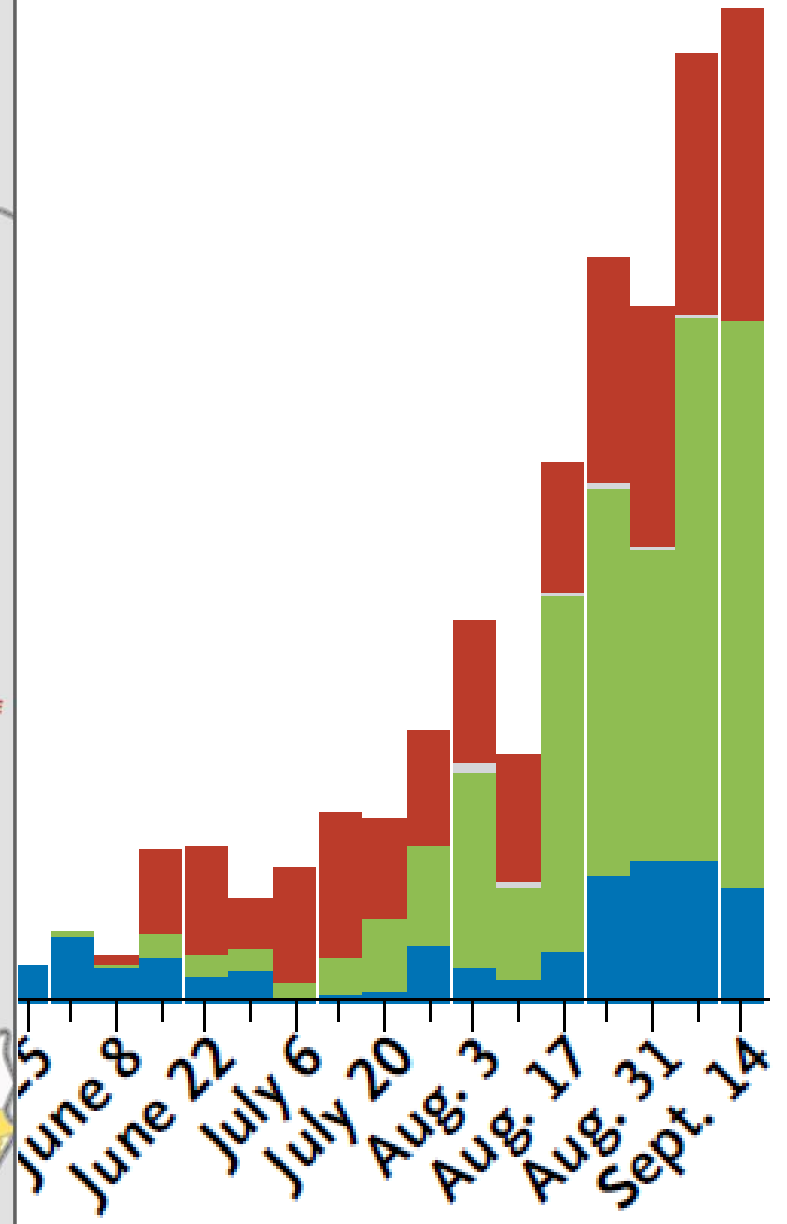
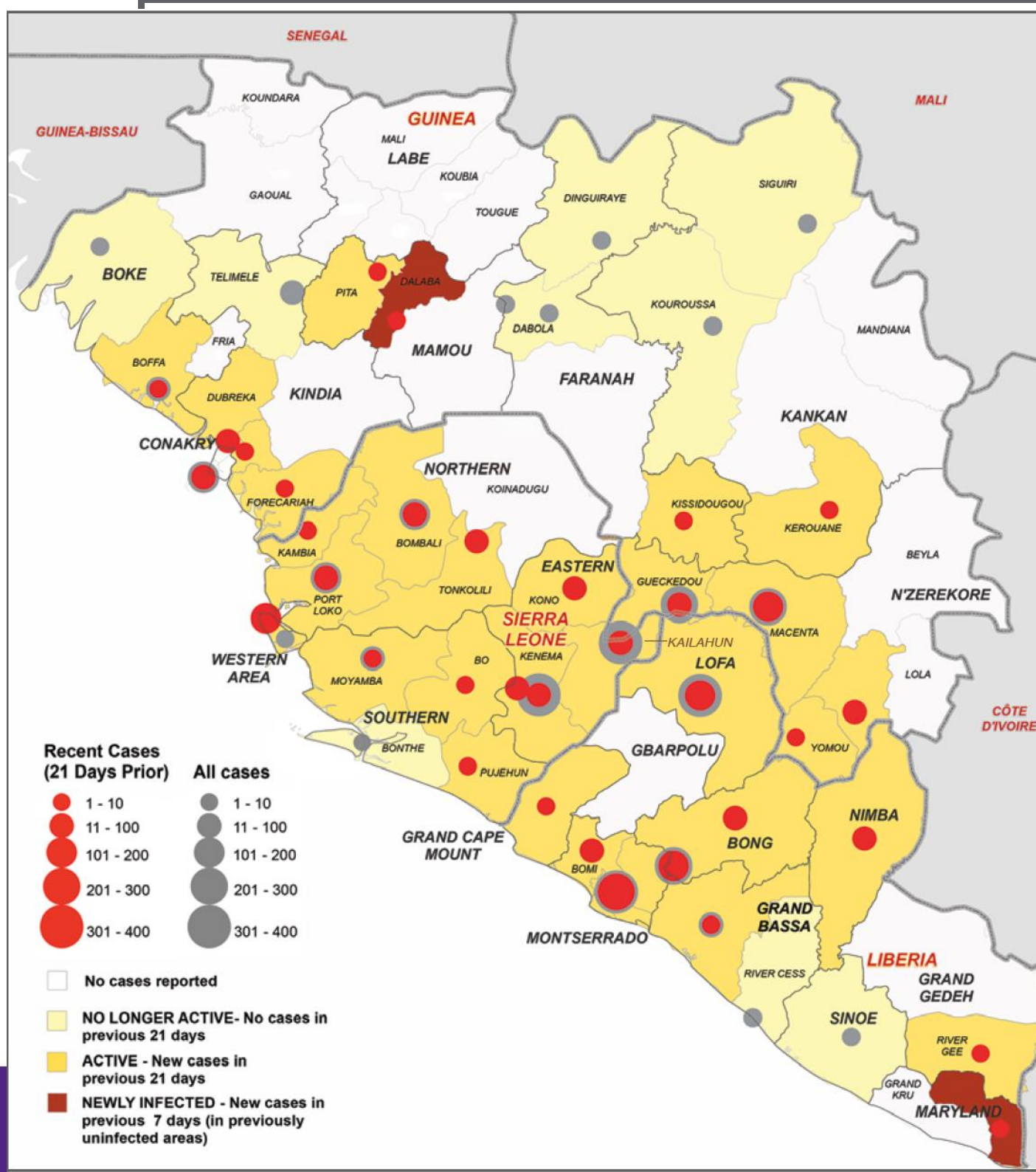


