Rapid Advice Guidelines At WHO

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Disclosure of Secondary Interests (5 years)

Financial: Teva Pharm, Athena Health, CVS Corp; none related to tobacco Intellectual

- Member, GRADE Working Group
- Member, (US) National Guideline Clearinghouse Editorial Board
- Publications: methods of nonrandomized studies, sources of bias in systematic reviews and guidelines
- Research focus: conflict of interest, bias in guideline development

Professional

- Current: Technical Officer, World Health Association
- Current: Faculty, Oregon Health & Science University, Portland, USA
- Investigator, Evidence-based Practice Center (AHRQ)
- Investigator, Kaiser Permanente Center for Health Research
- Funders: CDC, NIH, AHRQ, American College of Chest Physicians, American Urological Association



Outline

- Types of WHO guidelines
- Describe standards and quality control measures at WHO
- Guidelines in the context of a public health emergency
- History of rapid advice guidelines at WHO
- Methods for rapid advice guidelines at WHO, example
- The future?



Types of guidelines at WHO

Standard

- Systematic review(s) and full guideline development process
- 6 months to 2 years

Consolidated

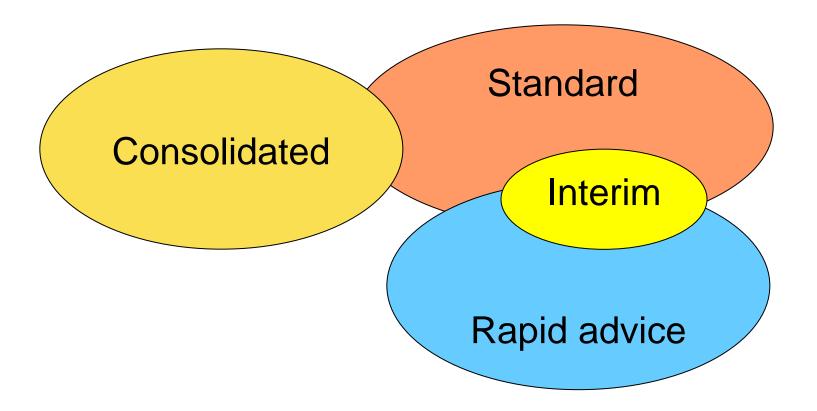
- Include GRC-approved recommendations
- Rapid advice guidelines
 - Compressed and abbreviated process, potential for bias
 - 1 to 3 months

Interim

- Standard or rapid advice guideline processes; often narrow scope
- Anticipate short shelf-life: follow with standard guideline



Types of guidelines





Guidelines produced by WHO

- 2007 to January 2015: 171 published guidelines approved by the Guideline Review Committee (GRC)
- Some guidelines are not reviewed by the GRC
 - SAGE (vaccines)
 - Essential Medicines
 - Expert Committees
 - Emergency situations



Guideline development at WHO

Scope the guideline

Set up GDG and External Review Group

DOI and manage conflicts of interest

Formulate questions (PICO) and Choose relevant outcomes

Evidence retrieval, assessment, synthesis (systematic review(s))

GRADE - evidence profile(s)

Formulate recommendations: GRADE

Include explicit consideration of:

