

From: Cockrell, Adam
Sent: Fri, 1 Apr 2016 13:00:42 +0000
To: (b)(6)
Cc: Stemmy, Erik (NIH/NIAID) [E]; Baric, Ralph
Subject: (b)(4) Therapeutic Data
Attachments: Summary of (b)(4) Therapeutic Study.pptx

Dear Brennan,

Through a collaboration between Dr. Marasco's and Dr. Baric's labs we have been testing (b)(4) and (b)(4) prophylactically and therapeutically (250ug at 24hrs post-infection). (b)(4) exhibit similar MERS-CoV neutralization profiles, therefore can be used interchangeably. Dr. Marasco has agreed to allow us to share the therapeutic data with you in an effort to not duplicate this study through the contract grant. Since this study was done during the contract period, and we are sharing this data with you, we would like to use this to fulfill our study obligation with AbViro.

Both antibodies perform similarly when prophylactically delivered, protecting mice from disease. The prophylactic data with (b)(4) will be in a paper from our group. (b)(4)

(b)(4)

(b)(4)

Cheers,

Adam Cockrell
Post-Doctoral Fellow
Department of Epidemiology
University of North Carolina at Chapel Hill
Chapel Hill, NC, 27599
Phone: (b)(6)

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Withheld pursuant to exemption

(b)(4)

of the Freedom of Information and Privacy Act

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(b)(4)

of the Freedom of Information and Privacy Act

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of the Freedom of Information and Privacy Act

Page 6 of 6

Withheld pursuant to exemption

(b)(4)

of the Freedom of Information and Privacy Act

From: Cockrell, Adam
Sent: Tue, 29 Mar 2016 20:21:25 +0000
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Baric, Ralph
Subject: (b) (4) data to share with AbViro

Hi Erik,

Wayne has given approval for use to share the (b)(4) data with AbViro, in the hopes that we can use this to fulfill their contract request, and not duplicate the therapeutic experiment with (b)(4)

Regards,

Adam Cockrell
Post-Doctoral Fellow
Department of Epidemiology
University of North Carolina at Chapel Hill
Chapel Hill, NC, 27599
Phone: (b)(6)

From: Cockrell, Adam
Sent: Mon, 28 Mar 2016 16:45:21 +0000
To: Stu Greenberg
Cc: Baric, Ralph; Stemmy, Erik (NIH/NIAID) [E]
Subject: RE: MERS Study

Hi Stu,

I have initiated the study, but it will not be completed (data analysis and all) for at least 2-3 weeks.

Regards,
Adam

From: Stu Greenberg [mailto:(b)(6)]
Sent: Monday, March 28, 2016 12:27 PM
To: Cockrell, Adam (b)(6)
Subject: MERS Study

Adam,

Would please let me know when you have initiated the protocol with our anti-MERS IgY.

Thanks,
Stu Greenberg

From: Perlman, Stanley
Sent: Thu, 24 Mar 2016 19:56:36 +0000
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Spiro, David (NIH/FIC) [E]; Baric, Ralph; Matthew Frieman
Subject: Re: Multi-PI grant

Dear Erik and David,

At the recent MERS Animal Workshop meeting, Ralph Baric, Matt Frieman and I proposed submitting a multi-PI grant comparing our different models of MERS, with the goal of elucidating factors important in pathogenesis. As you remember, we had three different hDPP4 “Knock-In” mice and several strains of mouse-adapted virus that resulted in lethal disease. In Matt’s experiments, the Regeneron mice infected with wild type MERS-CoV caused disease, without any requirement for additional murine adaptation. We think that comparing these different models will provide several approaches to understanding both virus and host factors that are important in severe MERS-CoV-mediated respiratory disease.

The three of us recently discussed details of a potential project and we would like to submit a grant for the June 5 deadline, although we may submit it a little later since I am eligible for continuous submission (I believe that this type of grant is eligible for continuous submission). When we discussed budgets, we decided that a budget of (b)(4) was required to complete the work. At this budget level, we need to obtain permission prior to submitting the application.

Does this sound reasonable to you and are you willing to look at a more complete pre-proposal application? If so, we plan to send you a document in the next 2 weeks. Should we use the same form that I recently used when we obtained approval for our PPG proposal or does require a different form?

I hope that all is well.

Stanley

Stanley Perlman, MD, PhD
Professor
Departments of Microbiology and Pediatrics
BSB 3-712
University of Iowa

(b)(6)

(b)(6)

From: Baric, Ralph S
Sent: Tue, 22 Mar 2016 16:58:25 +0000
To: Stemmy, Erik (NIH/NIAID) [E]; Cockrell, Adam
Subject: RE: Work with AbViro

Hi Erik, We put the NCE request into Mt. Sinai last week. Haven't heard status since that time. Ralph

From: Stemmy, Erik (NIH/NIAID) [E] [mailto:(b)(6)]
Sent: Tuesday, March 22, 2016 8:47 AM
To: Cockrell, Adam
Cc: Baric, Ralph S
Subject: RE: Work with AbViro

Ok, thanks. I'll let Brennan know they'll be next in the queue.

Any word yet on the NCE request? I don't think I've seen anything come in from MSSM yet.

Erik

From: Cockrell, Adam [mailto:(b)(6)]
Sent: Monday, March 21, 2016 5:37 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b)(6)
Cc: Baric, Ralph (b)(6)
Subject: RE: Work with AbViro

Hi Erik,

That sounds good. Once I get things to Wayne, and hear back from him, I will contact Brennan/AbViro.

Thanks,
Adam

From: Stemmy, Erik (NIH/NIAID) [E] [mailto:(b)(6)]
Sent: Monday, March 21, 2016 4:31 PM
To: Cockrell, Adam (b)(6)
Cc: Baric, Ralph S (b)(6)
Subject: RE: Work with AbViro

Great. Email addresses are below. Please copy me when you email them.

For Ostrigen, we're finalizing the service request form now. I don't mind if they ship the compound before that's finished, but we like to have the SRF signed before the study starts so there's documentation of the submitter signing off on the study design. Avoids any confusion later on!

Thanks!
Erik

Brennan Klose (b)(6)

Urban Ramstedt (b)(6)

From: Cockrell, Adam [mailto:(b)(6)]

Sent: Monday, March 21, 2016 3:38 PM

To: Stemmy, Erik (NIH/NIAID) [E] (b)(6)

Cc: Baric, Ralph (b)(6)

Subject: RE: Work with AbViro

Hi Erik,

I do not emails from any of the folks from AbViro. Could you provide?

Definitely would have to wait on discussing the therapeutic study with AbViro. I think it would be best for me to forward things to Wayne first, and ask him if it is alright to discuss things with AbViro. Do you think AbViro can wait until we get everything to Wayne, and hear back from him? May take a week, but the Ostrigen study will be in the works anyway. I am in agreement about the frustrating part!

Yeah, I received a call today from (b)(6) (Stu's connection at USAMRIID) to let me know that the antibodies should be shipped for arrival by Thursday. They are sending a boat load of antibody. I will be going forward with this one first.

Thanks,
Adam

From: Stemmy, Erik (NIH/NIAID) [E] [mailto:(b)(6)]

Sent: Monday, March 21, 2016 2:19 PM

To: Cockrell, Adam (b)(6)

Cc: Baric, Ralph S (b)(6)

Subject: RE: Work with AbViro

Hi Adam,

We may need to check with AbViro on that. If it will be useful for them then I am ok with it as long as it wouldn't cost more than the A57 studies. Though if they have different development plans for (b)(4) (b)(4) they may still want to complete the (b)(4) study. Is there a follow on study that might be useful as well? Do you mind emailing Brennan back to ask? I'm not sure if you'll have to check with Wayne or not before discussing the (b)(4) study. It's a little frustrating they don't seem to be communicating!

Regardless, it looks like things are in place for the other Ostrigen study. We got their agreement signed at the end of last week so while we work out what to do with AbViro you guys should be good to proceed with that study if you're ready. Let me know if you have questions.

Thanks!
Erik

From: Cockrell, Adam [mailto:(b)(6)]
Sent: Monday, March 21, 2016 2:07 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b)(6)
Cc: Baric, Ralph (b)(6)
Subject: Work with AbViro

Hi Erik,

Wanted to check with you on something before I send the protocol.

As a collaboration with Wayne Marasco, I just completed a therapeutic dose (250ug/mouse) study of (b)(4) today. This is very similar to (b)(4) except a single modification of a glycosylation site. I will be able to put together the initial data on this within the next week or so. I will be forwarding the data to Wayne.

We have also done a prophylactic study with (b)(4) (250ug/mouse). This data has been provided to Wayne.

Would the therapeutic data with (b)(4) at this dose, suffice for AbViro, and the contract obligation?

Adam Cockrell
Post-Doctoral Fellow
Department of Epidemiology
University of North Carolina at Chapel Hill
Chapel Hill, NC, 27599
Phone: (b)(6)

From: Stu Greenberg
Sent: Wed, 16 Mar 2016 16:18:12 -0400
To: 'Cockrell, Adam'
Cc: Stemmy, Erik (NIH/NIAID) [E]; Baric, Ralph; 'Leyva-Grado, Victor';
(b)(6)
Subject: RE: GoToMeeting Invitation - A57 Call with Ostrigen

Hi Adam,

If there is enough at USAMRIID, I am sure they can ship it to Chapel Hill on Monday. I'll let you know on Friday when I speak with (b)(6)

Regards,
Stu

From: Cockrell, Adam [mailto:(b)(6)]
Sent: Wednesday, March 16, 2016 2:35 PM
To: Stu Greenberg (b)(6) 'Stemmy, Erik (NIH/NIAID) [E]' (b)(6)
Cc: Baric, Ralph S (b)(6) 'Leyva-Grado, Victor' (b)(6)
(b)(6)
Subject: RE: GoToMeeting Invitation - A57 Call with Ostrigen

Hi Stu,

Thanks, that sounds good. If they are able to ship from USAMRIID, can we get the control and therapeutic shipped on Monday (03-21-16) for arrival on Tuesday (03-22-16)

The following is the shipping address:

Adam Cockrell
UNC-CH
135 Dauer Dr.
3105 MHRC, CB#7435
Chapel Hill, NC, 27599
Lab phone #: (b)(6)

Thanks,
Adam

From: Stu Greenberg [mailto:(b)(6)]
Sent: Wednesday, March 16, 2016 10:29 AM
To: Cockrell, Adam (b)(6) 'Stemmy, Erik (NIH/NIAID) [E]' (b)(6)
Cc: Baric, Ralph S (b)(6) 'Leyva-Grado, Victor' (b)(6)
(b)(6)
Subject: RE: GoToMeeting Invitation - A57 Call with Ostrigen

Adam and Erik,

If enough material is available at USAMRIID, we will send it to you from Ft. Detrick. I suspect that is the case, and (b)(6) will verify that for us on Friday of this week.

Should that not be the case, Dr. Tsukamoto will send the material from Japan.

Regards,
Stu Greenberg

From: Cockrell, Adam [mailto:(b)(6)]
Sent: Friday, March 11, 2016 12:25 PM
To: Stu Greenberg (b)(6) 'Stemmy, Erik (NIH/NIAID) [E]' (b)(6)
Cc: Baric, Ralph S (b)(6) 'Leyva-Grado, Victor' (b)(6)
(b)(6)
Subject: RE: GoToMeeting Invitation - A57 Call with Ostrigen

Hi everyone,

It was good meeting everyone this morning. I have attached a PDF with timeline for the study.

Once we have the antibodies in hand we will have a better idea of when we can initiate the study.

Regards,
Adam

From: Stu Greenberg [mailto:(b)(6)]
Sent: Friday, March 11, 2016 11:42 AM
To: 'Stemmy, Erik (NIH/NIAID) [E]' (b)(6)
Cc: Baric, Ralph S (b)(6) Cockrell, Adam (b)(6) 'Leyva-Grado, Victor' (b)(6)
Subject: RE: GoToMeeting Invitation - A57 Call with Ostrigen

Hi Erik,

I think my Japanese colleagues were able to hear most of what went on.

Here are their email addresses:

Dr. Yasuhiro Tsukamoto - (b)(6)

Koichi Kimura - (b)(6)

Makoto Goda - (b)(6)

Regards,
Stu Greenberg

From: Stemmy, Erik (NIH/NIAID) [E] [mailto:(b)(6)]
Sent: Friday, March 11, 2016 10:22 AM
To: 'Stu Greenberg' (b)(6); Baric, Ralph (b)(6); Cockrell, Adam (b)(6); 'Leyva-Grado, Victor' (b)(6)
Subject: RE: GoToMeeting Invitation - A57 Call with Ostrigen

Hi Everyone,
Thanks for all your patience with the audio difficulties. Stu, I don't believe I have email contacts from your Japanese colleagues. Could you please send them along so UNC can circulate the protocol directly?

Thanks!
Erik

-----Original Appointment-----

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Wednesday, March 9, 2016 6:40 PM
To: Stemmy, Erik (NIH/NIAID) [E]; 'Stu Greenberg'; Baric, Ralph; Cockrell, Adam; 'Baric, Toni C'; 'Leyva-Grado, Victor'; Umerah, Nina
Subject: GoToMeeting Invitation - A57 Call with Ostrigen
When: Friday, March 11, 2016 9:30 AM-10:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where:

Hi Everyone,
Please see below for dial in information the call to discuss the Ostrigen study. You should use the link to join, and then choose either VoIP through your computer or dial in using the toll free numbers for the audio. Let me know if you have trouble connecting. A brief agenda of the call is below as well.

Stu, please forward this information to your colleagues.

Thanks!
Erik

1. Overview of the therapeutic (Ostrigen)
2. Discuss details/requirements of the study (all)
3. Discuss scheduling (UNC)

1. Please join my meeting.

[\(b\)\(6\)](https://global.gotomeeting.com/join/(b)(6))

2. Use your microphone and speakers (VoIP) - a headset is recommended. Or, call in using your telephone.

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Japan (toll-free): 0 120 242 200

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From: Brennan Klose
Sent: Tue, 15 Mar 2016 20:07:23 +0000
To: Baric, Ralph; Stemmy, Erik (NIH/NIAID) [E]; Urban Ramstedt
Subject: Touching base on protocol slide

Hi Ralph and thanks again for the good discussion yesterday. Just thought I'd touch base on the draft protocol slide you mentioned.

Thanks & regards
Brennan

From: Baric, Toni C
Sent: Fri, 11 Mar 2016 22:14:01 +0000
To: Brennan Klose; Cockrell, Adam; Baric, Toni C; Urban Ramstedt; Stemmy, Erik (NIH/NIAID) [E]; Baric, Ralph; 'Leyva-Grado, Victor'; 'Umerah, Nina'
Subject: Re: GoToMeeting Invitation - A57 Call with AbViro

This is good for Ralph.

Thank you

Toni

Sent from my Verizon 4G LTE Smartphone

----- Original message-----

From: Brennan Klose

Date: Fri, Mar 11, 2016 4:59 PM

To: Cockrell, Adam; Baric, Toni C; Urban Ramstedt; Stemmy, Erik (NIH/NIAID) [E]; Baric, Ralph S; 'Leyva-Grado, Victor'; 'Umerah, Nina';

Cc:

Subject: RE: GoToMeeting Invitation - A57 Call with AbViro

That's fine

On Fri, Mar 11, 2016 at 1:54 PM -0800, "Stemmy, Erik (NIH/NIAID) [E]"

(b)(6) wrote:

Hi Everyone,

A schedule conflict has come up. Can we bump the call to 9am instead?

Erik

Sent with Good (www.good.com)

-----Original Message-----

From: Stemmy, Erik (NIH/NIAID) [E]

Sent: Friday, March 11, 2016 01:18 PM Eastern Standard Time

To: Stemmy, Erik (NIH/NIAID) [E]; Baric, Ralph; Cockrell, Adam; Baric, Toni C; 'Leyva-Grado, Victor'; Umerah, Nina; Brennan Klose; Urban Ramstedt

Subject: GoToMeeting Invitation - A57 Call with AbViro

When: Monday, March 14, 2016 10:00 AM-11:00 AM Eastern Standard Time

Where:

Hi Everyone,

Please see below for the dial in details for the next A57 study. Click the link to join the meeting, and then use either VoIP or the telephone number below to connect. A brief agenda also follows.

Erik

1. Overview of the therapeutic (AbViro)
2. Discuss details/requirements of the study (all)
3. Discuss scheduling (UNC)

1. Please join my meeting.

[https://global.gotomeeting.com/join](https://global.gotomeeting.com/join/(b)(6))

2. Use your microphone and speakers (VoIP) - a headset is recommended. Or, call in using your telephone.

Dial

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From: Baric, Toni C
Sent: Thu, 3 Mar 2016 15:19:12 +0000
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Cockrell, Adam; Baric, Ralph
Subject: RE: Call for MERS animal Models contract

Hi Erik
Any time except between 2:45 and 3:15.
Best regards,
Toni

From: Stemmy, Erik (NIH/NIAID) [E] [mailto:(b)(6)]
Sent: Thursday, March 03, 2016 10:18 AM
To: Baric, Toni C
Cc: Cockrell, Adam; Baric, Ralph S
Subject: RE: Call for MERS animal Models contract

Thanks Toni! Can we also block out a little time on March 14th? If possible I'd like to get a call on the books with the submitter for the last study so we can get things lined up for the rest of this period of the contract. Let me know if any time on 3/14 is best.

From: Baric, Toni C [mailto:(b)(6)]
Sent: Thursday, March 03, 2016 9:17 AM
To: Stemmy, Erik (NIH/NIAID) [E] (b)(6)
Cc: Cockrell, Adam (b)(6) Baric, Ralph (b)(6)
Subject: RE: Call for MERS animal Models contract

Wonderful, I will block out the time.

From: Stemmy, Erik (NIH/NIAID) [E] [mailto:(b)(6)]
Sent: Thursday, March 03, 2016 7:54 AM
To: Baric, Toni C
Subject: RE: Call for MERS animal Models contract

Great! I will aim for 9:30am. I'll send around dial in details once I confirm with the submitter.

Thanks!

From: Baric, Toni C [mailto:(b)(6)]
Sent: Thursday, March 03, 2016 7:37 AM
To: Stemmy, Erik (NIH/NIAID) [E] (b)(6)
Subject: Re: Call for MERS animal Models contract

Hi Erik,
Early morning is fine. We are on the road at 7:30 am so any time after 8 is good. We have cell dead zones so talking during our morning commute could be risky.
Keep me posted.

Toni

Sent from my Verizon 4G LTE Smartphone

----- Original message-----

From: Stemmy, Erik (NIH/NIAID) [E]
Date: Thu, Mar 3, 2016 7:29 AM
To: Baric, Toni C; Baric, Ralph S; Cockrell, Adam;
Cc:
Subject: RE: Call for MERS animal Models contract

Hi Toni,

Thanks very much for sending these times. I will aim to schedule it on Friday March 11th. Part of the group will be dialing in from Japan, so the call will likely need to be earlier in the day. Maybe around 9am. Would that be too early? I'll also need to get MSSM on too since they're the prime contractor.

Erik

From: Baric, Toni C [mailto:(b)(6)]
Sent: Wednesday, March 02, 2016 12:01 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b)(6) Baric, Ralph (b)(6)
Cockrell, Adam (b)(6)
Subject: Call for MERS animal Models contract

Hi Erik,

I am writing to set up a call between you, Ralph and Adam to discuss logistics issue regarding a future conversation with the 3rd party providing the therapeutic, and how they go about receiving it for testing.

Ralph has availability on March 11 any time except 12-1. He also has availability on Monday March 14 as well. Do either of these dates work for you?

Best regards,

Toni Baric

Department of Microbiology and Immunology
9025 Burnett Womack
CB# 7292

Chapel Hill, NC 27599-7292

Office: (b)(6)

(b)(6)

From: Dugan, Vivien (NIH/NIAID) [E]
Sent: Fri, 26 Feb 2016 17:30:45 -0500
To: 'Baric, Toni C'; Baric, Ralph; Beisel, Christopher (NIH/NIAID) [E]; Damania, Blossom A; Spiro, David (NIH/FIC) [E]; Stemmy, Erik (NIH/NIAID) [E]; Graham, Rachel; Mathur, Punam (NIH/NIAID) [E]; Sims, Amy C
Cc: Yao, Alison (NIH/NIAID) [E]
Subject: Canceled: 3/1 UNC-NIAID Monthly Conference call

The Tues 3/1/16 Orfeome call @12PM is canceled.

Vivien G. Dugan, Ph.D.
Program Officer in Systems Biology
Office of Genomics and Advanced Technologies (OGAT)
Division of Microbiology and Infectious Diseases/NIAID/NIH/DHHS
5601 Fishers Lane Room 7A29 MSC 9826
North Bethesda, MD 20892-9826

(b)(6) (phone)

(b)(6)

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-----Original Appointment-----

From: Baric, Toni C [mailto:(b)(6)]
Sent: Tuesday, December 01, 2015 11:46 AM
To: Baric, Toni C; Baric, Ralph; Beisel, Christopher (NIH/NIAID) [E]; Damania, Blossom A; Spiro, David (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Graham, Rachel; Mathur, Punam (NIH/NIAID) [E]; Sims, Amy C; Dugan, Vivien (NIH/NIAID) [E]
Subject: UNC-NIAID Monthly Conference call
When: Tuesday, March 01, 2016 12:00 PM-1:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Phone: (b)(6) Passcode: (b)(6)

From: Leyva-Grado, Victor
Sent: Mon, 22 Feb 2016 21:47:53 +0000
To: Stemmy, Erik (NIH/NIAID) [E]; Umerah, Nina
Cc: (b)(6) Baric, Ralph
Subject: RE: A57 call

Hi Erik,

That will work for us at Mount Sinai. When confirmed, please send us the call in information.

Cheers,

V

From: Stemmy, Erik (NIH/NIAID) [E] (b)(6)
Sent: Monday, February 22, 2016 3:16 PM
To: Leyva-Grado, Victor; Umerah, Nina
Cc: (b)(6) Baric, Ralph
Subject: RE: A57 call

Hi Everyone,
Will noon on 2/24 work for the group? Please let me know and I'll send the dial in details.

Erik

From: Leyva-Grado, Victor (b)(6)
Sent: Tuesday, February 16, 2016 11:20 AM
To: Stemmy, Erik (NIH/NIAID) [E] (b)(6) Umerah, Nina (b)(6)
Subject: RE: A57 call

Dear Erik,

These are some options:

2/17 10-2
2/18 1-2
Following week:
2/23 before 1
2/24 before 11 or 12-2:30
2/25 between 11-3

Please let me know.

Cheers,

V

From: Stemmy, Erik (NIH/NIAID) [E] (b)(6)
Sent: Thursday, February 11, 2016 10:24 AM
To: Umerah, Nina; Leyva-Grado, Victor
Subject: A57 call

Hi Nina and Victor,

I need to arrange a call with UNC and the next external submitter. Could you suggest two times that would work for UNC and MSSM? Should probably only need about 30-40 minutes.

Thanks!

Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, (b)(6)
Bethesda, MD 20892-9825
Phone: (b)(6)
Email: (b)(6)

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From: Baric, Ralph S
Sent: Wed, 3 Feb 2016 23:10:39 +0000
To: Stemmy, Erik (NIH/NIAID) [E]
Subject: RE: MERS Model Workshop Summary?

I would be delighted. Also, we have finished the 2nd animal model experiment with the therapeutic antibody.....so any more drugs? Ralph

From: Stemmy, Erik (NIH/NIAID) [E] [mailto:(b)(6)]
Sent: Wednesday, February 03, 2016 10:07 AM
To: Baric, Ralph S
Subject: MERS Model Workshop Summary?

Hi Ralph,
As we're finalizing the workshop agenda, we thought it would be good to have a short summary talk at the end of day two to recap some highlights from the science and discussion. David and I were wondering if you might be willing to fill that role. At the moment it's scheduled for 12:30-1pm on Tues March 1st, with the meeting adjourning afterwards. Please let me know if you think that would be able to do, or if you think someone else might be a better fit.

Thanks!
Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, (b)(6)
Bethesda, MD 20892-9825
Phone: (b)(6)
Email: (b)(6)

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From: (b)(6)
Sent: Fri, 22 Jan 2016 01:28:14 +0100
To: Cockrell, Adam
Cc: Stemmy, Erik (NIH/NIAID) [E]; Baric, Ralph
Subject: Re: Summary of LCA60 data for prophylaxis study

Dear Adam,
do you have some preliminary data to share?

Thanks!

Best regards,

(b)(6)

Il giorno 12 gen 2016, alle ore 15:54, Cockrell, Adam (b)(6) ha scritto:

Dear (b)(6)

Happy New Year!

The experiment is in progress.

Adam

From: (b)(6)
Sent: Tuesday, January 12, 2016 9:42 AM
To: Cockrell, Adam (b)(6)
Cc: Stemmy, Erik (NIH/NIAID) [E] (b)(6); Baric, Ralph S (b)(6)
Subject: Re: Summary of LCA60 data for prophylaxis study

Dear Adam,

I hope you had a good start of the New Year!

I am very curious to know what is the timeline to test LCA60 therapeutically.

Thanks!

Best regards,

(b)(6)

Humabs Biomed SA

Via Mirasole 1

CH-6500 Bellinzona

Switzerland

Tel: (b)(6)

E-mail: (b)(6)

<http://www.humabs.com>

Il giorno 19 dic 2015, alle ore 04:49, Cockrell, Adam (b)(6) ha scritto:

Hi everyone.

I have attached a summary of the LCA60 antibody data that includes survival, weight loss, hemorrhage score, and respiratory function for the prophylactic study. The remaining data will be collected in the new year.

Hope everyone has happy holidays.

Adam Cockrell

Post-Doctoral Fellow

Department of Epidemiology

University of North Carolina at Chapel Hill
Chapel Hill, NC, 27599
Phone: (b)(6)
<Summary of Data LCA60.pdf>

From: Subbarao, Kanta (NIH/NIAID) [E]
Sent: Fri, 18 Dec 2015 09:22:57 -0500
To: Stemmy, Erik (NIH/NIAID) [E]; Hensley, Lisa (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Munster, Vincent (NIH/NIAID) [E]; Baric, Ralph; Dreier, Thomas (OS/ASPR/BARDA); Spiro, David (NIH/FIC) [E]
Subject: Re: MERS Animal Model SAG

That seems fine to me.

Please note that the pathologist from the CDC that I recommended as a speaker is Sherif Zaki.

Thanks

Kanta

--

Kanta Subbarao, MD, MPH
Chief, Emerging Respiratory Viruses Section
Laboratory of Infectious Diseases,
NIAID, NIH
Bldg 33, Room 3E13C.1,
33 North Drive, MSC 3203
Bethesda, MD 20892-3203
Phone: (b)(6)
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From: "Stemmy, Erik (NIH/NIAID) [E]" (b)(6)
Date: Monday, December 14, 2015 at 2:46 PM
To: "Hensley, Lisa (NIH/NIAID) [E]" (b)(6) "Erlandson, Karl (OS/ASPR)"
(b)(6) "Munster, Vincent (NIH/NIAID) [E]" (b)(6) kanta s
(b)(6) Ralph Baric (b)(6) "Dreier, Thomas (OS/ASPR/BARDA)"
(b)(6) "Spiro, David (NIH/NIAID) [E]" (b)(6)
Subject: RE: MERS Animal Model SAG

Hi Everyone,

David and I have been considering the speakers list with the funds we have to work with for the workshop. Unfortunately due to the cost it appears we will be limited to supporting three international speakers. Based on our earlier discussions with the group we feel it is important to invite someone from both the Kingdom of Saudi Arabia and South Korea for their perspectives and potential case descriptions. Our last version of the agenda included several other foreign speakers on topics of epidemiology, lessons learned from SARS, as well as NHP and mice model work from China.

In looking at the agenda David and I propose the final international speak we support cover the lessons learned from SARS model and MCM development, and we were thinking of inviting Luis Enjuanes for that role. We will attempt to have the other topics covered by others already attending the workshop.

We'd appreciate it if you could let us know if you agree with this plan. If not, please let us know who you think would be a better choice for the final speaker slot we can support.

Many thanks!

Erik

From: Stemmy, Erik (NIH/NIAID) [E]

Sent: Monday, November 9, 2015 10:33 AM

To: Hensley, Lisa (NIH/NIAID) [E] (b)(6) Erlandson, Karl (OS/ASPR)

(b)(6) Munster, Vincent (NIH/NIAID) [E] (b)(6) Subbarao,

Kanta (NIH/NIAID) [E] (b)(6) Baric, Ralph (b)(6) Dreier,

Thomas (OS/ASPR/BARDA) (b)(6) Spiro, David (NIH/NIAID) [E]

(b)(6)

Subject: RE: MERS Animal Model SAG

Hi Everyone,

Thank you again for your time last week. I have attached an updated version of the agenda that I think incorporates the discussion and speaker suggestions. I would appreciate it if you could please review and send me any updates by Monday Nov 16th. In particular there are a few highlighted areas that we still need to identify a potential speaker.

Please let me know if you have any questions.

Erik

From: Hensley, Lisa (NIH/NIAID) [E]

Sent: Monday, November 2, 2015 9:30 AM

To: Erlandson, Karl (OS/ASPR) (b)(6) Munster, Vincent (NIH/NIAID) [E]

(b)(6) Stemmy, Erik (NIH/NIAID) [E] (b)(6) Subbarao, Kanta

(NIH/NIAID) [E] (b)(6) Baric, Ralph (b)(6) Dreier, Thomas

(OS/ASPR/BARDA) (b)(6) Spiro, David (NIH/NIAID) [E] (b)(6)

Cc: (b)(6)

Subject: Re: MERS Animal Model SAG

Waiting for the leader to admit

Lisa Hensley

Sent from b berry

From: Erlandson, Karl (OS/ASPR)

Sent: Monday, November 02, 2015 09:21 AM

To: Munster, Vincent (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Subbarao, Kanta (NIH/NIAID) [E]; Baric, Ralph; Munster, Vincent (NIH/NIAID) [E]; Dreier, Thomas (OS/ASPR/BARDA); Hensley, Lisa (NIH/NIAID) [E]; Spiro, David (NIH/NIAID) [E]

Cc: 'Baric, Toni C' (b)(6)

Subject: RE: MERS Animal Model SAG

(b)(5) (NIAID)
Code: (b)(5)

From: Munster, Vincent (NIH/NIAID) [E] [mailto:(b)(6)]
Sent: Monday, November 02, 2015 9:11 AM
To: Stemmy, Erik (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR); Subbarao, Kanta (NIH/NIAID) [E]; Baric, Ralph; Munster, Vincent (NIH/NIAID) [E]; Dreier, Thomas (OS/ASPR/BARDA); Hensley, Lisa (NIH/NIAID) [E]; Spiro, David (NIH/NIAID) [E]
Cc: 'Baric, Toni C'
Subject: Re: MERS Animal Model SAG

Trying to get onto the call?

Any ideas?

From: "Stemmy, Erik (NIH/NIAID) [E]" (b)(6)
Date: Wednesday, October 28, 2015 at 12:01 PM
To: "Erlandson, Karl (OS/ASPR)" (b)(6) "Subbarao, Kanta (NIH/NIAID) [E]" (b)(6) "Baric, Ralph" (b)(6) "Munster, Vincent (NIH/NIAID) [E]" (b)(6) "Dreier, Thomas (OS/ASPR/BARDA)" (b)(6) "Hensley, Lisa (NIH/NIAID) [E]" (b)(6) David Spiro (b)(6)
Cc: "'Baric, Toni C'" (b)(6)
Subject: RE: MERS Animal Model SAG

Hi Everyone,
I've chosen some times over the next week for our next call. Please see the Doodle poll link below.

Thanks!
Erik

<http://doodle.com/poll/8ubsbcih7kdpp2z5>

From: Erlandson, Karl (OS/ASPR)
Sent: Tuesday, October 27, 2015 11:18 AM
To: Stemmy, Erik (NIH/NIAID) [E] (b)(6) Subbarao, Kanta (NIH/NIAID) [E] (b)(6) Baric, Ralph (b)(6) Munster, Vincent (NIH/NIAID) [E] (b)(6) Dreier, Thomas (OS/ASPR/BARDA) (b)(6) Hensley, Lisa (NIH/NIAID) [E] (b)(6) Spiro, David (NIH/NIAID) [E] (b)(6)
Cc: 'Baric, Toni C' (b)(6)
Subject: RE: MERS Animal Model SAG

Hi Erik,

I also think it would be good to talk this over. I've made a few comments that could be used in the discussion.

Karl

From: Stemmy, Erik (NIH/NIAID) [E] [mailto:(b)(6)]
Sent: Friday, October 23, 2015 8:15 AM
To: Subbarao, Kanta (NIH/NIAID) [E]; Baric, Ralph; Munster, Vincent (NIH/NIAID) [E]; Dreier, Thomas (OS/ASPR/BARDA); Erlandson, Karl (OS/ASPR); Hensley, Lisa (NIH/NIAID) [E]; Spiro, David (NIH/NIAID) [E]
Cc: 'Baric, Toni C'
Subject: RE: MERS Animal Model SAG

Hi Everyone,

I haven't received any comments back on the updated agenda. If it is easier for the group I can have a shot at suggesting organizers for the sessions and we can discuss the agenda by phone. I would appreciate it if you could either send me your feedback, or let me know if scheduling a phone call would be easier, by Tuesday 10/27.

Thanks!
Erik

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Tuesday, October 13, 2015 8:58 AM
To: Subbarao, Kanta (NIH/NIAID) [E] (b)(6) Baric, Ralph
(b)(6) Munster, Vincent (NIH/NIAID) [E] (b)(6) Dreier, Thomas
(OS/ASPR/BARDA) (b)(6) Erlandson, Karl (OS/ASPR) (b)(6)
Hensley, Lisa (NIH/NIAID) [E] (b)(6) Spiro, David (NIH/NIAID) [E]
(b)(6)
Cc: 'Baric, Toni C' (b)(6)
Subject: RE: MERS Animal Model SAG

Hi Everyone,

Just a friendly reminder soliciting your feedback on the updated agenda draft attached again here. Also, I have looked into availability of the large conference room in our Fishers Lane building and come up with some potential dates (listed below.) Could you please let me know if there are any that should be off the table due to conflicts, any that might be good to use to piggy back on other meetings, or any other preferences you have? I would ideally like to reserve the room in the next week.

Thanks!
Erik

Current Room Availability:
January: 18-19, 20-21
February: 10-11, 15-18, 22-23, 22-25, 29-March 1
March: 9-10, 28-31

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Friday, October 02, 2015 12:55 PM
To: Subbarao, Kanta (NIH/NIAID) [E] (b)(6) Baric, Ralph
(b)(6) Munster, Vincent (NIH/NIAID) [E] (b)(6) Dreier, Thomas

(OS/ASPR/BARDA) (b)(6) Erlandson, Karl (OS/ASPR) (b)(6)
Hensley, Lisa (NIH/NIAID) [E] (b)(6) Spiro, David (NIH/NIAID) [E]
(b)(6)
Cc: 'Baric, Toni C' (b)(6)
Subject: MERS Animal Model SAG

Hi Everyone,

Thank you for your insightful discussion during our call on the 21st. David and I have incorporated your comments in the attached document. In particular we have expanded the agenda to a rough outline of a two day workshop, and would appreciate any feedback you have on the proposed session organization and topics. One other thing we'd like to ask is for volunteers to choose a session to chair. We anticipate the session chairs will take the lead in setting the format for the session, suggesting speakers, and leading the session during the workshop.

If possible we'd like to ask for your feedback on this draft agenda and deliverables on or before Oct 14th. Please let me know if you have any questions.

Many thanks!
Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, (b)(6)
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Phone: (b)(6)
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From: Cockrell, Adam
Sent: Wed, 16 Dec 2015 16:33:45 +0000
To: (b)(6)
Cc: (b)(6) Baric, Ralph; Maria Zambon; Baric, Toni C; Stemmy, Erik
(NIH/NIAID) [E]; (b)(6)
Subject: RE: UPDATE MERS MABS

Dear (b)(6)

I received the antibodies today.

Thank you and happy holidays.

Regards,

Adam

From: (b)(6)
Sent: Monday, December 14, 2015 5:45 AM
To: Cockrell, Adam (b)(6)
Cc: (b)(6) Baric, Ralph S (b)(6) Maria Zambon
(b)(6) Baric, Toni C (b)(6) Stemmy, Erik
(NIH/NIAID) [E] (b)(6)
Subject: Re: UPDATE MERS MABS

Dear Adam,

The antibodies were shipped today with Fedex, we expect them to arrive on December 16.

Here is the tracking nr. 775167325653

Please find attached the description of the materials sent

Best Regards

(b)(6)

On 04.12.2015 21:18, Cockrell, Adam wrote:

Dear (b)(6)

Just to be on the safe side it might be best to wait to ship the following Monday (12-14-15). That will give a week in case of unforeseen events.

Regards,

Adam

From: (b)(6)
Sent: Friday, December 04, 2015 3:14 PM
To: Cockrell, Adam (b)(6)
Cc: Baric, Ralph S (b)(6); Maria Zamboni (b)(6); Baric, Toni C (b)(6); Stemmy, Erik (NIH/NIAID) [E] (b)(6); (b)(6)
Subject: Re: UPDATE MERS MABS

Dear Adam,
Here Tuesday will be public Holiday and it will be therefore better ship on Wednesday, or alternatively organize the shipment for the following week on Monday.
What do you prefer?

Best regards,

(b)(6)

Humabs Biomed SA
Via Mirasole 1
CH-6500 Bellinzona
Switzerland
Tel: (b)(6)
E-mail: (b)(6)
<http://www.humabs.com>

Il giorno 03 dic 2015, alle ore 23:00, Cockrell, Adam (b)(6) ha scritto:

Dear (b)(6)

That sounds good. So the shipping goes smoothly, like the last shipment, could you ship on a Monday/Tuesday, and give me a notification of shipment so I can anticipate the date of receipt?

Once I have the data compiled I will definitely share it. I am leaving for the holidays on the 23rd and will not return until January 3rd. Provided all goes well I anticipate the initial experiment to be completed the 15th. I should be able to put together the weight loss and survival data.

Yes. I plan to use a mix of females/males that are 288-330 +/- homozygous mice. We do not currently have the numbers to include the 288-330 +/- hets.

Cheers,

Adam

From: (b)(6)
Sent: Thursday, December 03, 2015 9:23 AM
To: Cockrell, Adam (b)(6)
Cc: Baric, Ralph S (b)(6); Maria Zambon (b)(6); Baric, Toni C (b)(6); Stemmy, Erik (NIH/NIAID) [E] (b)(6); (b)(6)
Subject: Re: UPDATE MERS MABS

Dear Adam,
thanks for the clarifications.
We will aim to ship more material next week.
Would it be possible to have interim updates about the body weight loss and survival as soon as data will be available?

Another question, will you use 288-330 +/- homozygous mice only?

Best regards,

(b)(6)

Il giorno 02 dic 2015, alle ore 12:41, Cockrell, Adam (b)(6) ha scritto:

Dear (b)(6)

Thanks. It would be helpful to have all of the antibody on hand. The previous shipping arrangement worked well.

Regarding the timeline. I would anticipate the first results early-mid January (experiment 1). Provided our University EHS approvals have been received, and taking into account the holidays, I should initiate the second experiment by mid-January, and accumulate the necessary data to move forward on the third experiment by the end of January-beginning of February. Provided all goes well this would put us in mid-late February, possibly beginning of March to complete assays and assemble all the data.

Cheers,

Adam

From: (b)(6)
Sent: Tuesday, December 01, 2015 5:17 PM
To: Cockrell, Adam (b)(6)
Cc: Baric, Ralph S (b)(6); Maria Zambon (b)(6); Baric, Toni C (b)(6); Stemmy, Erik (NIH/NIAID) [E] (b)(6); (b)(6)
Subject: Re: UPDATE MERS MABS

Dear Adam,

Thanks for the slides! the description of the advantages of your model is indeed very helpful. Could you clarify what could be the overall timeline for the completion of the three experiments if performed stepwise?

Since you are using 12 mice/group (6 used for the day 3 analysis and 6 for the day 6 readouts) you should need a little bit more than 20 mg. We can plan a shipment of more LCA60 and a matched IgG1 Ab (MPE8) in a week or two.

Best regards,

(b)(6)

Humabs Biomed SA
Via Mirasole 1
CH-6500 Bellinzona
Switzerland

Tel: (b)(5)

E-mail: (b)(6)

<http://www.humabs.com>

Il giorno 01 dic 2015, alle ore 22:29, Cockrell, Adam (b)(6) ha scritto:

Hi everyone.

Here are the slides that we discussed on yesterday's phone call. The first couple describe the advantages of our model over existing mouse models and why it is the first model to recapitulate the severe respiratory disease that believe is occurring in humans.

The last 3 slides demonstrate the timeline for the study.

Please let me know if there are any comments/questions regarding the studies.

