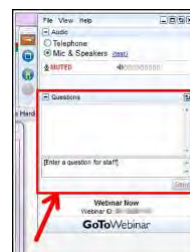




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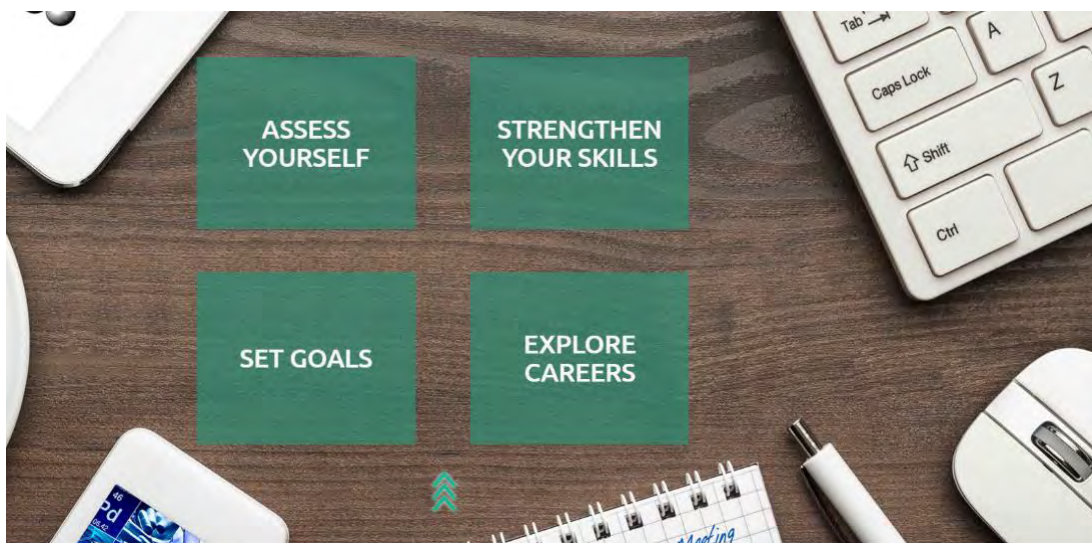


- Publish in top journals
- Find a job
- Effectively use research tools like SciFinder® and ACS ChemWorx
- Communicate your science
- Write grant proposals
- Build industry partnerships
- Prepare for a changing employment landscape

<http://acsoncampus.acs.org>

5

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<https://chemidp.acs.org>

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COVID-19

Understanding the
**Scientific and
Medical Aspects**
of the **Pandemic**

Co-produced with ACS Science & the Congress

THIS ACS WEBINAR WILL BEGIN SHORTLY...

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Understanding the Scientific and Medical Aspects of the Pandemic



Jon Lai
Professor of Biochemistry,
Albert Einstein College of Medicine



Raymond Forslund
Vice President, Head of CMC Development and
Project Management, Syner-G



Courtney Aldrich
Professor, Department of Medicinal Chemistry, College
of Pharmacy, University of Minnesota and Editor-in-
Chief, *ACS Infectious Diseases*

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SARS-CoV2: Structure and Immunity

Jon Lai

Professor of Biochemistry,
Albert Einstein College of Medicine



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Emerging Viruses and Recent Epidemics

2019-2020: SARS-CoV2

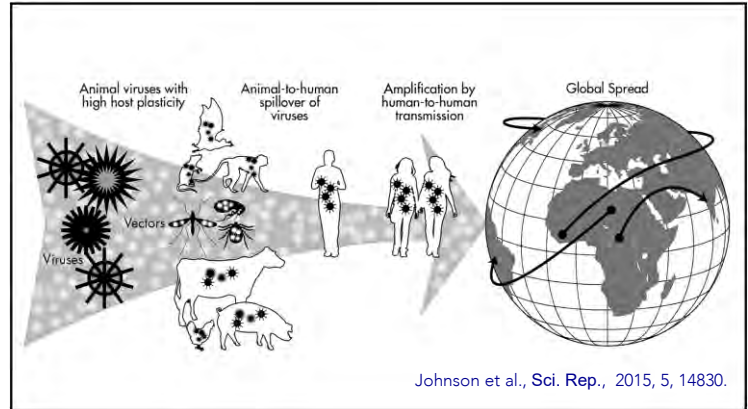
- 4.2M cases; 284,000 deaths.
- Respiratory transmission.
- Originated in a wet market.