- Benefits and harms
- Values and preferences
- Resource use

Disseminate, implement

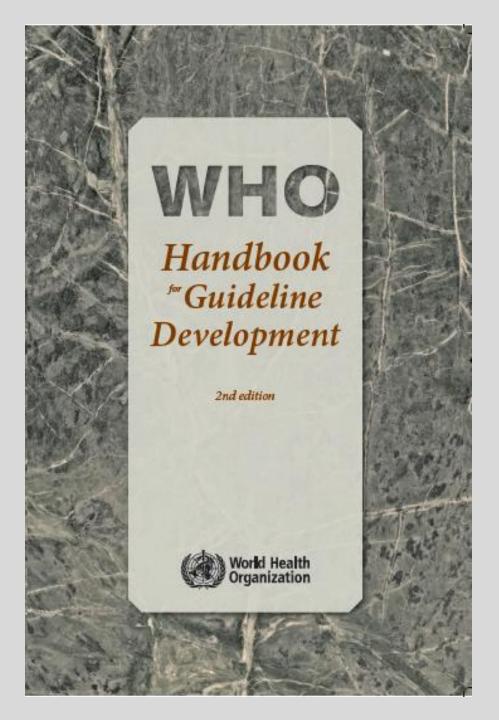
Evaluate impact

Plan for updating

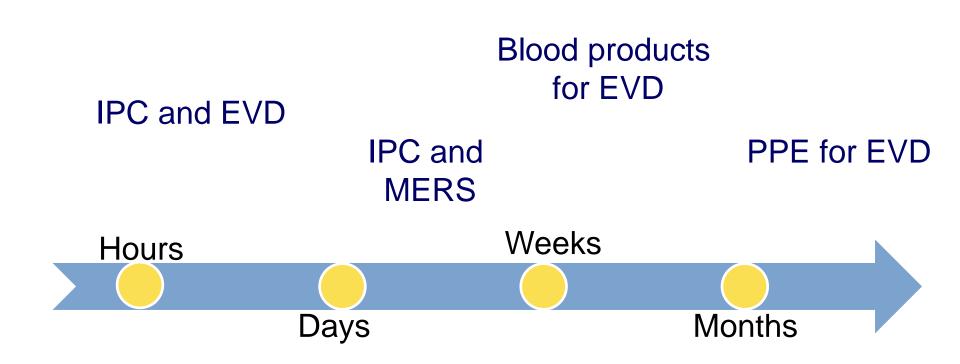
GRC approval of guideline development proposal



GRC approval of final guideline



WHO guidelines in the context of a public health emergency





Rapid advice guidelines at WHO (2007 – 2013)

- Rapid Advice: Treatment of tuberculosis in children (2010)
- Rapid Advice: Diagnosis, prevention and management of cryptococcal infection in HIVinfected adults and children (2011)
- Clinical management of human infection with pandemic (H1N1) 2009: revised guidance (Nov 2009)
 - WHO Guidelines for Pharmacological Management of Pandemic Influenza A (H1N1) and other Influenza Viruses (full guideline) (Feb 2010)



Rapid advice guidelines at WHO (2014-2015)

- Personal protective equipment in the context of filovirus disease outbreak response: Rapid advice guideline
- Guideline on hand hygiene in health care in the context of filovirus disease outbreak response
- Rapid advice on surgical interventions in the context of Ebola



Guideline on personal protective equipment for health care workers in context of Ebola Virus Disease

- June 27, 2014: request for consultation from Dr Cota Vallenas, Medical Officer in WHO Pandemic and Epidemic Diseases
- Issue: controversy between 2 types of PPE, 2 different users in the field, sparse data
- Timeline for a guideline: 8 to 10 weeks
- Plan: Rapid advice, interim guideline



Ebola Virus Disease outbreak 2014

- Declared in March 2014
- WHO clinicians deployed systematically for the first time
- A variety of IPC practices with potential for confusion
- Interim Guidance updated in August 2014

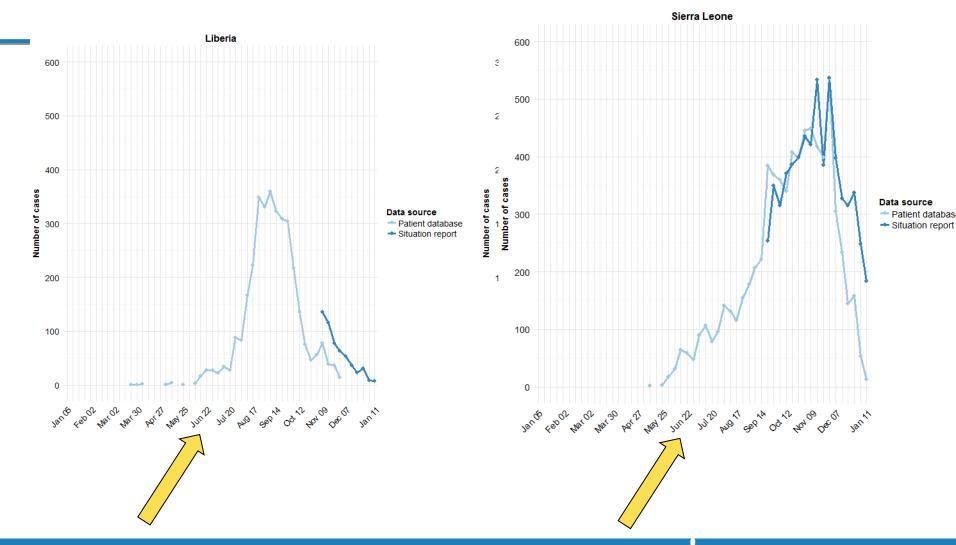


Photo credit: D. Brett-Major



Confirmed Ebola virus disease cases reported each week from Liberia and Sierra Leone