Regards,

Adam

From: Baric, Ralph S

Sent: Monday, November 30, 2015 9:06 AM

To: Maria Zamboni (b)(6) Baric, Toni C

(b)(6)

Cc: Stemmy, Erik (NIH/NIAID) [E] (b)(6) Cockrell, Adam (b)(6)

Subject: RE: UPDATE MERS MABS

From: Maria Zambon (b)(6)
Sent: Sunday, November 29, 2015 7:31 AM
To: (b)(6) Baric, Toni C
Cc: Stemmy, Erik (NIH/NIAID) [E]; Cockrell, Adam; Baric, Ralph S
Subject: RE: UPDATE MERS MABS

Colleagues,

Is there material in regards the mouse model set up by ralph Baric to be shared before this meeting tomorrow (as suggested in some of the earlier correspondance). I will be doing the phone call externally, so would appreciate an early view of any data, as I am not sure whether I will have good email access during the day tomorrow

thanks

Maria Zambon
Director, Reference Microbiology
Deputy Director, NIS
National Infection Service
Public Health England
(b)(6)
Tel: (b)(6)
www.gov.uk/phe Follow us on [Twitter@PHE.uk](https://twitter.com/PHEuk)
Protecting and improving the nation's health

From: (b)(6)
Sent: 10 November 2015 17:32
To: Baric, Toni C
Cc: Stemmy, Erik (NIH/NIAID) [E]; Maria Zambon; Cockrell, Adam; Ralph Baric; Robin Gopal
Subject: Re: UPDATE MERS MABS

Dear Toni,

This is fine. I can provide the call-in number.

Here it is:

UK: (b)(6)
Switzerland: (b)(6)
USA: (b)(6)

Participant access code: (b)(6)

Best regards,

(b)(6)

Il giorno 10 nov 2015, alle ore 17:52, Baric, Toni C (b)(6) ha scritto:

Hi Everyone,

Let's set this call for Nov 30 at 9 am EST/ 2pm UK time. Does this work? Also, does someone have a call-in number or should I set this up?

Thank you,

Toni

From: Stemmy, Erik (NIH/NIAID) [E] (mailto:(b)(6))
Sent: Thursday, November 05, 2015 9:30 AM
To: Baric, Toni C; Maria Zambon; Cockrell, Adam; (b)(6)
Cc: Baric, Ralph S; Robin Gopal
Subject: RE: UPDATE MERS MABS

My preference would be for 11/30. I can do any time before 1pm EST.

Erik

From: Baric, Toni C (mailto:(b)(6))
Sent: Thursday, November 05, 2015 9:26 AM
To: Maria Zambon (b)(6); Cockrell, Adam (b)(6); Stemmy, Erik (NIH/NIAID) [E] (b)(6)
Cc: Baric, Ralph (b)(6); Robin Gopal (b)(6)
Subject: RE: UPDATE MERS MABS

Hi Group,

Let's we revisit the following dates:

11/30 9-10 am EST or after 10 am EST

12/2 before 2 pm EST.

Please let me know the day and time range that works for all of you, keeping in mind that Maria will be calling in from UK.

Thanks

Toni

From: Maria Zambon (mailto:(b)(6))
Sent: Wednesday, November 04, 2015 5:49 PM

To: Cockrell, Adam; Baric, Toni C; Stemmy, Erik (NIH/NIAID) [E]; (b)(6)
Cc: Baric, Ralph S; Robin Gopal
Subject: RE: UPDATE MERS MABS

Hello,

Sorry if late to the party. I have already sent back a note saying the Monday of this week would work for me. Unfortunately I will be in Hng Kong the 17th to 20th, so would suggest we try earlier if we can

maria

Maria Zambon
Director, Reference Microbiology
Deputy Director, NIS
National Infection Service
Public Health England
(b)(6)
Tel: (b)(6)
www.gov.uk/phe Follow us on [Twitter@PHE.uk](https://twitter.com/PHEuk)
Protecting and improving the nation's health

From: Cockrell, Adam [mailto:(b)(6)]
Sent: 04 November 2015 20:21
To: Baric, Toni C; Stemmy, Erik (NIH/NIAID) [E]; (b)(6)
Cc: Baric, Ralph S; Maria Zambon; Robin Gopal
Subject: RE: UPDATE MERS MABS

That sounds good for me.
Thanks,
Adam

From: Baric, Toni C
Sent: Wednesday, November 04, 2015 3:11 PM
To: Stemmy, Erik (NIH/NIAID) [E]; (b)(6)
Cc: Baric, Ralph S (b)(6); Maria Zambon (b)(6); Cockrell, Adam (b)(6); Robin Gopal (b)(6)
Subject: RE: UPDATE MERS MABS

11/20 sounds good. How about 10 am? If this works for everyone, please let me know. Otherwise, please suggest a time before 1 pm that suits or a different day.
Thank you,
Toni

From: Stemmy, Erik (NIH/NIAID) [E] [mailto:(b)(6)]
Sent: Wednesday, November 04, 2015 3:07 PM
To: (b)(6) Baric, Toni C
Cc: Baric, Ralph S; Maria Zambon; Cockrell, Adam; Robin Gopal
Subject: RE: UPDATE MERS MABS

On 11/20 I can do any time before 1pm EST. Can we aim for that date?

Erik

From: (b)(6)
Sent: Wednesday, November 4, 2015 3:02 PM
To: Baric, Toni C (b)(6)
Cc: Stemmy, Erik (NIH/NIAID) [E] (b)(6) Baric, Ralph (b)(6) Maria Zambon (b)(6) Cockrell, Adam (b)(6) Robin Gopal (b)(6)
Subject: Re: UPDATE MERS MABS

Dear Toni,

I am available on all dates with the exception of 12/4.

Best regards,

(b)(6)

Il giorno 04 nov 2015, alle ore 20:25, Baric, Toni C (b)(6) ha scritto:

How about the following:

Friday 11/20 Ralph is open all day. Then the next day is 11/30 –after 11, Wednesday 12/2 before 2 and all day on 12/4.

Best regards,
Toni

From: Stemmy, Erik (NIH/NIAID) [E] [mailto:(b)(6)]
Sent: Wednesday, November 04, 2015 2:13 PM
To: Baric, Toni C; Baric, Ralph S; Maria Zambon; Cockrell, Adam
Cc: (b)(6) Robin Gopal
Subject: RE: UPDATE MERS MABS

I am leaving for a meeting in Riyadh on 11/12, so we'll have to schedule a call after I return on 11/16.

Erik

From: Baric, Toni C [mailto:(b)(6)]
Sent: Wednesday, November 4, 2015 12:06 PM
To: Baric, Ralph (b)(6); Maria Zambon (b)(6); Cockrell, Adam (b)(6)
Cc: (b)(6); Robin Gopal (b)(6); Stemmy, Erik (NIH/NIAID) [E] (b)(6)
Subject: RE: UPDATE MERS MABS

Hi Maria,
Ralph is available on 11/12 after 3:30 and between 11:30-3 on Friday 11/13
Best regards,
Toni

From: Baric, Ralph S
Sent: Tuesday, November 03, 2015 4:11 PM
To: Maria Zambon; Cockrell, Adam; Baric, Toni C
Cc: (b)(6); Robin Gopal; Stemmy, Erik (NIH/NIAID) [E]
Subject: RE: UPDATE MERS MABS

Hi Maria, We have recently received 20mg of pure antibody from (b)(6) and have support by Erik Stemmy to perform your studies in the mouse model. Initially, we will evaluate protection prior to infection. We currently don't have approval to use sharps for therapeutic intervention postinfection, but are in the process of putting in the paperwork to administer drug postinfection. I recommend a two phase study, first prior to infection to demonstrate efficacy and then drug dose at day 1 or 2 postinfection (single dose?). We likely need to set up a time to discuss the experiments. We will also share the model details at that time. Toni can assist. We also are planning on doing the protection study in early December, post infection study would likely be jan at best. Adam is a key contact person for discussion. Hope you are doing well. It's a pleasure to work with you again. Thoughts? ralph

From: Maria Zambon [mailto:(b)(6)]
Sent: Friday, October 23, 2015 3:52 PM
To: Baric, Ralph S
Cc: (b)(6); Robin Gopal
Subject: UPDATE MERS MABS

Dear Ralph,

Greetings , we have not corresponded for a while...I think another pesky virus (Ebola) has caused a bit of a diversion for all of us. (b)(6) has mentioned that you have developed a new animal model for MERS which is transgenic, and is very sensitive. This is just a brief note to explore the possibility of extending mouse model work for LCA60. We have submitted a proposal to the Medical Research Council (MRC) in the UK to take LCA60 into a Phase 1 clinical study. This proposal included the costs for Phase 1 scale up to GMP and also a Phase 1 Pk study in healthy volunteers, and is a large proposal.

The response from the MRC has been favourable, but they are requesting strengthening of the pre-clinical package in the proposal to try and give more indication of how the Mab could be used. We would appreciate your advice/collaboration in this

- (1) Could we propose more work in your mouse model to extend understanding of prophylaxis duration and the window for treatment. I am thinking about extending the time points post infection at which Mab is given and also refining knowledge of the duration of protection if given before challenge. One of the questions we are asked to address is to what are the parameters under which this might be used clinically. Currently the data we hold is more of a YES/NO format, rather than a considered model approach to window of treatment opportunity.
- (2) If you thought some more work was feasible, would this be possible without provision of funding from us under existing NIH contracts, or would you require additional funding, and if so, what would that be . (NB could we also slip in some work on LCA57, the non neutralising Mab that we have got ?). We would be pleased to include you as a co-applicant for MRC funding, subject to MRC rules for overseas applicants, but the full proposal application cannot be submitted before March, meaning that you might well have already done the work before we could provide any funding
- (3) What is your advice about whether the animal model you have developed is suitable for use...Suggestions welcome

Grateful for a rapid response

Maria Zambon
Director, Reference Microbiology
Deputy Director, NIS
National Infection Service
Public Health England
(b)(6)
Tel: (b)(6)
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<Slides for LCA60 Human mAb study.pdf>

--

(b)(6)

Humabs BioMed SA
Via Murate 5a
6500 Bellinzona

(b)(6)

From: (b)(6)
Sent: Tue, 15 Dec 2015 19:24:20 +0100
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Maria Zambon; Cockrell, Adam; Baric, Ralph; Leyva-Grado, Victor (b)(6)
(b)(6)
Subject: Re: Humab_In vivo SRF_03Dec2015

Dear Erik,
I am also sorry we could not talk more, the meeting was quite hectic.
Thanks for informing us.
I hope there will be a slot for a therapeutic study as soon as possible.
Best regards,

(b)(6)
Humabs Biomed SA
Via Mirasole 1
CH-6500 Bellinzona
Switzerland
Tel: (b)(6)
E-mail: (b)(6)
<http://www.humabs.com>

Il giorno 15 dic 2015, alle ore 18:01, Stemmy, Erik (NIH/NIAID) [E] (b)(6)
ha scritto:

Hi (b)(6)

It was good seeing you in Geneva, though sorry we didn't have the chance to speak more. Thanks for completing the SRF. I just wanted to let you and Maria know that for now I've approved the prophylactic study first, and then we'll be able to approve one of the therapeutic studies after. At the moment I have only four slots open in this contract, and I can't commit all (or most) of them to a single product since we have had a lot of other interest in access to this model. If I am able to exercise another option for this contract we may be able to support additional work with LCA60. Let me know if you have any questions.

Best,
Erik

From: Davide Corti [mailto:(b)(6)]
Sent: Friday, December 04, 2015 12:48 PM
To: Ghenbot, Ghiorghis (NIH/NIAID) [C] (b)(6)
Cc: Stemmy, Erik (NIH/NIAID) [E] (b)(6)
Subject: Re: Humab_In vivo SRF_03Dec2015

Dear Ghiorghis,
Here attached the compiled SRF. I hope this is fine.
I have already an account. I need to re-activate it because of the password expiring (the process of reactivation is not that friendly...).

Best regards,
(b)(6)

(b)(6)

Humabs Biomed SA
Via Mirasole 1
CH-6500 Bellinzona
Switzerland

Tel: (b)(6)

E-mail: (b)(6)

<http://www.humabs.com>

Il giorno 03 dic 2015, alle ore 16:42, Ghenbot, Ghiorghis (NIH/NIAID) [C]

(b)(6) ha scritto:

Hi (b)(6)

Please complete the SRF Form with pertinent information about your compound and with a brief description of the study and return to me. The partially approved SRF will be sent back to you for your signature.

Set up an account in MIS. If you do not have an account in MIS, let me know so one can be generated for you in which case you will be prompted by an e-mail asking you to setup your account.

Please note that we have an NCEA with your institution. Consult with your officer with regards to the details of the NCEA.

Thank you,

Ghiorghis

G. Ghenbot, Ph.D [c]
Scientific Program Manager
Respiratory Disease Branch (RDB)
Division of Microbiology and Infectious Diseases
NIAID/NIH/RDB
5601 Fishers Ln Room 8A16 MSC 9825
Bethesda, MD 20892-9825

Phone: (b)(6) (office)

Email: (b)(6)

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From: Stemmy, Erik (NIH/NIAID) [E]

Sent: Thursday, December 03, 2015 10:10 AM

To: Ghenbot, Ghiorghis (NIH/NIAID) [C] (b)(6)

Subject: FW: UPDATE MERS MABS

Hi Ghiorghis,

Can you please add the attached study design to the in vivo SRF and send it to (b)(6) (email below) for him to complete and upload to the MIS?

Thanks!

Erik

From: Stemmy, Erik (NIH/NIAID) [E]

Sent: Thursday, December 03, 2015 10:07 AM

To: (b)(6)

Subject: RE: UPDATE MERS MABS

Hi (b)(6)

I'll also need you to complete a similar service request form and upload to our MIS website. I'll have our MIS manager send you the form for the protocol outline shortly.

Thanks!

Erik

From: (b)(6)
Sent: Thursday, December 03, 2015 9:23 AM
To: Cockrell, Adam (b)(6)
Cc: Baric, Ralph (b)(6); Maria Zamboni (b)(6); Baric, Toni C (b)(6); Stemmy, Erik (NIH/NIAID) [E] (b)(6)
Subject: Re: UPDATE MERS MABS

Dear Adam,

thanks for the clarifications.

We will aim to ship more material next week.

Would it be possible to have interim updates about the body weight loss and survival as soon as data will be available?

Another question, will you use 288-330 +/- homozygous mice only?

Best regards,

(b)(6)

Il giorno 02 dic 2015, alle ore 12:41, Cockrell, Adam (b)(6) ha scritto:

Dear (b)(6)

Thanks. It would be helpful to have all of the antibody on hand. The previous shipping arrangement worked well.

Regarding the timeline. I would anticipate the first results early-mid January (experiment 1). Provided our University EHS approvals have been received, and taking into account the holidays, I should initiate the second experiment by mid-January, and accumulate the necessary data to move forward on the third experiment by the end of January-beginning of February. Provided all goes well this would put us in mid-late February, possibly beginning of March to complete assays and assemble all the data.

Cheers,

Adam

From: (b)(6)
Sent: Tuesday, December 01, 2015 5:17 PM
To: Cockrell, Adam (b)(6)
Cc: Baric, Ralph S (b)(6); Maria Zamboni (b)(6); Baric, Toni C (b)(6); Stemmy, Erik (NIH/NIAID) [E] (b)(6)
Subject: Re: UPDATE MERS MABS

Dear Adam,

Thanks for the slides! the description of the advantages of your model is indeed very helpful.

Could you clarify what could be the overall timeline for the completion of the three experiments if performed stepwise?

Since you are using 12 mice/group (6 used for the day 3 analysis and 6 for the day 6 readouts) you should need a little bit more than 20 mg. We can plan a shipment of more LCA60 and a matched IgG1 Ab (MPE8) in a week or two.

Best regards,

(b)(6)

(b)(6)

Humabs Biomed SA
Via Mirasole 1
CH-6500 Bellinzona
Switzerland

Tel: (b)(6)

E-mail: (b)(6)

<http://www.humabs.com>

Il giorno 01 dic 2015, alle ore 22:29, Cockrell, Adam (b)(6) ha scritto:
Hi everyone.

Here are the slides that we discussed on yesterday's phone call. The first couple describe the advantages of our model over existing mouse models and why it is the first model to recapitulate the severe respiratory disease that believe is occurring in humans.

The last 3 slides demonstrate the timeline for the study.

Please let me know if there are any comments/questions regarding the studies.

Regards,

Adam

From: Baric, Ralph S

Sent: Monday, November 30, 2015 9:06 AM

To: Maria Zambon (b)(6) Baric, Toni C

(b)(6)

Cc: Stemmy, Erik (NIH/NIAID) [E] (b)(6) Cockrell, Adam (b)(6)

Subject: RE: UPDATE MERS MABS

From: Maria Zambon [mailto:(b)(6)]

Sent: Sunday, November 29, 2015 7:31 AM

To: (b)(6) Baric, Toni C

Cc: Stemmy, Erik (NIH/NIAID) [E]; Cockrell, Adam; Baric, Ralph S

Subject: RE: UPDATE MERS MABS

Colleagues,

Is there material in regards the mouse model set up by ralph Baric to be shared before this meeting tomorrow (as suggested in some of the earlier correspondance). I will be doing the phone call externally, so would appreciate an early view of any data, as I am not sure whether I will have good email access during the day tomorrow

thanks

Maria Zambon

Director, Reference Microbiology

Deputy Director, NIS

National Infection Service

Public Health England

(b)(6)

Tel: (b)(6)

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From: (b)(6)

Sent: 10 November 2015 17:32

To: Baric, Toni C

Cc: Stemmy, Erik (NIH/NIAID) [E]; Maria Zambon; Cockrell, Adam; Ralph Baric; Robin Gopal

Subject: Re: UPDATE MERS MABS

Dear Toni,

This is fine. I can provide the call-in number.

Here it is:

UK: (b)(6)

Switzerland: (b)(6)

USA: (b)(6)

Participant access code: (b)(6)

Best regards,

Davide

Il giorno 10 nov 2015, alle ore 17:52, Baric, Toni C (b)(6) ha scritto:

Hi Everyone,

Let's set this call for Nov 30 at 9 am EST/ 2pm UK time. Does this work? Also, does someone have a call-in number or should I set this up?

Thank you,

Toni

From: Stemmy, Erik (NIH/NIAID) [E] (b)(6)

Sent: Thursday, November 05, 2015 9:30 AM

To: Baric, Toni C; Maria Zambon; Cockrell, Adam; (b)(6)

Cc: Baric, Ralph S; Robin Gopal

Subject: RE: UPDATE MERS MABS

My preference would be for 11/30. I can do any time before 1pm EST.

Erik

From: Baric, Toni C (b)(6)

Sent: Thursday, November 05, 2015 9:26 AM

To: Maria Zambon (b)(6) Cockrell, Adam (b)(6) Stemmy,
Erik (NIH/NIAID) [E] (b)(6)

Cc: Baric, Ralph (b)(6) Robin Gopal (b)(6)

Subject: RE: UPDATE MERS MABS

Hi Group,

Let's we revisit the following dates:

11/30 9-10 am EST or after 10 am EST

12/2 before 2 pm EST.

Please let me know the day and time range that works for all of you, keeping in mind that Maria will be calling in from UK.

Thanks

Toni

From: Maria Zambon (b)(6)

Sent: Wednesday, November 04, 2015 5:49 PM

To: Cockrell, Adam; Baric, Toni C; Stemmy, Erik (NIH/NIAID) [E]; (b)(6)

Cc: Baric, Ralph S; Robin Gopal

Subject: RE: UPDATE MERS MABS

Hello,

Sorry if late to the party. I have already sent back a note saying the Monday of this week would work for me. Unfortunately I will be in Hng Kong the 17th to 20th, so would suggest we try earlier if we can
maria

Maria Zambon

Director, Reference Microbiology

Deputy Director, NIS
National Infection Service
Public Health England

(b)(6)

Tel: (b)(6)

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From: Cockrell, Adam [mailto:(b)(6)]

Sent: 04 November 2015 20:21

To: Baric, Toni C; Stemmy, Erik (NIH/NIAID) [E]; (b)(6)

Cc: Baric, Ralph S; Maria Zambon; Robin Gopal

Subject: RE: UPDATE MERS MABS

That sounds good for me.

Thanks,

Adam

From: Baric, Toni C

Sent: Wednesday, November 04, 2015 3:11 PM

To: Stemmy, Erik (NIH/NIAID) [E]; (b)(6)

Cc: Baric, Ralph S; (b)(6); Maria Zambon; (b)(6); Cockrell,

Adam; (b)(6); Robin Gopal; (b)(6)

Subject: RE: UPDATE MERS MABS

11/20 sounds good. How about 10 am? If this works for everyone, please let me know. Otherwise, please suggest a time before 1 pm that suits or a different day.

Thank you,

Toni

From: Stemmy, Erik (NIH/NIAID) [E] [mailto:(b)(6)]

Sent: Wednesday, November 04, 2015 3:07 PM

To: (b)(6); Baric, Toni C

Cc: Baric, Ralph S; Maria Zambon; Cockrell, Adam; Robin Gopal

Subject: RE: UPDATE MERS MABS

On 11/20 I can do any time before 1pm EST. Can we aim for that date?

Erik

From: (b)(6)

Sent: Wednesday, November 4, 2015 3:02 PM

To: Baric, Toni C; (b)(6)

Cc: Stemmy, Erik (NIH/NIAID) [E]; (b)(6); Baric, Ralph; (b)(6); Maria Zambon; (b)(6); Cockrell, Adam; (b)(6); Robin Gopal

(b)(6)

Subject: Re: UPDATE MERS MABS

Dear Toni,

I am available on all dates with the exception of 12/4.

Best regards,

(b)(6)

Il giorno 04 nov 2015, alle ore 20:25, Baric, Toni C; (b)(6) ha scritto:

How about the following:

Friday 11/20 Ralph is open all day. Then the next day is 11/30 –after 11, Wednesday 12/2 before 2 and all day on 12/4.

Best regards,
Toni

From: Stemmy, Erik (NIH/NIAID) [E] [mailto:(b)(6)]
Sent: Wednesday, November 04, 2015 2:13 PM
To: Baric, Toni C; Baric, Ralph S; Maria Zambon; Cockrell, Adam
Cc: (b)(6) Robin Gopal
Subject: RE: UPDATE MERS MABS

I am leaving for a meeting in Riyadh on 11/12, so we'll have to schedule a call after I return on 11/16.
Erik

From: Baric, Toni C [mailto:(b)(6)]
Sent: Wednesday, November 4, 2015 12:06 PM
To: Baric, Ralph (b)(6) Maria Zambon (b)(6) Cockrell, Adam
(b)(6)
Cc: (b)(6) Robin Gopal (b)(6) Stemmy, Erik
(NIH/NIAID) [E] (b)(6)
Subject: RE: UPDATE MERS MABS

Hi Maria,
Ralph is available on 11/12 after 3:30 and between 11:30-3 on Friday 11/13
Best regards,
Toni

From: Baric, Ralph S
Sent: Tuesday, November 03, 2015 4:11 PM
To: Maria Zambon; Cockrell, Adam; Baric, Toni C
Cc: (b)(6) Robin Gopal; Stemmy, Erik (NIH/NIAID) [E]
Subject: RE: UPDATE MERS MABS

Hi Maria, We have recently received 20mg of pure antibody from (b)(6) and have support by Erik Stemmy to perform your studies in the mouse model. Initially, we will evaluate protection prior to infection. We currently don't have approval to use sharps for therapeutic intervention postinfection, but are in the process of putting in the paperwork to administer drug postinfection. I recommend a two phase study, first prior to infection to demonstrate efficacy and then drug dose at day 1 or 2 postinfection (single dose?). We likely need to set up a time to discuss the experiments. We will also share the model details at that time. Toni can assist. We also are planning on doing the protection study in early December, post infection study would likely be jan at best. Adam is a key contact person for discussion. Hope you are doing well. It's a pleasure to work with you again. Thoughts? ralph

From: Maria Zambon [mailto:(b)(6)]
Sent: Friday, October 23, 2015 3:52 PM
To: Baric, Ralph S
Cc: (b)(6) Robin Gopal
Subject: UPDATE MERS MABS

Dear Ralph,
Greetings , we have not corresponded for a while...I think another pesky virus (Ebola) has caused a bit of a diversion for all of us. (b)(6) has mentioned that you have developed a new animal model for MERS which is transgenic, and is very sensitive. This is just a brief note to explore the possibility of extending mouse model work for LCA60. We have submitted a proposal to the Medical Research Council (MRC) in the UK to take LCA60 into a Phase 1 clinical study. This proposal included the costs for Phase 1 scale up to GMP and also a Phase 1 Pk study in healthy volunteers, and is a large proposal.

The response from the MRC has been favourable, but they are requesting strengthening of the pre-clinical package in the proposal to try and give more indication of how the Mab could be used. We would appreciate your advice/collaboration in this

- (1) Could we propose more work in your mouse model to extend understanding of prophylaxis duration and the window for treatment. I am thinking about extending the time points post infection at which Mab is given and also refining knowledge of the duration of protection if given before challenge. One of the questions we are asked to address is to what are the parameters under which this might be used clinically. Currently the data we hold is more of a YES/NO format, rather than a considered model approach to window of treatment opportunity.
- (2) If you thought some more work was feasible, would this be possible without provision of funding from us under existing NIH contracts, or would you require additional funding, and if so, what would that be . (NB could we also slip in some work on LCA57, the non neutralising Mab that we have got ?). We would be pleased to include you as a co-applicant for MRC funding, subject to MRC rules for overseas applicants, but the full proposal application cannot be submitted before March, meaning that you might well have already done the work before we could provide any funding
- (3) What is your advice about whether the animal model you have developed is suitable for use...Suggestions welcome

Grateful for a rapid response

Maria Zambon

Director, Reference Microbiology

Deputy Director, NIS

National Infection Service

Public Health England

(b)(6)

Tel: (b)(6)

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<Slides for LCA60 Human mAb study.pdf>

<Humab_In vivo SRF_03Dec2015.docx>

From: Microsoft Outlook on behalf of Baric, Ralph
Sent: Thu, 3 Dec 2015 20:42:41 +0000
To: Stemmy, Erik (NIH/NIAID) [E]
Subject: Voice Mail from Baric, Ralph (17 seconds)
Attachments: (b)(6) 17 seconds) Voice Mail.mp3

Voice Mail Preview:

Hey Erik it's Ralph I'll try again in a little bit time send me an email sorry I'm calling late.

I was working on some paperwork and I just lost track of time I'll call you soon I'll call you again soon as possible talk to you soon bye bye.

Created by Microsoft Speech Technology. [Learn More...](#)

You received a voice mail from Baric, Ralph at (b)(6)

Caller-Id:	(b)(6)
Company:	NIH
Work:	(b)(6)
E-mail:	(b)(6)

From: Baric, Toni C
Sent: Tue, 1 Dec 2015 15:47:29 +0000
To: Baric, Ralph; Beisel, Christopher (NIH/NIAID) [E]; Damania, Blossom A; Spiro, David (NIH/FIC) [E]; Stemmy, Erik (NIH/NIAID) [E]; Graham, Rachel; Mathur, Punam (NIH/NIAID) [E]; Sims, Amy C; Dugan, Vivien (NIH/NIAID) [E]
Subject: UNC NIH conference call reminder

Hi Everyone,

Just a reminder that you will have the monthly UNC-NIH call for the Orfeome U19 today at 12pm. The calling instructions are below:

Phone: (b)(6)
Passcode: (b)(6)

Best regards,

Toni Baric

Department of Microbiology and Immunology

9025 Burnett Womack

CB# 7292

Chapel Hill, NC 27599-7292

Office: (b)(6)
(b)(6)

From: Mathur, Punam (NIH/NIAID) [E]
Sent: Fri, 20 Nov 2015 12:10:17 -0500
To: Baric, Ralph; Sean Crosson (b)(6)
(b)(6) 'Samuel Miller'; Rubin, Eric (b)(6) Baric, Toni C
(b)(6) Graham, Rachel; Hillary Hayden (b)(6)
Guinn, Ms Kristine (b)(6) Christopher X. Nelson (b)(6)
(b)(6) Yao, Alison (NIH/NIAID) [E]; Dugan, Vivien (NIH/NIAID) [E]; Lacourciere,
Karen (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Mukhopadhyay, Suman (NIH/NIAID) [E]
Cc: 'Sean Crosson'
Subject: Functional Genomics All PI meeting to discuss joint publication
Attachments: Steering Committee Feedback from Annual Program Meeting 042415PM.DOCX

Dear All,

This is a reminder for our call on **Monday, November 23rd from 12 – 1 pm EST** to discuss a joint publication from the 4 Functional Genomics Centers based on the recommendations of the Steering Committee. As discussed with all of you, the joint publication can be centered on defining “function” and the accomplishments of the centers. I have attached the feedback from Steering Committee on the Annual Functional Genomics Program Meeting held in Seattle in March.

Call in information

Toll free number: (b)(6)
Passcode: (b)(6)

Best,
Punam



NIAID/DMID Functional Genomics Annual Program Meeting

March 3, 2015

Emerging themes from the Steering Committee perspective

Three major themes emerged during the meeting:

- 1) How does NIAID or any of the center investigators define when an ORF or sRNA has been characterized, thus meeting the original goal?
 - The challenge arises in determining at what level an entity is "characterized" is well recognized by the investigators. Acceptable outcomes might include i) establishing a gene-ontology (GO) term; ii) defining enzymatic or regulatory activity; iii) identifying a binding partner; iv) solving a crystal structure.
- 2) How best to convey the work of the Functional Genomics centers to the larger research community?
 - A report integrating the collective activities of Centers would have two benefits: i) highlighting creative approaches being applied by the Functional Genomics centers that might be of interest to other researchers; ii) making other researchers aware of both successful and - importantly - failed approaches to expressing or otherwise characterizing specific ORFs. All communities would value knowing what has been attempted with each of organisms.
 - The Steering Committee concluded that the program leaders might consider writing a progress report describing "what we are doing, and why" that could be published in a broad-range venue like *PNAS* or *mBio*. Members of the Steering Committee would be willing to review or edit the manuscript.
- 3) Developing synergy across the Centers
 - The Center leaders identified four relevant areas for breakout sessions at the March 3 meeting - i) Bacterial phenotyping; ii) Functional analysis of molecules; iii) Non-coding RNA; iv) Data dissemination and analysis.
 - The challenge now is to extend these discussions beyond once per year so that they can really influence the strategies and workflow of each center.
 - Another area where synergy can take place across the Centers is in the data management. The cores from the four programs should have extensive discussion about what they can do to maximize efficiency and enhance the value from the extensive datasets that are being generated.

There appears to be good intra-Center communication and the leaders –have excellent knowledge about their centers at all scales. And the synergy that develops *within* Centers to address problems of common interest is considered a great value of the Program.

From: Erlandson, Karl (OS/ASPR)
Sent: Mon, 2 Nov 2015 15:00:58 +0000
To: Subbarao, Kanta (NIH/NIAID) [E]; Munster, Vincent (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Baric, Ralph; Dreier, Thomas (OS/ASPR/BARDA); Hensley, Lisa (NIH/NIAID) [E]; Spiro, David (NIH/FIC) [E]
Subject: RE: mbio papers
Attachments: Chan et al. - 2015 - Treatment with lopinavirritonavir or interferon- β .pdf

Marmoset work from State Key Laboratory of Emerging Infectious Diseases.

*Correspondence: Kwok-Yung Yuen, MD, State Key Laboratory of Emerging Infectious Diseases, Carol Yu Centre for Infection, Department of Microbiology, The University of Hong Kong, Queen Mary Hospital, 102 Pokfulam Road, Pokfulam, Hong Kong Special Administrative Region, China (b)(6).

From: Subbarao, Kanta (NIH/NIAID) [E] [mailto:(b)(6)]
Sent: Monday, November 02, 2015 9:58 AM
To: Erlandson, Karl (OS/ASPR); Munster, Vincent (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Baric, Ralph; Dreier, Thomas (OS/ASPR/BARDA); Hensley, Lisa (NIH/NIAID) [E]; Spiro, David (NIH/NIAID) [E]
Subject: mbio papers

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Kanta Subbarao, MD, MPH
Chief, Emerging Respiratory Viruses Section
Laboratory of Infectious Diseases,
NIAID, NIH
Bldg 33, Room 3E13C.1,
33 North Drive, MSC 3203
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Treatment with lopinavir/ritonavir or interferon- β 1b improves outcome of MERS-CoV infection in a non-human primate model of common marmoset

Jasper F. W. Chan^{1,2,3,4,a}, Yanfeng Yao^{5,a}, Man-Lung Yeung², Wei Deng⁵, Linlin Bao⁵, Lilong Jia², Fengdi Li⁵, Chong Xiao⁵, Hong Gao⁵, Pin Yu⁵, Jian-Piao Cai², Hin Chu², Jie Zhou², Honglin Chen^{1,2,3,4}, Chuan Qin^{5,b}, and Kwok-Yung Yuen^{1,2,3,4,b}

¹State Key Laboratory of Emerging Infectious Diseases,

²Department of Microbiology,

³Research Centre of Infection and Immunology,

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ABSTRACT

Middle East respiratory syndrome coronavirus (MERS-CoV) causes severe disease in human with an overall case-fatality rate of >35%. Effective antivirals are crucial for improving the clinical outcome of MERS. Although a number of repurposed drugs, convalescent-phase plasma, antiviral peptides, and neutralizing antibodies exhibit anti-MERS-CoV activity *in vitro*, most are not readily available or have not been evaluated in non-human primates. We assessed three repurposed drugs with potent *in vitro* anti-MERS-CoV activity (mycophenolate mofetil [MMF], lopinavir/ritonavir, and interferon- β 1b) in common marmosets with severe disease resembling MERS in human. The lopinavir/ritonavir-treated and interferon- β 1b-treated animals had better outcome than the untreated animals, with improved clinical (mean clinical scores $\downarrow$ 50.9%-95.0% and $\downarrow$ weight loss than the untreated animals), radiological (minimal pulmonary infiltrates), and pathological (mild bronchointerstitial pneumonia) findings, and lower mean viral loads in necropsied lung ($\downarrow$ 0.59-1.06 log₁₀copies/GAPDH, $P < 0.050$) and extrapulmonary ($\downarrow$ 0.11-1.29 log₁₀copies/GAPDH, $P < 0.050$ in kidney) tissues. In contrast, all MMF-treated animals developed severe and/or fatal disease with higher mean viral loads ($\uparrow$ 0.15-0.54 log₁₀copies/GAPDH) than the untreated animals. The mortality rate at 36 hpi was 67% (untreated and MMF-treated) versus 0-33% (lopinavir/ritonavir-treated and interferon- β 1b-treated). Lopinavir/ritonavir and interferon- β 1b alone or in combination should be evaluated in clinical trials. MMF alone may worsen MERS and should not be used.

BACKGROUND

Coronaviruses (CoVs) have repeatedly crossed species barriers and caused epidemics with significant socioeconomic impact (1). Middle East respiratory syndrome coronavirus (MERS-CoV) is a novel zoonotic lineage C β CoV discovered in 2012 (2). MERS-CoV infection in human, or MERS, commonly manifests as a severe acute respiratory disease which is often complicated by acute respiratory distress syndrome and multi-organ failure (3, 4). Clinical deterioration and death occur rapidly and at a few days earlier in MERS than in severe acute respiratory syndrome (SARS) (3). The case-fatality rate of MERS is the highest among all human coronavirus infections and exceeds 35% (5). Effective antiviral treatment, especially when given early to patients at risk of developing severe disease, may improve the clinical outcome of MERS. A number of new drug compounds, such as humanized or human monoclonal antibodies against the S1 subunit receptor-binding domain and antiviral peptides targeting the S2 subunit heptad repeat 2 domain of the MERS-CoV spike glycoprotein, have recently been developed and showed potent anti-MERS-CoV activity *in vitro* (6-9). However, their developments are still in the pre-clinical phase. Another possible treatment option for MERS is convalescent-phase plasma therapy. This has been previously used to treat other severe viral respiratory infections including SARS and pandemic influenza with good clinical and virological response (10-12). However, this is also not readily available as its preparation requires the recruitment of a large number of convalescent patients with high serum antibody titers. Convalescent-phase plasma with low serum antibody titers may be associated with immune enhancement, which could lead to worsened outcome as observed in *in vitro* and animal experiments on SARS (13, 14).

In order to find immediately available treatment for MERS before these novel agents and convalescent-phase plasma therapy become available, we and others have applied high-throughput screening to identify existing drugs that may be repurposed to treat patients with MERS (15-17). Examples of drugs identified using this drug discovery approach included inhibitors of virus entry, clathrin-mediated endocytosis, neurotransmitters, estrogen receptor, kinase signaling, lipid metabolism, protein processing, and DNA synthesis/repair (3, 15-19). Although all of them exhibit *in vitro* anti-MERS-CoV activity, only a few are likely clinically relevant as most are either associated with severe adverse effects or have anti-MERS-CoV half maximal effective concentrations (EC₅₀) that are not clinically achievable at therapeutic dosages. Previous studies have identified mycophenolate mofetil (MMF), ribavirin, lopinavir, interferon- α , and interferon- β as potential candidates for further *in vivo* evaluation (15-17, 20). Treatment with ribavirin and interferon- α has shown some effects *in vitro* and in MERS-CoV-infected rhesus macaques with mild disease, but the benefits in MERS patients were not obvious (20-22). In this study, we evaluated the treatment effects of MMF, lopinavir, and interferon- β in MERS-CoV-infected common marmosets. This recently described non-human primate model is the animal model which best represents severe human disease among all existing animal models for MERS (3, 23). Importantly, we found that lopinavir/ritonavir and interferon- β 1b, but not MMF, improved the outcome of MERS-CoV-infected common marmosets. The findings provide the basis for future clinical trials for this highly fatal disease.

METHODS

Virus strain and titration. MERS-CoV (EMC/2012 strain) was kindly provided by Ron Fouchier (Erasmus Medical Center). The virus was propagated in VeroE6 cells (ATCC) in

Dulbecco modified Eagle Medium (DMEM) supplemented with 10% fetal calf serum and 100 units/ml penicillin plus 100 µg/ml streptomycin. All experiments involving live MERS-CoV followed the approved standard operating procedures of the biosafety level 3 facility as previously described (24-28). The 50% tissue culture infectious dose (TCID₅₀) per ml was determined for MERS-CoV in VeroE6 cells as previously described (25).

Common marmoset infection model and treatment. All experiments involving common marmosets were performed as previously described with slight modifications and approved by the Institutional Animal Care and Use Committee (23, 26, 29). Briefly, twelve healthy male common marmosets (*Callithrix jacchus*; 3 years old; 230-395 g) were inoculated with 5×10^6 TCID₅₀ of MERS-CoV in 500 µl of DMEM intra-tracheally (Figure 1). The animals were randomly assigned to one of four treatment groups in a non-blinded manner (Table 1). Each treatment group included three animals. They were treated with sham treatment, MMF (CellCept®, Roche Pharmaceuticals, Inc., USA), lopinavir/ritonavir (4:1) (Kaletra®, Abbot Laboratories, USA), or recombinant interferon-β1b (Betaferon®, Bayer Schering Pharma, Germany) using previously described dosages (30-32). We administered MMF intraperitoneally and interferon-β1b subcutaneously instead of intravenously or orally respectively, because the small veins of the common marmosets prevented reliable drug delivery through the intravenous route and because critically ill MERS patients usually require parenteral treatment. Lopinavir/ritonavir was only available in oral preparation. We initiated treatment with MMF and interferon-β1b at 8 hours post-inoculation (hpi) according to a previously described treatment model using MERS-CoV-infected rhesus macaques (21). Treatment with lopinavir/ritonavir was started at 6 hpi as lopinavir/ritonavir takes longer to achieve its peak serum concentration (C_{max})

as compared to MMF and interferon- β 1b. The animals were observed twice daily for clinical signs and scored using a previously described clinical scoring system, which included the evaluation of the general appearance, skin and fur appearance, discharge (oral, nasal, and/or ocular), respiratory rate, and food consumption (23). Other clinical examinations in this study included measurement of body temperature (twice daily) and body weight (0, 24, and 72 hpi), and blood collection for hematology tests (0 hpi and necropsy). Dorsal-ventral and lateral chest X-rays (CXR) were performed on anesthetized animals (0, 24, and 72 hpi) as previously described (29). Necropsies were scheduled at 72 hpi or when the clinical score was ≥ 35 as previously described (21, 23). The necropsied tissues were collected for histopathology, immunohistochemistry, and viral load studies.

Histopathology and immunohistochemistry. The sections of the necropsied tissues were stained with hematoxylin and eosin for light microscopic examination and immunohistochemically stained with mouse anti-MERS-CoV nucleocapsid protein (1:200) antibody overnight at 4 °C for immunofluorescent examination of MERS-CoV nucleocapsid protein expression as described previously (27, 29, 33).

Viral load studies

RNA extraction and quantitative real-time reverse transcription-PCR were performed on necropsied lung, kidney, liver, spleen, and heart tissues as we previously described (25-27). Three areas with the most severe macroscopic lesions were obtained from each necropsied organ for viral load studies. Briefly, total RNA and viral RNA were isolated using Trizol (Life Technologies) and Viral RNA Mini kit (QIAGEN), respectively. After RNA quantification, 1 μ g

of RNA was reverse transcribed into cDNA using random hexamers. Total viral transcripts were detected using Novel Coronavirus 2012 Real-Time RT-PCR assay (CDC; Catalog # KT0136). The viral RNA were normalized to the mRNA expression level of GAPDH and a spike-in control, enterovirus 71 (strain SZ/HK08-5), using primers 5'-GCTCACTGGCATGGCCTTCCGTGT-3' and 5'-TGGAGGAGTGGGTGTCTGCTGTTGA-3' (GAPDH), and 5'-CCCCTGAATGCGGCTAATCC-3' and 5'-ACACGGACACCCAAAGTAGT-3' (enterovirus 71). For each reaction, equal amounts of cDNA were mixed with FS Universal SYBR Green Master Rox (Roche) plus 5 pmol each of forward and reverse primers. Amplification was done under the condition of 15 s at 95 °C and 1 min at 60 °C for 55 cycles in a 7900 real-time PCR detection system (ABI).