2015-2016: Zika virus

- 811,000 cases worldwide.
- Transmission by mosquitos.
- Infected traveler, followed by local spread.

2014-2016: Ebola virus

- 28,000 cases; 11,000 deaths.
- Transmission by mucosa; urban spread.
- Initial infection from bat.



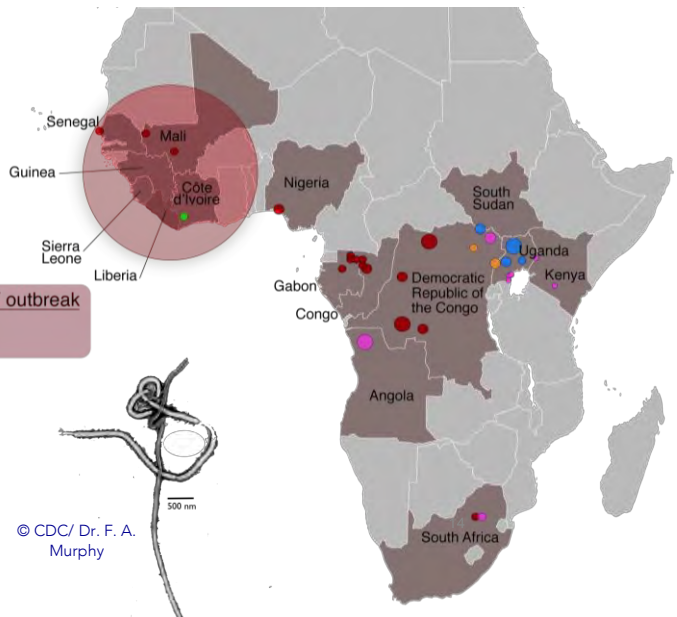
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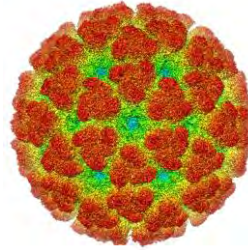
Case Study: Emergence of Ebola virus in West Africa (2014-2016)

- Filamentous virus spread via mucosal surfaces.
- Causes highly fatal hemorrhagic fever (case fatality rate up to 90%).
- Five "strains":
 - Ebola virus (EBOV)
 - Sudan virus (SUDV)
 - Bundibugyo virus (BDBV)
- 2014: First outbreak in W. Africa and spread in urban areas.
- Advanced countermeasures for EBOV only.

2014-2016 EBOV outbreak
Cases: 28,652
Deaths: 11,325



Case Study: Emergence of Chikungunya virus in the Americas (2013)

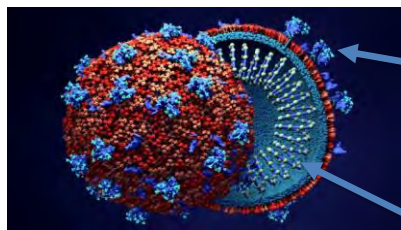
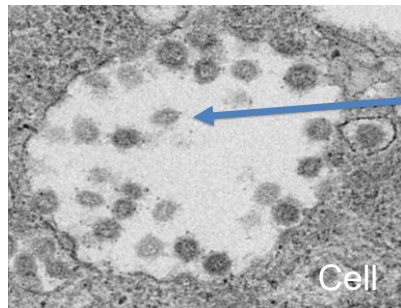


- Alphavirus transmitted by *Aedes aegypti* and *Aedes albopictus* mosquitos.
- Can cause a debilitating and persistent arthritis.
- 2006: 1.25 million suspected cases in multinational outbreak.
- 2013: First contemporary report of CHIKV in Americas, followed by 1.11 million suspected cases in 43 countries.
- Adaptation in the glycoprotein allowing transmission from both types of mosquitos.

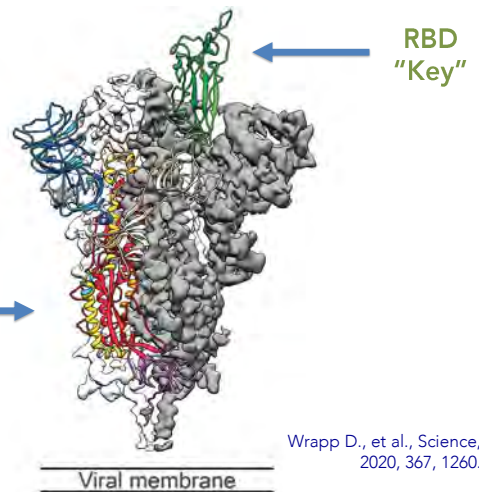
Morrison TE, J. Virol., 2014, 88, 11644.