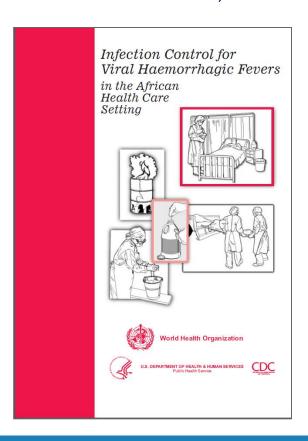
as of 14 January 2015





Previous guidance

WHO/DHHS/CDC, 1998



WHO, 2008

Interim Infection Control Recommendations for Care of Patients with Suspected or Confirmed Filovirus (Ebola, Marburg) Haemorrhagic Fever March 2008 **World Health**



Processes and methods for developing for rapid advice guidelines at WHO (6/14)

None!

...under construction...



Steps in the development of a RAG

- Determine if a RAG is needed
- 2. Establish the timeline and identify resources
- 3. Establish advisory groups
- 4. Establish the scope and write the key questions
- 5. Prepare the planning proposal
- 6. Perform the evidence review, synthesis and assessment
- 7. Formulate recommendations, draft the guideline
- 8. Conduct peer review
- 9. Publish



Step 1. Is a RAG needed?

- 1. What is the type of emergency and the risk to public health?
- 2. Is the event novel?
- 3. Is there uncertainty?
- 4. Does the uncertainty need to be urgently addressed?
- 5. What is the anticipated time frame for the event?
- 6. Will the recommendations be rapidly implemented?

Step 3. Establish advisory groups

- 1. WHO steering group
- 2. Guideline development group (external expert panel)
- 3. Peer reviewers

Involve the Guideline Review Committee Secretariat early



Step 4. Draft the scope and key questions

Recommendation question

What are the appropriate specifications for PPE, as well as optimal practices for donning and doffing of PPE, to decrease risk of virus transmission to healthcare workers?



Step 4. Draft the scope and key questions

What is the comparative effectiveness and comparative harms of using double gloves, face protection, and gowns with high impermeability ratings, as personal protective equipment for healthcare workers in healthcare facilities when treating patients with the filovirus, compared to single gloves and less robust types of equipment that may contribute to an increased risk of exposure to bodily fluids and the virus?



Step 5. Prepare the planning proposal

- Full PP as for standard guideline
- Took 2 weeks to develop
- Reviewed and approved by the GRC on an urgent basis (5 days)



Step 6. Perform the review, synthesis and assessment

- Commissioned a rapid review
- Resembled a systematic review, except:
 - English, French only
 - No peer review search strategy
 - 40% study extractions not verified
- Iterative approach to I/E criteria: study design, viruses





Effectiveness of PPE for healthcare workers caring for patients with filovirus disease

Adrienne Stevens,

Ottawa Hospital Research Institute, Canada

6 October 2014



Step 7. Formulate the recommendations

- Guideline Development Group meeting 6,7 October 2014
- 12 panel members, many observers
- Chair, methodologist
- Discussed PPE components one by one
- Drafted 12 recommendations at the end of 2 days
- Finalized recommendations: 3 weeks



Survey of health worker preferences regarding PPE and EVD

- Online survey n=38 expatriated physicians, MSF or WHO
- Ethics Review committee approval; 3 weeks start to finish
- Eye protection: 36 respondents had experience with goggles,
 7 face shields: goggles were uncomfortable and affected ability to provide care.
 - fogging affecting visibility, and lack of proper fit and slipping while providing care.
- Main concerns to health worker safety and wellbeing: heatassociated stress, fogging of eye wear affecting vision and the masks/respirators getting wet.
 - Need for training, quality of products, comfortable sizes and fit that does not slip while providing care



Recommendation 1

All health workers should have the mucous membranes of their eyes, mouth and nose completely covered by PPE while providing clinical care for patients with filovirus disease in order to prevent virus exposure.

