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ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

A Review of Emerging Therapeutic Guidelines for Ebola

Mr. Nacinovich:
The Ebola virus is severe and too often a fatal illness. With the emergence of clinical trial data, the World Health Organization has published its first therapeutic guidelines for the Ebola virus disease. What do these new guidelines recommend? And how will they impact how clinicians approach care?

Welcome to *Clinician's Roundtable* on ReachMD. I'm your host, Mario Nacinovich. And here with us to share insights on the recent guidelines is Dr. Richard Kojan, a Congolese physician who created a portable biosecure emergency care unit called the CUBE to allow for close monitoring of Ebola patients by medical staff in remote, low-resource areas. Dr. Kojan has dedicated his career to caring for the most vulnerable populations and is currently the co-chair of the guideline development group of experts selected by WHO, and President of ALIMA, the Alliance for International Medical Action.

Dr. Kojan, welcome to the program.

Dr. Kojan:
Thank you.

Mr. Nacinovich:
To start us off, Dr. Kojan, what can you tell us about the Ebola outbreak in the Democratic Republic of the Congo?

Dr. Kojan:
So the Democratic Republic of Congo is only one country with more than 10 Ebola outbreak. Let's say one in three outbreak in Ebola since I can say now 46 years ago, the last outbreak, is running now in Eastern DRC, so total one in three Ebola outbreak in DRC. The virus, Ebola virus, in their natural context in DRC with, as we know a big forest in the tropical context, the natural context for the Ebola virus.

Mr. Nacinovich:
So now, as we know, the largest trial was conducted in the Democratic Republic of the Congo. Can you give us some background on this actual trial?

Dr. Kojan:
Thinking about the last trial last study, clinical study in the Republic Democrat of Congo was start at the end of the large outbreak from the West Africa, the big outbreak Ebola the world never seen, you know, so the idea is from there, from this big, large outbreak which was from which one we lost more than 11 thousand patients, you know. So the experts start, you know, discuss that we need to ameliorate care for the patient, not only to ameliorate the care for the patient but to find a solution, to find a solution about, you know, care, optimize care, but also to try to start a vaccine study and a drug study, so the idea was from there.

And when the big outbreak from the West Africa finished another one start in DRC, in Eastern Congo, which the area is a conflict zone and a war zone and from this area, you know, and too many challenges. And when the outbreak start, all expert we start to discuss with different expert scientist and clinician and all expert, so we decided to come up with a large platform under leadership from the MOH, from DRC, and develop a platform. We receive, you know, too many partners: ALIMA and NIH, INRB. So those different partners came, you know, joined, you know, in the platform. And the design of the trial was randomized, study of drugs with four arms and different arms. One of the arms was a comparator with drugs called ZMapp, and the three other drugs was monoclonal antibody, called Mab114 and the Regeneron. And the last one was remdesivir.

So, yeah, the result from the big collaboration, you know, from different partners, official partners from DRC but also from U.S., NIH and from different other partners as ALIMA.

Mr. Nacinovich:
Certainly, it's impressive the number of organizations that led to this incredible collaboration, the rigor of the trial, but you've also created a portable biosecure emergency care unit called the CUBE, and I was wondering if you can tell our audience a little bit about the monitoring that CUBE allows you now to do.

Dr. Kojan:
Sure. To implement the study in area like this one in the context with low resource, you know, that is a really, very big challenge, you know, for scientists, for different expert, for the lab, for drugs company that, you have to come up with good standard of care. So it was also opportunity for us from ALIMA to implement the CUBE. CUBE is a singular room one, for the patient, and to be able to provide the intensive care, safe one for health workers but also for patient. As we know, Ebola is a terrible disease, you know, and the patient care with different, you know, trouble or metabolic trouble, you know, so the patient need really support with optimized care, so with the CUBE it was possible, you know, to come up with optimized care for our patient. And in this area for a study, we went with more than 20 CUBE and for all patient who need intensive care and who need drugs. So, for all participant for a study, so they was receiving their monitoring inside the CUBE, so that was possible. So the CUBE was, one of the important tool, you know, to help us, you know, to take care of our patient correctly but also to be able to implement the study in the area with low resource but also an area in conflict zone.