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How SARS-CoV2 Infects Cells



"Lock" on cells: ACE2



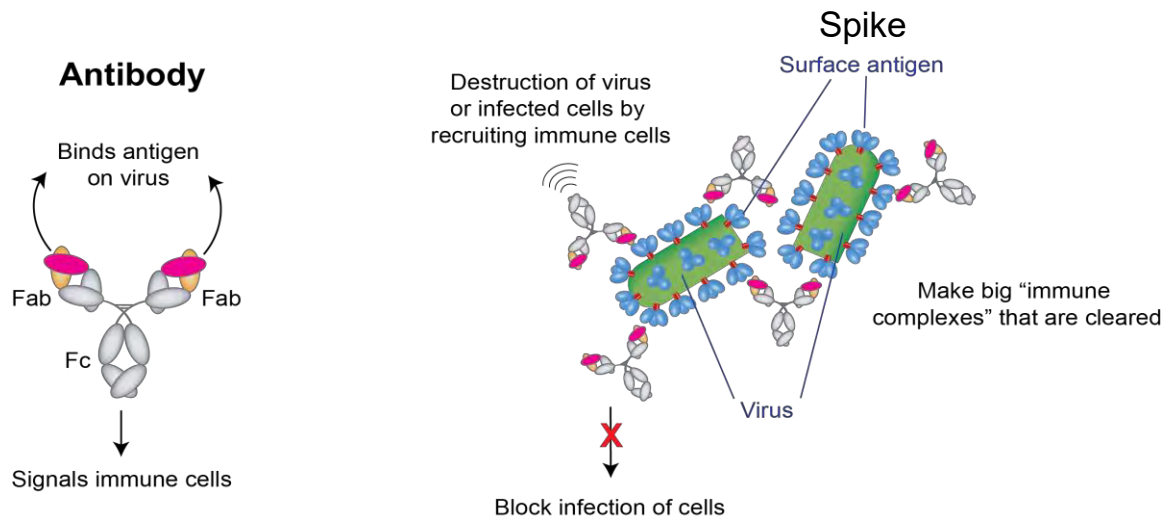
Wrapp D., et al., Science, 2020, 367, 1260.

www.livescience.com

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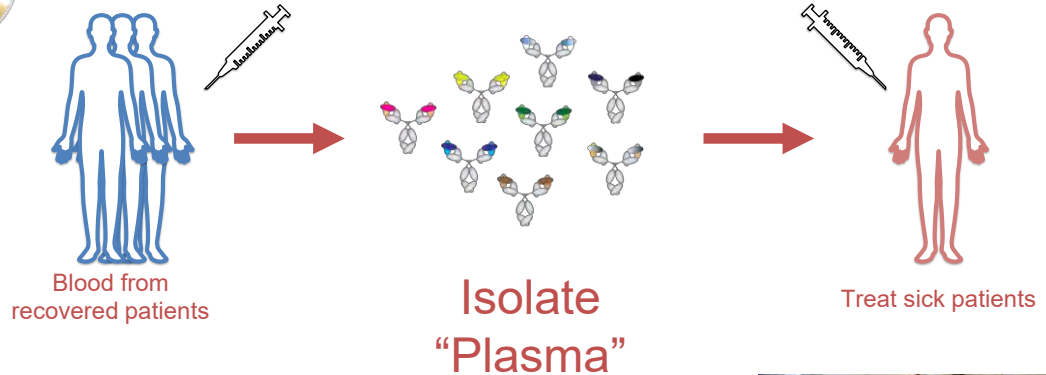
How Antibodies Protect Us from Viruses



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Convalescent Plasma Therapy



Dr. Lise-Anne Pirofski
EINSTEIN
 Albert Einstein College of Medicine

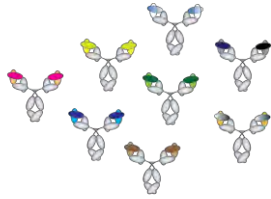
Montefiore
 Inspired Medicine



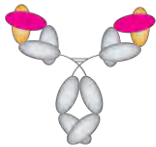
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Monoclonal Antibody Therapies



Polyclonal antibody (Convalescent plasma) "Machine gun"



- Easier to manufacture
- Safer
- More potent

Monoclonal antibody "Silver bullet"