Ebola Virus Disease in West Africa — The First 9 Months of the Epidemic and Forward Projections

WHO Ebola Response Team*

A West Africa





EBOLA VIRUS DISEASE
OUTBREAK RESPONSE PLAN IN WEST AFRICA

WORLD HEALTH ORGANIZATION
AND
THE GOVERNMENTS OF GUINEA, LIBERIA, AND
SIERRA LEONE



July – December 2014

EVD Outbreak Review

- **23 March 2014: Guinea**
Spread to Conakry (Capital) - WHO
- **30 March 2014: Liberia**
- **25 May 2014: Sierra Leone**
- **24 July 2014: WHO DG**
Level 3 ERF
Unprecedented rate – 1,360 cases and 767 deaths (Mar-July)
- **27 July 2014: Nigeria**
- **8 Aug 2014: WHO - EVD Epidemic**
“Public Health Emergency of International Concern”

SCOPE OF GUIDELINES

- ❖ **Worldwide deaths: 6,388**
Reported cases: 17,942
- ❖ **Patients unnecessarily die without emergency surgeries**
- ❖ **Tragic deaths of perioperative Healthcare Workers**

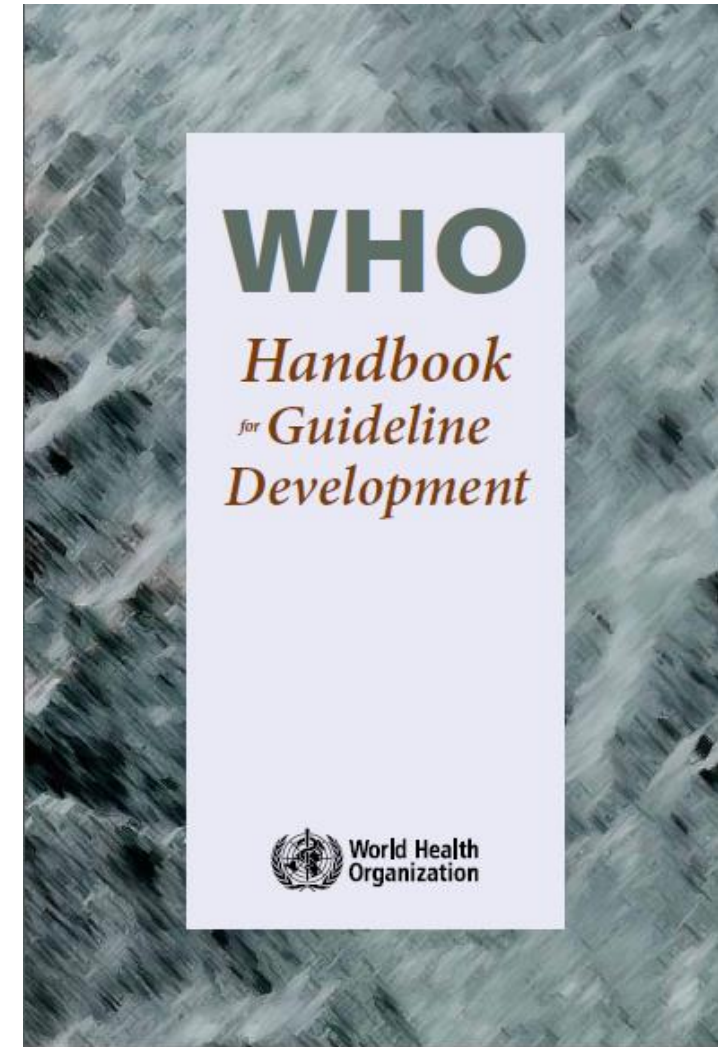
Rationale for Developing RAG Recommendations