Statistical analysis

Statistical comparison between different groups was performed by the Student *t* test using GraphPad Prism 6. A *P* value of <0.05 was considered statistically significant.

RESULTS

Clinical and radiological findings

The untreated and MMF-treated animals developed severe disease with increased respiratory rates, reduced movement, and loss of appetite soon after MERS-CoV inoculation. At 12 hpi, the untreated and MMF-treated animals both had a mean clinical score of 18.3 (Figure 2). Their mean clinical scores peaked at 36 hpi, at which point two untreated (U2 and U3) and two MMF-treated (M1 and M2) animals developed severe dyspnea with cyanosis, barely moved, and had blood-stained oral discharge. They were euthanized at 36hpi as their clinical scores exceeded 35.

The euthanized animals had severe hypothermia (≤ 34.5 °C) at necropsy, which was suggestive of severe disease with shock (Supplementary Figure 1). CXR performed on these four animals prior to necropsy showed bilateral interstitial infiltrates, which were indicative of extensive pneumonia (Figure 4A and 4B). The remaining untreated (U1) and MMF-treated animals (M3) survived, but continued to have severe symptoms with clinical scores ≥ 15 (Figure 2) and temperature ≤ 37.5 °C, which was below their baseline levels, throughout the remaining study period (Supplementary Figure 1). CXR at 24 and 72 hpi showed interstitial infiltrates at bilateral lung bases (data not shown). At 24 hpi, the untreated and MMF-treated animals had 9.0% and 9.3% of weight loss, respectively (Figure 3). At 72 hpi, the weight loss increased to 15.0% and 12.9% in the remaining untreated and MMF-treated animals, respectively. In contrast, none of the lopinavir/ritonavir-treated and interferon- β 1b-treated animals developed severe symptoms. However, one lopinavir/ritonavir-treated (K3) animal died unexpectedly during anesthesia at 24 hpi, which was likely related to the anesthesia procedure as common marmosets are very small and fragile. As we could not obtain ethics approval to add another animal in the study, only K1 and K2 were assessed after 24 hpi. The overall mortality rate at 36 hpi was 67% in the untreated and MMF-treated animals, and 0-33% in the lopinavir/ritonavir-treated and interferon- β 1b-treated animals. The mean clinical score of the lopinavir/ritonavir-treated animals peaked at 24 hpi and gradually improved, whereas that of the interferon- β 1b-treated animals peaked at 36 hpi and then improved (Figure 2). Throughout the study, their mean clinical scores were consistently lower than those of the untreated (50.9-95.0%) and MMF-treated (50.9-93.3%) animals. Their temperature trend grossly correlated with their clinical scores, with the lowest temperature occurring at around 36 hpi, followed by normalization to the baseline level at 72 hpi (Supplementary Figure 1). At 24 hpi, the lopinavir/ritonavir-treated animals had some weight

loss (6.0%) which was significantly less than the untreated animals ($P = 0.038$) (Figure 3). At 72 hpi, the weight loss slightly increased to 7.5%. The interferon- β 1b-treated animals also had mild weight loss of 7.9% and 8.7% at 24 and 72 hpi, respectively. The lopinavir/ritonavir-treated animals had grossly normal CXR appearances, while the interferon- β 1b-treated animals only had mild basal interstitial infiltrate at 24 and 72 hpi (Figure 4C and 4D). There were no obvious differences in the mean leukocyte, erythrocyte, and platelet counts obtained at 0hpi and at necropsy among the four treatment groups (data not shown). However, changes at other time points might have been overlooked, as the small size of the animals prevented serial and frequent blood taking as described (23).

Histopathology and immunohistochemistry

Macroscopically, the necropsied lungs of the untreated and MMF-treated animals showed extensive, multi-lobar hemorrhagic lesions. The lungs were firm and fluid-filled with fluid leak (Figure 4A and 4B). In contrast, the gross lesions in the necropsied lungs of the lopinavir/ritonavir-treated and interferon- β 1b-treated animals were confined to one to two lobes (Figure 4C and 4D). Corroborating with the mild symptoms and normal CXR findings in lopinavir/ritonavir-treated animals, the macroscopic lesions in their lungs were the mildest. Microscopically, the necropsied lungs of the untreated and MMF-treated animals showed severe, multifocal to coalescing acute bronchointerstitial pneumonia (Figure 5A and 5C). Pulmonary alveoli were infiltrated by large amount of inflammatory cells, consisting predominantly of macrophages, neutrophils and lymphocytes. The alveolar interstitium was thickened with edema, fibrin, and hemorrhage. Abundant MERS-CoV nucleocapsid protein expression was detected in immunohistochemical staining (Figure 5B and 5D). In contrast, the necropsied lungs of the

lopinavir/ritonavir-treated and interferon- β 1b-treated animals showed mild to moderate bronchointerstitial pneumonia confined to one to two lobes, with small amount of inflammatory cell infiltrates, edema, and hemorrhage (Figure 5E and 5G). Immunohistochemical staining showed scarce and focal MERS-CoV nucleocapsid protein expression (Figure 5F and 5H). The histopathological changes in the necropsied extrapulmonary tissues of the four treatment groups were similar and considered to be non-specific changes associated with hypoxic damage or incidental findings in common marmosets as described (data not shown) (23).

Viral load studies

The mean viral load of necropsied lungs was highest in the MMF-treated animals and lowest in the lopinavir/ritonavir-treated animals (Figure 6). The mean viral load of the necropsied lungs of the MMF-treated animals was 0.44 $\log_{10}$ copies/GAPDH higher than that of the untreated animals. The mean viral loads of the necropsied lungs of lopinavir/ritonavir-treated and interferon- β 1b-treated animals were significantly lower than that of the untreated animals by 1.06 ($P = 0.036$) and 0.59 ($P = 0.048$) $\log_{10}$ copies/GAPDH, respectively. The MMF-treated animals also had the highest mean viral loads in the kidney, liver, and spleen, which were 0.15-0.54 $\log_{10}$ copies/GAPDH higher than those of the untreated animals. In contrast, the mean viral loads in all extrapulmonary tissues of the lopinavir/ritonavir-treated and interferon- β 1b-treated animals were consistently lower than those of the untreated animals by 0.11-1.29 $\log_{10}$ copies/GAPDH. The mean viral load in the necropsied kidney tissues of the lopinavir/ritonavir-treated animals was significantly lower than that of the untreated animals by 0.90 $\log_{10}$ copies/GAPDH ($P = 0.032$). Notably, two of the three interferon- β 1b-treated animals actually had undetectable viral loads in necropsied kidney tissues, which accounted for a large standard deviation value and

apparent lack of statistically significant difference despite a 0.90 log₁₀copies/GAPDH reduction as compared to the untreated animals.

DISCUSSION

As in most other epidemics caused by emerging viruses, the *de novo* development of novel anti-MERS-CoV drugs has lagged behind the rapid expansion of the MERS epidemic (3). The recent large healthcare-associated outbreak involving more than 180 infected patients and over 5000 close contacts in South Korea re-emphasizes the urgent need to find effective anti-MERS-CoV treatment. Drug repurposing is an especially advantageous approach as repurposed drugs usually have well-known pharmacokinetics, pharmacodynamics, side effects, and dosing regimens. These data would facilitate drug use in patients with severe MERS, who often have comorbidities or are complicated by multiorgan dysfunction. However, the lack of suitable animal models has been a major obstacle to evaluating countermeasures for MERS in the past three years. BALB/c mice, Syrian hamsters, and ferrets are not susceptible to MERS-CoV infection, while MERS-CoV-infected rhesus macaques only developed very mild and self-limiting disease (3, 21, 34-36). Intranasal administration of adenoviral vectors encoding the human dipeptidyl peptidase-4 (DPP4) receptor has been used to transduce and render BALB/c and C57BL/6 mice susceptible to MERS-CoV infection (37). Using this animal model, the treatment effects of poly(I·C) and adoptive transfer of sera containing anti-MERS-CoV spike glycoprotein antibodies in accelerating virus clearance from the lungs were demonstrated (37). However, the infection was relatively mild and confined to the respiratory tract. The DPP4-transgenic mouse model with more severe pulmonary and disseminated extrapulmonary disease was definitely better, but it was still not a non-human primate model (38). Recently, the common

marmoset model, which mimicked severe, disseminated MERS-CoV human infection, was established (23). This is the first study to report on the use of this new primate model for evaluating the treatment effects of repurposed drugs for MERS.

Consistent with the findings in the original description of the common marmoset model for MERS, the untreated animals in our study developed severe disease after MERS-CoV inoculation (23). Comparatively, our untreated animals developed symptoms and died slightly earlier than those in Falzarano's report (23). This might be related to the different ages of the animals (our study, 3 years; Falzarano's study, 2-6 years) and routes of virus inoculation. Instead of combined intranasal (8×10^5 TCID₅₀), intratracheal (2×10^6 TCID₅₀), conjunctival (4×10^5 TCID₅₀), and oral (2×10^6 TCID₅₀) inoculation (total inoculum: 5.2×10^6 TCID₅₀), we used intratracheal inoculation (5×10^6 TCID₅₀) which likely resulted in more direct delivery of the virus to the lower respiratory tract with faster disease onset. Nonetheless, the overall clinical, radiological, pathological, and virological findings of our untreated animals were otherwise similar to those described previously and mimicked severe MERS in human.

We have previously demonstrated the potent *in vitro* anti-MERS-CoV activity of MMF (15). However, the immunosuppressive effects of MMF have so far limited its use in MERS patients. Compared to ribavirin, which has doubtful effects in MERS patients, MMF exhibited a much lower EC₅₀ (MMF, 0.17 µg/ml; ribavirin, 10-40 µg/ml) that was markedly below its peak serum level (10-50 µg/ml) at routine clinical dosages (15). It was therefore postulated that a less immunosuppressive dose of MMF could be used to treat MERS. Our primate study showed that a single dose of MMF with long half-life did not improve and might have worsened MERS-CoV infection in common marmosets. This may partially explain why renal transplant recipients on MMF still developed severe or fatal MERS (39, 40).

Lopinavir is a protease inhibitor which may inhibit the 3C-like protease of MERS-CoV and modulate apoptosis in human cells (17, 41). Kaletra is a ritonavir-boosted lopinavir preparation which is commonly used as an anti-HIV medication. Lopinavir exhibits anti-MERS-CoV activity with an EC_{50} of 8.0 μM *in vitro*, which is below its C_{max} achieved after a single 500 mg oral dose of Kaletra (400 mg lopinavir/100 mg ritonavir) (17, 42). We have previously demonstrated the *in vivo* treatment effects of lopinavir/ritonavir in SARS patients. Compared to control SARS patients who received ribavirin for 21 days, patients who additionally received lopinavir/ritonavir 500 mg twice daily for 14 days had milder disease with less diarrhea, recurrence of fever, lymphopenia, nosocomial infections, nasopharyngeal viral load, fecal RT-PCR positivity rate, and 21-day adverse outcome (43). Most patients tolerated a short course of lopinavir/ritonavir well, although some experienced gastrointestinal upset, deranged liver function, headache, blurred vision, anemia, and asymptomatic bradycardia (43). A MERS patient who received combinational lopinavir-ritonavir, pegylated interferon, and ribavirin had resolution of viremia after two days of treatment (44). Our present study showed that treatment with lopinavir/ritonavir improved the clinical, radiological, and pathological features in MERS-CoV-infected common marmosets. The lopinavir/ritonavir-treated animals had the lowest mean viral loads in lung and most extrapulmonary tissues at necropsy. These findings provided further support for the use of lopinavir/ritonavir in patients with severe MERS.

MERS-CoV attenuates interferon response to evade the host's innate immune system (45). MERS-CoV is 50-100 times more sensitive to pegylated interferon- α than SARS-CoV *in vitro* (46). Therefore, treatment of MERS with interferons was considered and evaluated *in vitro* and in a small number of patients. In Vero/Vero6 cells, interferon- β 1b (Betaferon) exhibited a lower EC_{50} : C_{max} ratio than interferon- α 2a, - α 2b, and - β 1a (15, 47). This might partially explain why

the treatment effects of interferon- α 2a, - α 2b, and - β 1a on the survival rates of a small cohorts of MERS patients were not obvious (22, 48-50). In this study, we showed that MERS-CoV-infected common marmosets treated with interferon- β 1b had less severe disease and lower mean viral loads in necropsied lung and extrapulmonary tissues compared with untreated animals. Notably, as the lesions in the lopinavir/ritonavir-treated and interferon- β 1b-treated animals were confined to one to two lobes, the overall mean viral load difference between these animals and the untreated animals were likely underestimated. Interferon- β 1b is commonly used to treat patients with multiple sclerosis and is usually well tolerated (32). Rarely, monoclonal gammopathy patients treated with interferon- β 1b may develop systemic capillary leak syndrome (32). Other uncommon side effects include hypersensitivity, pancreatitis, depression, cytopenia, cardiomyopathy, and liver and thyroid dysfunction (32). Given interferon- β 1b's good safety profile, and our *in vitro* and *in vivo* results, its use should be considered in clinical trials with MERS patients who have no contraindication for interferon therapy.

We did not evaluate the effects of combinational treatment with two or more drugs due to the difficulty in getting approval for using more primates. Nevertheless, the findings in this non-human primate study are encouraging for conducting clinical trials with MERS patients using monotherapy or combinational treatment with these repurposed drugs. The *in vivo* anti-MERS-CoV effects and the lack of drug interactions between lopinavir/ritonavir and interferon- β 1b make this an attractive combination in future clinical trials. In contrast, it is still uncertain if the combination of interferon- β 1b and/or lopinavir/ritonavir with a lower dose of MMF may provide better viral load suppression to overcome the deleterious effects of the latter drug. Notably, the combination of MMF and interferon- β 1b showed synergistic effects in MERS-CoV inhibition *in vitro* (15). If this combination is shown to be effective in common marmosets, it may become an

alternative treatment option in patients who are intolerant to interferon- β 1b and/or lopinavir/ritonavir. Other potentially effective treatment regimens such as the combination of ribavirin with interferon- β 1b and/or lopinavir/ritonavir should also be evaluated in the common marmoset model. Although the use of high-dose ribavirin is limited by its severe side effects, low-dose ribavirin combined with interferon- β 1b and/or lopinavir/ritonavir may be synergistic and should still be considered. Finally, the shorter median time interval between symptom onset and death in MERS than in SARS patients emphasizes the importance of early use of these antiviral combinations in MERS. This is because MERS-CoV not only dampens the host innate interferon response, but also effectively suppresses the adaptive immune response by infection of CD3⁺ lymphocytes and induction of apoptosis via the both extrinsic and intrinsic pathways in a high percentage of peripheral blood and splenic lymphocytes. Failure to control MERS-CoV replication during the early phase of disease may therefore lead to an impaired adaptive immune response with poor outcome.

NOTES

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Meetings. The information in this study has not been presented in any scientific meeting.

Table 1. Treatment groups and drug regimens used in this study

Group	Common marmoset	Treatment regimen
1	U1, U2, U3	Untreated (sham treatment with comparable volume per kg body weight of sterile saline)
2	M1, M2, M3	CellCept® (25 mg/kg of mycophenolate mofetil given ip once at 8 hpi)
3	K1, K2, K3	Kaletra® (12 mg/kg/day of lopinavir + 3mg/kg/day of ritonavir given orally once daily at 6, 30, and 54 hpi)
4	B1, B2, B3	Betaferon® (0.267 million IU/kg of interferon-β1b given sc at 8 hpi and at 56 hpi)

Abbreviations: hpi, hours post-inoculation; ip, intraperitoneal; sc, subcutaneous.

FIGURE LEGENDS

Figure 1. Schedule of MERS-CoV inoculation, examination, treatment, and necropsy of the common marmosets. ^aK3 died unexpectedly during anesthesia at 24hpi, which was likely related to the anesthesia procedure as common marmosets are very small and fragile. Abbreviations: MERS-CoV, Middle East respiratory syndrome coronavirus; MMF, mycophenolate mofetil.

Figure 2. Mean clinical scores of MERS-CoV-infected common marmosets at different time points after virus inoculation. Necropsies of the common marmosets were scheduled at 72 hpi or when the clinical score was ≥ 35 . The number of animals remaining in the experiment is indicated above the bar at each time point. Student *t* test was performed for comparison when all three animals in each group were available. ^aK3 died unexpectedly during anesthesia at 24 hpi, which was likely related to the anesthesia procedure as common marmosets are very small and fragile. Abbreviations: MERS-CoV, Middle East respiratory syndrome coronavirus; MMF, mycophenolate mofetil.

Figure 3. Serial measurements of body weight of MERS-CoV-infected common marmosets. Mean percentage of weight loss at 24 and 72 hpi, compared with the

baseline body weight at 0 hpi. The number of animals remaining in the experiment is indicated above the bar at each time point. ^aK3 died unexpectedly during anesthesia at 24hpi, which was likely related to the anesthesia procedure as common marmosets are very small and fragile. Asterisk indicates a P value of <0.05. Abbreviations: MERS-CoV, Middle East respiratory syndrome coronavirus; MMF, mycophenolate mofetil.

Figure 4. Representative radiological findings and macroscopic pathology of the lungs of MERS-CoV-infected common marmosets. Dorsal-ventral and lateral chest X-rays were performed immediately prior to necropsy. The circles represent areas of interstitial infiltration indicative of pneumonia. (A) Untreated common marmoset (U2) at 36 hpi; (B) MMF-treated common marmoset (M2) at 36 hpi; (C) Lopinavir/ritonavir-treated common marmoset (K1) at 72 hpi; and (D) Interferon- β 1b-treated common marmoset (B2) at 72 hpi. The arrows represent gross lesions in the necropsied lungs. Abbreviations: D, dorsal side; hpi; hours post-inoculation; L, left side; MMF, mycophenolate mofetil.

Figure 5. Representative photomicrographs of histopathology examination and immunohistochemical staining of necropsied lung tissues of MERS-CoV-infected common marmosets. Severe acute bronchiointerstitial pneumonia centered on terminal

bronchioles, with thickened alveolar interstitium and alveoli being filled with large amount of inflammatory cell infiltrate, edema, and hemorrhage in hematoxylin and eosin (H&E)-stained necropsied lung tissue of untreated (A) and MMF-treated (C) animals collected at 36 hpi (magnification, 100×). Abundant expression of MERS-CoV nucleocapsid protein was detected by mouse anti-MERS-CoV nucleocapsid protein (1:200) antibody (green) overlaid with counterstaining by propidium iodide (red) in the necropsied lung tissues of the untreated (B) and MMF-treated (D) animals (magnification, 100×). These pathological changes were seen extensively in multiple lobes of the necropsied lungs of the untreated and MMF-treated animals. Mild acute bronchointerstitial pneumonia with small amount of inflammatory cell infiltrate and preserved histological architecture in H&E-stained necropsied lung tissue of lopinavir/ritonavir-treated (E) animals collected at 72 hpi (magnification, 100×). Mild to moderate acute bronchointerstitial pneumonia with moderate amount of inflammatory cell infiltrate and hemorrhage in H&E-stained necropsied lung tissue of interferon- β 1b-treated (G) animals collected at 72 hpi (magnification, 100×). Small amount of MERS-CoV nucleocapsid protein expression was detected in the necropsied lung tissues of the lopinavir/ritonavir-treated (F) and interferon- β 1b-treated (H) animals (magnification, 100×). These pathological changes were only seen in lesions which were confined to one to two lobes of the necropsied lungs of the

lopinavir/ritonavir-treated animals. H&E-stained necropsied lung tissue (I) (magnification, 100×) without MERS-CoV nucleocapsid protein expression (J) of an uninfected control animal.

Figure 6. Mean viral load with standard deviation values in different tissues of MERS-CoV-infected common marmosets collected at the time of necropsy. Asterisk indicates a P value of <0.05. ^aTwo of the three interferon- β 1b-treated animals had undetected viral loads in necropsied kidney tissues, which accounted for a large standard deviation value and apparent lack of statistically significant difference from the mean viral load of the untreated animals. Abbreviations: GAPDH, glyceraldehyde 3-phosphate dehydrogenase; MERS-CoV, Middle East respiratory syndrome coronavirus; MMF, mycophenolate mofetil.

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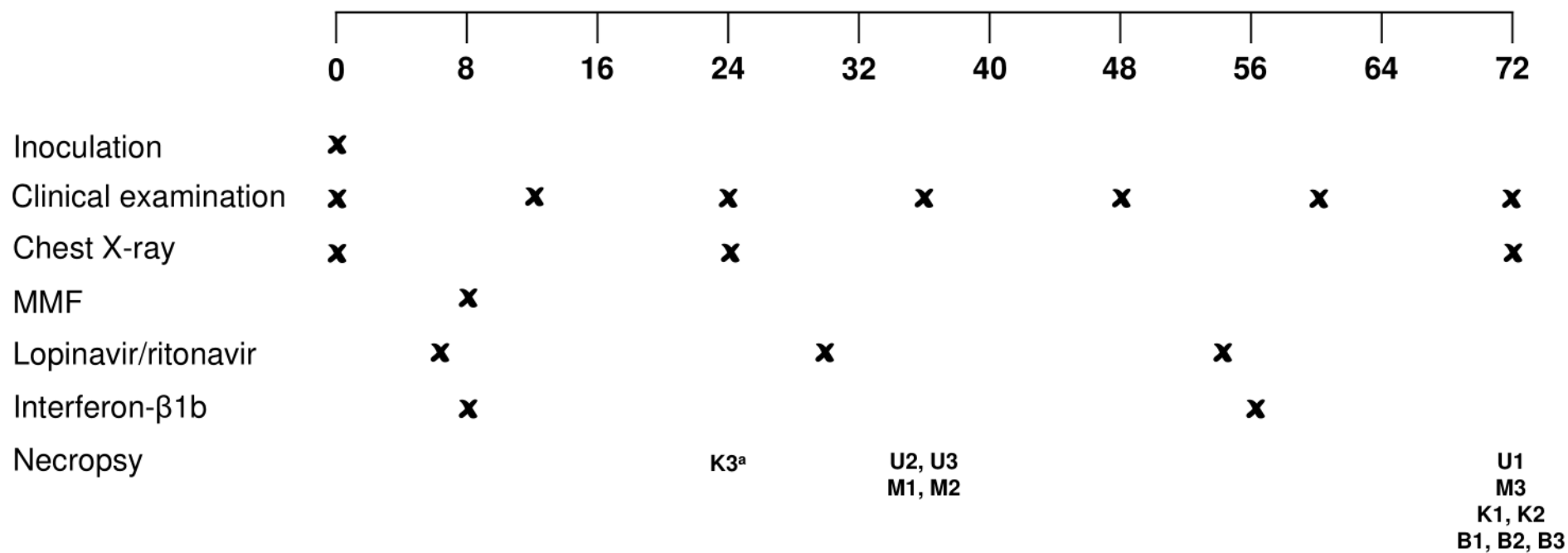
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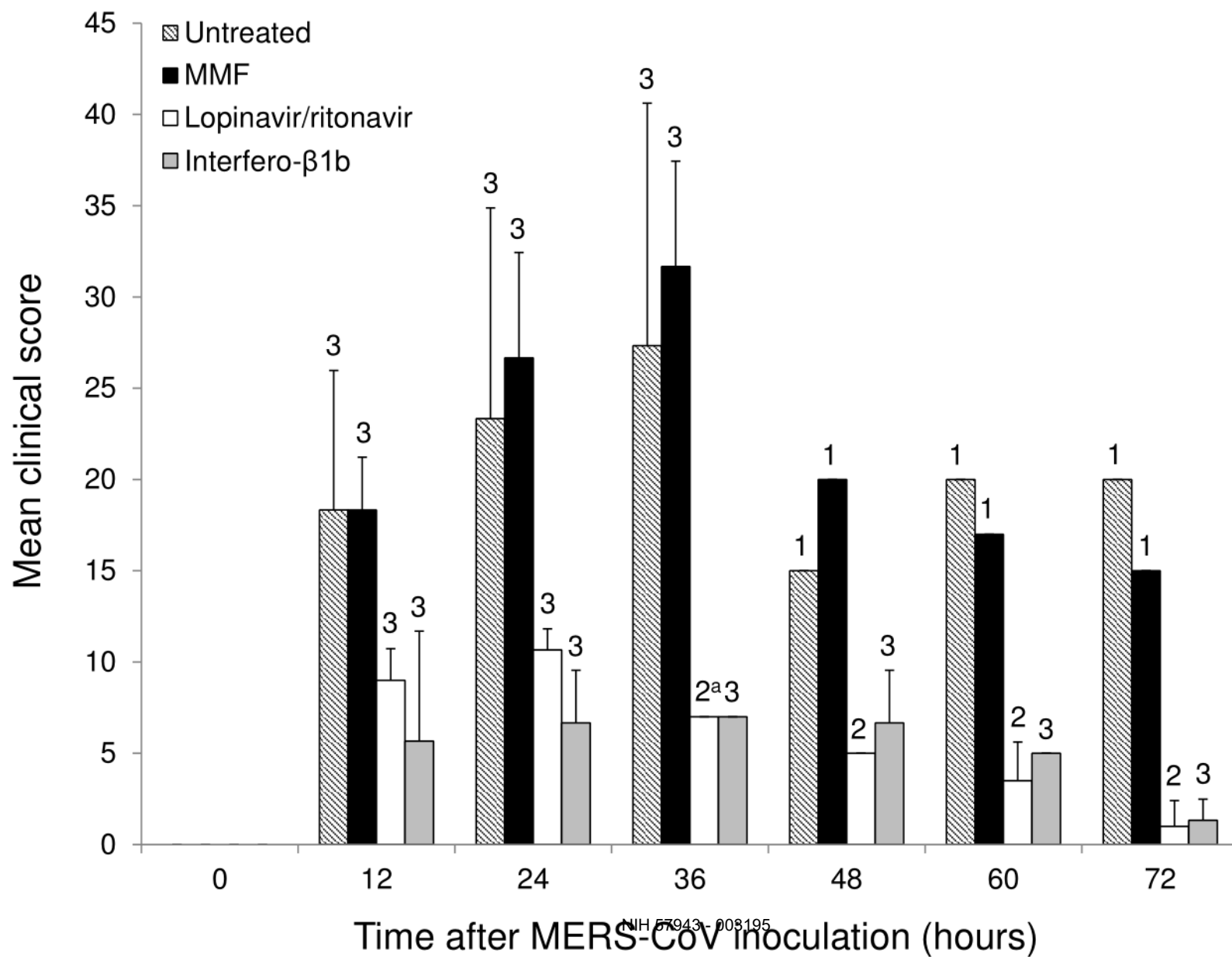
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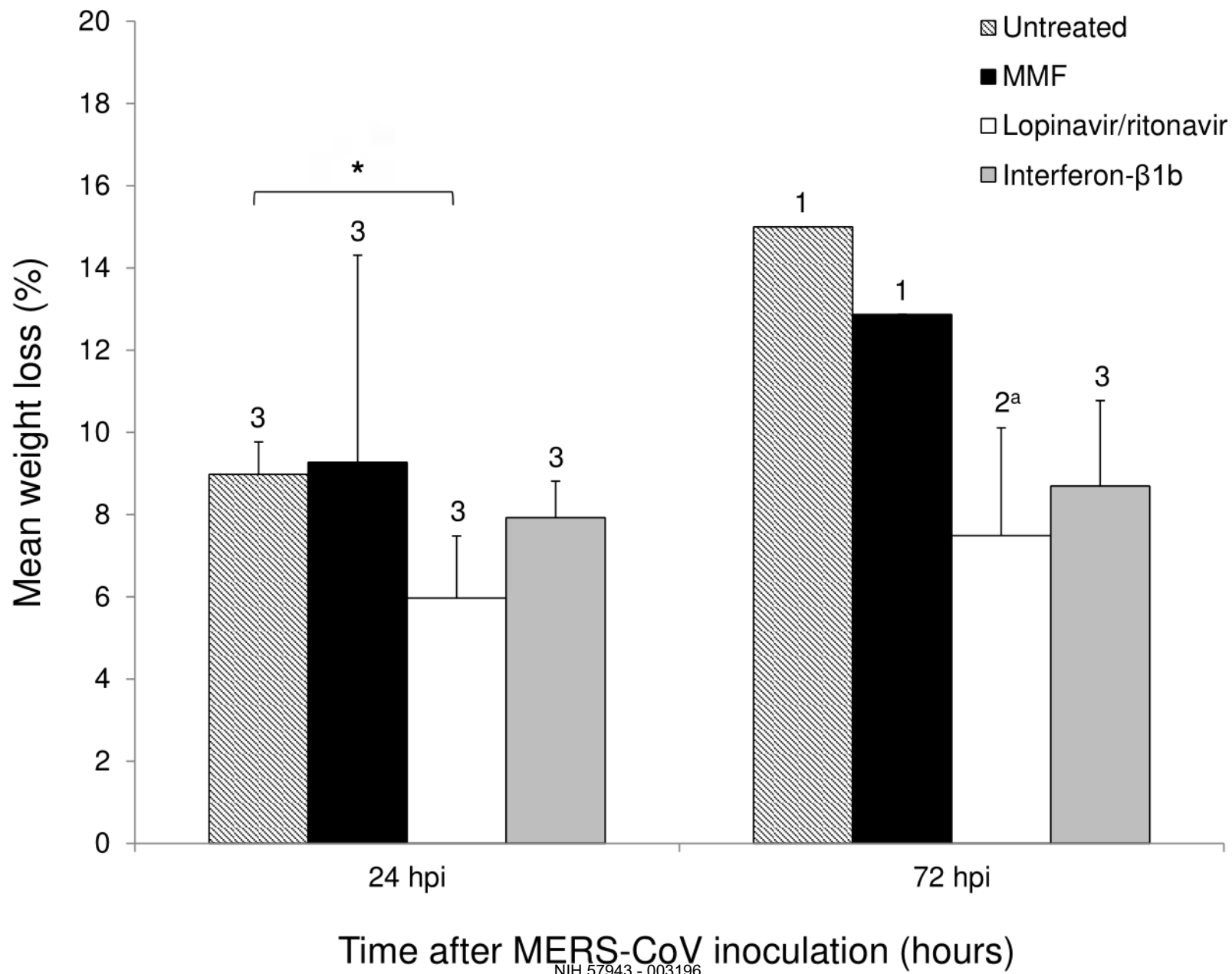
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Time after MERS-CoV inoculation (hours)



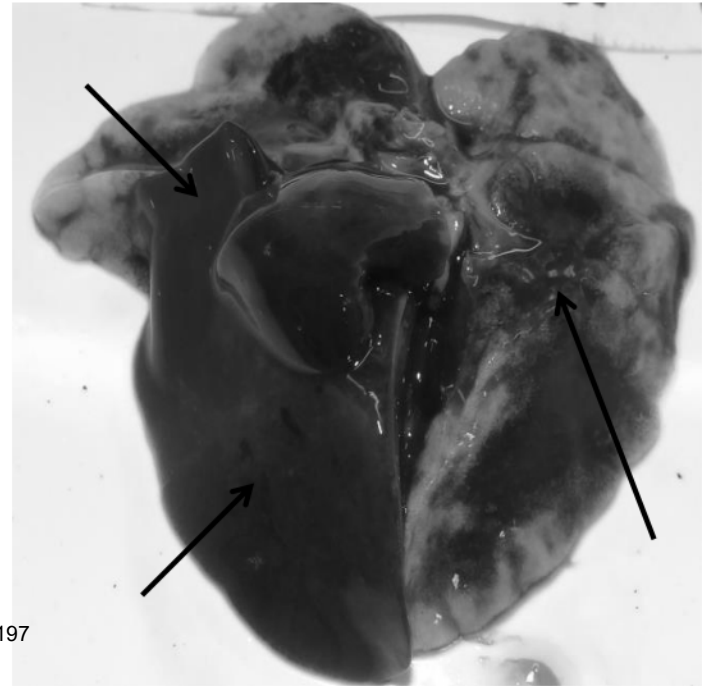
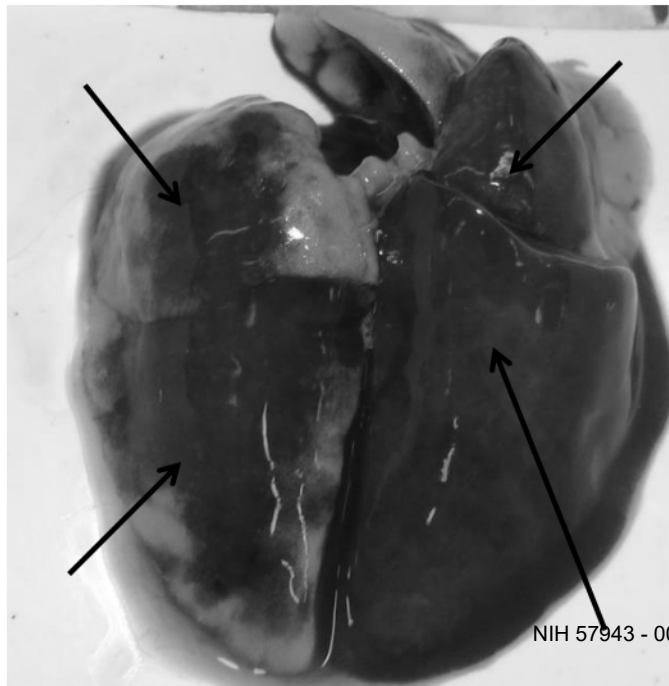




NIH 57943 - 003196

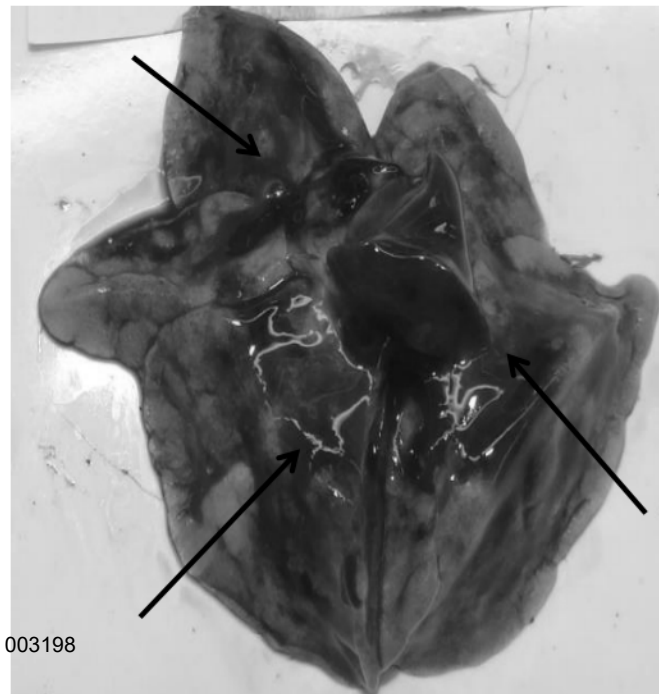
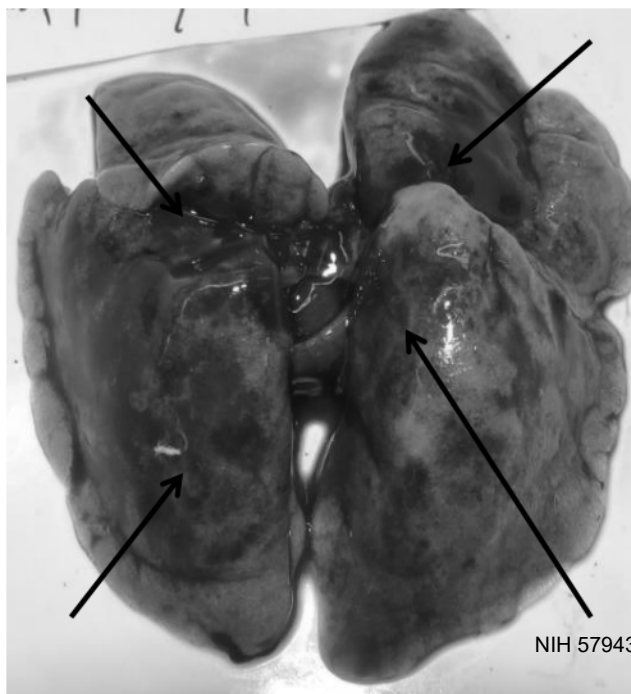
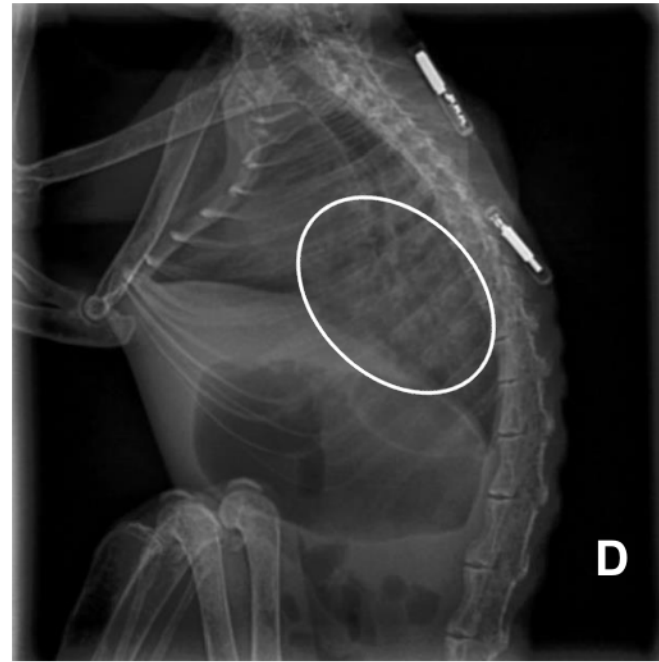
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Untreated (U2), 36 hpi



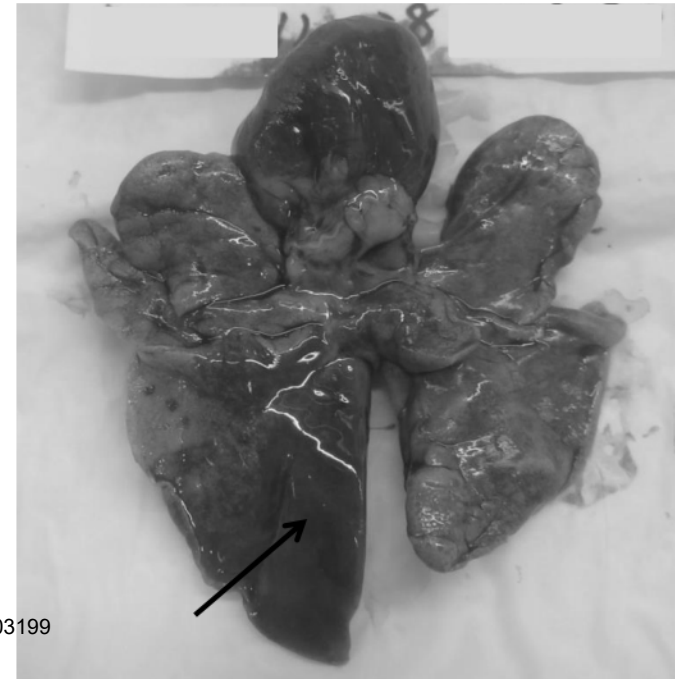
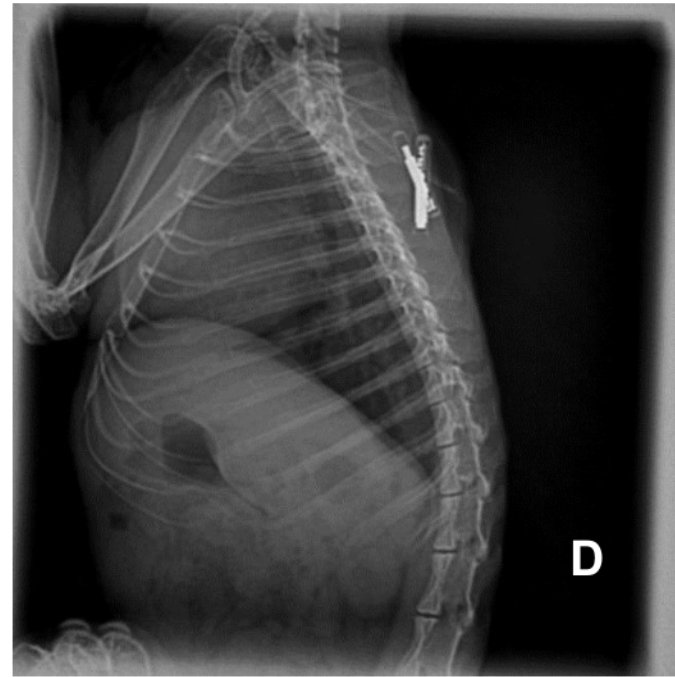
(B)