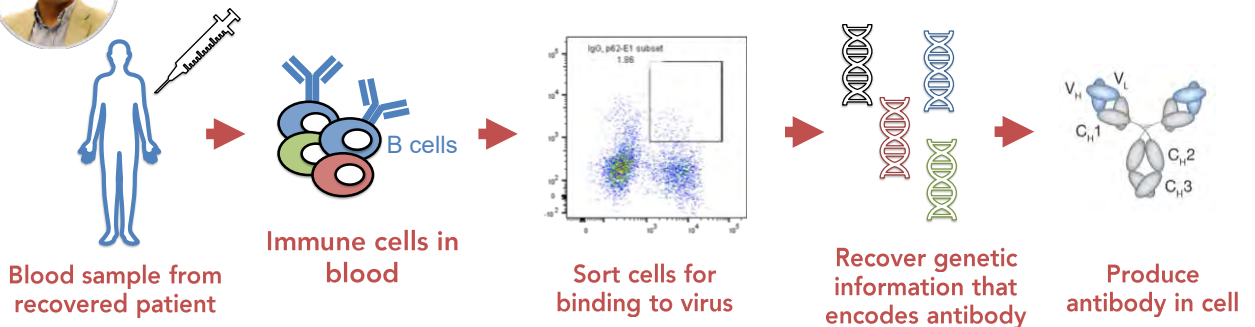
mAb therapy	Company	Virus	Development
Synagis	MedImmune/AstraZeneca	Respiratory syncytial virus	Approved
REGN-EB3	Regeneron	Ebola virus	Phase II
mAb 114	NIH/Ridgeback	Ebola virus	Phase II
3BNC117/10-1074	Rockefeller	HIV-1	Phase II
VRC01	NIH	HIV-1	Phase II
CM-JLD	Einstein/USAMRIID/Celdara Medical	Sudan virus	Preclinical



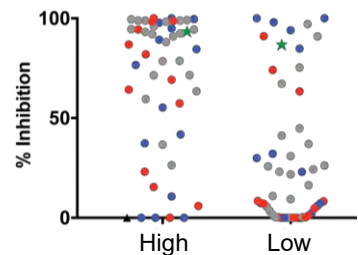
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Retrieving Monoclonal Antibodies from Recovered Patients



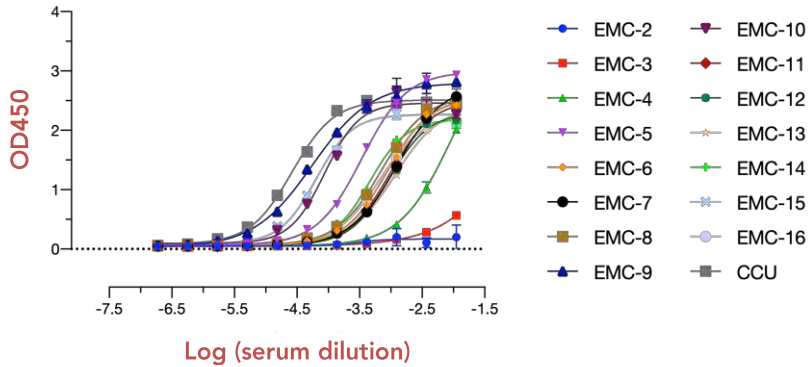
- **Advantages:**
 - Human antibodies have great safety profile.
 - Insight into human immune response, template for vaccine design.
- **New Therapeutics for:**
 - HIV-1 (NIH: VRC01)
 - Ebola virus (NIH: mAb114)
 - Chikungunya virus (our group: PLoS Pathog., 2019, 15, e1008061)



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Serum Antibody: Diagnosis and Protection?



- Can a person's serum antibody level be used to determine who has been infected and when?
- Does serum antibody level protect an individual from infection and disease?

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Acknowledgments



Funding:



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Treatment and Vaccine Development during a Pandemic

Raymond Forslund
Vice President, Head of CMC Development and Project Management, Syner-G



CMC (Chemistry, Manufacturing and Controls)



- **What is CMC?**

- CMC stands for Chemistry, Manufacturing and Controls
- It's how the active ingredient in a drug is made
- It's where all the "chemistry" takes place