- ❖ Member states: guidance on surgical interventions in suspected EVD to ensure protection of health-care workers and to prevent disease transmission in health-care settings, while appropriately managing surgery, during the current epidemic.
- ❖ A Rapid Advice Guideline (RAG) based on systematic review for screening/assessment, EVD testing and surgery with expert consensus on risks and benefits is crucial

Performing a Rapid Systematic Review to Support WHO Rapid Advice Guidelines

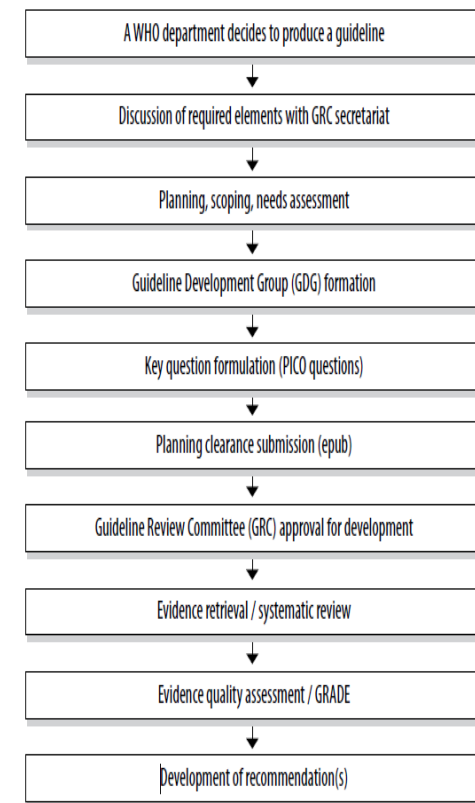
“Guidelines are recommendations intended to assist providers and recipients of health care and other stakeholders to make informed decisions.”

Rapid Advice Guidelines require expedited timelines



WHO Guidelines: Planning Stage

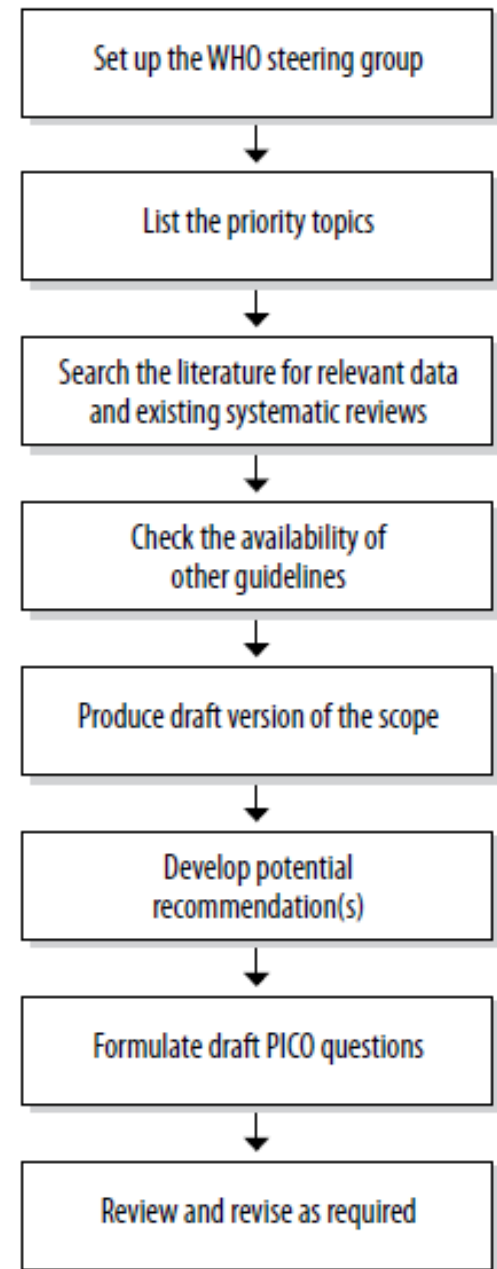
1. WHO Department decides to produce a guideline
2. Discussion of required elements with GRC secretariat
3. Planning, scoping, needs assessment
4. Guideline Development Group (GDG) formation
5. Key question formulation (PICO questions)
6. Planning clearance submission
7. Guideline (GRC) approval