MMF (M2), 36 hpi



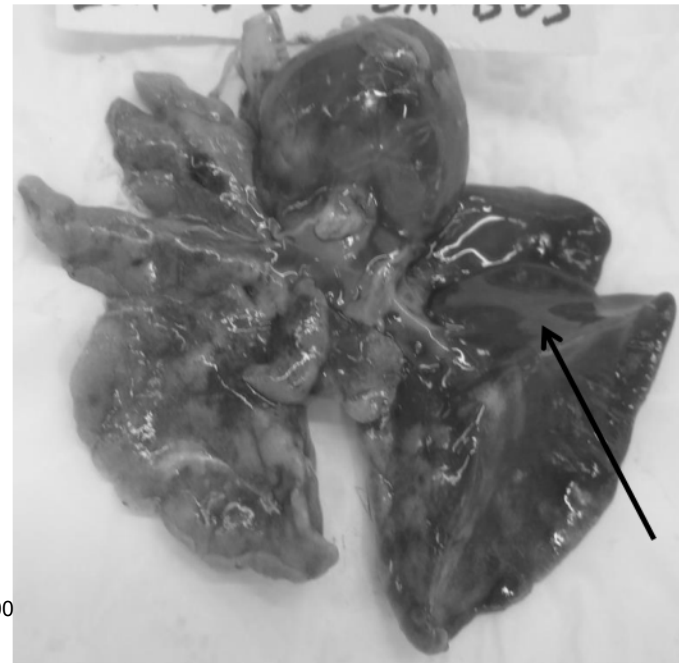
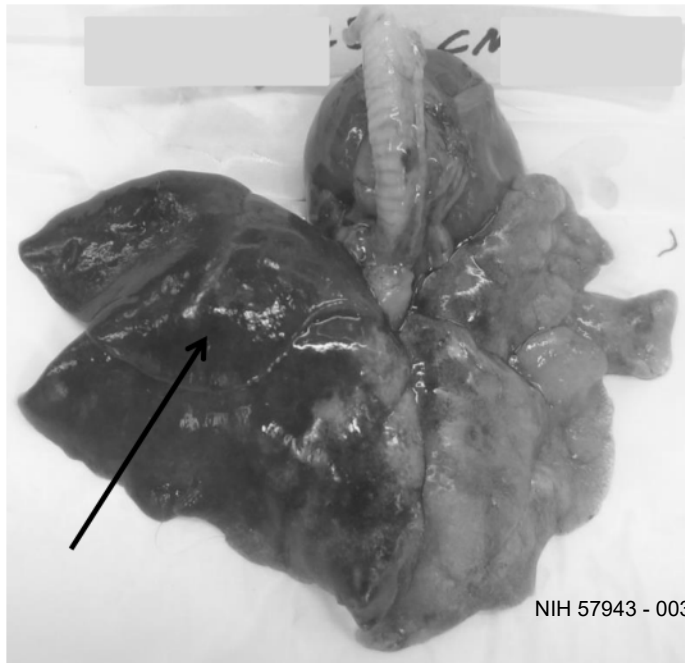
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Lopinavir/ritonavir (K1), 72 hpi



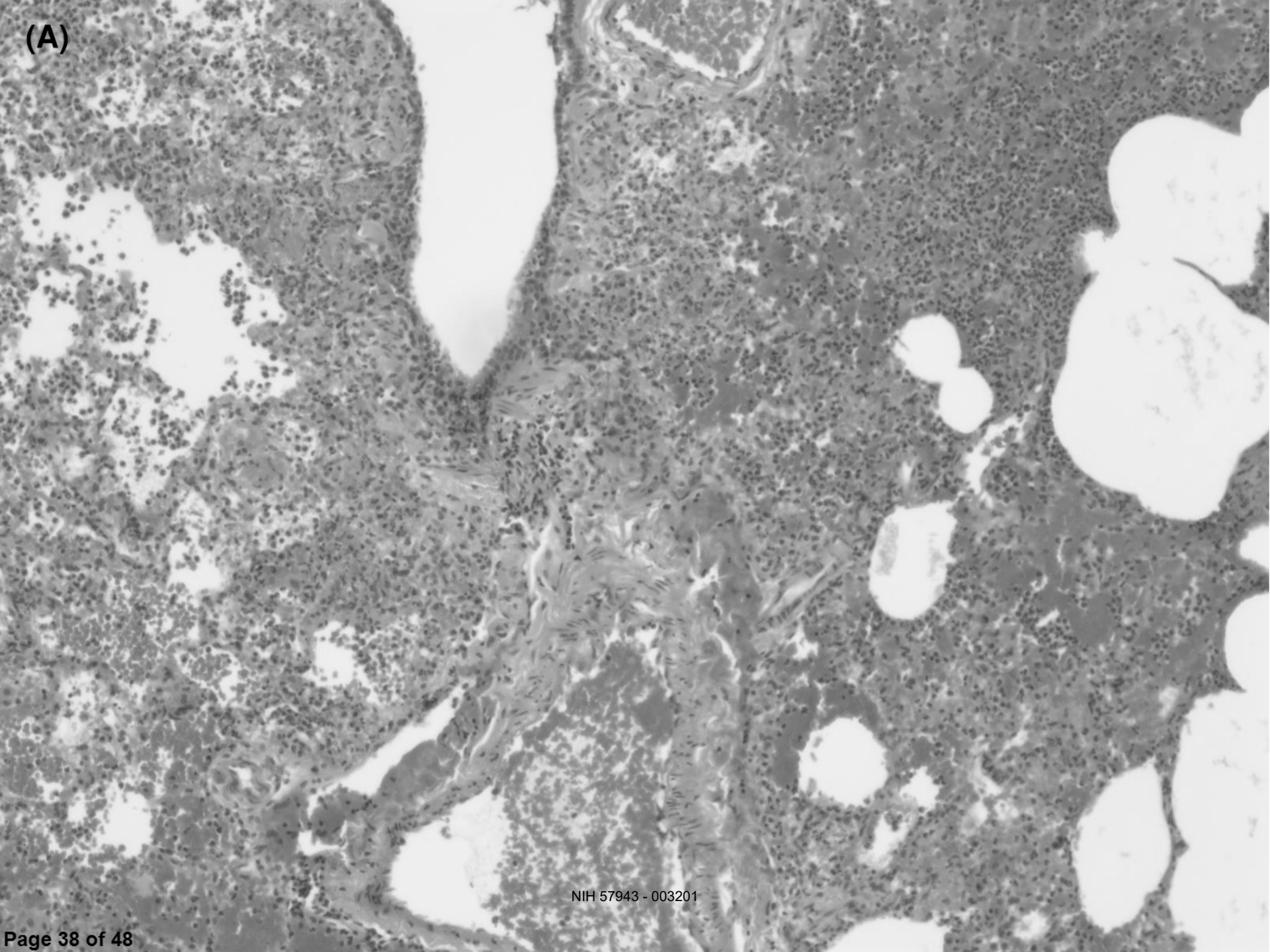
(D)

Interferon- β 1b (B2), 72 hpi



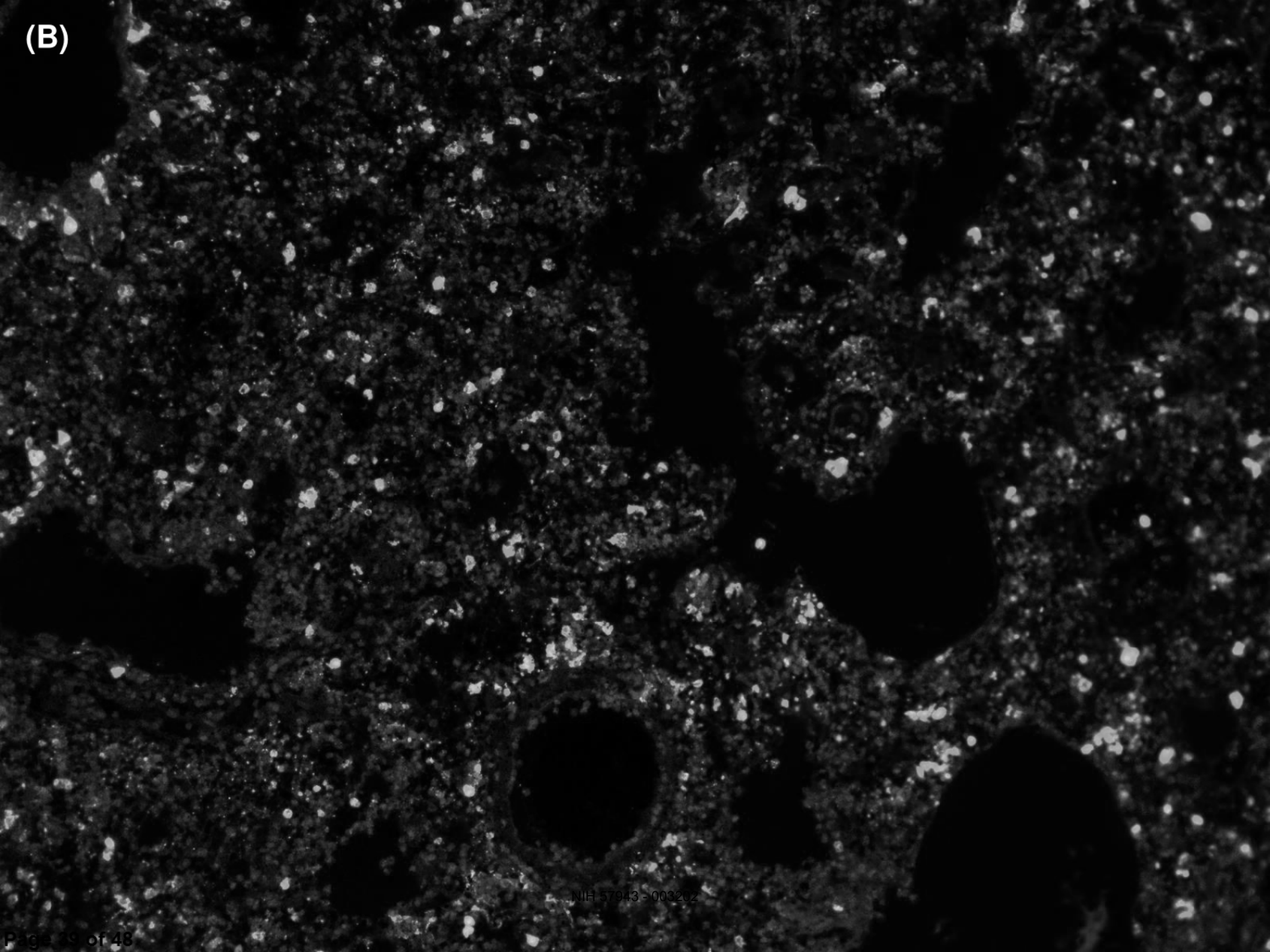
NIH 57943 - 003200

(A)



NIH 57943 - 003201

(B)



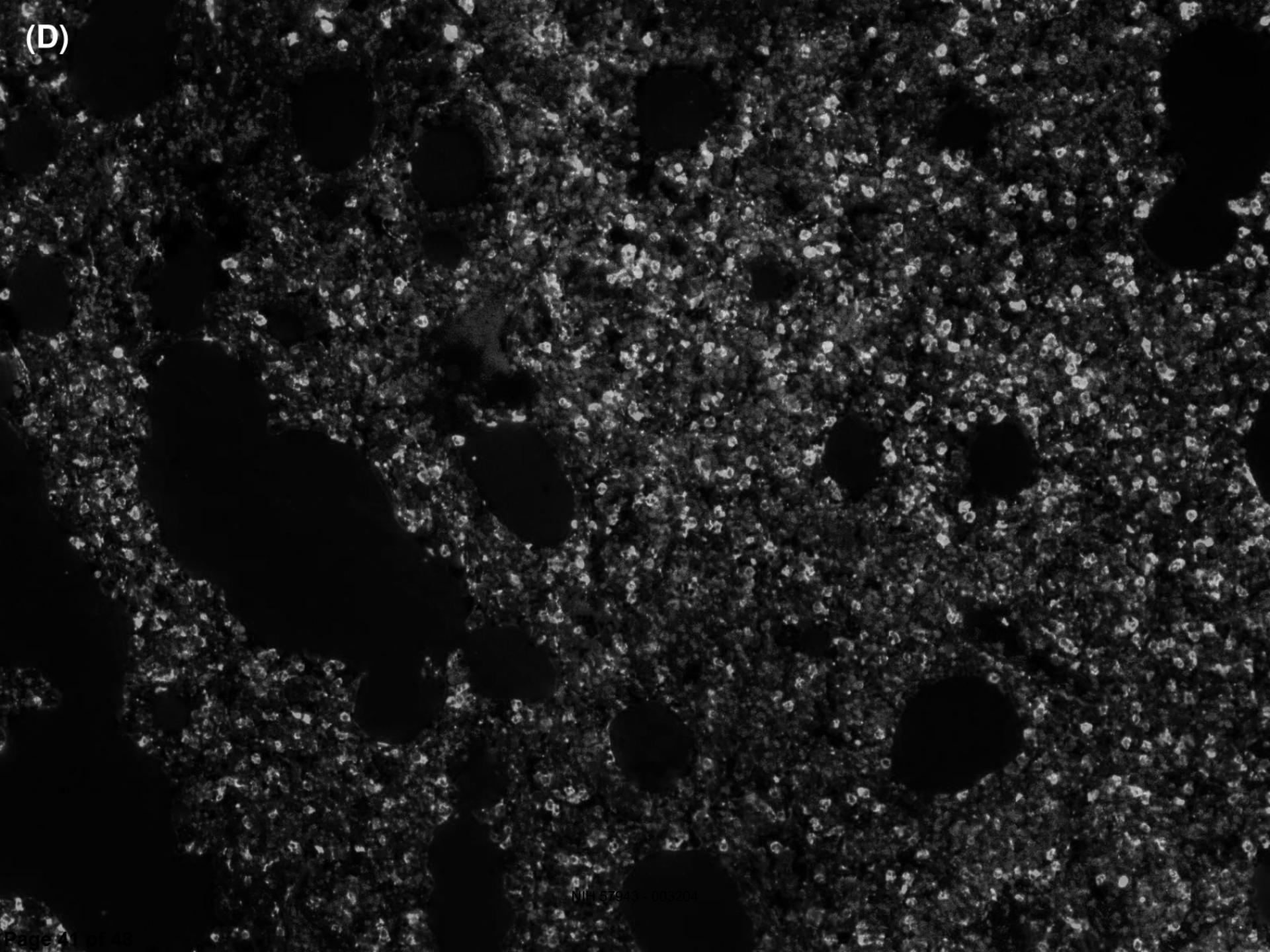
NIH 57943-003202

(C)

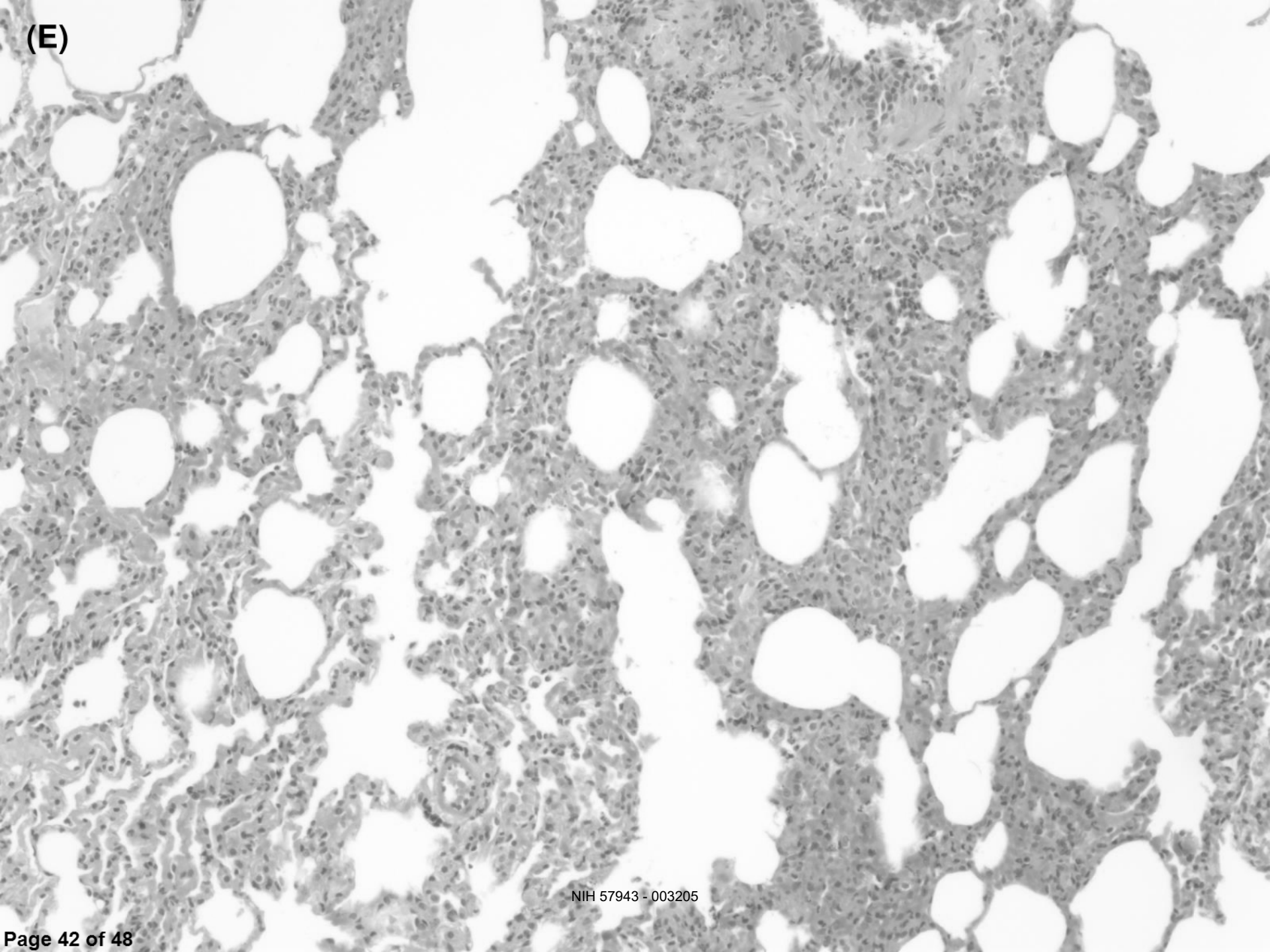


NIH 57943 - 003203

(D)



(E)

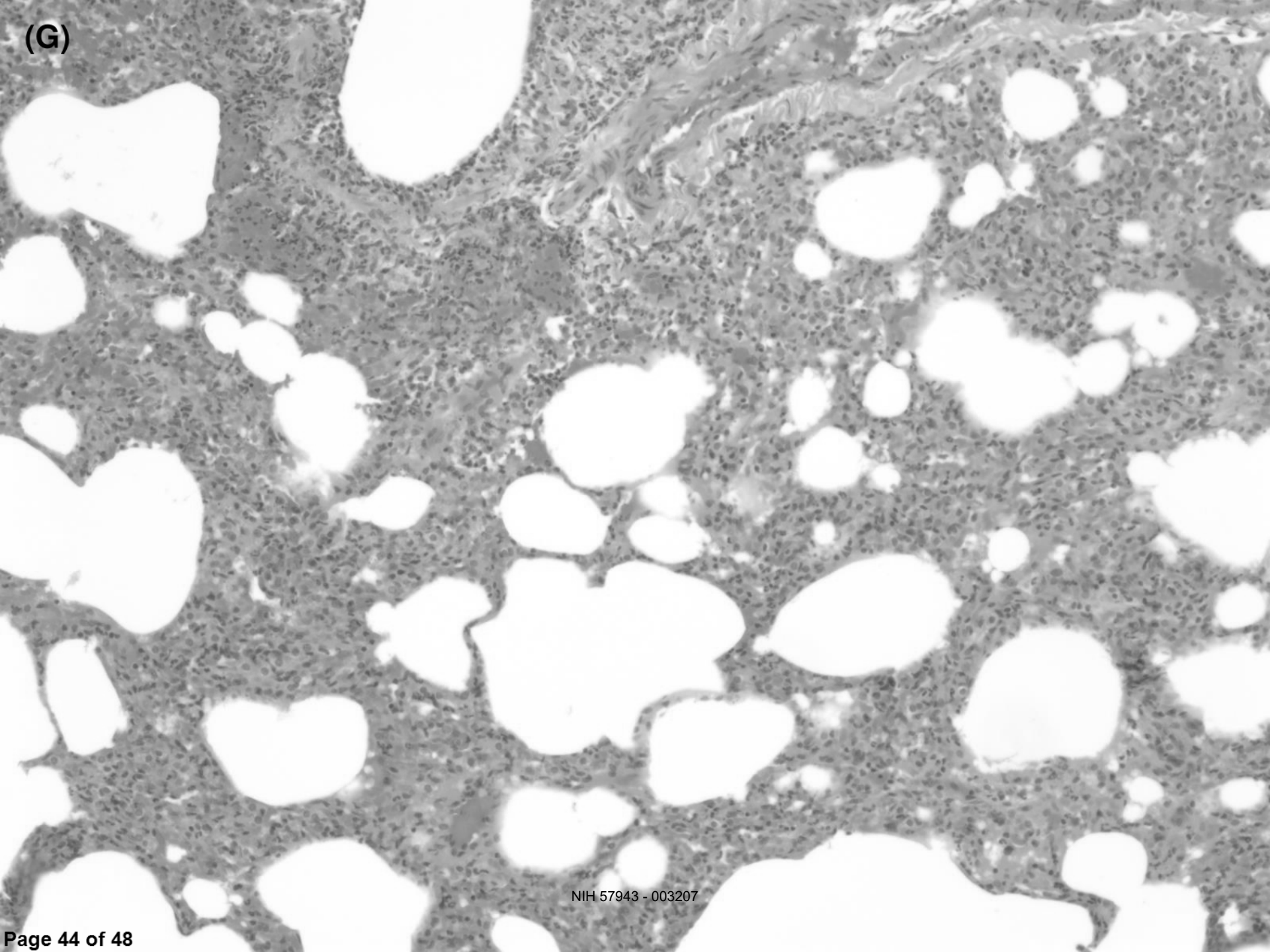


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(F)



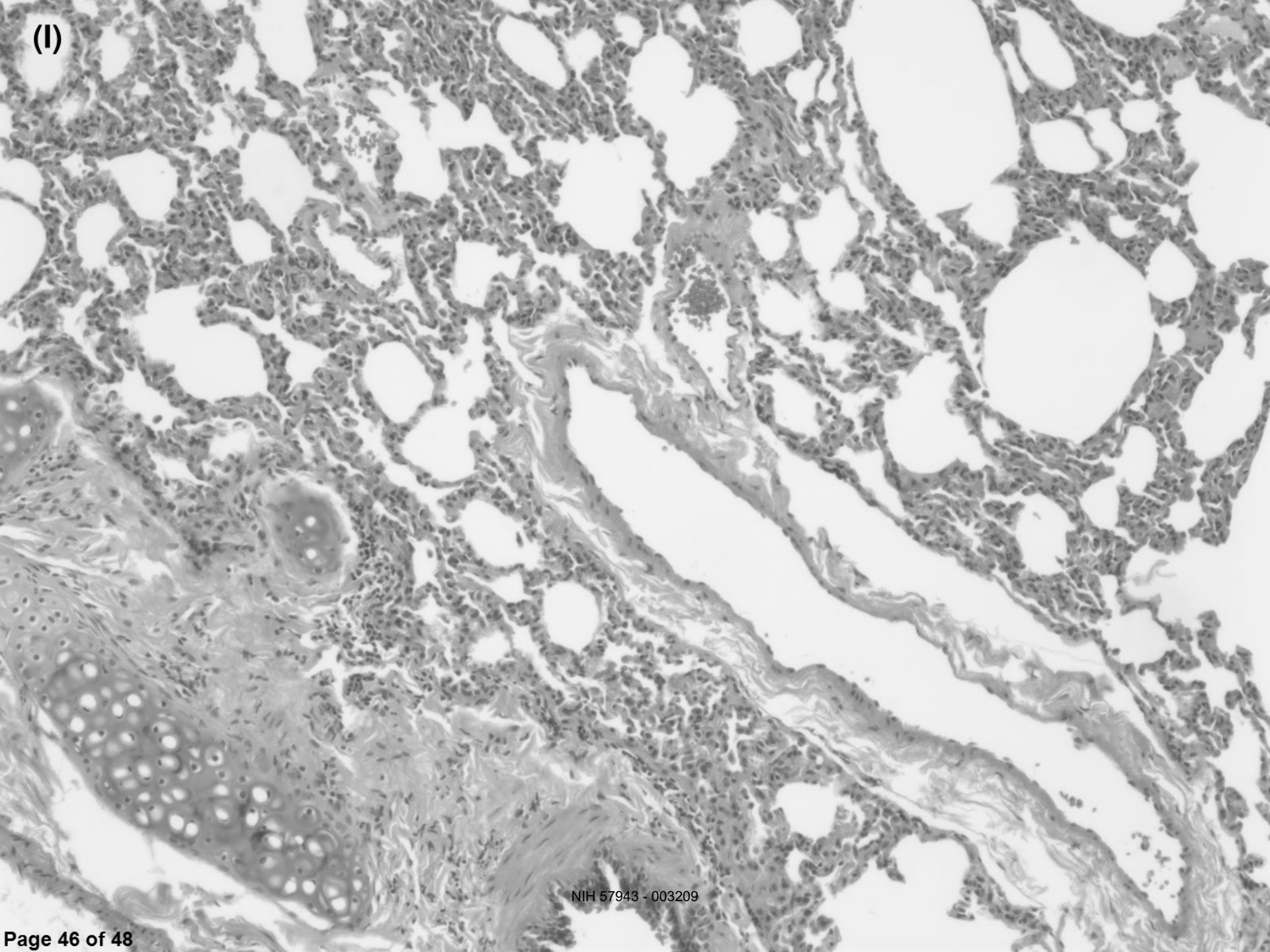
(G)



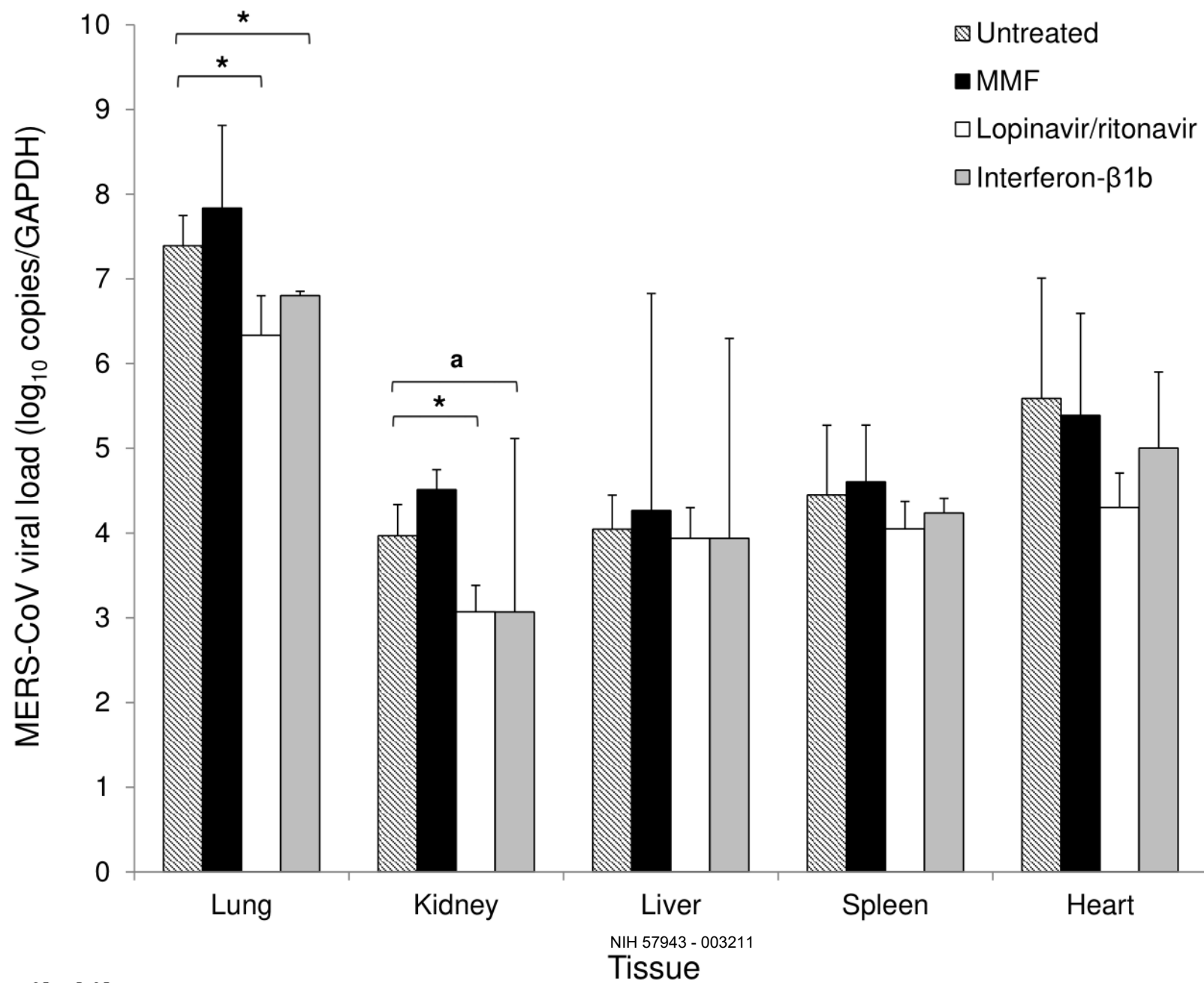
NIH 57943 - 003207

(H)

(I)



NIH 57943 - 003209



NIH 57943 - 003211

From: Baric, Ralph S
Sent: Sun, 1 Nov 2015 15:03:51 +0000
To: Stemmy, Erik (NIH/NIAID) [E]; Leyva-Grado, Victor (b)(6)
(b)(6)
Cc: Sims, Amy C
Subject: RE: A57 Option 1

Hi Erik, My understanding is that option 1 was for six months, not four. Amy is this correct? Thanks,
ralph

From: Stemmy, Erik (NIH/NIAID) [E] [mailto:(b)(6)]
Sent: Friday, October 30, 2015 12:37 PM
To: Baric, Ralph S; Leyva-Grado, Victor (b)(6)
(b)(6)
Subject: A57 Option 1
Importance: High

Hi Ralph, Victor, and Nina,
After our call yesterday I pulled up the option we exercised and noticed that the period of performance for the option ends in November (11/14/15). Did we discuss in the past requesting a no cost extension? We'll need to figure out what to do pretty quickly. Similar to what we did after the GoF pause we'll need a written request with the justification for why more time is needed (delays breeding and passaging to achieve the lethal model?). We'll also need a summary of the funds spent/remaining. The last thing to include should be an updated timeline for the extension setting out the timeframe for the four studies, starting with the LCA60 one in November.

Let me know if that makes sense. Thanks!
Erik

Erik J. Stemmy, Ph.D.
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Respiratory Diseases Branch
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From: Baric, Ralph S
Sent: Thu, 29 Oct 2015 18:07:24 +0000
To: Leyva-Grado, Victor; NIAID DMID IDIQ; Stemmy, Erik (NIH/NIAID) [E]
Cc: Umerah, Nina; Heise, Mark T
Subject: RE: HHSN272201000019I-HHSN27200003-Task A57 - November progress report
Attachments: AMC report for October 2015 (2)-rsb.docx

From: Leyva-Grado, Victor (b)(6)
Sent: Thursday, October 29, 2015 1:21 PM
To: (b)(6) 'Stemmy, Erik (NIH/NIAID) [E]'
Cc: Umerah, Nina; Baric, Ralph S; Heise, Mark T
Subject: HHSN272201000019I-HHSN27200003-Task A57 - November progress report

Dear Erik,

Attached you will find the October 2015 progress report for Task A57.

Please let us know if further information is required.

Thanks a lot,

Victor

Victor H Leyva-Grado DVM, PhD
Postdoctoral Fellow
Microbiology Department
Global Health and Emerging Pathogens Institute
Icahn School of Medicine at Mount Sinai
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MONTHLY REPORT

Contract HHSN272201000019I Task Order HHSN27200003 A57

Mouse Model for Evaluation of Medical Countermeasures Against Middle East Respiratory Syndrome Coronavirus (MERS-CoV)

Period of Performance:

August 1, 2015-August 31, 2015

Contractor's Name and Address:

Dr. Peter Palese

Horace W. Goldsmith Professor and Chair Department of Microbiology

Professor, Department of Medicine Mount Sinai School of Medicine

1 Gustave Levy Pl.

New York, New York 10029-6574

Tel (b)(6)

Fax 212-722-3634

e-mail: (b)(6)

Date of Submission:

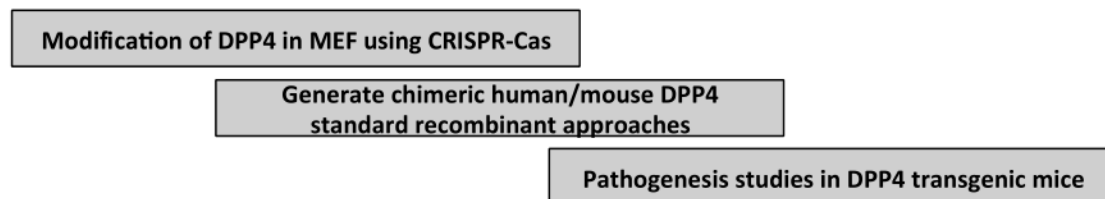
September 15, 2015

A. Scope

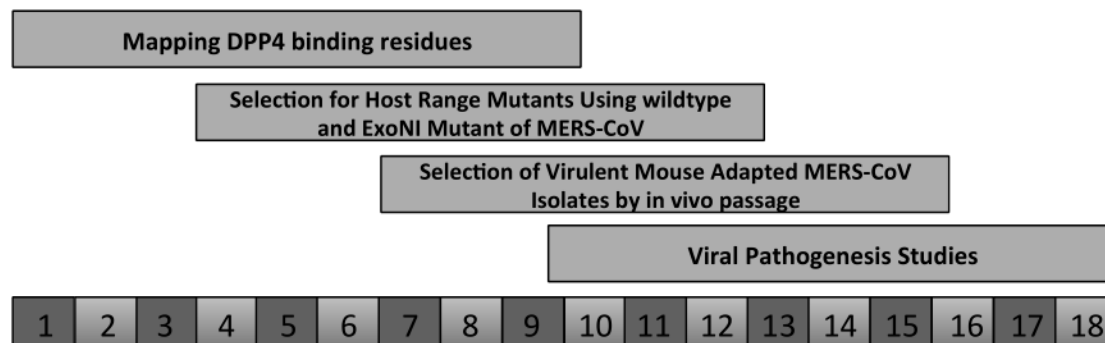
The objective of this task is to make a lethal mouse model (80% lethal by 10 days post infection) for the recently identified human coronavirus Middle East Respiratory Syndrome Coronavirus (MERS-CoV). Our group will develop transgenic mice that express humanized dipeptidyl-peptidase receptors and select for mouse-adapted strains of the MERS-CoV.

B. Timeline

TASK 1 Generation of Mice with Humanized DPP4 Receptor



TASK 2 Generation of Mouse Adapted Strain of MERS-CoV



Calendar Months for A57

C. Progress on Model and Supporting Data

A Disease Model of MERS-CoV infection through adaptation in 288-330 heterozygous mice. Central to our understanding of MERS-CoV viral pathogenesis are the underlying host responses to lung infection. Viral replication was robust in our current 288L/330R genetic model, but there was no clear evidence of disease in the lungs of these mice. Through viral adaptation in these mice we have been able to obtain a disease model within the CRISPR-Cas mice. The *in vivo* studies were initiated with a MERS-CoV that harbors a mutation in the S gene as a result of 9 *in vitro* passages on NIH3T3 cells overexpressing the 288L/330R mutant mDPP4. The first mouse was inoculated intranasally with 50ul of viral stock ($\sim 5 \times 10^6$ Pfu). Heterozygous mice were used for adaptation for at least two reason: i) current availability of these mice and ii) these mice express both the wild-type mDPP4 receptor and the mutant mDPP4 receptor, allowing for the virus to potentially adapt around our mutations and utilize the wild-type mDPP4 receptor. A MERS-CoV adapted to the wild-type mDPP4 would expand the use of this virus to all available mouse lines.

Virus was passaged every 3 days. At 3 days post-infection lungs were harvested for titering, RNA, and histology. Subsequently, 50ul of lung lysate was intranasally inoculated into the next mouse until getting to passage 20. Data from our previous report demonstrated that, through MERS-CoV adaptation in the 288-330 humanized mouse model, we can achieve a state of disease that reflects the human respiratory condition (see data from June report). **Pathological signs of acute respiratory distress syndrome (ARDS)** are readily detectable in the MERS-15 and MERS-20 infected mice at day 6 post-infection (see June report). In MERS-15 mice there are multiple sites of hyaline membrane formation and diffuse alveolar damage throughout the lungs, and in the MERS-20 infected mice there is clear non-cardiogenic pulmonary edema with massive inflammation. Similar results are observed in homozygous mice by day 6 post-infection (see June report).

MERS-15 mouse adapted virus was used to execute a large scale experiment in which a significant number of mice were assessed for infection and respiratory disease in both heterozygous and homozygous mice (September Report). The MERS-15 virus was initially expanded in Vero cells to make stocks and then clonal isolates were generated to determine if there were mutations selected for during mouse adaptation. We identified few differences between clonal isolates and the reference sequence (August report). Clonal isolates 1 and 2 have been further examined *in vivo* in both 288-330 +/+ and 288-330 +/- mice.

There are distinct differences between MERS-15 clones 1 and 2 with regard to survival (Figure 1). The MERS-15 clone 2 exhibits decreased survival in both heterozygous and homozygous mice compared to clone 1 (Figure 1). Both MERS-15 clone 1 and clone 2 exhibit dramatic weight loss (25-30%) through day 6 post-infection, in both heterozygous and homozygous mice (Figure 2). Homozygous mice infected with control virus MERS-0 exhibited no loss in weight. Moreover, control wild-type C57Bl/6J mice exhibit no weight loss following infection with MERS-15 (Figure 2). Notably, 5 female mice (mix of heterozygous and homozygous mice infected with clone 1 or clone 2) exhibited minimal weight loss (5-15%) with recovery (Data not shown), therefore, these mice were excluded from the current data. Importantly, although further

analysis will be necessary this could be an early indication of a gender effect with regard to weight loss. Also, these five female mice exhibited low to undetectable levels of virus in the lungs by day 6 post-infection. Together, these data may be indicative of gender differences with regard to viral clearance and associated symptoms. Nonetheless, it is important to note that several females did become severely ill, and a couple, did not survive infection.

Figure 1. Survival of homozygous and heterozygous mice infected with MERS-15 clone 1 and clone 2.