- **Why is it important?**

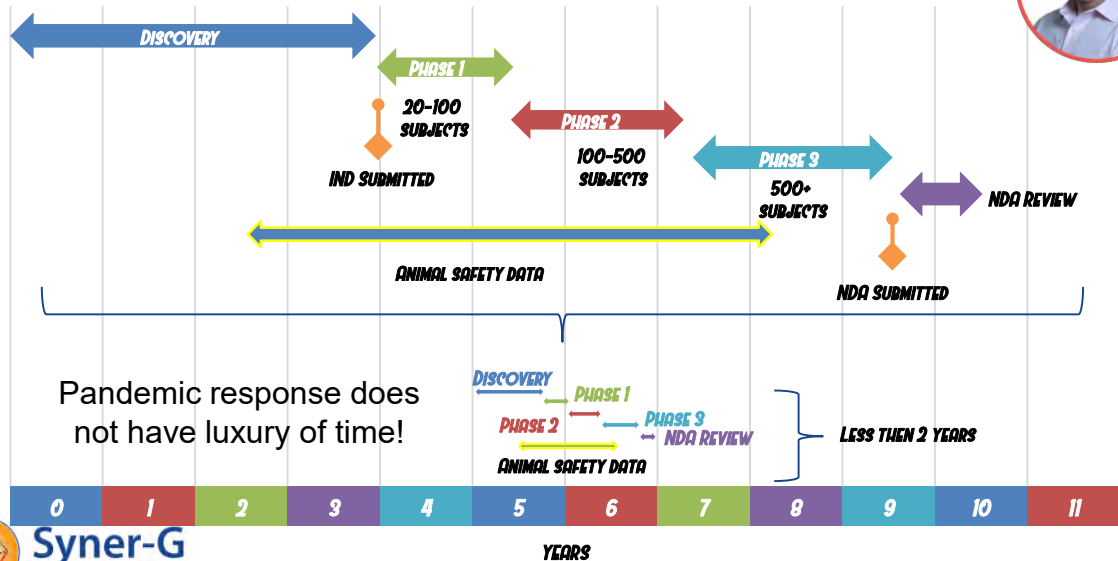
- Ensures the product is safe, effective and consistent between batches

- **How is safety, effectiveness and consistency ensured through chemistry**

- Thorough understanding and knowledge of the process of manufacturing (how its made)
- Thorough testing



Knowledge Takes Time



Vaccine Considerations



- **Vaccines are considered biologics**
 - Follow “Typical” timeline for discovery to approval to mitigate risk and cost
 - Control over manufacturing process and testing is difficult and costly
- **Pandemics increase urgency therefore more risk is tolerated however SAFETY can never be compromised**
 - Manufacturing scale must be quickly increased
 - Manufacturing control needs to be obtained to eliminate batch to batch variability
 - Analytical testing needs to be robust to ensure safety and potency
 - Manufacturing scale must be quickly increased

“Vaccine manufacture is one of the most challenging industries”

S. Plotkin et al Vaccine 35 (2017) 4064-4071



Small Molecule (Antiviral) Real Example!



- **Currently working on Avigan (favipiravir) an approved drug in Japan**
 - 13 active clinical trials
 - Was being developed in US for seasonal flu however NDA (New Drug Application) was never filed due to loss of funding
 - Drug has been given to over 3,000 patients
 - Major side effect: reproductive toxicology
- While drug is available in Japan **limited amounts** are available to rest of world
- US need could be **3 to 5 metric tons** by end of year



A major challenge to manufacture that much material so quickly!



<https://cen.acs.org/pharmaceuticals/drug-development/Fujifilm-tests-favipiravir-COVID-19/98/i15>

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Challenges to Manufacturing Material



- **Cost**
 - Can be overcome by private and government backing and collaboration
- **Availability of starting materials**
 - Need to secure 20+ metric tons diethyl malonate as a starting material
 - Limited world supply
- **Manufacturers with capacity**
 - Limited US manufacturers with large enough reactors and availability
- **Local and Federal regulations**
 - Some reagents have limitations on quantities allowed at one location
- **Ability to increase size of manufacturing scale**



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Register for Free!

What You Will Learn

- What types of fabrics and household cloth are effective in particle filtration and why
- The basics of particle filtration and data on filtration efficiencies as a function of size for common fabrics that are used in cloth masks
- How to disinfect N95 masks and how many times you can do it without reducing filtration efficiency

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- What makes beer cloudy and is "turbid" a bad word in the beer world
- How the raw materials and processes influence the clarity of beer
- What is the technological approach to ensuring the desired clarity every time

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Understanding the Scientific and Medical Aspects of the Pandemic



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 Professor of Biochemistry,
 Albert Einstein College of Medicine



Raymond Forslund
 Vice President, Head of CMC Development and
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Courtney Aldrich
 Professor, Department of Medicinal Chemistry, College
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