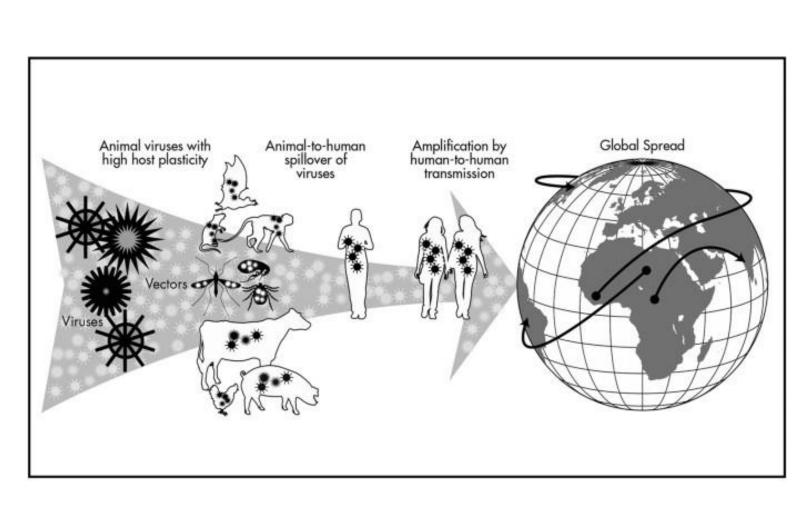
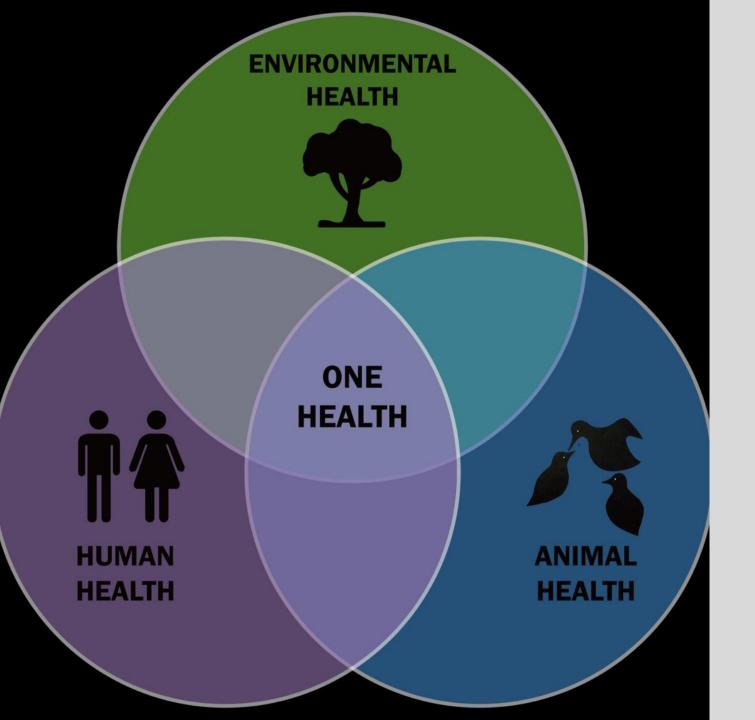
ONE HEALTH PANDEMIC PREVENTION AND MITIGATION: THE ROLE OF FDA