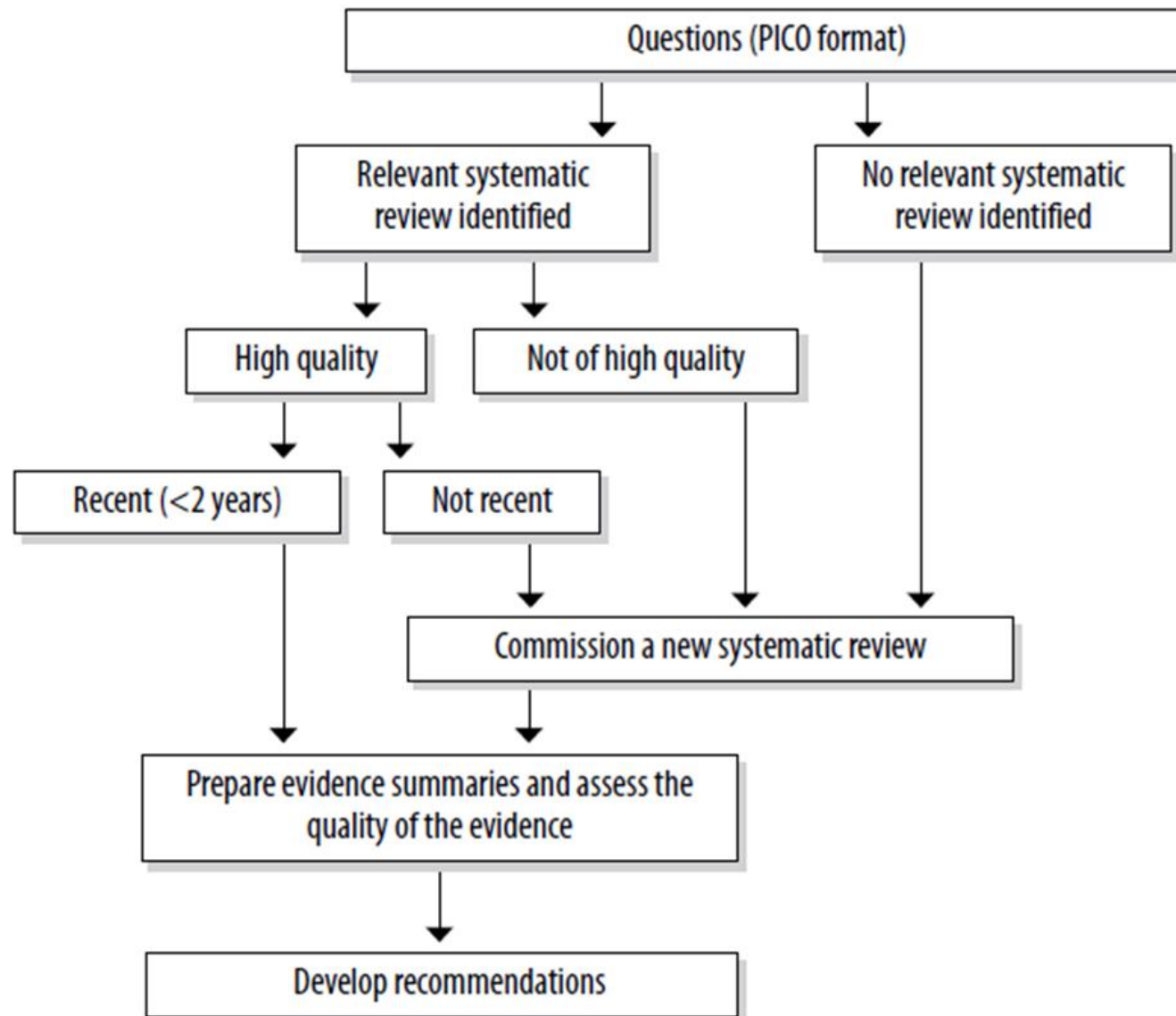
WHO Handbook for Guideline Development, 2012

SCOPING

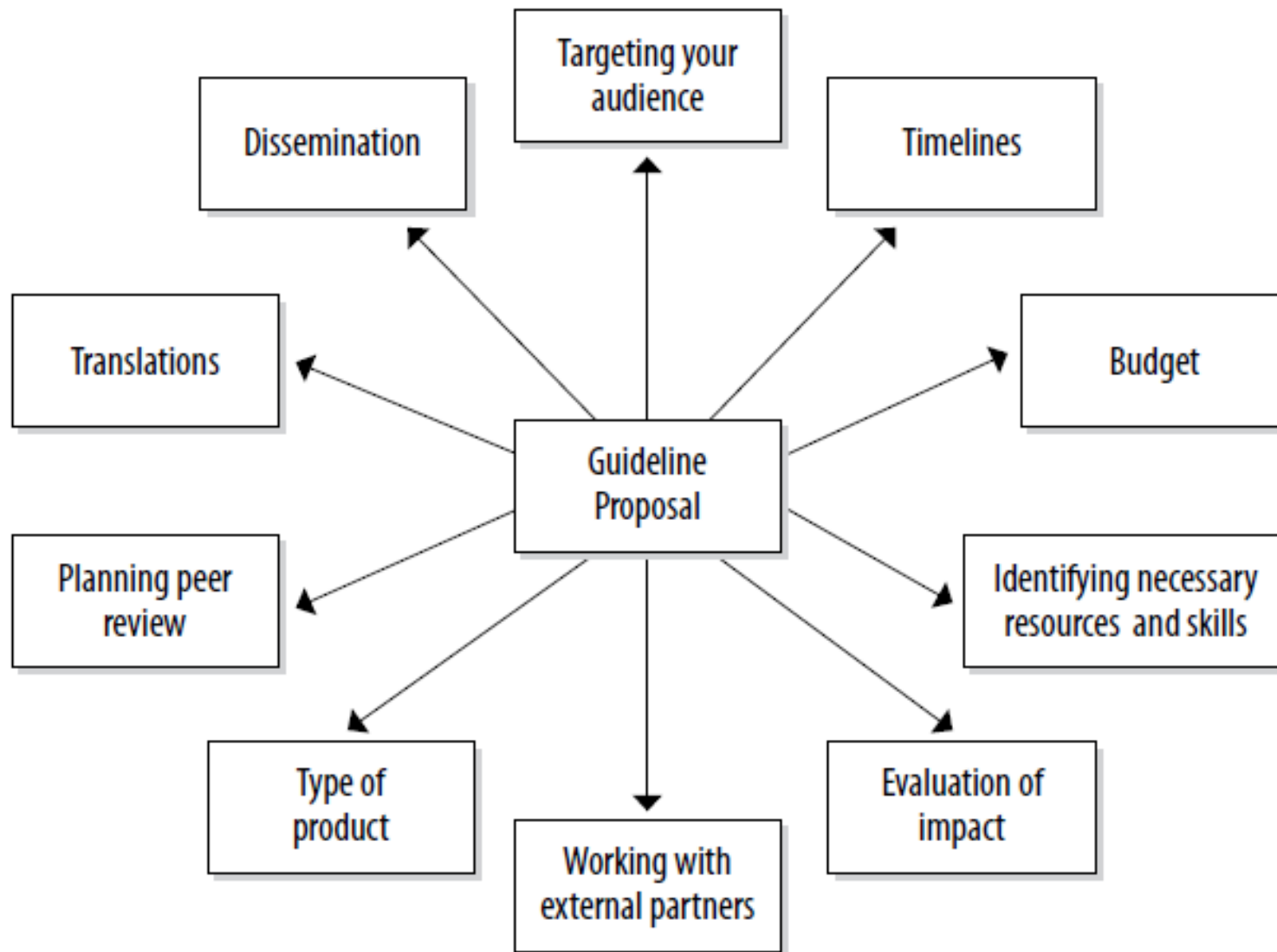
- ❖ Based on a **Draft Logic Model** (algorithm), preliminary scoping searches were conducted to identify
 - Existing guidelines (WHO)
 - Existing **systematic reviews**
 - Existing **studies** of surgery in EVD
 - Upcoming publications
 - Online discussions
- ❖ Based on the scoping searches, PICO questions were drafted



