

10th Euro Global Summit and Expo on

Vaccines & Vaccination

June 16-18, 2016 Rome, Italy

Implementing a randomized control trial (RCT) in the context of an Ebola epidemic

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The Ebola Virus Disease (EVD) outbreak in West Africa is by far the largest ever recorded. A safe and effective vaccine against EVD may help end the ongoing epidemic in West Africa and control future outbreaks. Evaluating vaccine efficacy during outbreaks can be challenging. To observe a sufficient number of events, trials may need to vaccinate very large numbers of people in populations believed to be at risk. Trials may fail because too few transmission events occur during the study period, leaving studies underpowered to detect a statistically significant vaccine effect. The Ebola virus spreads from person to person through direct physical contact with body fluids of symptomatic EVD patients. To evaluate the efficacy of an Ebola vaccine, it is critical that trials target populations with ongoing transmission. We describe a novel trial design - ring vaccination trial - since it adopts the outbreak containment strategy of ring vaccination. A patient newly diagnosed with EVD becomes the index case around whom a socially and geographically defined ring of his or her contacts and the contacts of these contacts is formed. We illustrate the approach by summarizing the protocol and results of a ring vaccination trial against EVD in Guinea, West Africa. This strategy may increase trial power, reduce the required sample size, and simplify trial logistics as compared to standard vaccine trial designs and can be useful for performing vaccine trials during outbreaks.

Biography

Dr Henao Restrepo obtained her Degree and Medical Doctor and Surgeon from the University of El Rosario in Bogota, Colombia, she received a master's degree in communicable disease epidemiology at the LSHTM, UK. In 1997 she completed a peripatic 10-year career in international health with WHO with assignments in SEARO, Eastern Africa, Nicaragua, El Salvador and Colombia where she worked in implementation and evaluation of strategies to eradicate poliomyelitis and eliminate measles and maternal and neonatal tetanus. In August 2014, she was assigned to Ebola Research and Development team and coordinated the Ring vaccination trial in Guinea and Sierra Leone.

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