Margaret Foster Riley, J.D. FDLI Symposium, November 12-13 2020

Zooinic disease: origins and vectors

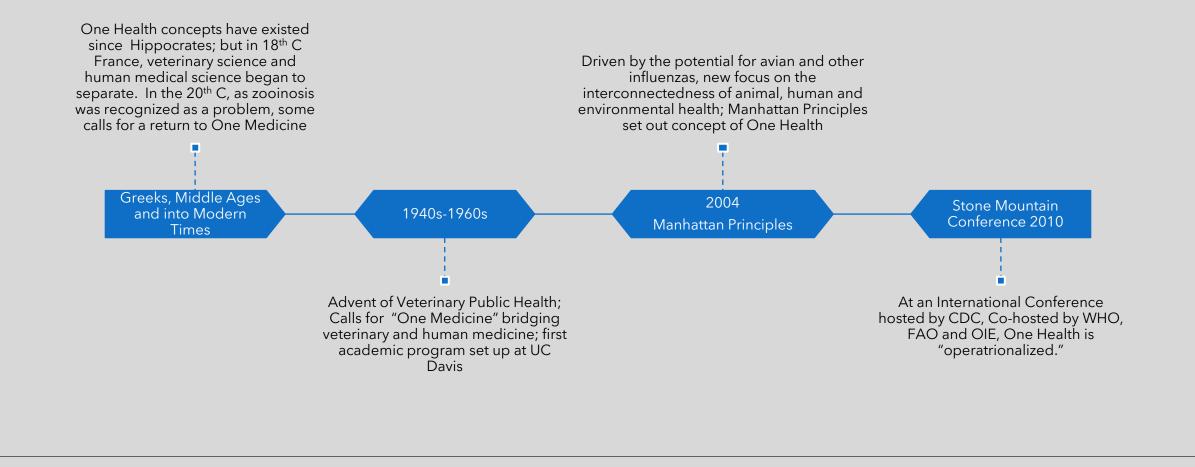


Source: Kreuder Johnson, C., Hitchens, P., Smiley Evans, T. *et al.* Spillover and pandemic properties of zoonotic viruses with high host plasticity. *Sci Rep* **5**, 14830 (2015). https://doi.org/10.1038/srep14830

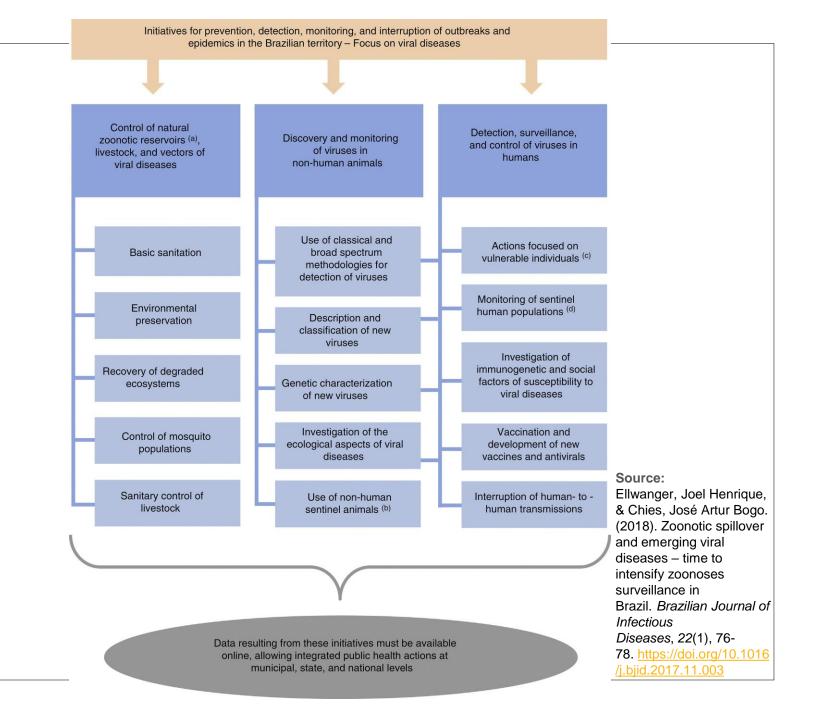


ONE HEALTH

History of One Health



A One Health Approach to Zoonotic Disease



One Health









Oie

World Organisation for Animal Health





FDA

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS



Singapore City's skyline. May_Lana/Shutterstock



One Health and FDA

- Zoonotic disease
- Translational medicine
- Links between foodborne illness, antimicrobial resistance, and nutrition
- Human-animal bond