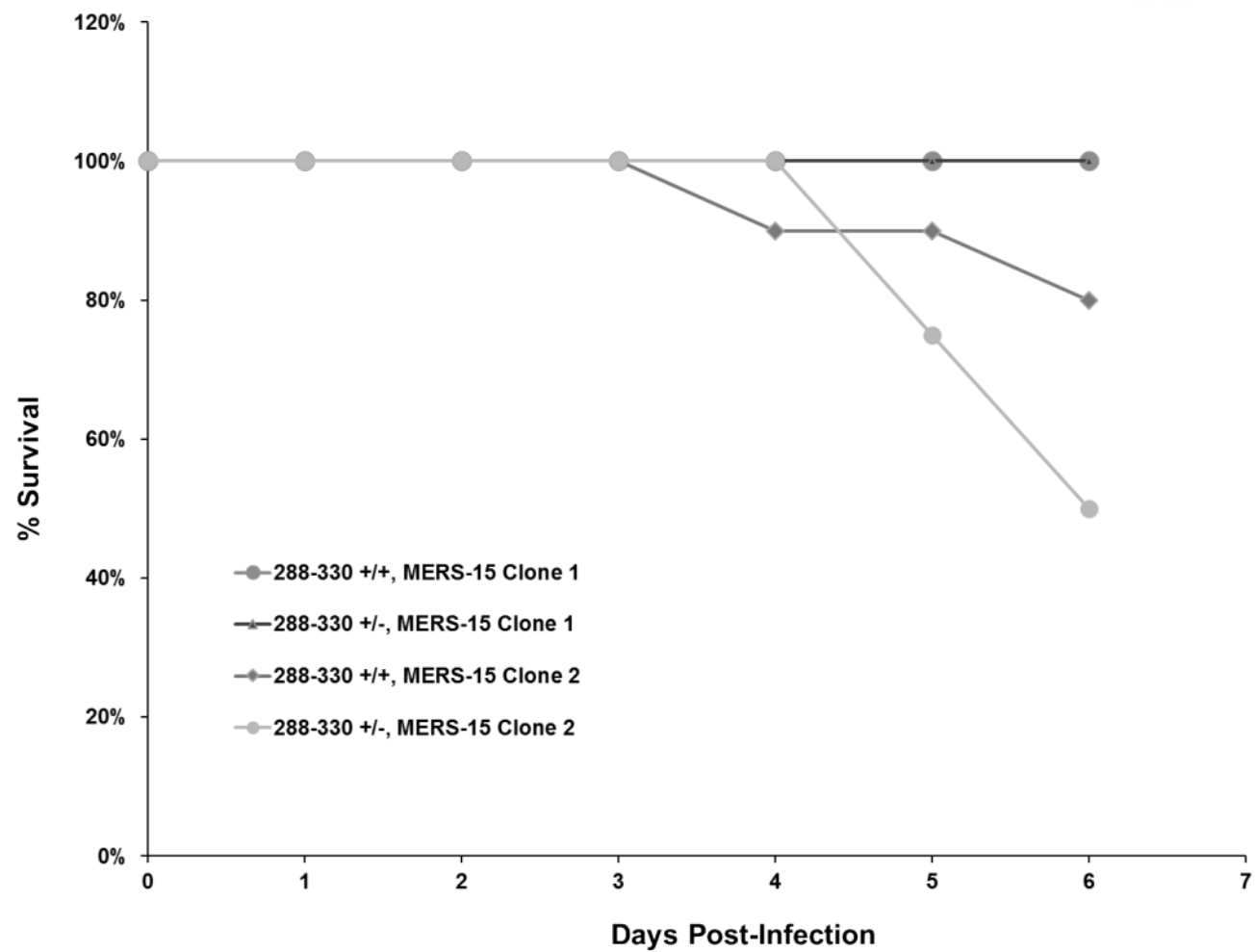
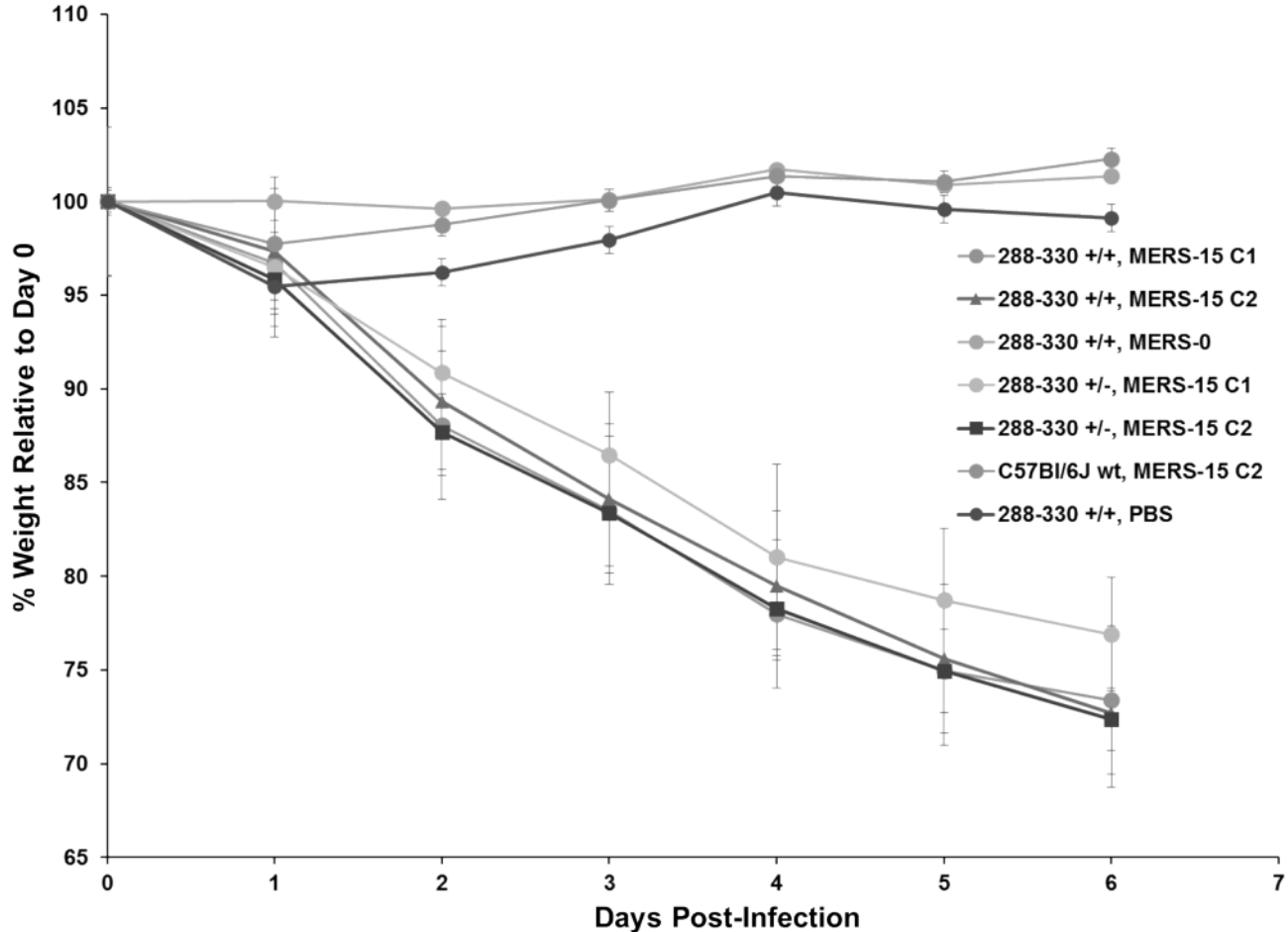
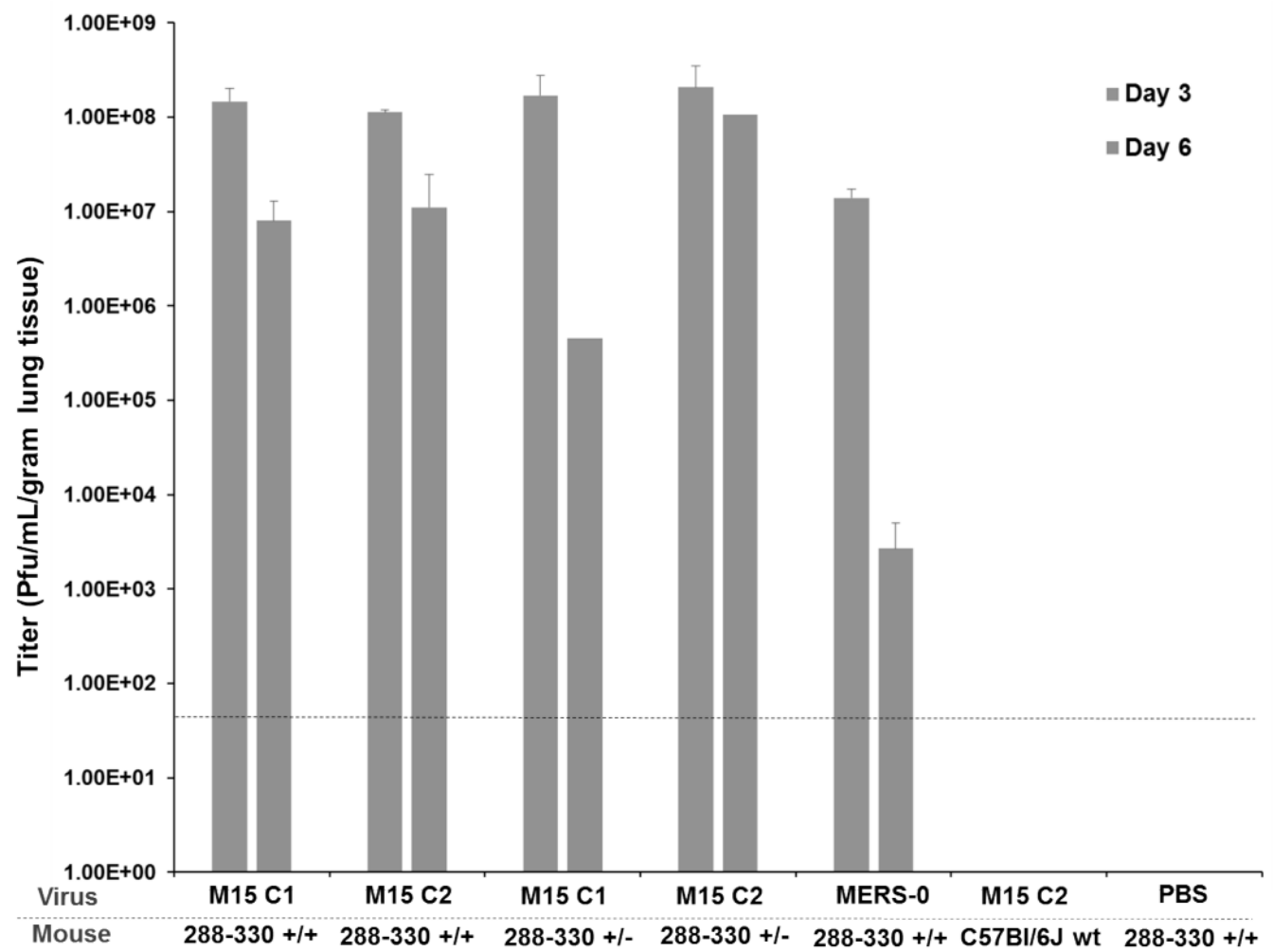


Figure 2. Weight loss of homozygous and heterozygous mice infected with MERS-15 clone 1 and clone 2.



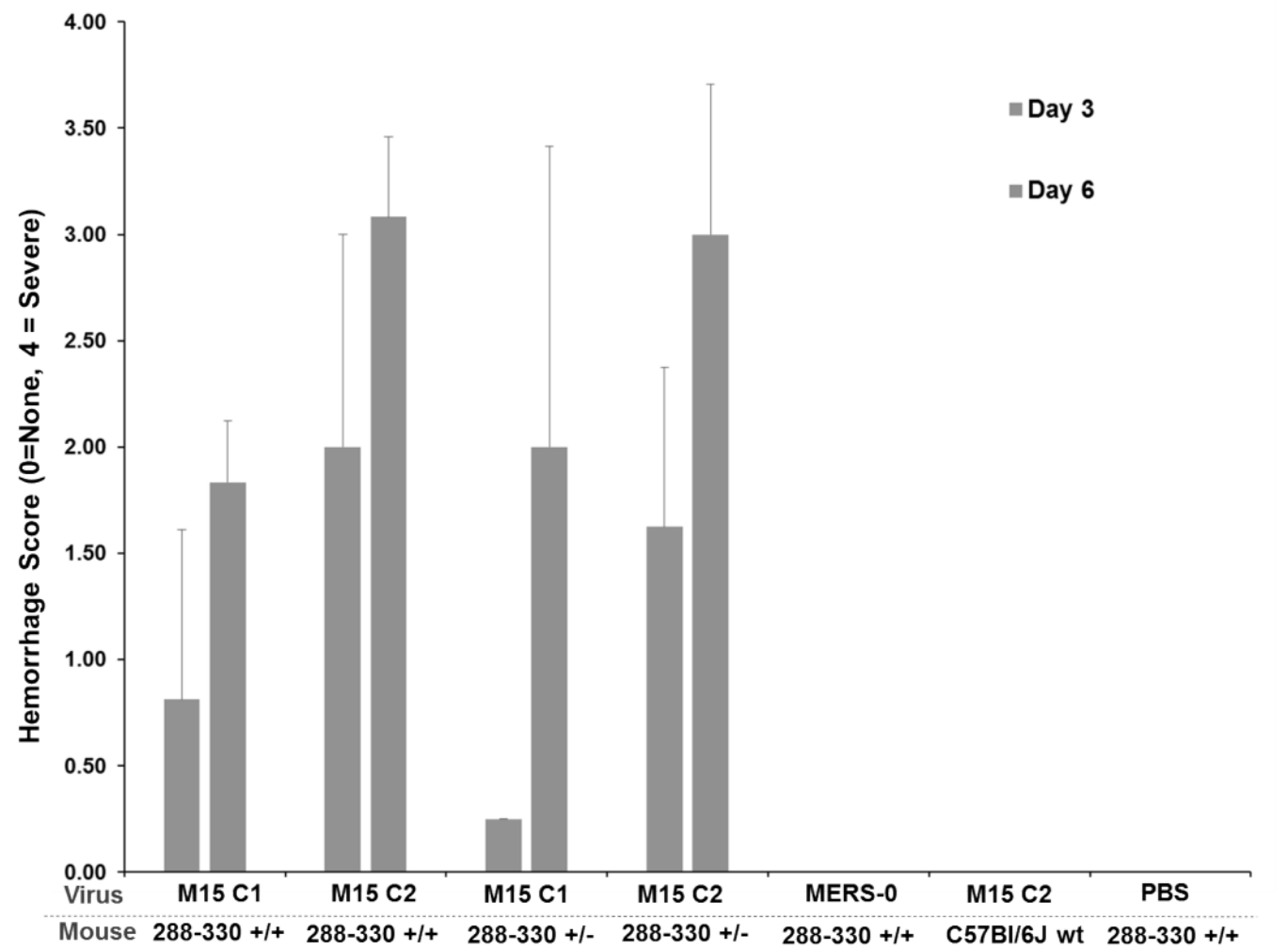
MERS-15 clone 1 and clone 2 titers were measured at days 3 and 6 post-infection in heterozygous and homozygous mice (Figure 3). MERS-15 clones 1 and 2 are referred to M15 C1 and M15 C2 in figure 3. 288-330 +/+ mice infected with MERS-0 and C57Bl/6J mice infected with MERS-15 clone 2 are shown as controls. PBS was included as a control at Day 6 only. Titers appeared to remain high through day 6 for both clones 1 and 2. No detectable infection was observed for wild-type mice infected with MERS-15 clone 2.

Figure 3. MERS-15 Clones 1 and 2 Titers in the lungs of 288-330 +/+ and 288-330 +/- mice.



Lastly, the severity of lung disease was scored by gross observation for hemorrhaging (Figure 4). Following a similar timeline as outlined for viral titers, MERS-15 infected mice were scored for hemorrhaging. Hemorrhaging severity is scored on a scale of 0-4, with increasing score being indicative of an increase in severity of hemorrhaging (i.e. generally 0 = no hemorrhaging, 1 = hemorrhaging observed in single lobe, 2 = 2 lobes, 3 = 3 lobes, and 4 = all lobes). Homozygous and heterozygous mice infected with MERS-15 clones 1 and 2 exhibited severe hemorrhaging in the lungs by day 6 post-infection (Figure 4). Mice infected with MERS-15 clone 2 exhibited more severe hemorrhaging than those infected with MERS-15 clone 1. The severity of the observed hemorrhaging may be related to survival, wherein the MERS-15 clone 2 mice exhibit a decreased survival compared to the MERS-15 clone 1 mice. No hemorrhaging was observed for homozygous mice infected with MERS-0, or for wild-type mice infected with MERS-15 clone 2.

Figure 4. MERS-15 Clones 1 and 2 induced hemorrhaging in 288-330 +/+ and 288-330 +/- mouse lines.



The distinct effects of MERS-15 clonal isolates may allow us to determine which adapted MERS-15 mutations are responsible for the observed phenotypes. The identified mutations will be cloned back into the reference MERS virus to determine those mutations that cause disease.

Technical/Performance Issues and Proposed Corrective Action

None

D. Expenditures Reporting

UNC estimates we will bill \$ for January 2015.

From: Hensley, Lisa (NIH/NIAID) [E]
Sent: Mon, 21 Sep 2015 13:21:20 -0400
To: Subbarao, Kanta (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Baric, Ralph; Munster, Vincent (NIH/NIAID) [E]; Dreier, Thomas (OS/ASPR/BARDA); Erlandson, Karl (OS/ASPR/BARDA); 'Baric, Toni C'; Spiro, David (NIH/FIC) [E]
Subject: RE: SARS animal models WHO summary

All

My 12 is still going. I will join when I can – my apologies.

Lisa E. Hensley
Associate Director, Science
NIH/NIAID/IRF
Ft Detrick MD

ph: (b)(6)
b berry: (b)(6)

From: Subbarao, Kanta (NIH/NIAID) [E]
Sent: Monday, September 21, 2015 1:12 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b)(6) Baric, Ralph (b)(6)
Munster, Vincent (NIH/NIAID) [E] (b)(6) Dreier, Thomas (OS/ASPR/BARDA)
(b)(6) Erlandson, Karl (OS/ASPR) (b)(6) Hensley, Lisa
(NIH/NIAID) [E] (b)(6) 'Baric, Toni C' (b)(6) Spiro, David
(NIH/NIAID) [E] (b)(6)
Subject: SARS animal models WHO summary

From: (b)(6)
When: 1:00 PM - 2:00 PM September 21, 2015
Subject: MERS Animal Model SAG Call
Location: Lync Meeting

Greetings!

Thanks again for your willingness to help organize the MERS Animal Model Standardization workshop. This time seems to work for the group, so I wanted to send along the dial in details. You may either join by VoIP using the Lync Meeting link below, or use the dial in number to connect by phone. I have attached a document with some overarching goals we identified for the workshop, as well as a series of draft sessions. Please consider these a tool for brainstorming and a place to get our discussion started. We very much value your input and welcome suggestions for changes! The agenda for the call will be as follows:

1. Brief background and introductions
2. Identify goals and deliverables from the workshop

3. Format for the workshop and sessions
4. Division of responsibilities
5. Timeframe and milestones for moving forward
6. Future call frequency?

Let me know if you have any questions before the call. Otherwise, we look forward to speaking with you next week!

Erik

→ Join Lync Meeting

Join by phone

(b)(6) (NIAID) English (United States)

[Find a local number](#)

Conference ID: (b)(6)

[Forgot your dial-in PIN?](#) | [Help](#)

From: Baric, Ralph S
Sent: Wed, 2 Sep 2015 15:00:18 +0000
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Spiro, David (NIH/FIC) [E]; Baric, Toni C
Subject: RE: NIAID Workshop on MERS Animal Models

Hi Erik, I would be delighted to attend. I have cc'd Toni, who keeps my calendar. Thanks for the opportunity to participate. Great idea. ralph

From: Stemmy, Erik (NIH/NIAID) [E] [mailto:(b)(6)]
Sent: Wednesday, September 02, 2015 10:57 AM
To: Baric, Ralph S
Cc: Spiro, David (NIH/NIAID) [E]
Subject: NIAID Workshop on MERS Animal Models

Dear Ralph,

In an effort to advance the development of MERS-CoV vaccines and therapeutics NIAID is planning a workshop to address outstanding questions around MERS-CoV animal models and to consider whether any standardization would be beneficial to advance promising vaccine and therapeutic candidates to eventual clinical trials. We anticipate hosting a 1-2 day workshop here in Bethesda in the winter of 2016 and would like to ask for your assistance in participating in a small Scientific Advisory Group to help plan the workshop, frame the sessions, and facilitate discussion. Some of the questions we hope to address through the workshop include (but are certainly not limited to):

1. What is the current status of the various models in development, and what are the similarities/differences between the models?
2. Is there a need for standardization of viral challenge, such as: viral strain; route of inoculation, etc?
3. Is there a better, or more appropriate, model for MCM development? Are different models needed for vaccine vs therapeutic development? What endpoints are currently possible/desirable?
4. What are current gaps/hurdles in advancing model development?
5. What are potential regulatory pathways for promising MCM candidates?

We would like to have a first planning call for the workshop within the next couple of weeks. Please let me know if you (or a designate) are willing and able to be a part of the Scientific Advisory Group and I will circulate a doodle poll to find a convenient time for the first call.

Many thanks,
Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
NIAID/NIH/HHS
5601 Fishers Lane (b)(6)
Bethesda, MD 20892-9825

Phone: (b)(6)
Email: (b)(6)

Getting ready to publish? Share the good news with your program officer asap! NIAID may be able to help publicize your article. And, remember to list your NIAID grant or contract number in the publication.

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From: Aleksei Chmura
Sent: Tue, 1 Sep 2015 10:57:48 -0400
To: Pone, Laura (NIH/NIAID) [E]
Cc: Dr. Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]
Subject: Re: Grant Number: 5R01AI110964 - 02 PI Name: DASZAK, PETER

Dear Laura,
Great to hear this!
Cheers,
-Aleksei

Aleksei Chmura
Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b)(6) direct)
(b)(6) (mobile)
(b)(6) (Skype)

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On Sep 1, 2015, at 10:22, Pone, Laura (NIH/NIAID) [E] (b)(6) wrote:

Hi Aleksei,
Thanks for letting me know. Since there is no restriction on the NOA no additional information is needed.
In accepting an award that supports human subjects research, the recipient institution assumes responsibility for all research conducted under the award, including protection of human subjects at all participating and consortium sites, and for ensuring that an FWA and certification of IRB review and approval exists for each site before human subjects research may begin.
[http://grants.nih.gov/grants/policy/nihgps/HTML5/section 4/4.1 public policy requirements and objectives.htm#Human3](http://grants.nih.gov/grants/policy/nihgps/HTML5/section%204/4.1_public_policy_requirements_and_objectives.htm#Human3)

Thank you,

Laura Pone
Grants Management Specialist
DHHS/NIH/NIAID/GMP
5601 Fishers Lane, Room 4E29, MSC 9824
Bethesda, MD 20892-9824
Phone: (b)(6)
e-Fax: 301-493-0597
Email: (b)(6)



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From: Aleksei Chmura [mailto:(b)(6)]
Sent: Thursday, August 27, 2015 5:51 PM
To: Pone, Laura (NIH/NIAID) [E] (b)(6)
Cc: Peter Daszak (b)(6); Stemmy, Erik (NIH/NIAID) [E] (b)(6)
Subject: Re: Grant Number: 5R01AI110964 - 02 PI Name: DASZAK, PETER

Dear Laura,
Just following up with whether we need to upload any details to eRA Commons.
Hope all is well and you and yours are enjoying the last weeks of summertime!
Many thanks,
Aleksei Chmura
Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b)(6) direct)
(b)(6) mobile)
(b)(6) (Skype)

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On Jul 20, 2015, at 01:44, Aleksei Chmura (b)(6) wrote:

Dear Laura,
Just resending from before, in case you did not receive this:
Wuhan University our collaborating institution now has an FWA number.
IORG0008522 - School of Public Health, Wuhan University
IRB: 00010207
FWA: 00023218
Please let me know, if you require further details or if we must enter the FWA number via eRA Commons.

Many thanks!
Aleksei Chmura
Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b)(6) (direct)
(b)(6) (mobile)
(b)(6) (Skype)

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On May 14, 2015, at 16:00, Pone, Laura (NIH/NIAID) [E] (b)(6) wrote:
Hi Aleksei,

I apologize for the confusion. I see that the summary statement concern was responded to and have submitted that for review. Please let me know once Wuhan has the FWA.

Thank you!

Laura Pone

Grants Management Specialist

DHHS/NIH/NIAID/GMP

5601 Fishers Lane, Room 4E29, MSC 9824

Bethesda, MD 20892-9824

Phone: (b)(6)

e-Fax: 301-493-0597

Email: (b)(6)



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From: Aleksei Chmura [mailto:(b)(6)]

Sent: Wednesday, May 13, 2015 4:36 PM

To: Pone, Laura (NIH/NIAID) [E]

Cc: Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]

Subject: Re: Grant Number: 5R01AI110964 - 02 PI Name: DASZAK, PETER

Importance: High

Dear Laura,

Apologies for any delays or confusion on my part, but I am not certain what summary statement concerns you are requesting. We provided details about protection of human subjects via our Just in Time Report in May of last year and sent our US IRB approval for our human research protocol under our award last month (attached here for reference). We expect to have an FWA for Wuhan University before the end of the month, but I will update you on our progress in the next week.

Can we have a quick chat about the summary statement concerns anytime that is good for you.

Once we are clear on what is required, we will provide the requested details immediately.

Is the deleted reference with updated My NCBI report for Dr. Daszak ok as well? I have not yet had a response from the NCBI support re. removing and/or disassociating the reference.

Please call me anytime day/night at (b)(6)

Many thanks!

Aleksei Chmura

Senior Coordinator of Operations

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b)(6)	(direct)
(b)(6)	(mobile)
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From: Knight, Stanley (NIH/NIAID) [E]
Sent: Mon, 17 Aug 2015 09:54:50 -0400
To: Moise, Jessica (MSSM) (b)(6)
Cc: Stemmy, Erik (NIH/NIAID) [E]; Dowling, William (NIH/NIAID) [E]; PETERPALESE; Hartmann, Richard (NIH/NIAID) [E]; Glowinski, Irene (NIH/NIAID) [E]; Grewe, Charles (NIH/NIAID) [E]; Baric, Ralph; Adams, Miranda (NIH/NIAID) [E]
Subject: A57 GOF Letter
Attachments: MSSM Exception Clarification 8-17-2015 final.pdf

Good morning Jessica,

Please see attached letter concerning the GOF exception. Let me know if you have any questions.

Regards,

Stanley A. Knight, Sr.
Team Leader/Contracting Officer
Microbiology and Infectious Diseases
Research Contracts Branch-A (MIDRCB-A)
Office of Acquisitions, DEA, NIAID, NIH-DHHS
5601 Fishers Lane, Room 3D50, MSC 9821
Rockville, MD 20892-9821
Phone: (b)(6)
Email: (b)(6)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

August 17, 2015

Transmitted via e-mail to:

(b)(6)

Jessica Moise
Grants and Contracts Officer
Mount Sinai School of Medicine
One Gustave L. Levy Place, Box 1075
New York, NY 10029

Subject: Contract HHSN272201000019I Task Order No. HHSN27200003 (A57) "Mouse Model for Evaluation of Medical Countermeasures against Middle East Respiratory Syndrome (MERS-CoV)

Dear Ms. Moise:

On January 7th, 2015 NIAID notified you that work proposed under the contract referenced above was determined by the NIAID and NIH to be urgently necessary to protect public health, and that the NIH Director had granted an exception from the U.S. Government-wide pause on gain-of-function (GoF) research for the following experiments:

- **Performing targeted mutagenesis on MERS-CoV to increase receptor binding efficiency**
- **Serial passaging of MERS-CoV *in vitro* and/or *in vivo***

NIAID has contracted you to create a mouse model of MERS-CoV and the Exception noted above allowed you to serially passage wild type MERS-CoV to achieve that end. We understand that an important step in model development is the creation of a molecular clone of the adapted virus, which will be used to advance the development of medical countermeasures against MERS-CoV. Therefore any mutations arising from the serial passaging work, regardless of where they occur in the MERS-CoV genome, may be inserted into a molecular clone if you identify them as being important to creating a mouse model of MERS-CoV.

Please note that this Exception covers only the experiments listed above. Additional mutagenesis work on the virus, if reasonably anticipated to enhance pathogenicity and/or transmissibility via the respiratory route, will still be subject to the GoF Research Funding pause.

**Stanley A.
Knight -S**

Digitally signed by Stanley A. Knight -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=NIH, ou=People,
0.9.2342.19200300.100.1.1=0011868212,
cn=Stanley A. Knight -S
Date: 2015.08.17 09:13:30 -04'00'

Stanley A. Knight, Sr
Contracting Officer, MID
Research Contracts Branch-A
Office of Acquisitions, DEA, NIAID, NIH
5601 Fishers Lane, Room 3D50, MSC 9821
Bethesda, Maryland 20892-9825

(b)(6)

Erik J. Stemmy, Ph.D.
Contracting Officer Representative
RDB, DMID, NIAID
5601 Fishers Lane, (b)(6)
Rockville, MD 20850-9825

cc: Dr. Peter Palese, Contract PI, Icahn School of Medicine at Mt Sinai
Dr. Ralph Baric, Subcontract Co-PI, University of North Carolina at Chapel Hill
Dr. Mark Heise, Subcontract Co-PI, University of North Carolina at Chapel Hill
Dr. Erik Stemmy, Contract COR, RDB, DMID, NIAID
Dr. Bill Dowling, Contract CPO, OBRTR, DMID, NIAID
Dr. Irene Glowinski, Deputy Director, DMID, NIAID
Charles W. Grewe, C.C.O., Office of Acquisitions, DEA, NIAID
Richard L. Hartmann, Chief, MIDRCB-A, OA, DEA, NIAID
Miranda Adams, Contract Specialist, OA, DEA, NIAID, NIH

Please acknowledge receipt of this notice as provided below:

ACKNOWLEDGEMENT OF NOTICE

The undersigned acknowledges receipt of a signed copy of this notice on _____. A signed, scanned and emailed copy of this notice is returned to the Contracting Officer.

Signature

Position / Title

From: Colin Parrish
Sent: Fri, 31 Jul 2015 12:18:39 -0400
Cc: Kahn, Eleanor J.; W. Ian Lipkin; Park, Eun-Chung (NIH/NIAID) [E]; raul. andino
Subject: "The Emergence of New Epidemic Viruses" workshop - Program details and attendees.
Attachments: Emerging virus workshop Program 7-30-2015.pdf, Emerging Epidemic Workshop Attendee List.xlsx

Dear Meeting Attendees,

We would like to thank you for your interest in the workshop on "The Emergence of New Epidemic Viruses", which is being held next Monday August 3rd through noon on Wednesday August 5th.

Just to reiterate that the workshop is intended to be a broadly based discussion of the area of viral emergence leading to epidemics in new hosts, and to allow an open examination of the challenges that remain in identifying and confronting such viral threats. The last version of the program is attached - that also has a preamble that describes more about the purpose of the meeting, and the goals that we are trying to accomplish.

A number of attendees and observers are coming from different areas of the NIH and other parts of the US government - for your information we attach a list of those who have indicated that they will be attending for some or all of the workshop, in addition to the list of speakers who will be attending.

Look forward to seeing you next week -

Colin Parrish
Raul Andino, W. Ian Lipkin, Eun-Chung Park
--
Colin Parrish
John M. Olin Professor of Virology
Director, Baker Institute for Animal Health and Feline Health Center
Baker Institute
Department of Microbiology and Immunology
College of Veterinary Medicine
Cornell University
Ithaca, NY 14853

(b)(6)

The Emergence of new Epidemic Viruses: what knowledge have we gained, what questions have we not asked, and what more do we need to do?

Monday August 3 – Wednesday August 5, 2015

Room 1D13

5601 Fishers Lane, Rockville, MD 20851

Organizers

Colin Parrish (Cornell University), W. Ian Lipkin (Columbia University), Raul Andino (UC San Francisco), Eun-Chung Park (NIAID).

Objectives of the Workshop: Both novel and known viruses in wild and domestic animals can evolve to jump species barriers, while other viruses may gain new properties to increase their transmissibility and virulence in humans. These pose major threats to human health and wellbeing, and while we are beginning to understand the diversity of animal viruses, we have no way to predict which of them is a higher risk, or how to identify and forestall their emergence in humans. The stream of new viruses emerging in the past few years that are associated with pandemics (H1N1 influenza), or that appear to have pandemic potential (MERS coronavirus, H5N1 and H7N9 or other influenza viruses, SARS coronavirus, Ebola virus), reminds us that the next emerging virus outbreak is not a matter of if but when, and also that we need to gain a better understanding of the factors involved in such events.

In 2005, Division of Microbiology and Infectious Diseases (DMID) sponsored a workshop entitled “The Emergence of Epidemic Viruses by Host Switching” to examine the status of research in the field and to identify gaps in knowledge. The workshop led to a major published review by several of the meeting participants, and also to associated RFAs seeking projects on virus discovery and prediction. These in turn resulted not only in an increased interest in the topic among the virology, viral evolution and ecology communities, but also in important new discoveries made possible by the RFA, such as the demonstration that bats are the likely direct hosts for SARS and MERS and the discovery and characterization of thousands of new animal viruses from many regions of the world.

The purposes of this workshop are to continue the discussions of this important topic, to update and assess the progress that has been made in this area, and to identify remaining or additional areas of research in order to target future investigations. As part of this project we also wish to discuss the development of new technological and analytical approaches that can facilitate understanding of the key principles underlying viral emergence. The attendees have been chosen to allow us to obtain a comprehensive understand of these topics. Some researchers from different disciplines that are not traditionally involved in the field of viral emergence will provide fresh perspectives and/or expertise that are essential for developing new tools and fresh ideas.

Emergence of New Epidemic Viruses – Understanding the Processes.

The workshop will focus on the special instances of viruses crossing-species barriers or becoming more transmissible in humans to cause epidemics or pandemics, along with the similar emergence events in animals that can provide create clear comparative examples. We

will not be explicitly discussing spill-overs by viruses that cause single infections or self-limiting outbreaks, except where those are contributing factors in epidemic emergence.

The program is loosely organized around the different factors associated with the processes of epidemic emergence. Large scale factors include viral discovery and the inventory of extant animal viruses, as well as ecological, landscape, and epidemiological processes associated with their maintenance and spread. Other factors include the evolution of the viruses in the context of new hosts, and the biophysical interactions of viral proteins with one another or with host factors such as receptors or innate response effectors. The goals of the meeting are to think broadly about these different factors and to integrate the various components to provide a more complete understanding of the processes leading to emergence of new epidemic viral pathogens. The presentations and discussions will focus on the general principles that are illustrated by the presenter's work or subject area. We aim to achieve a better understanding of the different issues, and also to identify where we are missing knowledge that could be gained through new, more effective, or better targeted research.

For the purposes of this project, we would like to work on the assumption that much of our accepted knowledge about viral emergence is not proven, or may not be broadly applicable. We would also not assume *a priori* that any particular viral type or animal reservoir poses a greater risk or should be prioritized over any other. The goal is to provide a fresh look at this area and to derive a clearer understanding of the processes involved. Our ability to better define the basic principles of viral emergence will contribute to more effective prediction and interventions to head-off or control new diseases before they cause widespread outbreaks, which are the long-term goals of this program.

Location and Getting There

Accommodations: Even Hotel, 1775 Rockville Pike, Rockville, MD 20852

9:00am – Take shuttle from hotel to the meeting site, or walk (15 mins) to **5601 Fishers Lane, Rockville, MD 20851**.

9:00am – 10:00am. Check in and complete security – allow time. Please bring your government issued ID (e.g. drivers license); if not a US citizen or permanent resident your passport.

PROGRAM.**MONDAY AUGUST 3RD.**
Room 1D13**10:00am – 10:15am. Introduction to the Meeting – Organization and Goals.****Colin Parrish, Eun-Chung Park, W. Ian Lipkin, and Raul Andino.*****Session 1.***

Understanding the Sources of New Viruses – from reservoirs in animals or by modification of existing viruses. Strategies for virus discovery and detection, as well as for testing and assessment of discovered viruses. How much do we know about the inventory of viruses infecting animals which have the potential to infect other animals or humans. Where should we be looking for additional viruses if that is useful? What do we know about viruses of domestic animals or wild life species? What new technologies can be developed or implemented to anticipate zoonosis. How should we conduct surveillance of populations exposed to wild or domestic animals – if so, what kind of reagents or tests should be developed.

Session 1.

10:15 – 10:45am **W. Ian Lipkin:** Columbia University
10:45 – 11:15am **William (Billy) Karesh:** EcoHealth Alliance
11:15 – 11:45 am **Simon Anthony:** Columbia University
11:45 – 12:15pm **Vincent Munster:** Virus Ecology Unit, NIAID

12:15 – 1:00pm **Lunch**

1:00 – 1:30pm **Eric Delwart:** UC San Francisco
1:30 – 2:00pm **Malik Peiris:** Hong Kong University
2:00 – 2:30pm **Ben Larman:** Johns Hopkins University

2:30 – 3:15pm **Coffee break, and Discussion of Virus Discovery Session 1*****Session 2.***

Host-virus interactions controlling viral host ranges - at tissue, cellular, molecular and/or receptor levels and the nature of host barriers. What are the host barriers to virus infection and spread? Do we have necessary tools to address these questions? If not, what tools would have to be developed? Connections between laboratory work and epidemiological processes.

3:15 – 3:45pm **Adolfo Garcia-Sastre:** Mount Sinai School of Medicine
3:45 – 4:15pm **Pablo Murcia:** University of Glasgow
4:45 – 5:15pm **Sara Sawyer:** University of Colorado
5:15 – 5:45pm **Pascal Gagneux:** UC San Diego

5:45 – 6:30pm **Discussion and summary of Host Interactions Session 2.**

7:00 – 8:00pm Reception and mixer for the group. Even Hotel, 1775 Rockville Pike, Rockville, MD 20852 [sponsored by Columbia University].

8:00pm + Dinner at nearby restaurant [note that because of US government regulations this cannot be covered by the NIH – would be covered by your per diem].

TUESDAY AUGUST 4TH.

8:30am. Allow time to pass through security.

Session 3.

Adaptation to and pathogenesis in the new host; mechanisms for new host invasion, viral evasion and host responses; overcoming those allowing epidemic emergence. What applicable animal models are available? If new models need to be developed, what are the important parameters to be considered and how do we develop models that meet these requirements?

9:00 – 9:30am Stacey Schultz-Cherry: St Jukes Childrens Hospital

9:30 – 10:00am Ralph Baric: UNC Chapel Hill

10:00 – 10:30am Coffee break

10:30 – 11:00am Lin-Fa Wang: Duke-NUS Graduate Medical School, Singapore.

11:00 – 11:30am Paul Duprex: Boston University

11:30 – 12:30am Discussion of Adaptation and Pathogenesis Session 3.

12:30 – 1:00pm Lunch – cafeteria in building.

Session 4.

Viral evolution - general principles and related to the processes of transfer and adaptation to new hosts. What do we know about the evolutionary processes involved in acquiring high transmissibility by viruses that lead to direct epidemic spread? How do invertebrate vector adaptation of arboviruses allow for increased transmission? What are the critical tools needed to address remaining questions?

1:00 – 1:30pm Elodie Ghedin: New York University

1:30 – 2:00pm Raul Andino: UC San Francisco

2:00 – 2:30pm (b)(6)

2:30 – 3:00pm Coffee break

3:00 – 3:30pm Discussion of Viral Evolution Session 4.

Session 5.

Virus-host interactions, and the processes of post-transfer adaptation. How often, and by what mechanisms do viruses become optimized for replication in and transmission to the new host?

3:30 – 4:00pm **Colin Parrish:** Cornell University
 4:00 – 4:30pm **Scott Weaver:** U Texas Medical Branch
 5:00 – 5:30pm **Jesse Bloom:** Fred Hutch, U of Washington

5:30 – 6:30pm **Discussion and summary of Post-Transfer Adaptation Session 5.**

7:30pm - **Dinner at local restaurant [note that this cannot be covered by the NIH as part of the meeting – would be covered by your per diem].**

WEDNESDAY AUGUST 5TH.**Session 6.**

The epidemiology of new pathogens at different stages of the emergence process and implications for control strategies. What are the epidemiologic steps involved in new-virus emergence and spread? What are the roles of contact networks, super-spreaders, population structures, invertebrate vectors, and other changes that may occur to enhance transmission?

8:30 – 9:00am **Jamie Lloyd Smith:** UC Los Angeles
 9:00 – 9:30am **Susan Holecchek:** Arizona State University
 9:30 – 10:00am **Stuart Nichol:** Centers for Disease Control

10:00 – 10:30am **Coffee break**

Session 7.

10:30am – 12:00pm. Discussion and summary of previous topics; overall summary and conclusions of the workshop. What do we know, and where are the remaining questions? What needs to be done next?

Attendess - NAME	Institution	EMAIL
Alarcon, Rodolfo	NIAID	(b)(6)
Bogdan, John	NIAID	
Cassetti, Cristina	NIAID	
Clayton, April	NIAID	
Costero-Saint Denis, Adrian	NIAID	
Dempsey, Walla	NIAID	
Ghenbot, Ghiorghis	NIAID	
Gupta, Ranjan	NIAID	
Hauguel, Teresa	NIAID	
Heilman, Carole	NIAID	
Hoffman, Megan	NIAID	
Meegan, James	NIAID	
Koshy, Rajen	NIAID	
Krafft, Amy	NIAID	
Kraigsley, Alison	NIAID	
Lambert, Linda	NIAID	
Laughlin, Catherine	NIAID	
Mathur, Punam	NIAID	
McSweegan, Edward	NIAID	
Morens, David	NIAID	
Nelson, Martha	NIH	
Parker, Tina	NIAID	
Payne, Susan	NIAID	
Repik, Patricia	NIAID	
Salomon, Rachelle	NIAID	
Sanz, Patrick	NIAID	
Schiltz, Helen	NIAID	
Spiro, David	NIAID	
Stemmy, Erik	NIAID	
Taubenberger, Jeffery	NIAID	
Taylor, Christopher	NIAID	
Williams, Mark	NIAID	
George, Dylan	OS/ASPR	
(b)(6)		
Speakers - NAME	Institution	(b)(6)
Andino, Raul	UC San Francisco	
Anthony, Simon	Columbia Univ	
Baric, Ralph	Univ of North Carolina	
Bloom, Jesse	Fred Hutchinson Cancer Res Ctr	
Delwart, Eric	UC San Francisco	
Duprex, Paul	Boston Univ School of Med	
Gagneux, Pascal	UC San Diego	
Garcia-Sastre, Adolfo	Mt. Sinai School of Med	
Ghedin, Elodie	New York Univ	
Holechek, Susan	Arizona State Univ	
Karesh, Billy	EcoHealth Alliance	
Larman, Ben	Johns Hopkins Univ	
Lipkin, Ian	Columbia Univ	
Lloyd-Smith, Jamie	UC Los Angeles	

Morse, Stephen	Arizona State Univ	(b)(6)
Munster, Vincent	RML - NIAID	
Murcia, Pablo	Univ of Glasgow	
Nichol, Stuart	CDC	
(b)(6)		
Park, Eun-Chung	NIAID	
Parrish, Colin	Cornell Univ	
Peiris, Malik	Hong Kong Univ	
Sawyer, Sara	Univ of Colorado	
Schultz-Cherry, Stacey	St. Jude Child. Res Hosp	
Wang, Lin-Fa	Duke - NUS	
Weaver, Scott	UTMB	

From: Morens, David (NIH/NIAID) [E] [b6]
[b6]
Sent: 10/31/2019 6:00:08 PM
To: Ellen Carlin [b6]
Subject: RE:
Attachments: [Untitled].pdf

Ellen, WOW, this is wonderful, you've done a great job! Extremely well written and clear. I have no substantial comments, just a few tweak suggestions to tighten or clarify. They can be ignored if you think best.