Finding Best Available Evidence



GUIDELINE PLANNING



GUIDELINES = EVIDENCE + RECOMMENDATIONS

EVIDENCE: Comprehensive systematic review using highest methodologic rigor to identify, retrieve, appraise and synthesize evidence using **GRADE**

RECOMMENDATIONS: Based on objective assessment of the available evidence, using transparent, predefined, reproducible processes of evidence-informed consensus using **GRADE**

WHO Handbook for Guideline Development

RAG: TARGET AUDIENCE

1. **Surgical Healthcare workforce** providing direct (e.g. surgery, obstetrics, trauma, anesthesia, physicians and nurses) and indirect care (e.g., cleaners, laboratory staff, burial teams) to EVD patients in the field;
2. **Patients**, family members, visitors to health-care facilities, community members;
3. **Policy makers** at the national or subnational level;
4. Health-care **managers** and supervisors.

PICO: OVERARCHING QUESTION

- In patients with suspected EVD who present with a surgical condition, what approach to **screening/assessment, testing, triage and perioperative/surgical management** is most likely to maximize benefit and minimize risk to the patient, surgical care team, and support staff; while appropriately respecting the socio-ethical and resource-related impacts?

1. Screening/Assessment?

- a) What should be the role of immediate **isolation** in relation to **symptom** severity?
- b) What should be the **differential diagnostic** considerations, and baseline probabilities, given the context and setting? (ie, probability of malaria, lassa, typhoid, etc., relative to EVD?)
- c) Which **Surgical Subgroups** require special considerations; e.g. acute abdomen, penetrating wound injury, obstetric patients, others?

2. EVD Testing and Interpretation?

- a) Which are the trade-offs of **availability, turnaround time, sensitivity/specificity, and cost** for EVD testing?
- b) When should **repeated** EVD testing be recommended?

3. Triage?

- a) How should **emergency** surgical patients be managed **while awaiting test results**?
- b) How should **elective** surgical patients be managed **while awaiting test results**?
- c) How should **risks** of delaying surgery be weighed against EVD exposure (patient' vs healthcare workers' risks)?

4. Surgery be Recommended?

- a) When does surgery become **futile**? i.e. renal failure, EVD-related bleeding or shock?
- b) What are the **contextual** ethical, social, and cultural issues that should be brought to bear?