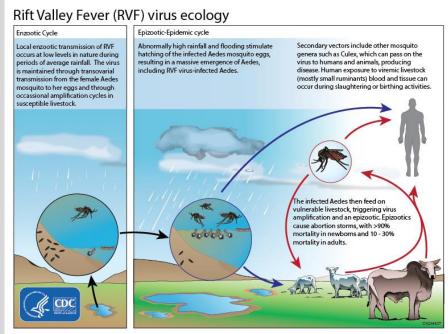




COVID, ONE HEALTH, AND FDA

One Health Generated Platforms: Pro-Active Vaccine, Treatment and Diagnostic Development

- Simultaneous/Parallel livestock and wildlife vaccinations, treatments and diagnostics
- Platform technologies (vaccination and treatment) for specific types of viruses: e.g.
 coronaviruses
 - Moderna head-start with MERS



One Health Generated Platforms--Challenges

- Insufficient Surveillance
- Insufficient Funding
 - Outside User-Fee funding
- Gaps in Authority
 - Pre-clinical oversight
- Overlapping Authority
 - FDA oversight for veterinary drugs/USDA oversight for veterinary biologics

ANTIBIOTIC RESISTANCE

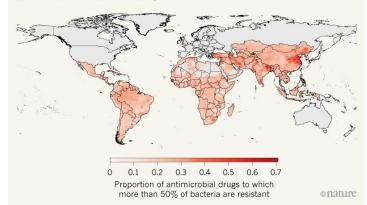
ONE HEALTH PERSPECTIVES

Environment (e.g Citrus)

Human Medical Use Animals (e.g.Livestock)

RESISTANCE HOTSPOTS

Farm animals harbour more drug-resistant bacteria in countries where meat production has increased rapidly.





Antibiotic Resistance-Challenges for FDA

Limited authority over physician use

Overlapping authority; failures of coordination between EPA, FDA, USDA and CDC

Ambiguous Development of the Judicial Use framework

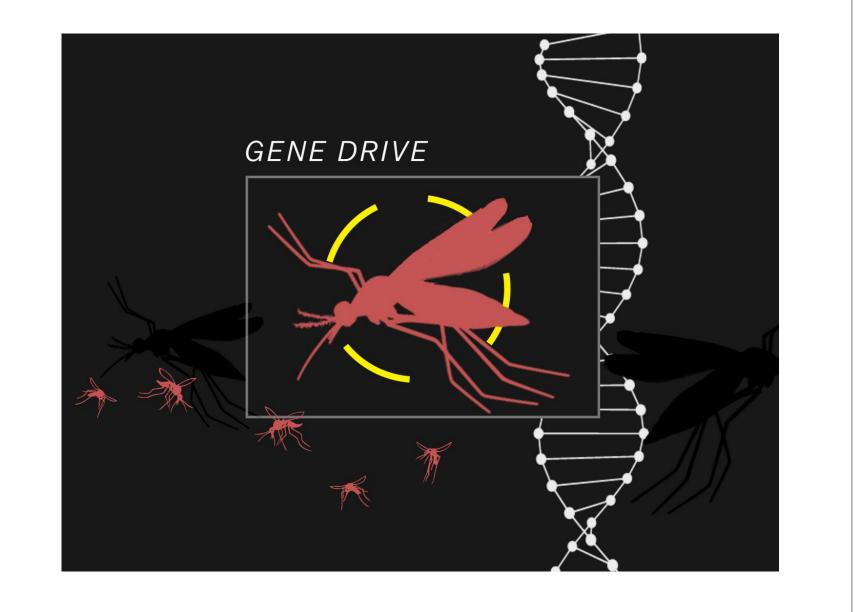
Limits on authority

Questions on veterinary supervision

Gaps in Livestock Surveillance

Gene Drives

• <u>VOX overview of gene</u> <u>drives</u>



GENE DRIVES



Conclusions

- One Health provides a potentially powerful tool to prevent the next pandemic
- Challenges
 - Dominance of a reactive medical model
 - Funding
 - Coordination at the international and national levels
- Challenges for FDA
 - One Health needs to be taken seriously by all Centers to have any significant role
 - Funding
 - Limits on authority
 - Agency cooperation