Yes, [b6] is sort of a bulge in [b6], and the [b6] is nice, nicer than around [b6]. The [b6] are huge, like [b6], and the [b6] and [b6]. You may remember the 1970's hit song called [b6] Fitzgerald by Gordon Lightfoot, which has since become a sort of modern folk classic. It's about the [b6]

b6

David

David M. Morens, M.D.

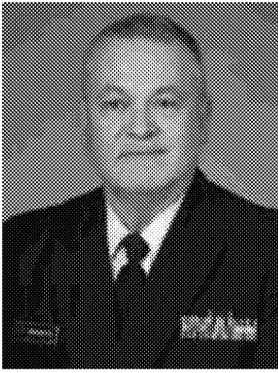
CAPT, United States Public Health Service
Senior Advisor to the Director
Office of the Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Building 31, Room 7A-03
31 Center Drive, MSC 2520
Bethesda, MD 20892-2520

☎ [b6] (assistants: Kimberly Barasch; Whitney Robinson)

📠 301 496 4409

💻 [b6]

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From: Ellen Carlin [b6]

Sent: Thursday, October 31, 2019 10:03 AM

To: Morens, David (NIH/NIAID) [E] [b6]

Subject: Re:

Hi David! Well, you've definitely sold me. I thought of [b6]
[b6] I think [b6] will be right on [b6]. I'll have a great excuse to visit now even if I skip
[b6]! 😊

Please find attached a draft of our proposed paper. Billy, Catherine, Franck, and Kanya and I have all been through it and it represents my best attempt at compromise of everyone's inputs. We need to keep the core text to 750 words. Please edit and change things as you see fit! If you do add anything more than a sentence, you'll need to find something comparable to cut. (I'm assuming Lancet is a stickler for word counts...)

Thanks again for being interested in partnering with us.

Ellen

From: "Morens, David (NIH/NIAID) [E]" [b6]

Date: Friday, October 25, 2019 at 3:33 PM

To: Ellen Carlin [b6]

Subject: RE:

There's one big ugly awful city – [b6] – and a few moderate sized towns, but most of the rest is pretty much the boondocks. [b6] means [b6], and even if you don't count the [b6] it is by far the wateriest place in the US. It's hard to be anywhere and drive a few miles in any direction without hitting a pond or small lake. Mostly just woods and water. Not a lot of people. [b6]
[b6], and is maybe 50-100 miles long and a mile or less wide – and it is so beautiful.... All of the hundreds of times [b6]
[b6] and I never recognized its beauty [b6].

OK, don't get me started.

By the way, [b6] is OK but sort of touristy. I think of it as [b6] Las Vegas, but without the gambling Lines of shops selling kitschy junk and souvenirs.

David

David M. Morens, M.D.

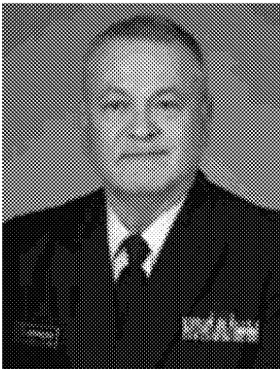
CAPT, United States Public Health Service
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National Institutes of Health
Building 31, Room 7A-03
31 Center Drive, MSC 2520
Bethesda, MD 20892-2520

[b6] (assistants: Kimberly Barasch; Whitney Robinson)

[b6] 301 496 4409

[b6]

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From: Ellen Carlin [b6]

Sent: Friday, October 25, 2019 2:02 PM

To: Morens, David (NIH/NIAID) [E] [b6]

Subject: Re:

Are you sure that's all [b6]? Some of it looked like the Caribbean to me! I honestly had no idea... I think most of us think of [b6] when we think of [b6]. Honestly you've sold me! [b6] has long been on my list, I just didn't know there was so much else to see...)

From: "Morens, David (NIH/NIAID) [E]" [b6]

Date: Friday, October 25, 2019 at 1:04 PM

To: Ellen Carlin

b6

Subject: FW:

Ellen, you're gonna think I work for the tourism industry, but below is the email I sent to

b6

b6

do. Take a look at some of the photos. In the middle is the

b6

b6

b6

. I never found it very interesting, but now I see what a beautiful place it really is..... Not selling tickets, but hoping to convince you of its charm!

David

David M. Morens, M.D.

CAPT, United States Public Health Service

Senior Advisor to the Director

Office of the Director

National Institute of Allergy and Infectious Diseases

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Building 31, Room 7A-03

31 Center Drive, MSC 2520

Bethesda, MD 20892-2520



b6

(assistants: Kimberly Barasch; Whitney Robinson)

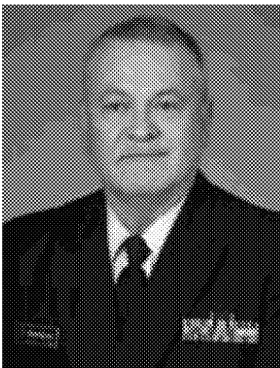


301 496 4409



b6

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From: Morens, David (NIH/NIAID) [E]

Sent: Friday, March 1, 2019 1:27 PM

To: b6

Cc: b6

b6

b6

Subject:

Hi **b6**, I hope you are still thinking of some time out in **b6** this summer.

Here's a few interesting pix to give you an idea of the place: for you AND **b6**!

Basically, except for a few big cities like **b6**, just think, water, forests, lots of Wide open spaces with small towns here and there.

b6

b6 has many ghost towns, like this one, **b6**, an old mining town abandoned in the 1800s, and still sitting there just like it was. **b6**...

b6

Lots of water and outdoor sports like kayaking

b6

Water, water, water everywhere, this is in the

b6

b6

b6

b6

b6

at tulip time (gone long before summer, alas....)

b6

b6, where you can practically touch the boats, some over
1,000 long

b6

b6

b6 The colors come from minerals like
copper in the rocks. **b6**
b6

b6

b6

b6, one of many historical German towns

b6

Forests and wilderness everywhere

b6

Hydroplane races are unforgettable experiences especially for kids. The boats can go close to 300 mph as they slip and slide over the water, and the sound of the engines is deafening. On the open straightaways the rooster tails (the spray they kick up) can be 80+ feet tall and, incredibly, over a mile long (that's how fast they are going: the planes are a mile away by the time the spray falls back down to the water). Not for people with heart problems!

b6

Hundreds of lighthouses....

b6

b6

A freighter on the

b6

b6



The totally to-die-for **b6** whitefish, from up near the **b6**

b6

b6

b6 today....

b6

b6

b6

, which are a kazillion square miles of sand

b6

b6

b6

b6

b6

David

David M. Morens, M.D.

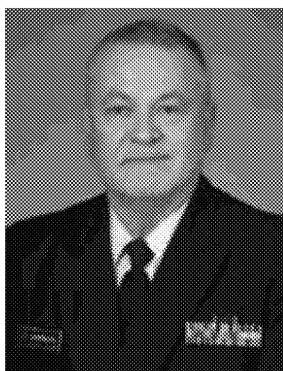
CAPT, United States Public Health Service
Senior Advisor to the Director
Office of the Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Building 31, Room 7A-03
31 Center Drive, MSC 2520
Bethesda, MD 20892-2520

 **b6** (assistants: Meaghan Vance; Silvia Flores Rivas)

 301 496 4409

 **b6**

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Formatted for The Lancet Global Health as a "Comment"

This section contains Commentaries that accompany papers published in The Lancet Global Health or on issues of wide-reaching concern in global health. Comments linked to policy decisions are welcomed. Most Comments are commissioned, but unsolicited Comments (no more than 750 words, ten references, and one figure, panel, or small table) are also welcome. Comments may be peer reviewed.

Title

Global health security: targeting investments toward unmet needs

Authors

Ellen P. Carlin, DVM

EcoHealth Alliance, 460 West 34th Street, New York, NY 10001

b6

Catherine Machalaba, MPH

EcoHealth Alliance, 460 West 34th Street, New York, NY 10001

Kanya C. Long, PhD

University of California San Diego, 6304 Atkinson Hall, La Jolla, CA 92093

Dr. Long was a fellow at the World Bank at the time of the study.

Franck C. J. Berthe, DVM

World Bank, 1818 H Street, NW, Washington, DC 20433

David Morens, MD

National Institutes of Allergy and Infectious Diseases; Address

William B. Karesh, DVM

EcoHealth Alliance, 460 West 34th Street, New York, NY 10001

As the second largest Ebola outbreak in history finally appears to be waning in the Democratic Republic of the Congo, a global reckoning is ~~now~~ due. Understanding why especially dangerous pathogens are emerging with increasing frequency continues to take a back seat to response and response preparedness. This crisis-centered approach is bound to keep us trapped in a ~~cycle~~ of perpetual cycle of panic and neglect.¹

To document this ^{disease emergence} dynamic and reveal its extent, we collated the functions needed for effective prevention through recovery from major biological incidents and assessed which areas are receiving insufficient attention. Our organizing construct included four "pillars"—prevent, detect, respond, and recover. Through extensive review of the scientific and gray literature, and with expert input via roundtables, interviews, and peer review, we identified 60 functions that undergird these pillars and to which countries must have sufficient access to optimize their health security. We identified 22 major initiatives that were global in architecture or oversight but designed to support ^{4/50} ~~the~~ development of local, country, or regional capacities. We then mapped the programs to the pillars to reveal areas of global neglect (Figure 1).

[Insert Figure 1 here]

As the figure shows, activities directed at prevention are minimal in number. We defined prevention as a multi-dimensional concept that captures prevention of 1) epidemics at pre-initiation (*before* pathogens emerge into people); 2) bioweapons development and deployment; and 3) accidental laboratory release of pathogens. The majority of funded efforts do not address prevention at all, and even fewer deal with the underlying risk factors that lead to disease emergence. Most programs view prevention narrowly (i.e., preventing small outbreaks from growing) rather than addressing what drives outbreaks to occur in the first place. The latter entails politically challenging decisions about societal priorities ranging from land use, urbanization, and agricultural practices, to climate change.

Few efforts address recovery, and the very inclusion of recovery as a core pillar in our construct is novel among frameworks. (A recent World Bank publication on which some of the authors worked, which is designed to strengthen human, animal, and environmental public health systems at their interface, is one of the only examples and has not yet been adopted in global efforts.³) Since ~~strong~~ recovery from one epidemic event can pre-empt future outbreaks, systematic and sustained attention to this pillar is badly needed.

We also found two strategic points of concern. One is that, by current design, global health security implementation efforts and their attached financing tackle particular objectives—vaccine development, regional surveillance, training—while no governance effort or strategic inter-institutional guiding framework aligns them toward a commonly defined set of goals. The other is that there seems to be a tendency to view biothreats in terms of the single end consequence that worries people the most: our own health. The problem with this approach is that it drives reverse engineering of structures and decisions to deal with only human health consequences, and forward engineering of response activity tailored to human health needs. Defense, environment, and animal health are often treated as needs outside of human health security frameworks, even though their full inclusion would restore the ~~full~~ breadth of the health security concept. Ebola in DRC exists at this nexus: viral circulation in an ecological

environment that supports spillover and a fragile, violent, and conflict-ridden environment that hampers both prevention and response.

The international community's approach ²⁰diverges from what may be fundamentally needed to grapple with the new epidemic threat reality and ultimately stave off its worst consequences. Some of the functions we identified require less investment than others to achieve great benefit—addressing drivers of epidemics is a case in point. The World Bank estimates that an annual expenditure of ~\$3.4 billion to prevent one in every eight severe pandemics will save \$30 billion.⁴ Assessing cost-benefits and returns on investment of particular activities is precisely what a unifying strategic framework could do. The release of the 2019 Global Health Security Index, which finds among 195 countries assessed an average preparedness score of 40.2 out of a possible 100, may provide new impetus to act.⁵ A substantial but feasible rethinking of the orientation of global and national investment is achievable within the major guiding frameworks and efforts that are already underway. As the Global Health Security Agenda embarks on its second five years, this is a timely opportunity to strengthen underserved lines of effort and support a holistic approach to dealing with the global health challenge of epidemic disease.⁵

Ellen: needs a different word?

Acknowledgements

This work was funded by the Smith Richardson Foundation, which had no other role in the development of the study.

References

1. World Bank. *From panic and neglect to investing in health security: Financing pandemic preparedness at a national level*. Washington, DC: World Bank;2017.
2. Carlin EP, Machalaba C, Berthe FCJ, Long KC, Karesh WB. *Building resilience to biothreats: An assessment of unmet core global health security needs*. New York, NY: EcoHealth Alliance;2019.
3. World Bank. *Operational framework for strengthening human, animal and environmental public health systems at their interface*. Washington, DC: World Bank Group;2018.
4. World Bank. *People, pathogens, and our planet: The economics of one health, volume 2*. Washington, DC: World Bank;June 2012.
5. Nuclear Threat Initiative. *Global health security index: Building collective action and accountability*. Washington, DC: Nuclear Threat Initiative;2019.

Figure 1: Mapping of global health security initiatives to core needs

Initiative	
Australia Group	
CEPI*	
CP3	
Gavi†	
GLASS	
GLEWS‡	
Global Financing Facility	
Global Fund	
GHSA§	
GHSI	
Global Partnership	
International Reagent Resource	
OIE WAHIS	
Proliferation Security Initiative	
World Bank PEF¶	
World Bank Pandemic Preparedness Plan	
WEF Epidemics Readiness Accelerator	
WHO CFE	
WHO Global Influenza Programme	
WHO GOARN	
WHO Health Emergencies Program	
WHO R&D Blueprint	

Major global health security initiatives were mapped to four pillars of global health security activity: prevent, detect, respond, and recover, revealing a predominance of focus on detection and response. Figure reprinted from Carlin EP, Machalaba C, Berthe FCJ, et al. *Building Resilience to Biothreats: An assessment of unmet core global health security needs*. EcoHealth Alliance. 2019.

*Committed to funding through Phase 2 investigational stockpiles; not funded for Phase 3 or linked to a system for procurement, distribution, or dispensing. †To the extent that Gavi covers Prevent it is for the specific prevention of yellow fever spillover through vaccination in high-risk areas; does not address drivers. ‡Predominantly focused on risk monitoring and information alerts for Rift Valley fever in livestock. §Addresses prevention in the sense of containing outbreaks; attention to and capacity for spillover risk management is extremely limited. ¶Disbursement of funds only applies to select viruses.

From: Morens, David (NIH/NIAID) [E] [b6]
[b6]
Sent: 11/5/2019 8:05:15 PM
To: Ellen Carlin [b6]
BCC: Morens, David (NIH/NIAID) [E] [b6]
[b6]
Subject: Re:

Ellen, i plan to be there so see you i hope

I emailed [b6] but daid i know you must be crazybusy so no need to reply now but plz send contact info when you are settled there

I have been promiding myself to go up to [b6] more often, like evry summer i hope. I also may heed to go up very soon to see [b6]
[b6] You should go up some time and see [b6] and check the place out. If i am there I'll show you some of the sights. Also i hope to go up to [b6] when [b6] is there and check thst out

A hydroplane race: that's the real thing to see! It defines the overused word AWESOME. d

David M Morens MD
OD, NIAID, NIH
Sent from my iPhone

> On Nov 5, 2019, at 14:34, Ellen Carlin [b6] wrote:
>

Ha, it's not boring, the stories are amazing! You should write them down as a sort of [b6]
[b6] (Though the [b6] makes it sound more like New Orleans. Scary!!) I really enjoy maritime history and am going to read up on the Fitzgerald.

Thanks again for the compliments on the study and the paper. We'll see if we can get any purchase with it.. A few of us on the paper will be at Cosmos tomorrow so we can talk more then about publishing prospects.

From: "Morens, David (NIH/NIAID) [E]" [b6]
Date: Friday, November 1, 2019 at 10:20 AM
To: Ellen Carlin [b6]
Subject: RE:

Ellen, yes, I plan to be there next week at the Cosmos Club.

The story of the Fitzgerald has become sort of a modern legend (see Wikipedia site:
https://en.wikipedia.org/wiki/SS_Edmund_Fitzgerald)

b6

I have to say now, [b6], being up close to those moving freighters, whether in a small boat nearby or on the shore, is pretty awesome. When the big ships were loaded and speeding above the speed limit, which was almost always, [b6]

b6

b6

Sorry if this is all boring, I am just b6 I guess, and am still pumped about b6 b6 this summer. I am really fired to b6.

Yes, the paper is really REALLY good, you did a great job, not just with the paper but the original work. I'm impressed, and honored to be associated with your work

[cid:image001.gif@01D593E6.0B371CA0]

David M. Morens, M.D.
CAPT, United States Public Health Service
Senior Advisor to the Director
Office of the Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Building 31, Room 7A-03
31 Center Drive, MSC 2520
Bethesda, MD 20892-2520

- b6 (assistants: Kimberly Barasch; Whitney Robinson)
- 301 496 4409
- b6 <mailto:b6>

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[DMM Portrait B 12 29 15 P0923]

From: Ellen Carlin b6
Sent: Friday, November 1, 2019 9:33 AM
To: Morens, David (NIH/NIAID) [E] b6
Subject: Re:

Thanks so much for the rapid turn-around! All edits accepted. I think it's a nice piece. Billy is going to reach out to his editorial contact at The Lancet and see if he can get it invited.

I didn't realize the size of the b6 until I visited b6 a few years ago. They are indeed like b6. That story about the Edmund Fitzgerald would make an amazing book (though I'm sure it's already been written...).

Will keep you posted on the article. See you next week if you are coming to Cosmos Club!

Ellen

From: "Morens, David (NIH/NIAID) [E]" b6 <mailto:b6>
Date: Thursday, October 31, 2019 at 2:00 PM
To: Ellen Carlin b6 <mailto:b6>
Subject: RE:

Ellen, WOW, this is wonderful, you've done a great job! Extremely well written and clear. I have no substantial comments, just a few tweak suggestions to tighten or clarify. They can be ignored if you think best.

Yes, b6 is sort of a bulge in b6, and the b6 is nice, nicer than around b6. The b6 are huge, like oceans, and the b6 and b6. You may remember the 1970's hit song called b6 which has since become a sort of modern folk classic. It's about the b6

b6

[cid:image003.gif@01D593E6.0B371CA0]

David M. Morens, M.D.
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Building 31, Room 7A-03
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- b6 (assistants: Kimberly Barasch; Whitney Robinson)

- 301 496 4409
- [b6] <mailto:[b6]>

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[DMM Portrait B 12 29 15 P0923]

From: Ellen Carlin [b6] <mailto:[b6]>
Sent: Thursday, October 31, 2019 10:03 AM
To: Morens, David (NIH/NIAID) [E] [b6] <mailto:[b6]>
Subject: Re:

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sentence, you'll need to find something comparable to cut. (I'm assuming Lancet is a stickler for word
counts...)
Thanks again for being interested in partnering with us.
Ellen

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Date: Friday, October 25, 2019 at 3:33 PM
To: Ellen Carlin [b6] <mailto:[b6]>
Subject: RE:

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without the gambling Lines of shops selling kitschy junk and souvenirs.

[cid:image005.gif@01D593E6.0B371CA0]
David M. Morens, M.D.
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Building 31, Room 7A-03
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• [b6] (assistants: Kimberly Barasch; Whitney Robinson)
• 301 496 4409
• [b6] <mailto:[b6]>

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[DMM Portrait B 12 29 15 P0923]

From: Ellen Carlin [b6] <mailto:[b6]>
Sent: Friday, October 25, 2019 2:02 PM
To: Morens, David (NIH/NIAID) [E] [b6] <mailto:[b6]>
Subject: Re:

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From: "Morens, David (NIH/NIAID) [E]" [b6] <mailto:[b6]>
Date: Friday, October 25, 2019 at 1:04 PM
To: Ellen Carlin [b6] <mailto:[b6]>
Subject: FW:

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[cid:image007.gif@01D593E6.0B371CA0]

David M. Morens, M.D.
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- [b6] (assistants: Kimberly Barasch; Whitney Robinson)
- 301 496 4409
- [b6] <mailto:[b6]>

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[DMM Portrait B 12 29 15 P0923]

From: Morens, David (NIH/NIAID) [E]
Sent: Friday, March 1, 2019 1:27 PM
To: [b6] <mailto:[b6]>
Cc: [b6] ([b6] <mailto:[b6]>)
Subject: [b6] <mailto:[b6]>

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Here's a few interesting pix to give you an idea of the place: for you AND [b6]!

Basically, except for a few big cities like [b6], just think, water, forests, lots of wide open spaces with small towns here and there.

[cid:image046.jpg@01D5909D.8AF142F0]

[b6] has many ghost towns, like this one, [b6], an old mining town abandoned in the 1800s, and still sitting there just like it was. [b6]

[Image result for [b6]]

Lots of water and outdoor sports like kayaking

[Image result for [b6]]

Water, water, water everywhere, this is in the [b6]

[Image result for [b6]]

[b6]

[Image result for [b6]]

b6

[Image result for b6]

b6

[Image result for b6]

b6

at tulip time (gone long before summer, alas...)

[Image result for b6]

The b6, where you can practically touch the boats, some over 1,000 long

[Image result for b6]

b6

[Image result for b6]

b6. The colors come from minerals like copper in the rocks.

b6

b6

[Image result for b6]

b6

[Image result for b6]

b6

, one of many historical German towns

[Image result for b6]

Forests and wilderness everywhere

[Image result for hydroplane b6]

Hydroplane races are unforgettable experiences especially for kids. The boats can go close to 300 mph as they slip and slide over the water, and the sound of the engines is deafening. On the open straightaways the rooster tails (the spray they kick up) can be 80+ feet tall and, incredibly, over a mile long (that's how fast they are going: the planes are a mile away by the time the spray falls back down to the water). Not for people with heart problems!

[Image result for b6]

Hundreds of lighthouses...

[Image result for b6]

b6

[Image result for ice sail boat]

Ice sailboats

[Image result for b6]

A freighter on the

b6

b6

[Image result for whitefish dinner b6]

The totally to-die-for **b6** whitefish, from up near the **b6**..

[Image result for **b6**]

b6

[Image result for **b6**]

b6 today...

[Image result for **b6**]

b6

[Image result for **b6**]

b6

[Related image]

b6

, which are a kazillion square miles of sand

[Image result for **b6** beauty]

[Related image]

[Image result for **b6** beauty]

[Related image]

[Image result for **b6** beauty]

[Image result for **b6**]

[Image result for **b6**]

[cid:image044.gif@01D5909D.8AF142F0]

David M. Morens, M.D.

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- **b6** (assistants: Meaghan Vance; Silvia Flores Rivas)
- 301 496 4409
- **b6** <mailto:**b6**>

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[DMM Portrait B 12 29 15 P0923]

From: Ellen Carlin [b6]
Sent: 11/5/2019 7:33:52 PM
To: Morens, David (NIH/NIAID) [E] [b6]
Subject: Re: [b6]

Ha, it's not boring, the stories are amazing! You should write them down as a sort of [b6] (Though the [b6] makes it sound more like New Orleans. Scary!!) I really enjoy maritime history and am going to read up on the Fitzgerald.

Thanks again for the compliments on the study and the paper. We'll see if we can get any purchase with it... A few of us on the paper will be at Cosmos tomorrow so we can talk more then about publishing prospects.

From: "Morens, David (NIH/NIAID) [E]" [b6]
Date: Friday, November 1, 2019 at 10:20 AM
To: Ellen Carlin [b6]
Subject: RE:

Ellen, yes, I plan to be there next week at the Cosmos Club.

The story of the Fitzgerald has become sort of a modern legend (see Wikipedia site: https://en.wikipedia.org/wiki/SS_Edmund_Fitzgerald)

b6

I have to say now, [b6] being up close to those moving freighters, whether in a small boat nearby or on the shore, is pretty awesome. When the big ships were loaded and speeding above the speed limit, which was almost always, [b6]

b6

b6

Sorry if this is all boring, I am just [b6] I guess, and am still pumped about [b6]
[b6] this summer. I am really fired to [b6].

Yes, the paper is really REALLY good, you did a great job, not just with the paper but the original work. I'm impressed, and honored to be associated with your work



David M. Morens, M.D.

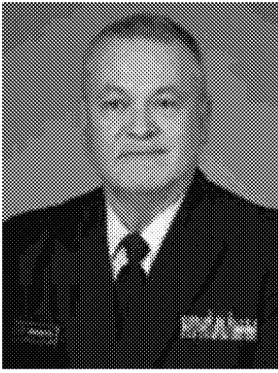
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 [b6] (assistants: Kimberly Barasch; Whitney Robinson)

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 [b6]

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From: Ellen Carlin [b6]
Sent: Friday, November 1, 2019 9:33 AM
To: Morens, David (NIH/NIAID) [E] [b6]
Subject: Re:

Thanks so much for the rapid turn-around! All edits accepted. I think it's a nice piece. Billy is going to reach out to his editorial contact at The Lancet and see if he can get it invited.

I didn't realize the size of the [b6] until I visited [b6] a few years ago. They are indeed like [b6]. That story about the Edmund Fitzgerald would make an amazing book (though I'm sure it's already been written...).

Will keep you posted on the article. See you next week if you are coming to Cosmos Club!

Ellen

From: "Morens, David (NIH/NIAID) [E]" [b6]
Date: Thursday, October 31, 2019 at 2:00 PM
To: Ellen Carlin [b6]
Subject: RE:

Ellen, WOW, this is wonderful, you've done a great job! Extremely well written and clear. I have no substantial comments, just a few tweak suggestions to tighten or clarify. They can be ignored if you think best.

Yes, [b6] is sort of a bulge in [b6], and the [b6] is nice, nicer than around [b6]. The [b6] are huge, like [b6], and the waters rough and dangerous. You may remember the 1970's hit song called [b6]
[b6], which has since become a sort of modern folk classic. It's about the

b6

David

David M. Morens, M.D.

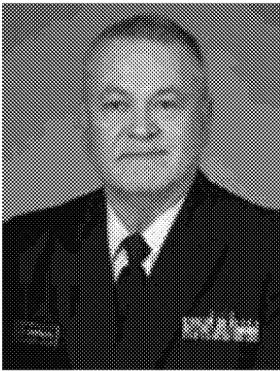
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☎ [b6] (assistants: Kimberly Barasch; Whitney Robinson)

☎ 301 496 4409

💻 [b6]

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From: Ellen Carlin [b6]

Sent: Thursday, October 31, 2019 10:03 AM

To: Morens, David (NIH/NIAID) [E] [b6]

Subject: Re:

Hi David! Well, you've definitely sold me. I thought of [b6]
[b6] I think [b6] will be right on [b6] I'll have a great excuse to visit now even if I skip
[b6] 😊

Please find attached a draft of our proposed paper. Billy, Catherine, Franck, and Kanya and I have all been through it and it represents my best attempt at compromise of everyone's inputs. We need to keep the core text to 750 words. Please edit and change things as you see fit! If you do add anything more than a sentence, you'll need to find something comparable to cut. (I'm assuming Lancet is a stickler for word counts...)

Thanks again for being interested in partnering with us.

Ellen

From: "Morens, David (NIH/NIAID) [E]" [b6]
Date: Friday, October 25, 2019 at 3:33 PM
To: Ellen Carlin [b6]
Subject: RE:

There's one big ugly awful city – [b6] – and a few moderate sized towns, but most of the rest is pretty much the boondocks. [b6] means [b6], and even if you don't count the [b6] it is by far the [b6] place in the US. It's hard to be anywhere and drive a few miles in any direction without hitting a pond or small lake. Mostly just woods and water. Not a lot of people. [b6] [b6], and is maybe 50-100 miles long and a mile or less wide – and it is so beautiful.... All of the hundreds of times [b6] [b6], and I never recognized its beauty [b6].

OK, don't get me started.

By the way, [b6] is OK but sort of touristy. I think of it as [b6] Las Vegas, but without the gambling Lines of shops selling kitschy junk and souvenirs.

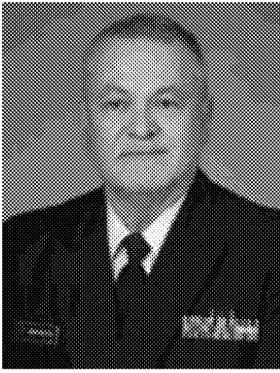
David

David M. Morens, M.D.

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☎ [b6] (assistants: Kimberly Barasch; Whitney Robinson)
☎ 301 496 4409
💻 [b6]

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From: Ellen Carlin [b6]

Sent: Friday, October 25, 2019 2:02 PM

To: Morens, David (NIH/NIAID) [E] [b6]

Subject: Re:

Are you sure that's all [b6]? Some of it looked like the Caribbean to me! I honestly had no idea... I think most of us think of [b6] when we think of [b6]. Honestly you've sold me! ([b6] has long been on my list, I just didn't know there was so much else to see...)

From: "Morens, David (NIH/NIAID) [E]" [b6]

Date: Friday, October 25, 2019 at 1:04 PM

To: Ellen Carlin [b6]

Subject: FW:

Ellen, you're gonna think I work for the tourism industry, but below is the email I sent to [b6]

[b6]

[b6]. Take a look at some of the photos. In the middle is the [b6]

[b6]. I never found it very interesting [b6], but now I see what a beautiful place it really is..... Not selling tickets, but hoping to convince you of its charm!

David

David M. Morens, M.D.

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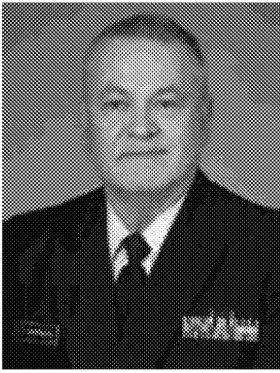
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 **b6**

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From: Morens, David (NIH/NIAID) [E]

Sent: Friday, March 1, 2019 1:27 PM

To: **b6**

Cc: **b6**

Subject:

Hi **b6**, I hope you are still thinking of some time out in **b6** this summer.

Here's a few interesting pix to give you an idea of the place: for you AND **b6**!

Basically, except for a few big cities like **b6**, just think, water, forests, lots of Wide open spaces with small towns here and there.

b6

b6 has many ghost towns, like this one, **b6**, an old mining town abandoned in the 1800s, and still sitting there just like it was. **b6**

b6

Lots of water and outdoor sports like kayaking

b6

Water, water, water everywhere, this is in the

b6

b6

b6

b6

b6

b6

at tulip time (gone long before summer, alas....)

b6

The **b6**, where you can practically touch the boats, some over 1,000 long

b6

b6

b6. The colors come from minerals like copper in the rocks.

b6

b6

b6

b6

b6, one of many historical German towns

b6

Forests and wilderness everywhere

b6

Hydroplane races are unforgettable experiences especially for kids. The boats can go close to 300 mph as they slip and slide over the water, and the sound of the engines is deafening. On the open straightaways the rooster tails (the spray they kick up) can be 80+ feet tall and, incredibly, over a mile long (that's how fast they are going: the planes are a mile away by the time the spray falls back down to the water). Not for people with heart problems!

b6

Hundreds of lighthouses....

b6

Ice sailboats

b6

A freighter on the

b6

b6



The totally to-die-for **b6** whitefish, from **b6**

b6

b6

b6 today....

b6

b6

b6

, which are a kazillion square miles of sand

b6

b6

b6

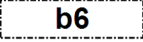
b6

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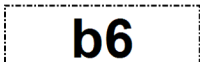


David M. Morens, M.D.

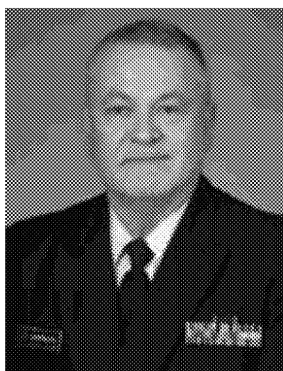
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From: Morens, David (NIH/NIAID) [E] ([b6])
[b6]
Sent: 10/5/2021 11:33:41 AM
To: Taubenberger, Jeffery (NIH/NIAID) [E] ([b6])
[b6]; Peter Daszak ([b6])
[b6]; Keusch, Jerry ([b6]) ([b6]); Rich Roberts ([b6])
[b6]
Subject: Collins retiring... FW: NIH director's move, questions about Merck's new Covid pill, & rural hospital puts telehealth to the test

David

David M. Morens, M.D.

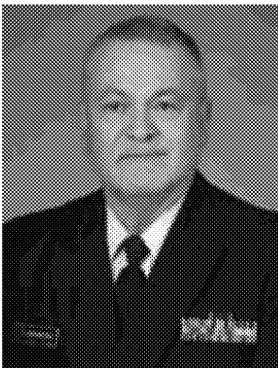
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☎ ([b6]) (assistant: Whitney Robinson)

☎ 301 496 4409

💻 ([b6])

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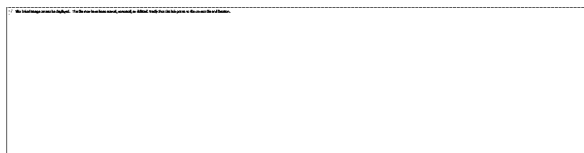
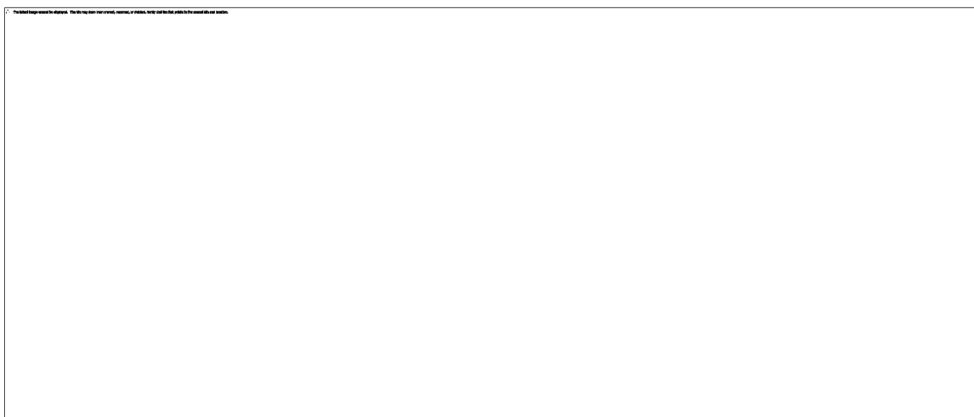
From: STAT | Morning Rounds <newsletter@statnews.com>

Sent: Tuesday, October 5, 2021 6:01 AM

To: Morens, David (NIH/NIAID) [E] b6

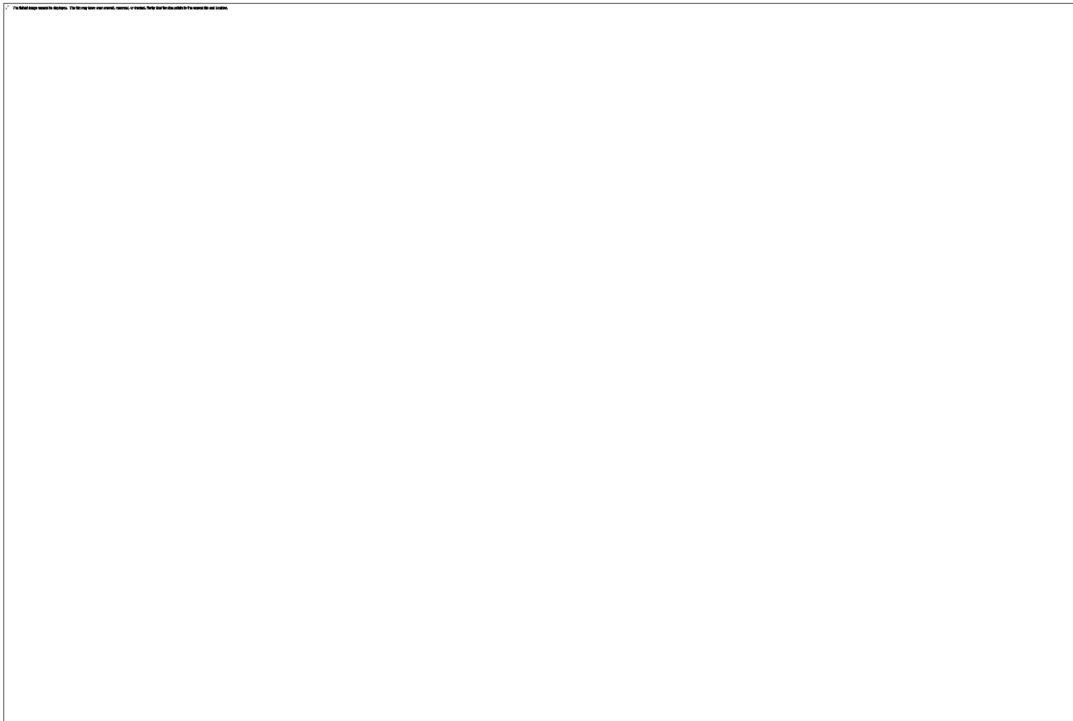
Subject: NIH director's move, questions about Merck's new Covid pill, & rural hospital puts telehealth to the test

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How do you make health care accountable? That's up for discussion at 1 p.m. ET today during a STAT+ Conversation with Farzad Mostashari, CEO and co-founder of Aledade, and STAT's Nicholas St. Fleur. STAT+ subscribers can join [here](#).

NIH leader to announce retirement today



NIH DIRECTOR FRANCIS COLLINS. (GRAEME JENNINGS/AP)

Francis Collins, the pioneering genetics researcher and longtime director of the National Institutes of Health, will announce his retirement from the agency today, two sources told STAT. His departure, first reported last night by Politico, marks the end of an era for the \$40 billion government research agency. He has worked at the NIH since 1993, and was nominated to serve as director in 2009 by President Obama. An evangelical Christian with a medical degree and Ph.D. in physical chemistry, Collins, 71, is among the most revered political figures in Washington — so much so that President Trump and President Biden, upon their elections, each chose to reappoint him to lead the agency. [Read more.](#)

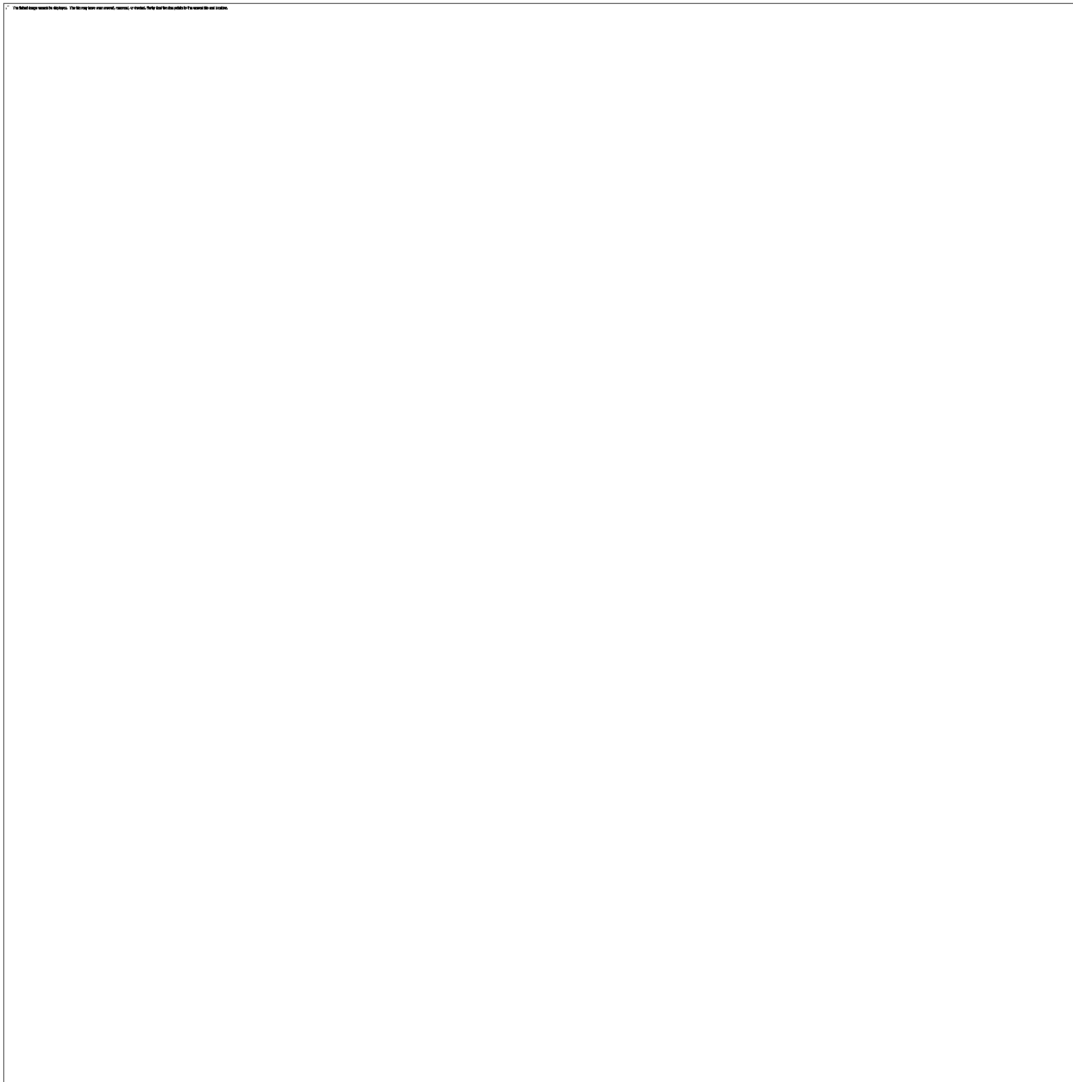
We have questions about Merck's new Covid pill

Last Friday's announcement that a pill from Merck and partner Ridgeback Biotherapeutics kept Covid patients out of the hospital made headlines and moved stocks. But as is so often true when data are released by press release, there are still many questions left unanswered. STAT's Matthew Herper takes up some of them:

- How many other anti-Covid pills will end up proving effective?
- How safe is molnupiravir?
- Will molnupiravir be used only in unvaccinated patients?
- What will it cost and who will pay?
- How will the availability of Covid pills affect vaccines and other treatments?