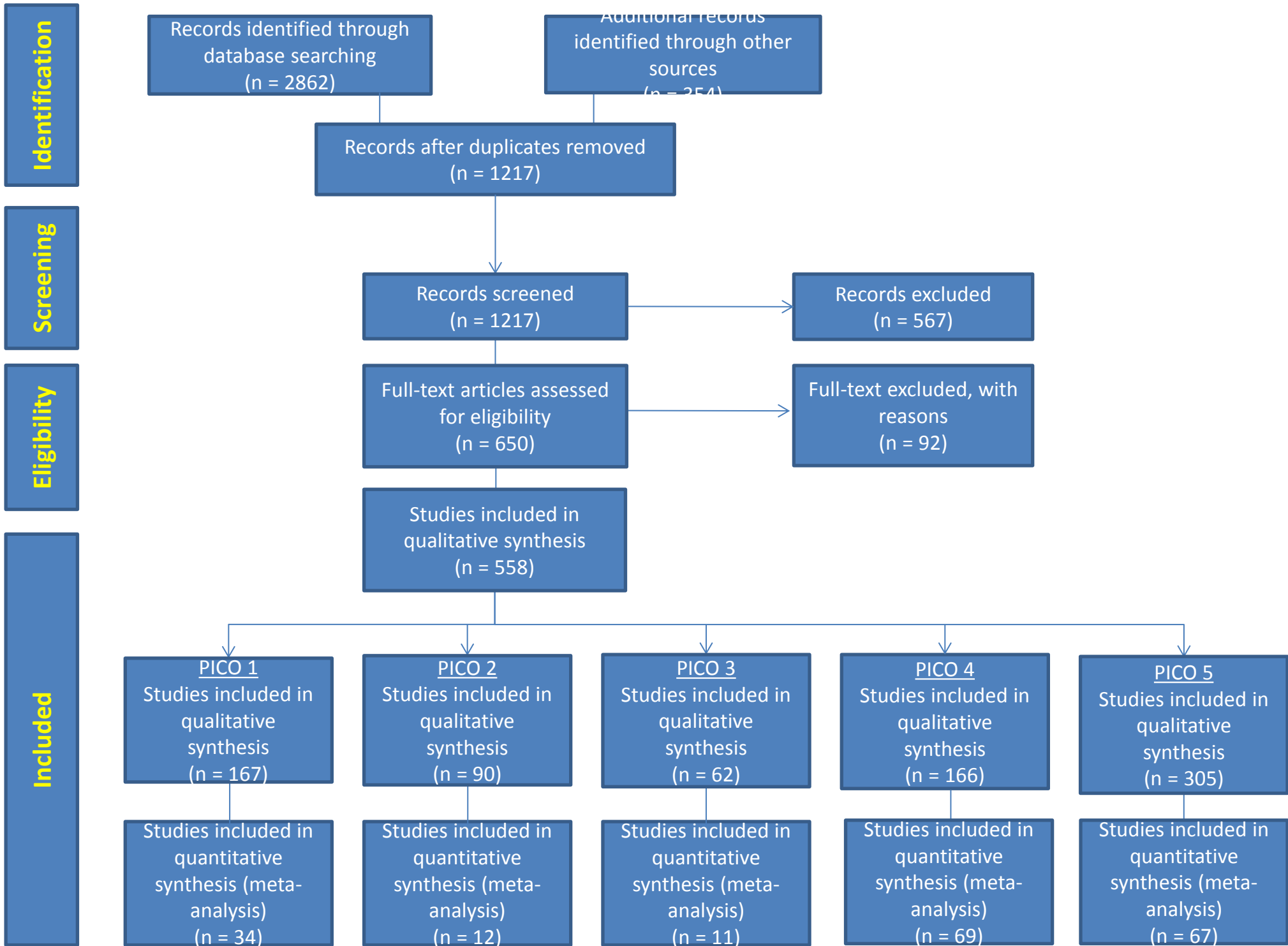
5. Surgical/Perioperative Management?

- a) Are there **special PPE** requirements in surgery beyond WHO PPE guidelines?
- b) Should the **surgery** take place in local isolation room or operating room?
- c) What should be the special preparation and equipment requirement for surgery and anesthesia management?

Comparative studies – ‘No Evidence’

Non-comparative – several hundred potential studies (very low quality)

Such evidence double every two weeks.....



EVIDENCE-INFORMED DECISION MAKING FOR MANAGEMENT OF SURGICAL CONDITIONS IN THE CONTEXT OF EBOLA VIRUS DISEASE (EVD)

ASYMPTOMATIC PATIENT HAS NO EVD SYMPTOMS

SYMPTOMATIC, SUSPECTED SUSPECTED or PROBABLE EVD PATIENT

SYMPTOMATIC, CONFIRMED ACUTE or CONVALESCING EVD PATIENT

ASYMPTOMATIC: EVD REGION

EVIDENCE INFORMED DECISION MAKING FOR PATIENTS PRESENTING WITH SURGICAL CONDITIONS IN THE CONTEXT OF EBOLA VIRUS DISEASE

Proceed With Usual Surgical Care

If any symptoms present themselves, EVD testing should be completed immediately and the "Suspected/Probable" course should be followed

SYMPTOMATIC: SUSPECTED / PROBABLE EVD

EVIDENCE INFORMED DECISION MAKING FOR PATIENTS PRESENTING WITH SURGICAL CONDITIONS IN THE CONTEXT OF EBOLA VIRUS DISEASE

ISOLATION: using WHO PPE and Infection Prevention Guidelines (IPG)

EVD TESTING

EMERGENCY

Surgery cannot wait until EVD test results are returned

Prognosis GOOD

Prognosis POOR

Local Team Decision

Inform & consent patient / family

Proceed with Surgery

- Surgery/Anaesthesia and Support Team require Full EVD protection
- **SURGERY LOCATION:** Isolation room or Designated operating room

Surgery
NOT
Recommended

Supportive & palliative care as appropriate

EVD Post-Op Management

EVD TEST RESULT POSITIVE [+]

EVD TEST RESULT NEGATIVE [-]

Return to Isolation

Follow WHO Guidelines for Clinical Management of EVD and for IPG

Return to Isolation

Repeat testing after 48-72h

EVD [+] after 2nd test

EVD [-] after 2nd test

Remove from Isolation and proceed with usual post-operative care

SURGERY CAN WAIT

Surgery can be postponed until EVD test results are returned

EVD TEST RESULTS NEGATIVE [-]