Strong recommendation, high quality evidence for protecting mucous membranes compared to no protection.



Recommendation 2

All health workers should use either a face shield or goggles while providing clinical care for patients with filovirus disease in order to prevent virus exposure.

Strong recommendation, very low quality evidence for the comparative effectiveness of face shields and goggles for the prevention of filovirus transmission to health workers.



Step 8. Conduct peer review

- Peer review of full guideline document = 5
- Occurred after the release of the summary of the guideline
- Focused on clarity, implementation issues
 - Can't change recommendations

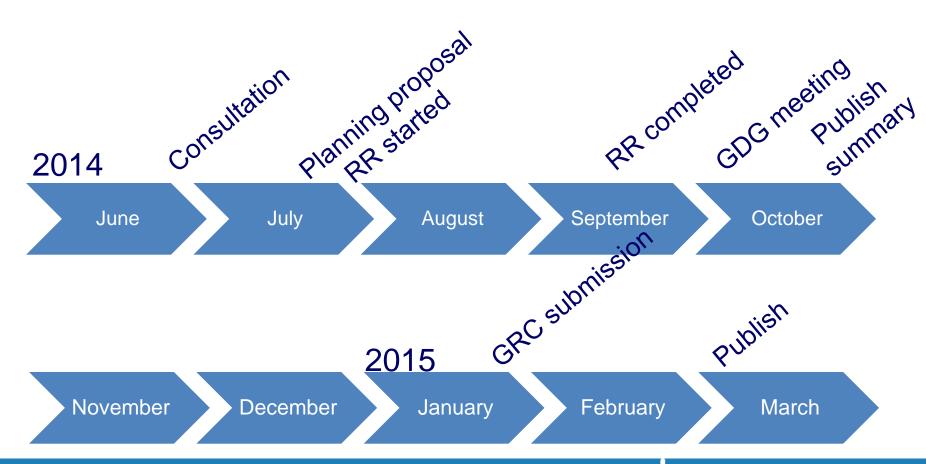


Step 9. Obtain approval and publish

- GRC and Organizational approval was in 2 parts:
 - summary guideline: overnight
 - final guideline: standard processes (3 weeks)



Timeline: Personal protective equipment and EVD rapid advice guideline





GUIDELINE ON HAND HYGIENE IN HEALTH CARE IN THE CONTEXT OF FILOVIRUS DISEASE OUTBREAK RESPONSE, Nov. 2014



Rapid advice guideline on PPE and EVD: What worked?

Procedural

- GRC Secretariat involved early and continuously
- Detailed (standard) planning proposal
- GRC review, approval process efficient, flexible
- Publication of summary before full guideline

Technical

- High quality rapid review team
- Expert consultations on background questions: virus characteristics, materials permeability

World Health

Survey of values and preferences in field workers

Organizational

The technical unit approached the GRC Secretariat:
 Why? High profile, needed to do it right

Rapid advice guideline on PPE and EVD: Challenges

Procedural

- Inefficiency in contracting mechanisms for rapid review team
- Violation of confidentiality agreements
- Delay getting full guideline completed
- Small pool of potential contractors

Technical

- Scope creep
- Sparse data, use of indirect evidence
- Inclusion of non-comparative studies: quality, heterogeneity
- Studies poorly reported
- Difficulty collecting primary data

Organizational

- Obtaining adequate funding
- Getting WHO leadership on board; reasonable expectations
 Dissention among GDG members and their organization
 Organization

Essential elements for developing a rapid advice guideline at WHO

Procedural

- GRC Secretariat involvement early and continuously
- GRC oversight: flexible and efficient processes
- Obtain DOI, manage COI
- Release of summary prior to full guideline

Technical

- Contractor with experience with rapid reviews
- Early involvement of guideline methodologist
- Streamlined, flexible rapid review process

Organizational

- Involve all relevant technical units
- Adequate funding
- High level support and understanding



Key questions going forward

- How evaluate and adapt off-the-shelf guidelines?
- When are de novo RAGs indicated?
- What corners can and cannot be cut?
- What are the essential steps given different timeframes?
- How develop guidelines overnight or within days?
- What is the role of the GRC in emergency guidelines?
- Do RAGs impact policy? Health outcomes?



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