Spoiler: Matt also asks how this treatment relates to ivermectin. "This is simple: it doesn't. But it's worth taking a look at what data are available for each." [Read more.](#)

'Information alone is not enough,' new leader of Jackson Heart Study asserts



APRIL CARSON, DIRECTOR OF THE JACKSON HEART STUDY. (COURTESY UNIVERSITY OF MISSISSIPPI MEDICAL CENTER)

The nation's largest and longest-running study of cardiovascular disease in African Americans calls Jackson, Miss., home. That community, like others in the southeastern U.S., has long experienced disproportionately high rates of cardiovascular disease. April Carson, an epidemiologist who just became the Jackson Heart Study's new director, talked with me recently about her new role.

How do you see the study's mission?

Research is important to provide us with information, but information alone is not enough. We know there are disparities in health outcomes. But what can we do about it?

What is your vision for success?

I would love to see the Jackson Heart Study be a leader in preventing the occurrence of cardiovascular risk factors. In an ideal world, that's Mississippi having the lowest problems of hypertension, Mississippi really making strides in the prevention of cardiovascular risk factors.

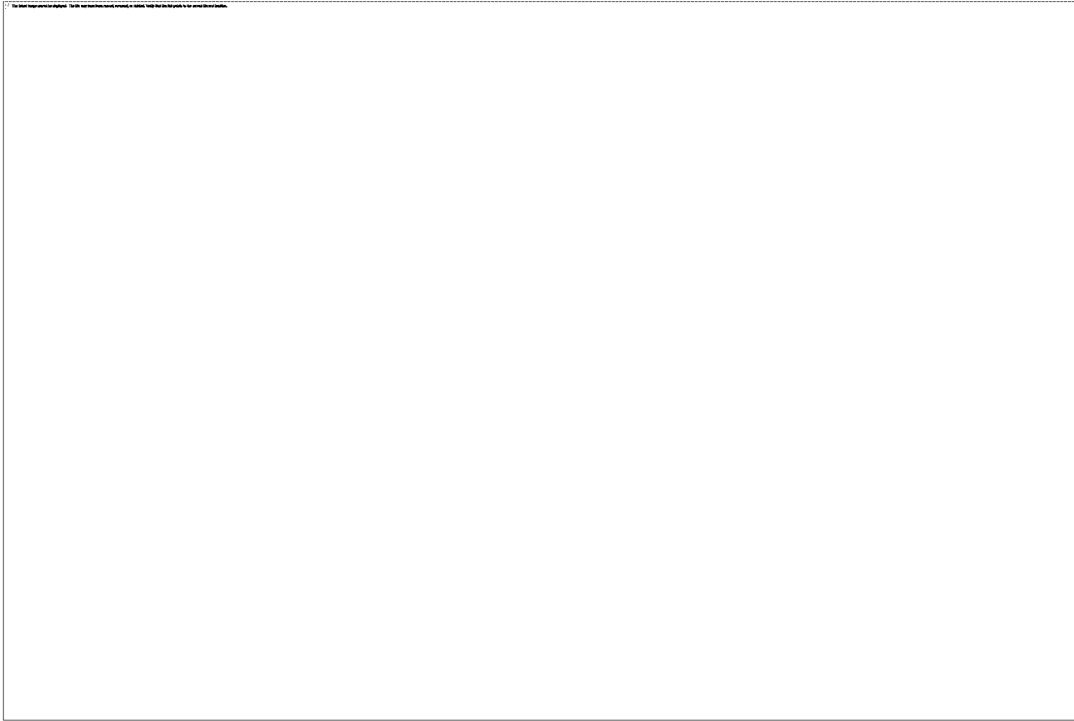
You can read the full interview [here](#).

SPONSOR CONTENT BY HUMANA

Three groups that benefit most from senior-focused primary care, according to senior care expert Reneé Buckingham

The Medicare Annual Enrollment Period (AEP) is upon us. That means seniors are evaluating the offerings of Traditional Medicare compared with Medicare Advantage plans, and they should consider what type of care they will receive not only next year but also down the line, when they have more complex care needs. Chief among the options is senior-focused primary care, explained [here](#) by Reneé Buckingham, leader of Humana-owned CenterWell Senior Primary Care and Conviva Care Solutions.

Inside STAT: Telehealth gave a rural Alabama hospital a lifeline. Then the pandemic hit



AT UAB, DOCTORS AND NURSES WORK OUT OF A NEW OPERATIONS CENTER, SUPPORTING THE HOSPITAL'S TELE-ICU. (UNIVERSITY OF ALABAMA AT BIRMINGHAM)

On the surface, there's nothing about Whitfield Regional Hospital that would make it a safety net for the sickest Covid-19 patients. It has a small ICU with only eight beds, and no critical care doctors on staff. The rural hospital has spent decades focused on caring almost exclusively for the community surrounding Demopolis, Ala., population 7,000, in the heart of the state's Black Belt. But over the summer, Whitfield became an unlikely landing pad for critically ill Covid-19 patients from across the entire state — with the help of a team of telemedicine specialists calling in from more than 100 miles away. STAT's Katie Palmer explains how that ICU's outsized role in Alabama's critical care is a contortion borne of the pandemic.

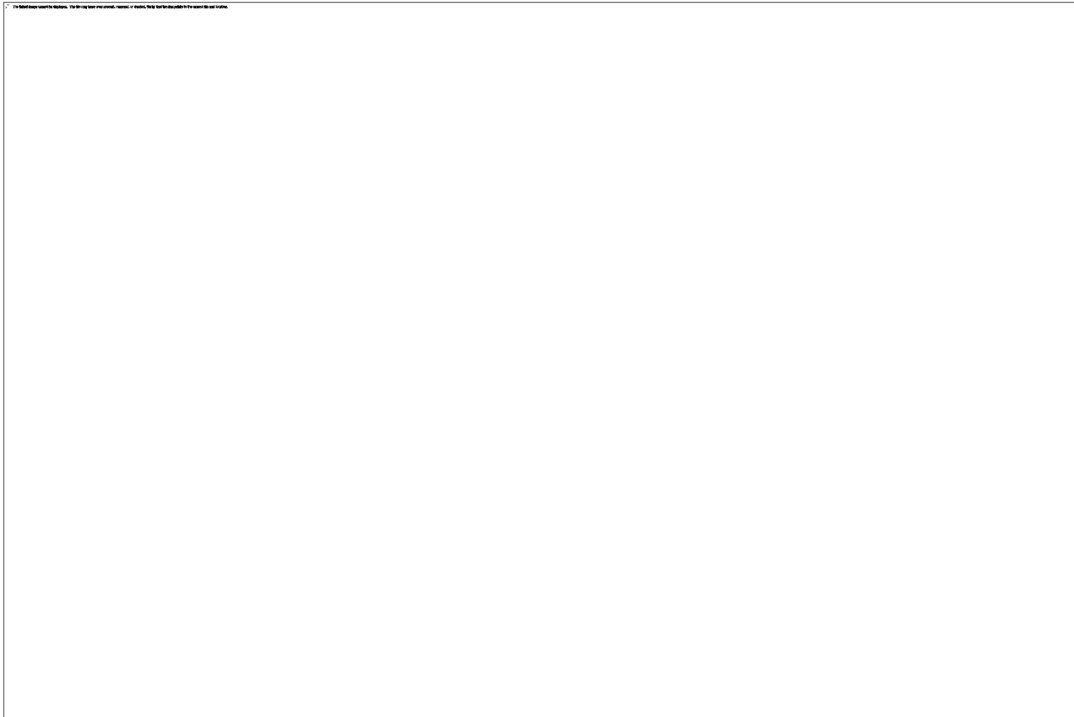
Proof of hope: Jolts from a brain implant provided relief to one severely depressed person

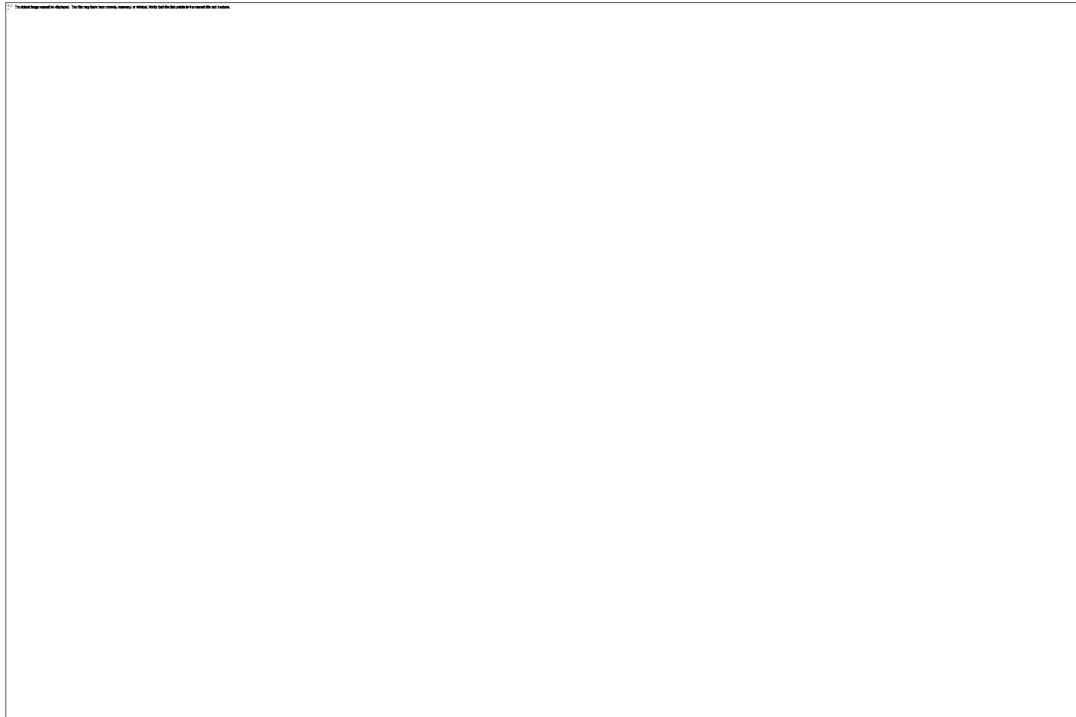
It's just one patient, but her one laugh is inspiring cautious optimism. Last year Sarah, 36 years old and severely depressed (and who chose to only reveal her first name publicly), sat down in a lab with a head full of surgically implanted sensors. After a subtle electrical shock deep in her brain interfered with the dark spirals her depression had sent her on since she was a child, she laughed. Here's how it works: By mapping out a depressed patient's brain circuitry, researchers were able to identify biological markers that told them symptoms were coming, and implant a device to deliver targeted electrical stimulation and provide immediate relief in something like a cranial call and response. Now researchers want to see if they can recreate her experience. STAT's Isabella Cueto has [more](#).

Lacks family sues biotech over use of her cells

Henrietta Lacks died of cervical cancer in a Baltimore hospital decades ago, but her cells — the first human cells to be successfully cloned — live on in laboratories around the world, and have helped develop the polio vaccine, genetic mapping, and Covid-19 vaccines. Her story of tumor tissue being taken without her consent is behind Rebecca Skloot's book "The Immortal Life of Henrietta Lacks" and an HBO movie starring Oprah Winfrey. Now a lawsuit, filed yesterday, 70 years after her death on Oct. 4, 1951, seeks profits made from her cell by Thermo Fisher Scientific, of Waltham, Mass., saying the biotech company knowingly mass produced and sold tissue taken

from Lacks by doctors at Johns Hopkins Hospital. Thermo Fisher did not immediately comment on the lawsuit, the Associated Press said in its story.





What to read around the web today

- First they targeted generic drugs. Now a group of hospitals wants to build a better digital health marketplace. [STAT+](#)
- Covid precautions put more prisoners in isolation. It can mean long-term health woes. [NPR](#)
- 20 years after the anthrax attacks, we're still unprepared. [Wired](#)
- Losing your hair? You might blame the great stem cell escape. [New York Times](#)
- I didn't know my Mom was dying. Then she was gone. [The Atlantic](#)

Thanks for reading! More tomorrow,



@cooney_liz

HAVE A NEWS TIP OR COMMENT?

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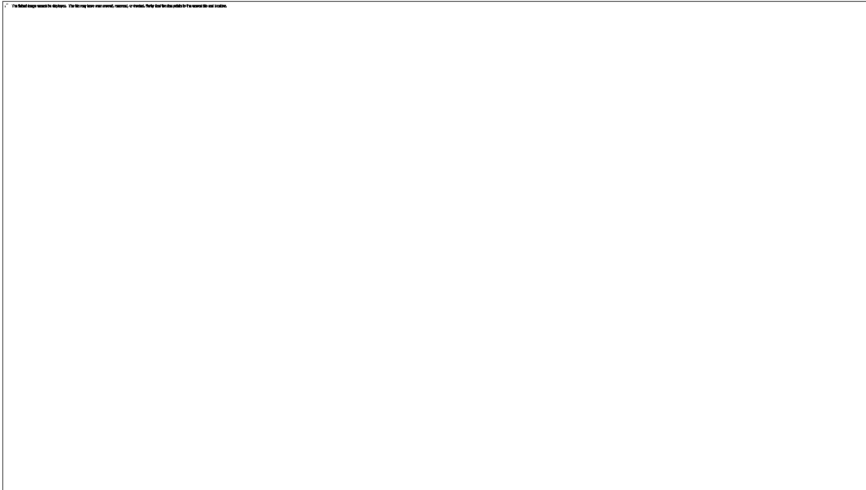
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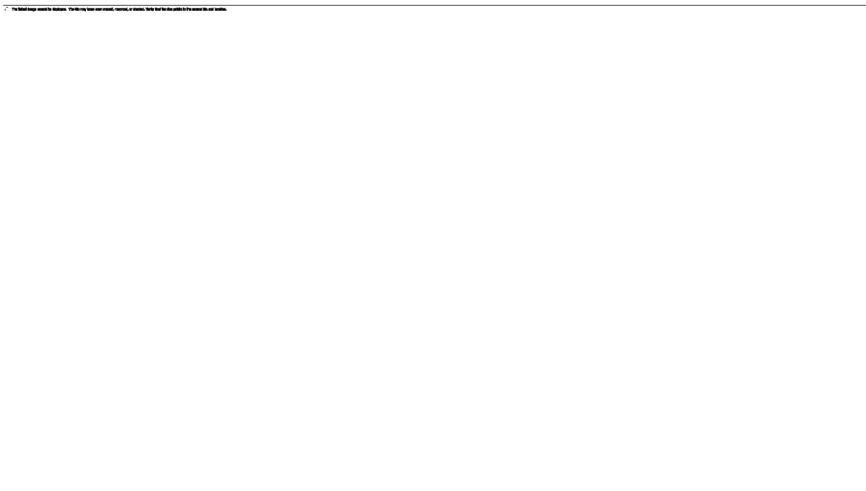
Nov. 16 - 18



VIDEO CHAT

CAR-T
comes of
age?

Oct. 14

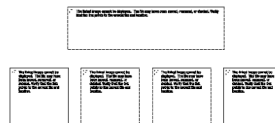


VIDEO CHAT

Bispecifics:
the next
weapon
against
cancer

Oct. 28

Tuesday, October 5, 2021



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From: EcoHealth Alliance [communications@ecohealthalliance.org]

Sent: 3/4/2021 2:59:29 PM

To: Morens, David (NIH/NIAID) [E] [REDACTED] **b6**

([REDACTED] **b6**)

Subject: An ounce of prevention is worth a pound of cure 🙏🙏

An ounce of prevention is worth a pound of cure 🙏🙏

Event is open to the public. Sponsorship and VIP ticket packages are available for purchase.

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From: EcoHealth Alliance [communications@ecohealthalliance.org]
Sent: 10/7/2019 3:59:33 PM
To: Morens, David (NIH/NIAID) [E] [b6]
([b6])
Subject: Join EcoHealth Alliance at the Cosmos Club

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Future Earth: Health and Our Changing Planet

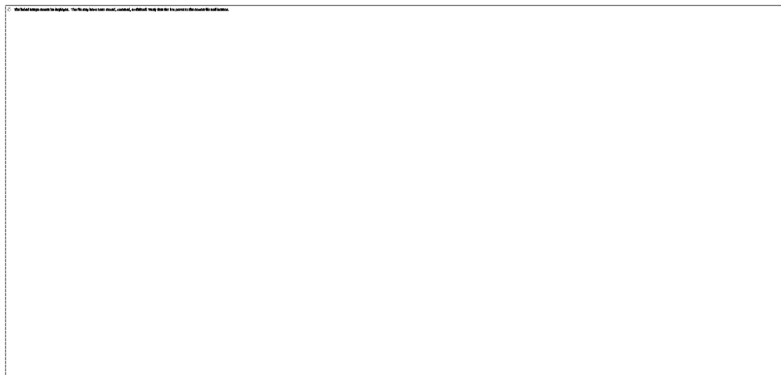
Wednesday, November 6, 2019 from 6:00 PM - 9:00 PM

Join EcoHealth Alliance at the venerated Cosmos Club for a discussion about health and our changing planet.

Remarks from:

- Dr. Peter Daszak, EcoHealth Alliance
- Dr. Amy Luers, FutureEarth

Wine and light fare will be served.



Warne Ballroom
Cosmos Club
2121
Massachusetts
Avenue Northwest
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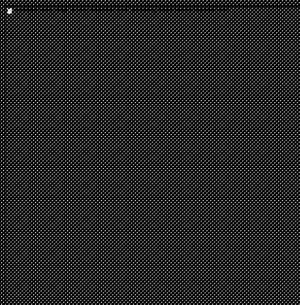
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From: EcoHealth Alliance [communications@ecohealthalliance.org]
Sent: 3/25/2021 3:59:47 PM
To: Morens, David (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12de367cc65c42879ea45d128710a383-dmorens]
Subject: We want our MTV 

We want our MTV 

This year has shown us all the importance of scientific communication. Research and discovery can only truly lead to positive change when those findings are communicated in accurate and equitable ways to the communities impacted.

That's why EcoHealth Alliance is excited to honor the MTV Staying Alive Foundation during our virtual benefit on April 29.



We hope you will join us on April 29 as we come together to discuss how we can prevent pandemics and how EcoHealth Alliance plans to seize this moment to implement practical solutions for the problems of a Pandemic Era. Hear from global leaders in the science, medical, technology, and public health communities about the work that needs to be done to put an end to it.

The event is open to the public. Sponsorship and VIP ticket packages are available for [purchase](#).



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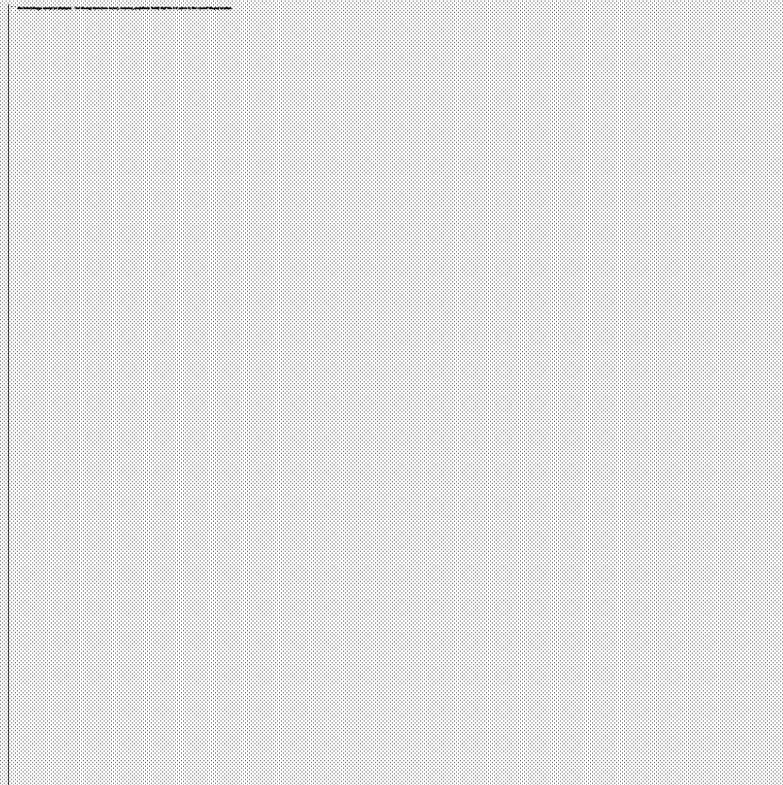
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From: EcoHealth Alliance [communications@ecohealthalliance.org]
Sent: 2/18/2021 2:59:25 PM
To: Morens, David (NIH/NIAID) [E] [REDACTED] b6
[REDACTED] b6
Subject: Check out our latest report on defense, military, and security sector engagement in global public health

Check out our latest report on defense, military, and security sector engagement in global public health

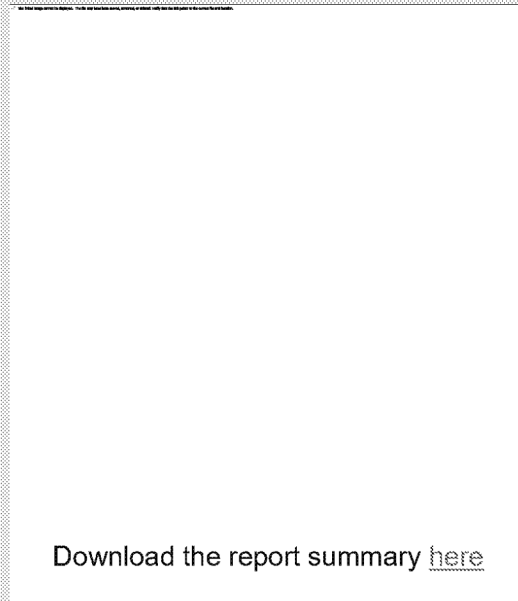
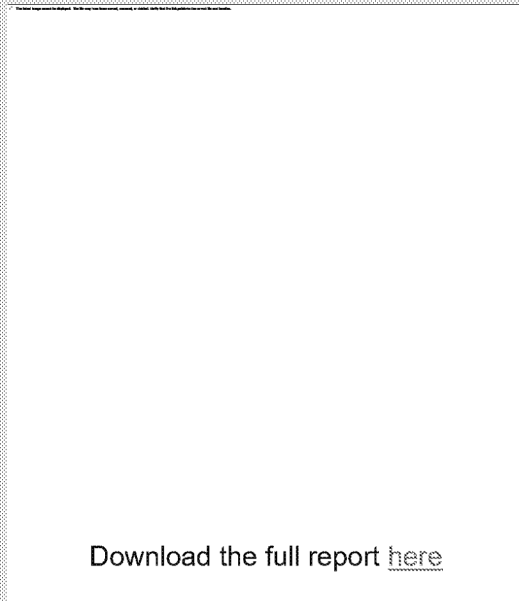


It's been a while.

We've so dearly missed seeing you all at the Cosmos Club. As the vaccine rolls out, we hope to get back to D.C. soon, but until then we hope that you are well and safe.

Today, we released our latest report on defense, military, and security sector engagement in global health security and we wanted you to be some of the first to see it. The 88-page report is a thorough analysis of specific ways these separate but related sectors can assist in efforts to prevent, detect, and

respond to outbreaks of emerging infectious disease. You can download the full report—or a short summary—[on our website](#).



Until we may see each other again!

-- the EcoHealth Alliance team



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From: EcoHealth Alliance [communications@ecohealthalliance.org]

Sent: 2/18/2022 7:33:56 PM

To: Morens, David (NIH/NIAID) [E] [REDACTED] b6

[REDACTED] b6

Subject: [EXTERNAL] Save the Date 

Save the Date 

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From: [b6] [b6]
Sent: 8/23/2021 11:36:19 AM
To: Jason Gale [b6]
CC: [b6]
[b6]; Garry, Robert F [b6]
[b6]; [b6]
BCC: Morens, David (NIH/NIAID) [E] [b6]
[b6]
Subject: Re: Economist - Shared Article 'Putting it all together'

TY, i think this is different from the article in The Economist a week or two ago? That one was interesting as i recall,.. d

Sent from my iPhone
David M Morens
OD, NIAID, NIH

On Aug 23, 2021, at 03:08, Jason Gale (BLOOMBERG/ NEWSROOM:) <j.gale@bloomberg.net> wrote:

In case you missed it, FYI.
Seems to lay things out well. I feel sorry for the int'l team. They didn't decide on/agree to the terms of reference, so the response from the DG on the final report (which he waited for until weighing in) seems disingenuous to me.

From: Paul Geitner (BLOOMBERG/ NEWSROOM:) At: 08/23/21 16:40:56 UTC+10:00
To: Jason Gale (BLOOMBERG/ NEWSROOM:)
Subject: Re:Fwd:Economist - Shared Article 'Putting it all together'

“The virus mystery” broadcast on August 12th, drew uncommonly wide attention for a Danish television documentary. That was because it featured Peter Ben Embarek, an expert on food security and zoonotic diseases, casting doubt on the conclusions of a “joint study” on the origins of the covid-19 pandemic carried out earlier this year under the auspices of the World Health Organisation (who). Dr Ben Embarek was the senior who figure who went to China as part of that study.

In March the joint study reported that it was “extremely unlikely” that the virus had been released in a laboratory accident. Dr Ben Embarek revealed that this conclusion did not come from a balanced assessment of all the relevant evidence but from a steadfast refusal by the Chinese members of the joint study to support anything stronger. Indeed they only allowed even that minimal assessment on the condition that the report did not call for further investigation into the question. He also pointed out that the idea that the point of spillover was someone collecting bat samples for research purposes belongs in the “likely” basket, along with other human interactions with wild bats.

Problems in the joint study had long been clear. Within the

who one source describes it as “riddled with compromises and sloppiness”. Tedros Adhanom Ghebreyesus, the who’s director-general, was uneasy about the way it was carried out. He pushed back at the marginalisation of the lab-leak hypothesis, particularly when the final report was released in March. He has since called for further investigations into it, as well as into other possibilities.

The further unravelling of the joint study matters because, more than a year and a half after the covid-19 outbreak in Wuhan, a city in Hubei, was first recognised as the work of a new pathogen, there has been nothing like a thorough international investigation of how that pathogen, sars-cov-2, got into humans and spread round the world. The pandemic’s death toll stands at 9m-18m, according to a model which *The Economist* has built on the basis of excess-mortality reports and other indicators. The question of how it started matters both for the relatives of the dead and for those who wish to prevent such an outbreak happening again. China’s efforts to stop the world from answering it are both shabby and, to an extent, self-defeating. The more the truth seems hidden, the more it seems suspicious.

Earnest calls for an international investigation into the origins of covid-19 began in April 2020, voiced most clearly by Scott Morrison, the prime minister of Australia. The next month the World Health Assembly, the gathering of government representatives which serves as the who’s decision-making body, passed a motion calling for a study into the origins of the pandemic. But in order to be acceptable to China—which had reacted furiously to Mr Morrison’s original suggestion—the work was set up as a joint research project between two teams of scientists, one Chinese, one international. And it was to be based on “scientific and collaborative field missions”, rather than a targeted and forensic inquiry into all the relevant circumstances.

The terms of reference, which were subsequently negotiated behind closed doors, allowed the Chinese hosts to frame the joint study’s work in the way which best suited them. The study was set up to build on pre-existing Chinese research, not to delve into unvetted data. Investigating the laboratories that had been working with coronaviruses like sars-cov-2 in Wuhan was not part of its terms of reference.

After a lot of wrangling, the international team got to China in January this year. Data about the first reported covid-19 cases, those from December 2019, were one subject of friction with their hosts. The Chinese had reported 174 such cases, but would not share the underlying data on which those reports were based. Hearing that these vital data were not being made available worried Dr Tedros enough that he lobbied the Chinese government for access. The authorities declined, citing concerns over citizens’ privacy. It could have been anonymised.

Elsewhere the team appears to have been knowingly misled. Take, for example, the live-animal trade at the Huanan seafood and wildlife market, a site associated with a number of Wuhan’s earliest recorded cases of covid-19. In its final report, the study group took at face value claims there was no credible evidence that live mammals were sold there in 2019. A lot of eyewitness accounts gainsay that; so does a study published in *Scientific Reports*, a journal, this summer.

One report and no more

The *Scientific Reports* paper found that 18 species of mammal had been for sale in Wuhan between May 2017 and November 2019; gunshot wounds and trapping injuries suggested that almost a third of them were taken from the wild. Although the paper was published only recently, it was submitted to the journal in October 2020. Chinese law requires that all covid-19 research be reviewed by the government before it is sent to a journal. Some Chinese authorities would have known of its contents before the team arrived.

The market is not the only way for animals and the pathogens they carry to get into Wuhan. The horseshoe bats in which the closest wild relatives to

sars-cov-2 have been found do not live anywhere near the city, but the two laboratories there that were known to have engaged in coronavirus research received samples from bat caves around the country. The joint-study team was not allowed to investigate the procedures around, or documentation of, this research; when it visited the laboratories the team was shown presentations on safety procedures but no more.



When the researchers left Wuhan the who

's Geneva headquarters told them that their report needed to be laid out scientifically and could express dissenting opinions; the international members and the Chinese members did not have to reach a consensus. However, according to sources within the who

, the team felt committed to producing a joint report with their Chinese counterparts. Dr Tedros was so unhappy with what finally emerged from the processes that he nobbled the report as it left the starting blocks, rejecting its contention that the possibility of a lab leak needed no further investigation.

On May 26th President Joe Biden ordered America's intelligence services to report on the pandemic's origins in 90 days (time will be up on August 24th). When he and his fellow

g7

leaders met in June they joined in calling for a timely, transparent and science-based follow-up study. On July 16th Dr Tedros laid out the next steps which the

who

wants to see taken. They include further work on the Wuhan animal markets, studies of early cases and audits of local laboratories.

The Chinese government has reacted angrily to the idea of further studies on its territory. Zeng Yixin, the vice-minister of China's National Health Commission, said he was "shocked" by the plan to investigate a lab leak, saying it was "impossible" to accept. According to the *Global Times*, a tub-thumping tabloid run by the Communist Party, 55 countries have sent written complaints about the proposal for further investigations to the who

. Dr Tedros, elected director-general with China's support in 2017 and derided by President Donald Trump as China's puppet, may now face a Chinese-backed candidate when he looks for reappointment later this year.

In the absence of any hope that China will co-operate, sources of data beyond its control have become increasingly important. One area of interest is genetic sequence data. Another is early cases exported from China.

See what you did there

An online open-source-intelligence group which calls itself drastic

has been scouring sequencing data to get insight into activities at the Wuhan Institute of Virology (wiv). When researchers publish sequences they typically post the raw data from which those sequences are assembled to public databases such as the sequence-read archive at America's National Centre for Biotechnology Information. Contamination events in the laboratory, or within sequencing machines themselves, mean these data sometimes contain sequences not meant to be there. In theory such evidence could reveal nefarious goings-on.

Such work, while promising, takes a lot of resources. If you have the sort of supercomputers available to America's national labs it gets easier.

Gilles Demaneuf, a data scientist who works with drastic

, says he has a hunch the American intelligence community's 90-day study is working the same angle. It is conceivable that the intelligence services might have been able to filch raw sequence reads directly from Chinese sequencing machines, thus picking up even more data.

Sequencing data only offers a way forward if the virus did indeed leak out of a lab, something which remains a possibility but which is far from proven. The study of early cases should be useful whatever route it took; the closer you get to understanding the when and where of the crossing-over from animal to human, the easier it should be to learn something of the how.

On the basis of information provided by China the joint study concluded it was unlikely for there to have been any substantial transmission in Wuhan before December 2019. That is unlikely to be true. For one thing the *South China Morning Post*, a newspaper based in Hong Kong, obtained government documents in 2020 which showed one to five new cases a day in Wuhan from November 17th 2019 onwards. Further evidence has strengthened the possibility that the virus could have been in circulation much earlier than the official story allows.

That circulation need not have been limited to China. There is increasing evidence suggesting early infections elsewhere. These cases would have been exported from China; no virologists doubt that Hubei was where the virus got going within humans. But if circulation in Hubei goes back further than thought and cannot be directly assessed through studies there, the presence of cases elsewhere offers an alternative way to get an idea of the timing. If a specific travel link were identified, that might help identify a group in Hubei which was infected early on.

A recent study of blood samples from 9,144 adults in 12 different regions of France found seven which contained antibodies against sars-cov-2, all of them taken in November 2019. An Italian lung-cancer screening trial has found samples taken in September 2019 which seem to contain anti-sars-cov-2 antibodies. Another antibody study suggests the virus was circulating at a low level in northern Italy at the same time, notably in

Lombardy, a region which has close connections to Wuhan through the garment trade, and saw Europe's first major outbreak of covid-19 in March 2020.

Antibody tests can give false positives. In a preprint published on August 6th by the *Lancet*, researchers in Lombardy reported on looking instead for sars-cov-2 gene sequences. Examining 289 swabs and urine tests taken from people who had presented with a rash as far back as the second half of 2019, they found

sars-cov-2 sequences in 13, the earliest of which was taken on September 12th.

Sudhir Kumar of Temple University in Philadelphia says the *Lancet* preprint is likely to inspire other investigators to go back and look at retrospective hospital samples. That should help his own research into the origins of the virus. A family tree Dr Kumar and his colleagues have built from vast numbers of published sars-cov-2 genomes allows them to predict the sequence of the progenitor virus from which they are all descended. This sequence differs in three places from that found in the earliest samples taken from patients in Wuhan, meaning there had been enough spread for a certain amount of viral mutation to take place before December. Dr Kumar says that an analysis of the Lombardy sequences suggests that the timeline for the origin of the virus in China might now extend back to the late summer.

More systematic international research into these early infections and their circumstances is needed. Maria Van Kerkhove, head of emerging diseases and zoonoses at the

who, suggests it may be possible to prioritise work in areas which saw the earliest outbreaks in America, France, Italy and Spain. "I think the floodgates will open one day," says Dr Kumar.

A last line of light

An early origin would fit with the timeline that lab-leak proponents tend to favour. Early this August, the minority Republican staff on the House foreign-affairs committee released an 84-page report arguing this case. It makes much of a small but deadly disease outbreak which took place at an abandoned copper mine in Yunnan in 2012. As drastic showed last year, a virus studied at WIV which had been taken from that mine is the closest known relative to sars-cov-2.

The report sees importance in the removal, on September 12th 2019, of a database containing details of sequences and samples from the wiv

. This is read as the beginning of a cover-up, and thus as the point when the authorities first knew something had gone amiss, arguing for a leak in late August or early September. The

wiv

says it was a response to cyber-attacks.

A leak is not the only research-related possibility. The first person infected could have been someone employed by the

wiv

or another lab to collect bats and samples—the prospect to which Dr Ben Embarek pointed in his television interview. And it is important to remember that some other form of spillover outside the lab, either directly from a bat or by way of some other species, may well be to blame.

China clearly does not want lab-leaks investigated; but that does not mean it knows one happened. It is also being misleading about Huanan market, denying access to early-case data and obfuscating in various other non-lab-leak-specific ways. The most obvious explanation is that it does not really want any definitive answer to the question. An unsanitary market, a reckless bat-catcher or a hapless spelunker would not be as bad in terms of blame as a source in a government laboratory. But any definite answer to the origin question probably leaves China looking bad, unless it can find a way to blame someone else. To that end China has called for an investigation of Fort Detrick in Maryland, historically the home of American bioweapons research; state media regularly publish speculations about its involvement.

The possibility of spillover from wild bats does not have to be studied in China. Yunnan abuts onto Laos, Myanmar and Vietnam, and bats are not sticklers in matters of territory. Samples taken outside China could provide a good idea of viral diversity the other side of the border. A thorough evaluation of the existing farm-animal and wildlife trade in the region would also be useful.

Yet there is an inherent risk in such work that needs to be considered.

Efforts to uncover the roots of covid-19 by seeking out a natural reservoir of something very like

sars-cov-2 would, by definition, expose people to the sort of risks that can seed pandemics. Ironically, the very possibility of a lab leak raises questions about how most safely to pursue investigations into other possibilities.

When he called for further inquiries in July, Dr Tedros also announced the formation of a new permanent group of pathogen hunters, the International Scientific Advisory Group for Origins of Novel Pathogens (sago). He wants it to organise further studies of sars-cov-2. But it will also need to look at more general questions for the future—such as how to be sure that, come what may, studies of pathogens involved in past disease outbreaks never create further outbreaks of their own.

From: Jason Gale (BLOOMBERG/ NEWSROOM:) At: 08/23/21 14:34:52 UTC+8:00
To: Paul Geitner (BLOOMBERG/ NEWSROOM:)
Subject: Re:Fwd:Economist - Shared Article 'Putting it all together'

I saw. But it's behind a paywall. U have full access?

From: Paul Geitner (BLOOMBERG/ NEWSROOM:) At: 08/23/21 16:23:52 UTC+10:00
To: Jason Gale (BLOOMBERG/ NEWSROOM:)
Subject: Fwd:Economist - Shared Article 'Putting it all together'

icymi

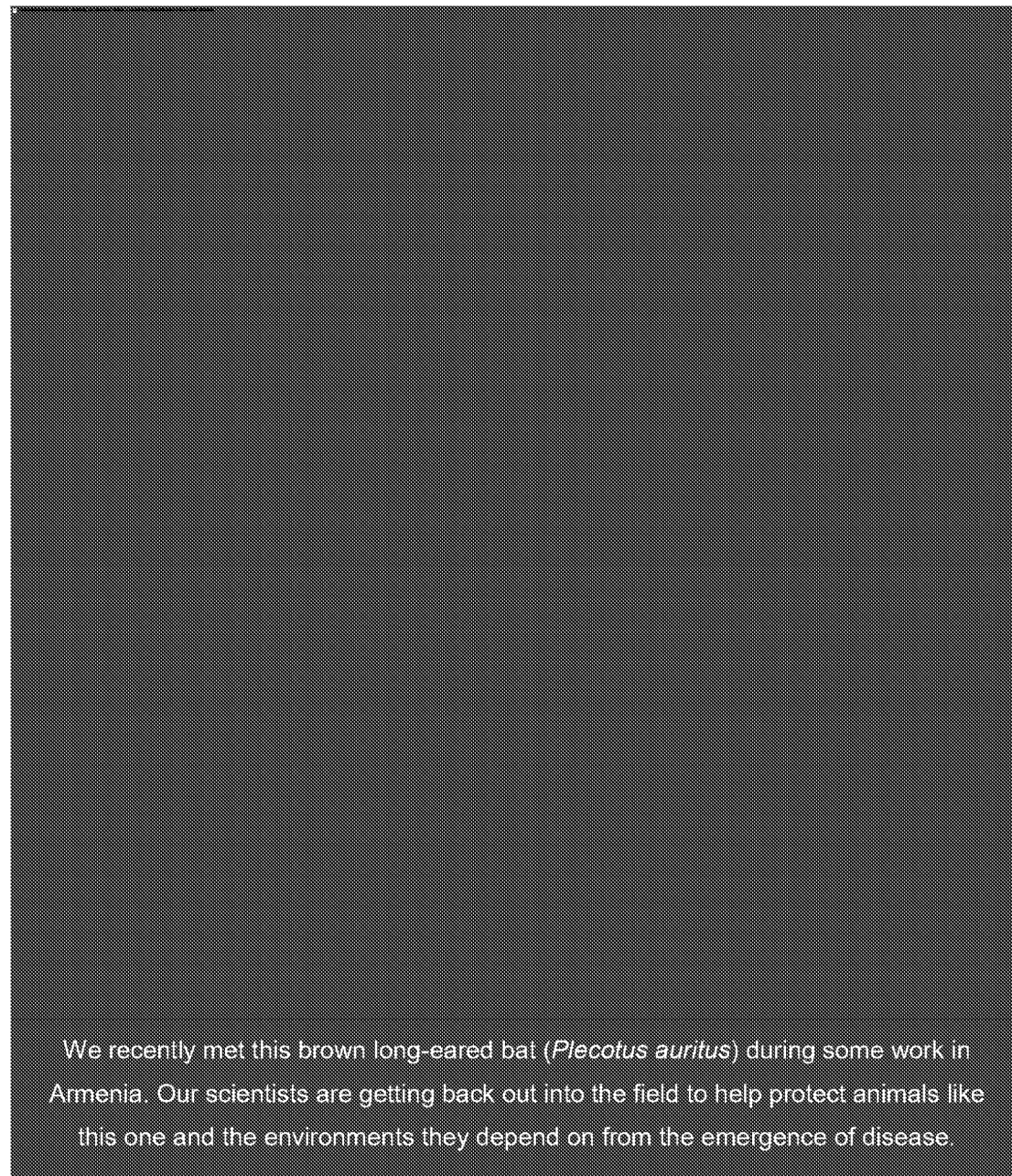
From: [b6] At:
08/22/21 15:23:17 UTC+8:00
To: Paul Geitner (BLOOMBERG/
NEWSROOM:)
Subject: Economist - Shared
Article 'Putting it all together'

The Economist | Putting
it all together
[https://www.economist.co
m/international/2021/08/
19/the-world-needs-a-
proper-inve
stigation-into-how-
covid-19-
started?frsc=dg%7Ce](https://www.economist.com/international/2021/08/19/the-world-needs-a-proper-investigation-into-how-covid-19-started?frsc=dg%7Ce)

From: EcoHealth Alliance [communications@ecohealthalliance.org]
Sent: 11/24/2021 2:59:56 PM
To: Morens, David (NIH/NIAID) [E] [REDACTED] b6
[REDACTED] b6
Subject: Thank you!