Repeat testing after 48-72h in Isolation

EVD [-] after 2nd test

EVD [+] after 2nd test

Remove from Isolation and proceed with usual surgical care

EVD TEST RESULTS POSITIVE [+]

Elective Surgery
NOT
Recommended

Return to Isolation

Follow WHO Guidelines for Clinical Management of EVD and for IPG

SYMPTOMATIC: CONFIRMED [ACUTE OR CONVALESCENT]

EVIDENCE INFORMED DECISION MAKING FOR PATIENTS PRESENTING WITH SURGICAL CONDITIONS IN THE CONTEXT OF EBOLA VIRUS DISEASE

ISOLATION: using WHO PPE and Infection Prevention Guidelines (IPG)

EMERGENCY

Surgery is required immediately

Prognosis GOOD

Prognosis POOR

Local Team Decision

Inform & consent patient / family

Proceed with Surgery

- Surgery/Anaesthesia and Support Team require Full EVD protection
- **SURGERY LOCATION:** Isolation room or Designated operating

Surgery
NOT
Recommended

Supportive & palliative care as appropriate

EVD Post-Op

Return to Isolation

Follow WHO Guidelines for Clinical Management of EVD and for IPG

SURGERY CAN WAIT

Surgery can be postponed

Elective Surgery
NOT
Recommended

Keep in Isolation

Follow WHO Guidelines for Clinical Management of EVD and for IPG

Lesson Learned

In the context of new and emerging diseases with extreme pressure, such as EVD:

- ❖ **Conventional approaches to Evidence-Informed guideline development may fail to identify and contextualize the best evidence**
- ❖ **Innovative approach for rapid and effective capturing, filtering, synthesizing available evidence – contextualize recommendations – Know4Go framework**