Mr. Nacinovich:
Which is just so impressive that you and this impressive collaboration were able to not only give care to patients in such an area but able to evaluate them, from a care standpoint and then conduct the rigor of a clinical trial.

So, what were the results of the trial? And how did the findings from the clinical trial impact these newly developed guidelines through the World Health Organization?

Dr. Kojan:
So the monoclonal antibody was decreasing mortality for patient, was admitted early in the Ebola centers, so that was the preliminary result. The decision from the DSMB was to stop with the other drugs, you know, ZMapp and the remdesivir. And after that the final result come up and show that definitely, the monoclonal antibodywas showing efficacy, you know, to decrease the mortality for the Ebola patient mainly for patient who are admitted early in the Ebola centers. So that was the recommendation from the DSMB. And after that, you know, all of the group, the platform, and we wrote finally the result in the New England Journal.

And what is the impact after that? So the impact is huge, for health workers, for the patient, you know, because now it was clear for us and become clear for us that we can take care of Ebola. We have drugs, and now we have one of the main tools to care correctly our patient. That is very, very important, and the impact is huge for the patients and for health workers.

Mr. Nacinovich:
For those just tuning in, you're listening to *Clinician's Roundtable* on ReachMD. I'm Mario Nacinovich, and I have the pleasure of speaking with Dr. Richard Kojan about the first guideline that has been published regarding the Ebola virus disease therapeutics.
So, Dr. Kojan, now let's shift our attention from the trial and its results more to the guidelines. Can you give us an overview of what these guidelines recommend?

Dr. Kojan:
The recommendation from the guideline is the first is a strong recommendation when that for a patient who is confirmed Ebola after lab analysis, we have to think that they must receive the monoclonal antibody, which one called Mab and Regeneron, so it's important for those patients confirmed Ebola disease to receive monoclonal antibody.

This is a strong recommendation from the guideline. And for all patients whether they are adult man or woman, pregnant, they can receive monoclonal antibody to treat Ebola but also the newborn. So let's say because they are the newborn, they are really high risk contact from their mother, so this is also a strong recommendation for the newborn and this is the main recommendation from therapeutic new guideline from made by WHO.

Mr. Nacinovich:
How will these guidelines impact the way we care for our patients and the way we may address other diseases that they may have in the future?

Dr. Kojan:
The impact from this guideline publishing this data was huge because the approach from this guideline was integrate the advice from

different expert but also the data from not only one trial but different trial. You know, the process was, the process was long. So, the WHO guideline is huge tools, you know, for different, MOH and different country that can help different country to, you know, for their advocacy to get the drugs, to buy drugs, to get the drugs, for their population.

I think the next stop must be huge advocacy for access of drugs or different, different drugs. This guideline will help, you know, all community of health workers how to treat correctly the Ebola patient.

This is a change of life, you know. It change completely our practice as health workers. Before, this guideline was, as I was saying, was really complicated for Ebola patient but also for health workers to take care safely patient, but now it's possible, you know, it's possible.

Mr. Nacinovich:
I want to thank you, Dr. Kojan, for all of the work that you have done and for coming on our program here to share your insights on the emerging therapeutic guidelines for Ebola. And I also want to thank you on behalf of mankind for really providing not only the care for these vulnerable patient populations but also thinking about the life-threatening impact on the healthcare workers. It was absolutely my pleasure to speak with you today. Thank you very much.

Dr. Kojan:
Thank you.

Mr. Nacinovich:
I'm Mario Nacinovich. To access this and other episodes in our series, please visit ReachMD.com/CliniciansRoundtable where you can Be Part of the Knowledge. Thanks for listening.