Know4Go = contextualization



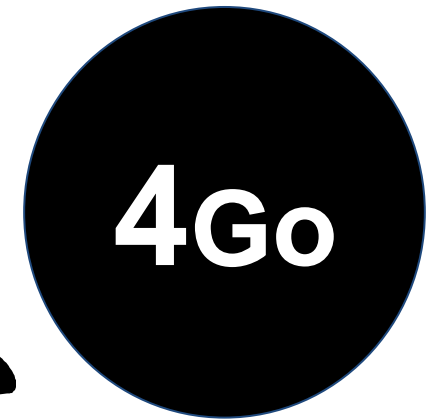
Evidence
Synthesis



Resources



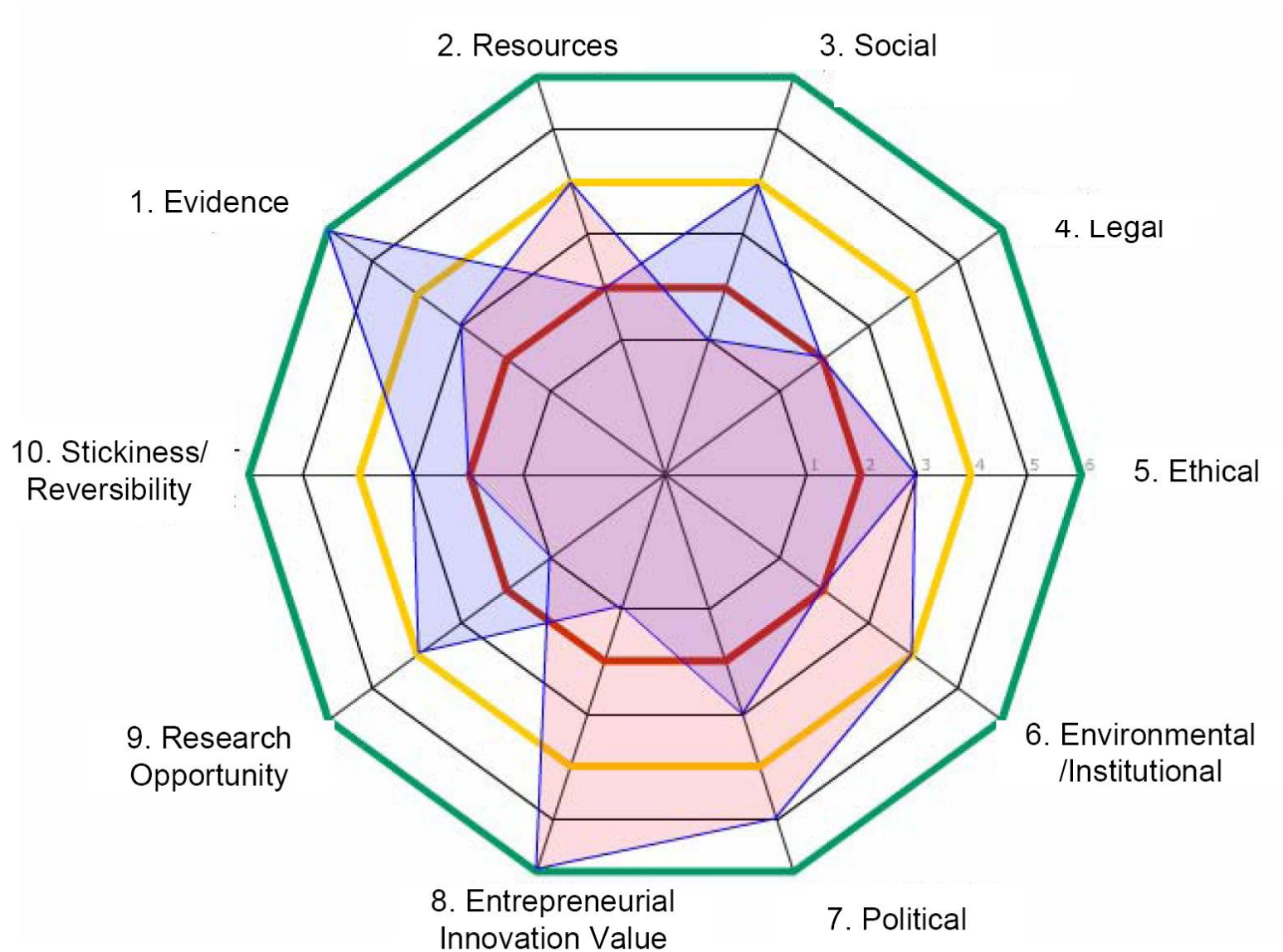
SLEEPERs



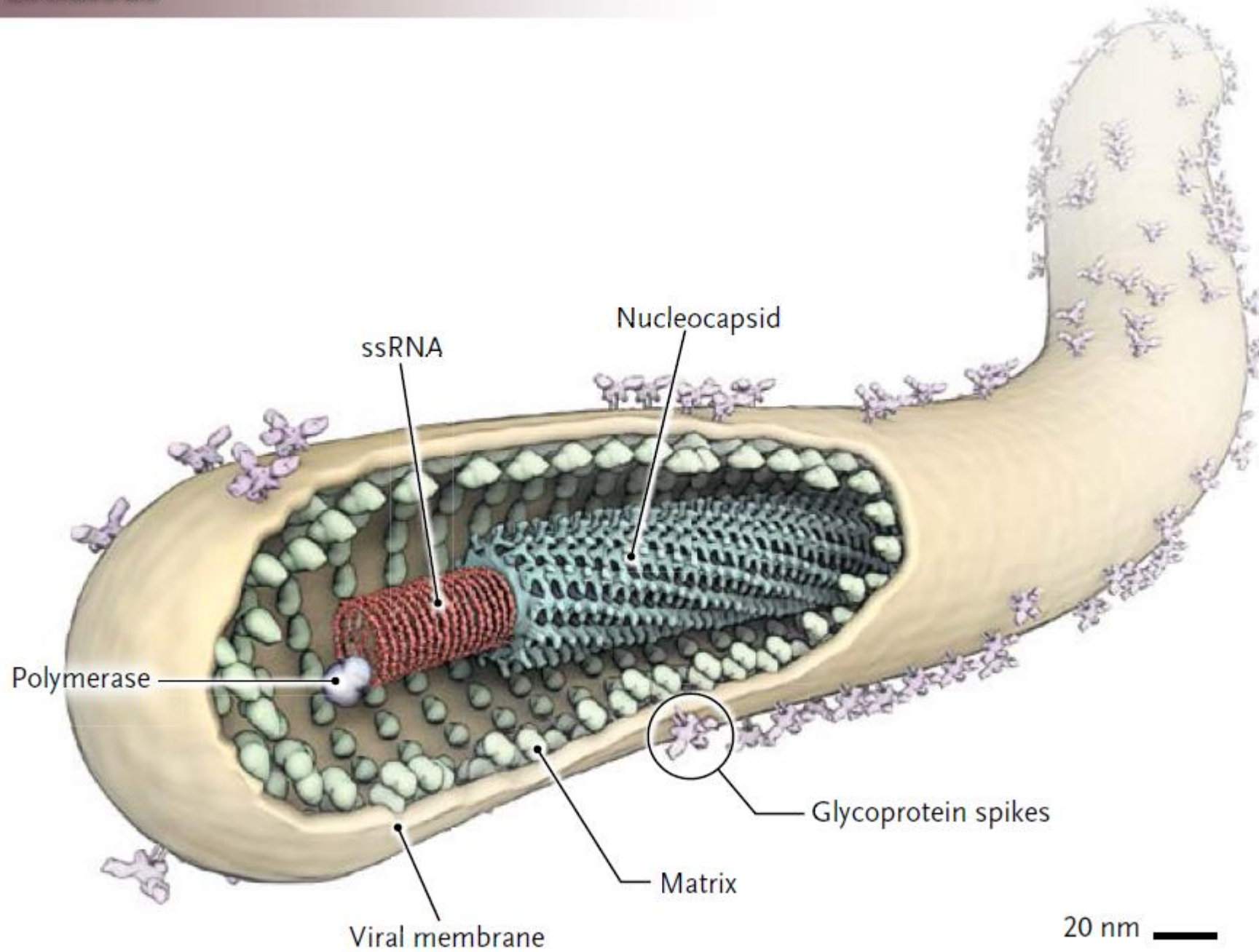
Opportunity Cost

SLEEPERs Assessment:

Rate the Importance of Each Domain for Decision



Ebolavirus



particles. The image is based on Protein Data Bank identifiers 3CSY and 1ES6 (www.rcsb.org) and Electron Microscopy Data Bank identifier EMD-2043 (www.emdatbank.org). The abbreviation ssRNA denotes single-stranded RNA.