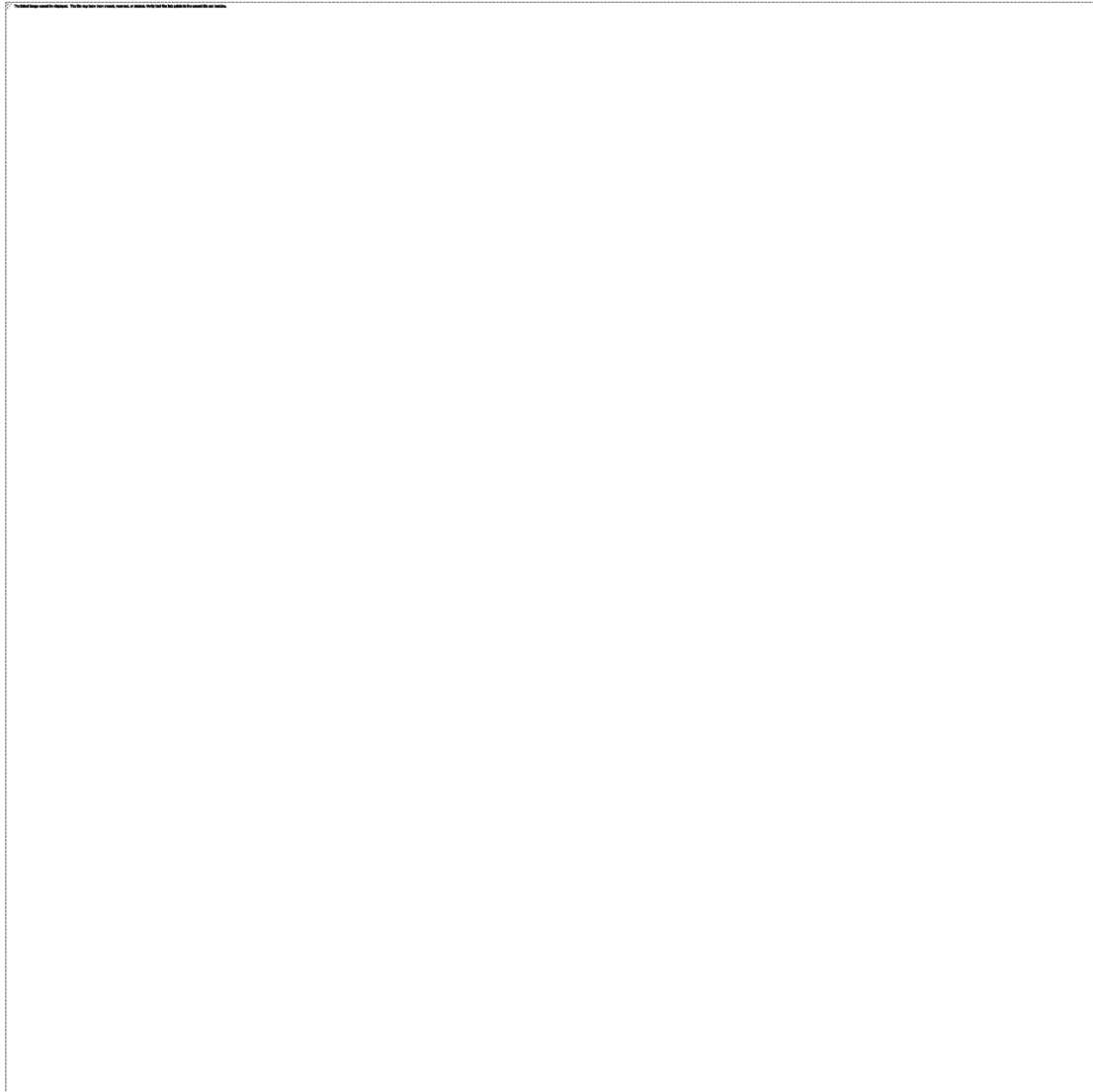
Thank you!

This year has just flown by!



EcoHealth Alliance scientists have resumed field work in many countries around the world and that is thanks to your support. We know the last couple years have been hard and we hope that you and yours are well. COVID-19 has strengthened our resolve and our dedication to our mission: to develop solutions that prevent pandemics and promote conservation.

Pandemics do not have to be a reality of life on Earth and it is with you in mind that we seek better knowledge of where they come from and how we can stop them.





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From: Morens, David (NIH/NIAID) [E]
Sent: Sun, 15 Aug 2021 22:29:52 +0000
To: Jason Gale
Cc: (b)(6)
(b)(6) Garry, Robert F; (b)(6)
Subject: RE: feedback on wild animals

I did not know he was in (b)(6). Is he retired, I assume?

David

David M. Morens, M.D.

CAPT, United States Public Health Service
Senior Advisor to the Director
Office of the Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Building 31, Room 7A-03
31 Center Drive, MSC 2520
Bethesda, MD 20892-2520

📞 (b)(6) (assistant: Whitney Robinson)

📠 301 496 4409

📧 (b)(6)

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From: Jason Gale (BLOOMBERG/ NEWSROOM:) <j.gale@bloomberg.net>

Sent: Sunday, August 15, 2021 6:29 PM

To: Morens, David (NIH/NIAID) [E] (b)(6)

Cc: (b)(6); Garry,

Robert F (b)(6)

Subject: RE: feedback on wild animals

Be great to have you back in Australia, David. And of course, (b)(6) (b)(6) (known to virtually every virologist on this planet!) is in (b)(6).

From: (b)(6) At: 08/16/21 08:26:25 UTC+10:00

To: Jason Gale (BLOOMBERG/ NEWSROOM:)

Cc: (b)(6)

(b)(6)

Subject: RE: feedback on wild animals

Jason, not sure whose office politics is worse, but there is many a day I'd rather be in Australia, even if I had to drink that awful beer Fosters. (To quote Groucho Marx as he help up a glass of questionable beer: "last time I saw something like this, they had to shoot the horse").... But I do have fond memories of Australia, and (b)(6) (b)(6), are out in (b)(6), the only large city there (if oy can call it that) I have never been, although it's high on my bucket list if this damn pandemic ever ends. (b)(6)

(b)(6)



David M. Morens, M.D.

CAPT, United States Public Health Service

Senior Advisor to the Director

Office of the Director

National Institute of Allergy and Infectious Diseases

National Institutes of Health

Building 31, Room 7A-03

31 Center Drive, MSC 2520

Bethesda, MD 20892-2520

(b)(6) (assistant: Whitney Robinson)

301 496 4409

(b)(6)

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From: Jason Gale (BLOOMBERG/ NEWSROOM:) <j.gale@bloomberg.net>

Sent: Saturday, August 14, 2021 7:54 PM

To: Morens, David (NIH/NIAID) [E] (b)(6)

Cc: (b)(6)

(b)(6); Garry, Robert F (b)(6);

Subject: Re: feedback on wild animals

Thanks, David.

I just got off a video conf call with the current editor in NY (the one asking all the latest questions). He's very nice and I feel like he gets it. He thinks it's a fascinating story. Problem we have in journalism is that there are some people who aren't interested in actual journalism and telling stories; they want to climb to the top and manage people. (b)(6)

(b)(6), but am so grateful that I still get to meet so many remarkable people, visit cool places and see all aspects of humanity.

A difficulty working for a NY-based organization is that it's assumed that all the best people are in NYC, so being in Melbourne (where I need to be (b)(6)

(b)(6)), is that folks consider Australia a backwater and, by

association, I mustn't be all that important/valuable. But my new role as "global biosecurity czar" is helping somewhat. Ahhhhh... Office politics!

From: (b)(6) At: 08/15/21 09:03:03 UTC+10:00
To: Jason Gale (BLOOMBERG/ NEWSROOM:)
Cc: (b)(6)
(b)(6)
Subject: Re: feedback on wild animals

Jason, all I can say is that it must be harder to be a journalist than a scientist... I had no idea someone at your level would get pushed back.

Usually i get from one to 4 reviewer responses to a ms. and three of those are out to lunch. Occasionally i get a reviewer who really understands the work: half of those are helpful, the other half are trashers.

Maybe it's like being in the government where i am: there is endless push back, but the push-backers are brainless idiots who don't know what they are talking about.

Do you ever get to a point where the editors leave you alone on the science? Or do they all think they are science geniuses? d

Sent from my iPhone
David M Morens
OD, NIAID, NIH

On Aug 14, 2021, at 16:05, Jason Gale (BLOOMBERG/ NEWSROOM:) <j.gale@bloomberg.net> wrote:

Thanks, Bob. In journalism, getting to the truth even when it's genuinely and actively pursued, can be a tortuous process!

----- Original Message -----

From: Robert F Garry (b)(6)

To: JASON GALE, (b)(6)

(b)(6)

At: 08/15/21 01:45:11 UTC+10:00

Looking forward to this important article. Truth is stronger than fiction.

From: Jason Gale (BLOOMBERG/ NEWSROOM:) <j.gale@bloomberg.net>

Sent: Saturday, August 14, 2021 6:41 AM

To: (b)(6)

(b)(6)

(b)(6) : Garry, Robert F (b)(6)

(b)(6)

Subject: Fwd:Re:feedback on wild animals

External Sender. Be aware of links, attachments and requests.

Hi guys, in case you have nothing better to read over the weekend, this is some of the dialog I am having with editors in the U.S. Essentially, my response to questions from editor #6. I thought I could claim victory when it looked like the story could be published this morning, but the (b)(6) Businessweek objected and thinks (b)(6) can make it better with another revision and an ETA of Tuesday. Sigh.

Jason

From: Jason Gale (BLOOMBERG/ NEWSROOM:) At: 08/14/21 16:36:58 UTC+10:00

To: Cristina Lindblad (BLOOMBERG/ NEWSROOM:), Eric Gelman (BLOOMBERG/ NEWSROOM:)

Cc: Joel Weber (BLOOMBERG/ NEWSROOM:)

Subject: Re:feedback on wild animals

Hi.

Thanks for the feedback and the questions, which I have tried to answer in detail.

It's often easier to have a conversation over Nexi or the phone to explain nuanced information, or details that are clear to me, but might not be to someone coming at this fresh, but that's tricky with the time difference.

When you look back at what's happened here, it seems that in trying to deflect blame for the pandemic, which became increasingly vicious as the cataclysmic nature of the Covid-19 pandemic unfolded around March-April 2020, China tried to conceal a very obvious, very plausible source of the pandemic: it's flourishing wildlife trade (worth about \$90 billion in 2016).

It was an obvious cause of the pandemic because an almost identical scenario triggered an international outbreak caused by a very similar coronavirus (SARS) in 2003-04. But in attempting to cover up the wildlife trade, and making like there were never any wild animals being sold in Wuhan's wet markets, things began

to backfire on China; questions were raised about the nearby lab studying these coronaviruses. The more geopolitical, heated and vicious the arguments and accusations became, the less cooperative China became. In response, the more intent/adamant some groups have become in their belief that China is covering up a lab-leak. It's become a vicious circle. If China isn't coming clean on the wild animals, what else is it trying to hide?? China's defensiveness means we may never get the cooperation needed to find the answers. If China had been honest and transparent about the wild animals in the wet markets, it might not be in this mess now.

Anyway, here are my response to your queries in green.

By the way, I wonder if the current headline:

Delayed Paper Gives Credence to Wuhan Market Covid Origin Story
doesn't convey much more than what we had 2 months earlier when
we reported Xiao's findings: China Markets Sold Mink, Civets,
Stoking Natural Origins Theory

Perhaps Obscured China Paper Scuppered Chance to Trace Covid
Origins

would hits "China", "Covid" and "Origins" in a way that won't
alienate people who already believe it was a lab-leak

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According to the report, minks, civets, raccoon dogs and other mammals known to harbor coronaviruses were sold in plain sight for years in shops across the city, including the now infamous Huanan wet market, to which many of the earliest Covid cases were traced. The evidence collected over 30 months by **Xiao Xiao** a I'D NAME HIM HERE [[i don't know that naming a researcher no one has ever heard of adds much]] researcher working at a lab affiliated with China's Ministry of Education was hastily drafted into a manuscript and submitted to a scientific journal [Joel, we cannot name the first journal they delivered it to because the authors decline to give us the name, saying it may affect their future chances of being published] in February 2020, just weeks before the outbreak was declared a pandemic.

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While the study received wide attention when it was eventually released by a different publisher [Publisher (Springer Nature) and publication (Scientific Reports) are different. Might add confusion DO YOU WANT TO ADD NAME HERE?], its long and torturous

journey to publication gave **Chinese officials an opportunity to weave alternative narratives in which the virus may have come from abroad, even from a U.S. Army biological research facility.**

[the stuff in bold is not contested and we go on to show how that happened, documenting with links when available] I TWEAKED WORDING HERE BUT THIS STILL ISN'T QUITE RIGHT. IF THE REPORT HAD BEEN PUBLISHED EARLIER CHINESE OFFICIALS COULD STILL HAVE DONE WHAT THEY DID--THEY COULD HAVE JUST SAID THE REPORT WAS SHODDY, OR WHATEVER, AND THEY ALSO COULD HAVE JUST IGNORED IT. I disagree. The evidence that Xiao et al provide was meticulously documented and supported by photographs that would have been difficult/impossible for China to dismiss (as older published photos and media reports had been). What's more, Newman understands that Xiao collected blood-sucking ticks from the wild animals he studiously cataloged. His frozen tick samples could be tested for blood/antibodies/virus, which could be extremely helpful in identifying infected species PRIOR to December 2019. The WHO team knew nothing of this, so couldn't have asked China for this research or any results, had they actually done the research. The delay in the publication of Xiao's paper delayed the evidence that there were live animals sold in the Huanan market. The WHO researchers couldn't have asked about tests on wildlife that ostensibly were never there. Likewise, Chinese authorities couldn't have done the tests on animals that didn't exist. The problem is that in January and February 2020, it was widely assumed the animals HAD been there and that the necessary tests and tracing of animals (the sampling of animals on farms they were raised on, testing of farm workers, animal hunters, transporters and traders **had all been done** by researchers in China -- the very things that ultimately led to the discovery of the origins of SARS and of MERS viruses. **None of these things were done** (or at least, there is nothing publicly available to show that they were done) **because the animals "weren't there"**. Now that we all know they were there, China has lost considerable face. The issue has become so political that there is much less/no willingness to cooperate and conduct the additional research that the WHO-led team recommended. Ideally, Xiao's ticks should be studied, but it's doubtful that will now happen (I wouldn't be surprised if he's been ordered to incinerate them!) Hope this is clear.

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An international team of experts convened by the WHO traveled to Wuhan earlier this year to seek answers--a trip that might have yielded different results if the scientists had known about the work of Xiao Xiao, a virologist whose roles straddled

epidemiology and animal research at the government-funded Key Laboratory of Southwest China Wildlife Resources Conservation and at Hubei University of Traditional Chinese Medicine. 'MIGHT HAVE YIELDED DIFFERENT RESULTS' SEEMS HIGHLY SPECULATIVE. WHAT RESULTS DID IT YIELD? I'D CUT THIS GRAF

As mentioned above, the WHO-convened team of researchers was told by market authorities, vendors and regular market visitors that there were no live animals sold in the Huanan market. That undermined completely the premise that the Huanan market was the kind of place where live animals from different species are stacked in cages, with urine and fecal material drips from one cage to the one below it, where there are splatters of blood and guts from animals, and lots of potential for the spread of diseases from one species to another (including Homo sapiens). Instead, the market (and one other one known to have been selling live wild animals in 2019) was presented as selling only frozen wild animals and aquatic species and things unlikely to be the source of SARS-CoV-2. The WHO researchers were told there were frozen ferret badgers and other wildlife found in freezers. Some of the carcasses actually came from Yunnan, the province where the closest coronavirus related to SARS-CoV-2 was found in bats -- thus establishing a potential route from Yunnan to Wuhan in wildlife. That was actually important. When the researchers showed their Chinese counterparts photos of caged raccoon dogs taken in the Huanan market by Prof. Edward Holmes five or six years earlier, they were told by Chinese scientists that the photos may have been faked, and that the market had ceased selling such live animals anyway. The WHO researchers saw no evidence (empty cages, animal pelts, etc) to dispute what the Chinese scientists told them, although they did smell "animals" -- but were told they were smelling rotten meat, sewage etc. Three people associated with the WHO-led mission told me that they didn't believe the information they were given by anyone associated with the market. But since there was no evidence to the contrary, they were unable to push the Chinese scientists further on this. **The fact that the mission concluded that frozen, not live wild animals were sold in the market undermined the thesis that Covid resulted from an animal spillover.** And the absence of strong evidence pointing to a spill over from wild animals to humans made the lab-leak theory look, in relative terms, more plausible.

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Six months and two revisions later, the journal's publishers rejected the paper. "They did not think it would have widespread appeal," says Newman, who declined to name the publication [do

you want us to say why he won't name it? I don't think it's necessary. There's no upside for scientists to make a publisher look bad (most journals are published by a handful of publishers)] "It caused us, especially our Chinese co-authors, concern that these data would not be taken seriously."

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The manuscript underwent a third revision to include data on China's pangolin trade networks (an earlier study, later contested, had implicated pangolins in the virus's spread to humans)WHO ASKED THAT THIS INFO BE INCLUDED? (I did, because we're trying to explain here why WHO missed the significance of Xiao's evidence. The WHO was slammed by other papers being submitted PLUS Xiao's paper had a weird title. That title seemed relevant to the authors back in January-February 2020, when pangolins were considered a possible SARS-CoV-2-spreading culprit. But in October 2020, pangolins were off the hook, so the title would have seem irrelevant/unimportant at first glance at WHO). It was then sent to the online journal Scientific Reports.

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The China-based researchers had reason to be cautious. In February 2020, the China Center for Disease Control (CCDC lets not use "CCDC". It's not commonly used like the U.S. "CDC" is, and it's going to force readers to go back and figure out what the "CCDC" is) prohibited scientists working on Covid-relate

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~~CCDC~~Disease detectives arriving from Beijing (think this makes it clear that these are China's disease "feds" arriving) on the first day of 2020 ordered environmental samples to be collected from drains and other surfaces at the market. Some 585 specimens were tested, of which 33 turned out to be positive for SARS-CoV-2. "All current evidence points to wild animals sold illegally," China CDC Director George Gao and colleagues wrote in the agency's weekly bulletin in late January. All but two of the positive specimens came from a cavernous and poorly-ventilated section of the market's western wing, where many shops sold animals.

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~~The information void kindled a raging political debate that's already caused a trade war between China and Australia, as nations demand to know how Covid emerged.~~

Australia in April 2020 called for a global inquiry into the origins of the pandemic, including China's handling of the initial outbreak. Days later, then-U.S. Secretary of State Mike Pompeo used part of his Earth Day message to call on China to close its wet markets to "reduce risks to human health inside and outside of China."

Based on a discussion today with someone with knowledge of the WHO-led mission to Wuhan in Jan-Feb 2021, a significant catalyst for China's defensiveness is the emergence of **claims for reparations** that extended from the finger-pointing at China's wet markets. These surfaced in April 2020, and have continued as recently as June 2021 (when Trump pushed for it again at a rally in the Midwest)

SO IS THIS THE POINT AT WHICH CHINA, WHICH SEEMINGLY ACCEPTED THE WET MARKET HYPOTHESIS, BEGAN TRYING TO CREATE A DIFFERENT NARRATIVE? (I think it was incremental. I believe China was embarrassed that its citizens were still buying wild animals in wet markets to eat -- a well-known hazard for zoonotic disease transmission that China tried unsuccessfully to outlaw almost 20 years ago. But that embarrassment/humiliation morphed into rigid denial and obfuscation when governments began openly blaming the Chinese Communist Party and agitating for China to pay reparations for the pandemic. See these clips:

- USA Today: Blame the Chinese Communist Party for the coronavirus crisis: Coronavirus crisis proves communism is still a grave threat to the entire world. If Beijing had just been honest, the pandemic could be preventable. April 5, 2020
- Yahoo News: More than half of Americans think China should pay coronavirus reparations, poll shows April 9, 2020
- Voice of America: Americans Join Coronavirus Lawsuit to Make China Pay April 10, 2020
- Washington Post Opinion: China must pay reparations to Africa for its coronavirus failures April 16, 2020
- Reuters: In a first, Missouri sues China over coronavirus economic losses April 22, 2020
- Washington Post: Missouri is suing China over the coronavirus pandemic. It's the latest conservative gambit, April 22, 2020

- New York Post: Top German paper demands \$165 billion coronavirus reparations from China April 22, 2020
- Attorney General Fitch Prepares to Sue China on Behalf of Mississippians April 22, 2020
- Newsweek: Trump on U.S. Seeking Compensation From China Over COVID-19: 'We Have Not Determined the Final Amount' April 28, 2020
- The Guardian: Trump says China could have stopped Covid-19 and suggests US will seek damages April 28, 2020
- Intelligencer: Trump Thinks He Can Make China Pay for the Virus Like Mexico Paid for the Wall, April 30, 2020
- Washington Post: U.S. officials crafting retaliatory actions against China over coronavirus as President Trump fumes April 30, 2020
- Lawfare: Does China Really Owe the World Trillions of Dollars? May 7, 2020
- Fortune: Trump's demand that China pay coronavirus reparations evokes an ugly history May 8, 2020
- South China Morning Post: Why China won't be paying the West coronavirus reparations any time soon May 15, 2020
- Deccan Herald, India: Abhijit Bhattacharyya | Why China needs to pay reparations to the world June 4, 2020
- Why calls for reparations from China for coronavirus are an unfeasible distraction June 9, 2020
- Newsweek: Trump Demands China 'Pay Reparations' for COVID, Says \$10 Trillion Not Enough June 12, 2021

In response, Geng Shuang, a spokesman for China's Foreign Ministry, denied "wildlife wet markets" existed in the country. Government researchers CAN WE BE MORE SPECIFIC? Twenty-two researchers from mostly nationally-funded laboratories (I think it's the Chinese equivalent of the NIH in the U.S.) and institutes attached to the Chinese Academy of Sciences) now dismiss the market hypothesis completely. "SARS-CoV-2 could not have possibly evolved in an animal market in a big city and even less likely in a laboratory," they wrote in a paper released last month ahead of publication WHERE/WHEN WILL IT BE PUBLISHED? It was released as a "pre-print" on a Chinese academic repository ahead of publication that appears to be managed/owned by the Chinese Academy of Sciences. Papers are usually released in pre-print form before they have been accepted for publication or peer-reviewed as a way of expediting public access to the information. In this case, there is no information to suggest if, where or when the paper will be published.

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A more recent paper BY WHOM? (China CDC's Gao and eight other scientists mostly from the Chinese of Academy of Sciences' institutes) contends that the virus may have been imported from multiple locations worldwide, including parts of Europe where mink are raised in areas inhabited also by horseshoe bats known to harbor coronaviruses. "The official narrative changed not because the evidence changed," says Robert Garry, a professor of microbiology and immunology at Tulane University's School of Medicine in New Orleans "A spillover from a wet market was what caused SARS, and, embarrassingly for China, those wet markets were never shut down." Garry is the co-author of one of the earliest papers on the origins of Covid but wasn't involved in the research on Wuhan's markets.

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I DON'T REALLY UNDERSTAND WHAT POINT THIS GRAF IS TRYING TO MAKE. This is intended to demonstrate the kind of gaslighting that has occurred. Some of the WHO-led researchers are veterinarians and zoologists -- they know what animals smell like, and could smell their lingering presence a year later, but were told essentially that it was impossible that they were smelling animals because **there "were no live animals there".**) The researchers noted a mixed smell of animals and disinfectant in some areas of the market, but they were told by the market's manager that they were probably smelling the lingering stench of rotten meat and sewage, according to a joint WHO-China report. [should we add "according to Laing Wannian etc here? Liang Wannian was the leader of the Chinese research team collaborating jointly with the WHO-led research team. The source for the above description are in the annexes to the official joint WHO-China report released at the end of March 2021.]

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Earlier the same day, the international research team visited Wuhan's larger Baishazhou market, where Xiao had regularly surveyed two sellers of live wild animals. Yet the group was told only frozen food, ingredients, and kitchenware were on offer there. Liang Wannian, an epidemiologist who led the Chinese experts collaborating with the WHO-convened team, says his group had no knowledge of Xiao's data either. [if the above information on what the delegation saw all comes from this same source, maybe we should include his name higher up (The source for the description of what the origins researchers saw on Jan.

31, 2021, comes from the official 120-page joint WHO-China report and its 193-page annexes, not from Liang. Since we are essentially accusing China of concealing the information that Xiao documented, we asked Liang at a press conference in late July 2021 when the Chinese team first knew about Xiao's findings -- that the Huanan market and three others in Wuhan were selling live animals permissive to SARS-CoV-2 infection -- and what research China has done subsequently as a follow-up on this information? Liang gave a very long-winded response in Chinese in which he said essentially "we didn't have that information in January-February 2021 when the research team was in Wuhan". I think it's important we keep this to demonstrate that we have tried to ascertain what China knew/has done and have given the Chinese researchers the opportunity to respond. In addition, I have emailed China CDC Director George Gao at least twice and not received any response.]

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Among the earliest clusters of infections recorded in Wuhan, one involved three Covid cases among staff working at a stall in Huanan. One of the employees, a 32-year-old who fell ill on Dec. 19, traded goods back and forth between the Huanan and Baishazhou markets.

WHERE DOES THIS FACT COME FROM? NOT THE REPORT, RIGHT? WHEN DID IT FIRST BECOME KNOWN? This information was from the joint WHO-China report released in March 2021, however, the WHO-led researchers went to the Baishazhou market more as a demonstration by the China team of what a perfectly functioning large food market looks like. The WHO-led team was oblivious to Xiao's research that showed there were at least two stalls in Baishazhou that had been selling live wild animals for human consumption. So this detail and its significance was lost on the WHO researchers at the time.)

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A confirmed case linking two markets that sold wild animals is "very intriguing," says Stephen Goldstein, a research associate in evolutionary virology at the University of Utah in Salt Lake City. But tracing any contact the employee might have had with infected wildlife is impossible now that the animals are long gone. WOULD TIMELY PUBLICATION OF THE REPORT HAVE CHANGED THIS? It's unlikely that Xiao et al.'s paper would have been *published* soon after it was drafted in February 2020, but it could have been *released* as a pre-print ahead of publication and peer-

review that same month. That would have **confirmed** what almost everyone had suspected: that there **was** a flourishing wildlife trade in Wuhan that provides a plausible pathway by which coronavirus-infected wildlife from Yunnan and beyond could have introduced the virus to the city, sparking the Covid outbreak. It's also possible that swift recognition of these potential wild-animal vectors could have allowed scientists to test them for the virus and for antibodies against the virus while they were still alive (perhaps not the ones from Huanan, but wildlife in the three other Wuhan markets). Because of the statements the Chinese authorities had been making in January and February that strongly supported the animal spill over theory, it was assumed that this research was being done. Of course, the pandemic was raging then, so it would have been challenging. But, because of the denial by Chinese researchers that wild animals were being sold in Wuhan wet markets before the pandemic, there was never that level of follow up. At least, if there was, it was never made public.)

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"It seems to me, at a minimum, that local or regional authorities kept that informationWHAT INFORMATION? (that Wuhan had a flourishing live wild animal business going on in its wet markets before the pandemic) quiet deliberately," Goldstein says. "It's incredible to me that people theorize about one type of cover-up, but an obvious cover-up is staring them right in the face."

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From: Peter Daszak
Sent: Tue, 17 Aug 2021 08:35:49 -0400
To: Morens, David (NIH/NIAID) [E]; Jason Gale
Cc: (b)(6); Garry, Robert F;
(b)(6)
Subject: Nicholas Wade's piece today in Bull Atom. Sci.

Nicholas Wade's at it again – another miserable innuendo-filled attack on science and the process by which scientists email, talk and come to decisions. Nothing new of course, just trash journalism published in a pseudo-scientific journal. Pretty shameless smear on some of us – no facts of course, no sue-able accusations, just snikey comments and excerpts from Social Media. It's as if we can't now be scientists and actually colleagues who break bread and share a glass any more.

<https://thebulletin.org/2021/08/how-covid-19s-origins-were-obscured-by-the-east-and-the-west/>

The irony is in the ending – he claims the lab leak is an albatross hanging around China's neck that they won't be able to shake off until they open up the lab videos, books, freezers etc. The truth is his and others continued attacks are what put the albatross there in the first place. Does anyone really believe that if China gave access to all the above and no further evidence was found, that these folks would simply say "OK, it wasn't a lab leak after all"!!!

Cheers,

Peter

How COVID-19's origins were obscured, by the East and the West

By [Nicholas Wade](#) | August 17, 2021



A bus carrying a team of experts from the World Health Organization departs an airport in Wuhan on Jan. 14, 2021, after arriving in the Chinese city to investigate the origins of the coronavirus pandemic. That investigation is widely seen as having been obstructed by Chinese authorities. (Photo by Kyodo News via Getty Images)

Some 20 months after the Covid-19 pandemic first broke out, its origins remain obscure. A vigorous campaign of concealment by the Chinese authorities is the principal reason. But China received considerable help, strange to say, from senior medical research officials in the United Kingdom and United States who mishandled and effectively derailed the initial inquiry into the virus's origins.

The mishandling began at a pivotal teleconference held on February 1, 2020. The organizer was Jeremy Farrar, director of the Wellcome Trust, a large medical research charity in London. News of the conference emerged with the release this June of emails from the office of Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases (NIAID). Farrar supplied further information in his book *Spike*, published on July 22.

The conference was held to discuss the unanimous view of a group of virologists that the SARS2 virus had been manipulated in a lab. Yet within a few days of the meeting, the virologists abruptly reversed their conclusion. The meeting's participants were later involved in two letters to scientific

journals that stated the virus must have emerged naturally and that condemned any suggestion of manipulation as a conspiracy theory. These two letters, to *The Lancet* and *Nature Medicine*, shaped the views of the mainstream media for more than a year.

THE LANCET

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CORRESPONDENCE | VOLUME 395, ISSUE 10226, E42-E43, MARCH 07, 2020

Statement in support of the scientists, public health professionals, and medical professionals of China combatting COVID-19

Charles Calisher, Dennis Carroll, Rita Colwell, Ronald B Corley, Peter Daszak, Christian Drosten, Luis Enjuanes, Jeremy Farrar, Hume Field, Josie Golding, Alexander Gorbalenya, Bart Haagmans, James M Hughes, William B Karesh, Gerald T Keusch, Sai Kit Lam, Juan Lubroth, John S Mackenzie, Larry Madoff, Jonna Mazet, Peter Palese, Stanley Perlman, Leo Poon, Bernard Roizman, Linda Saif, Kanta Subbarao, Mike Turner, Show less

Published: February 19, 2020 • DOI: [https://doi.org/10.1016/S0140-6736\(20\)30418-9](https://doi.org/10.1016/S0140-6736(20)30418-9)

PlumX Metrics

Correspondence | Published: 17 March 2020

The proximal origin of SARS-CoV-2

Kristian G. Andersen, Andrew Rambaut, W. Ian Lipkin, Edward C. Holmes & Robert F. Garry

Nature Medicine 26, 450–452 (2020) | Cite this article

5.50m Accesses | 1618 Citations | 36819 Altmetric | Metrics

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We are public health scientists who have closely followed the emergence of 2019 novel coronavirus disease (COVID-19) and are deeply concerned about its impact on global health and welfare. We have signed and published this statement to express the

To the Editor – Since the first reports of novel pneumonia (COVID-19) in Wuhan, Hubei province, China^{1,2}, there has been considerable discussion on the origin of the causative virus. SARS-

Letters published by *The Lancet* and *Nature Medicine* in early 2020. Even today, no one can say for sure whether the SARS2 virus emerged naturally or escaped from a lab. Much less could anyone have been sure back then. If the conferees had stuck to known facts, they would have left the question open to the two hypotheses, and the full exploration of the virus's origins might not have been sidetracked for over a year. More significant, the Chinese government would have found it much harder, if not impossible, to manipulate the World Health Organization (WHO) into setting terms of reference that favored China's obstructive goals and kept WHO inspectors who visited China this February from accessing records vital to understanding the origin of the pandemic. China now insists those terms of reference cannot be changed, blocking further investigation into the origin of the SARS2 virus. "The two groups that produced the infamous letters in *The Lancet* and *Nature Medicine* paved the way for the Chinese government and helped enormously to facilitate all of that," says Milton Leitenberg, an arms control expert at the University of Maryland. The reversal of the virologists' conclusion about SARS2's artificial origin is thus a matter of some significance.

At 10:32 p.m. on the evening before the February 1 conference, Fauci had received an electrifying memo from Kristian G. Andersen, a virologist at the Scripps Research institute in California. Andersen reported that the virus seemed to be man-made. "The unusual features of the virus make up a really

small part of the genome,” he wrote, referring presumably to a genetic component known as a furin cleavage site, which greatly enhances the virus’s infectivity, “so one has to look really closely at all the sequences to see that some of the features (potentially) look engineered.”

From: Kristian G. Andersen (b) (6) >
Sent: Friday, January 31, 2020 10:32 PM
To: Fauci, Anthony (NIH/NIAID) [E] (b) (6)
Cc: Jeremy Farrar (b) (6) >
Subject: Re: FW: Science: Mining coronavirus genomes for clues to the outbreak’s origins

Hi Tony,

Thanks for sharing. Yes, I saw this earlier today and both Eddie and myself are actually quoted in it. It’s a great article, but the problem is that our phylogenetic analyses aren’t able to answer whether the sequences are unusual at individual residues, except if they are completely off. On a phylogenetic tree the virus looks totally normal and the close clustering with bats suggest that bats serve as the reservoir. The unusual features of the virus make up a really small part of the genome (<0.1%) so one has to look really closely at all the sequences to see that some of the features (potentially) look engineered.

We have a good team lined up to look very critically at this, so we should know much more at the end of the weekend. I should mention that after discussions earlier today, Eddie, Bob, Mike, and myself all find the genome inconsistent with expectations from evolutionary theory. But we have to look at this much more closely and there are still further analyses to be done, so those opinions could still change.

Best,
Kristian

_A key email from Kristian Andersen to Anthony Fauci. Andersen went on to note that “after discussions earlier today, Eddie, Bob, Mike and myself all find the genome inconsistent with expectations from evolutionary theory”— meaning that, in their unanimous view, the virus didn’t come from nature. “Those opinions could still change,” Andersen added. Eddie is Edward C. Holmes of the University of Sydney. Bob is Robert F. Garry of Tulane University. Mike is Michael Farzan at Scripps Research. The message sent Fauci into a whirlwind of activity. “You will have tasks today that must be done,” he emailed his deputy director, Hugh Auchincloss, two hours later at 12:29 am on February 1. One of these urgent tasks evidently concerned NIAID funds that had been passed, via the EcoHealth Alliance of New York, to Zhengli Shi, China’s leading bat virus expert, at the Wuhan Institute of Virology. Fauci was doubtless anxious to check whether his agency’s funding of Shi’s work had complied with US law, which banned funding gain-of-function research from 2014 to 2017 and required it be reported to a government panel thereafter. “Gain of function” refers to research in which a pathogen’s ability to cause disease is enhanced.

Auchincloss replied a few hours later that efforts were underway to ascertain “if we have any distant ties to this work abroad.”

Meanwhile Farrar, who had independently heard of the Andersen team’s conclusion from Holmes, says in *Spike* that he arranged a teleconference set for 7 p.m. London time, convenient for both Washington and Australia, where Holmes was based.

The participants included Fauci and possibly his nominal boss, Francis Collins, the director of the National Institutes of Health. (Farrar says in *Spike* that Collins was present, but Collins’s name is not on the list of invitees in the Fauci emails.) Officials on the UK side were Farrar and Patrick Vallance, the chief scientific adviser to the UK government. The others were mostly virologists, including Andersen, Holmes, and Andrew Rambaut of the University of Edinburgh.

Far from being selected at random, the conferees were associated through a complicated web of relationships, a sort of virologists’ old boy network that included senior medical officials in China. Farrar was well acquainted with George Fu Gao, the head of China’s counterpart of the US Centers for Disease Control and Prevention. He has described Gao as an “old friend,” who in fact had called a month earlier, on December 31, 2019, to tell Farrar about the initial cases in Wuhan of what turned out to be Covid-19. Farrar says in his book *Spike* that on the weekend of the teleconference, he called another highly placed Chinese official, Chen Zhu, China’s minister of health from 2007 to 2013, to tell him of “rumours that the novel coronavirus could be the result of a lab accident.” As for Holmes, he has published many papers both with Farrar and with Gao and has been a guest professor at Gao’s CDC from 2014 until 2020.

Because of these varied connections, it seems likely that Chinese authorities knew about the conference almost from the moment it occurred and, if so, would have had the opportunity to influence deliberations that followed it.

At the conference there was a notable imbalance of power between the virologists and the officials. Fauci and Farrar together control a large portion of the funds available for virological research in the Western world. A virologist keen to continue his career would be very attentive to their wishes. Two of the conference participants had multimillion-dollar grant proposals under final review with NIAID at the time of the call.

Almost all references to what was discussed at the teleconference have been redacted from the Fauci emails under exceptions to the Freedom of Information Act. The conference would doubtless have included explanation from Andersen and Holmes as to why they had concluded the previous evening that the virus had been altered through laboratory manipulation.

“Kristen and Eddie have shared this and will talk through it on the call,” Farrar writes in one of the Fauci emails.

RELATED:

The known knowns, known unknowns, and unknown unknowns of COVID-19

From: Jeremy Farrar (b) (6) >
Sent: Saturday, February 1, 2020 1:13 PM
To: Fauci, Anthony (NIH/NIAID) [E] (b) (6) >; Patrick Vallance (b) (6)
(b) (6)
Cc: Drosten, Christian (b) (6); Marion Koopmans
(b) (6) >; R.A.M. Fouchier (b) (6); Edward Holmes
(b) (6); Andrew Rambaut (b) (6)
Kristian G. Andersen (b) (6); Paul Schreier (b) (6);
(b) (6); Ferguson, Mike (b) (6); Collins, Francis (NIH/OD) [E]
(b) (6)
Subject: Re: Teleconference

Kristen and Eddie have shared this and will talk through it on the call. Thank you.

Hope it will help frame the discussions.

_A Jeremy Farrar email about the teleconference.

Whatever was said at the meeting, it was followed by a remarkable and almost immediate about-face. By at most three days later, Andersen had executed a 180 degree turn in his views about the virus. In an email of February 4, 2020 to Peter Daszak, president of the EcoHealth Alliance, which had directed NIAID funds to Shi, Andersen wrote, “The main crackpot theories going around at the moment relate to this virus being somehow engineered with intent and that is demonstrably not the case.” The email was obtained by U.S. Right to Know, an investigatory group.

Participants have not explained what was said at the meeting or found in the days immediately following it to induce the change of mind. Media offices at the Wellcome Trust and NIAID declined to comment on this article. Andersen, Holmes and Rambaut did not reply to emails seeking an account of the reversal.

Farrar, not Fauci, seems to have been the leader in the teleconference’s deliberations. “This is not my area of expertise so I have backed off and am leaving it all to Jeremy,” Fauci wrote on February 13 to a CDC official. US officials were not to take the lead in this pivotal inquiry.

From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Thu, 13 Feb 2020 22:36:17 +0000
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Subject: RE: NAS

Nancy:

The official USG group will be convened by NAS. Bob Kadlec is the person with direct knowledge of that. In addition, there is an ad hoc group informally led by Jeremy Farrar of Wellcome Trust. This group has about 15 people, all of whom are highly respected scientists, mostly evolutionary biologists who are convening by e-mail and conference calls (I have been on 2 of these calls since Jeremy invited me) to look at all of the bat, pangolin and human coronavirus sequences to try and determine the evolutionary origin. This is not my area of expertise and so I have backed off and am leaving it all to Jeremy.

Best,
Tony

Fauci's "leaving it all to Jeremy" email.

Farrar had a direct hand in the two letters that went out to the *Lancet* and *Nature Medicine*. He was a signatory of the *Lancet* letter, a draft of which Daszak, the organizer of the letter, began circulating just five days after the conference. The letter sought to squelch all discussion of the possibility that the virus had escaped from a lab by deriding it as a conspiracy theory. When Daszak wrote an article in the *Guardian* elaborating on the same theme, Farrar promoted it with a [tweet](#), saying "as always worth reading @PeterDaszak."

Farrar also [recruited the five authors](#) who drew up the *Nature Medicine* [letter](#), his spokesman told the writer Ian Birrell. (The spokesman referred to the *Lancet* letter but evidently meant the *Nature Medicine* letter, which has five authors.) The *Nature Medicine* letter, accepted on March 6 and published on March 17, 2020, presented a detailed and influential case that the virus had emerged naturally from animals. Its authors were Andersen, Rambaut, W. Ian Lipkin, Holmes and Garry.

In his book *Spike*, Farrar portrays the events between the February 1 conference and publication of the two medical journal letters as a judicious process in which he held an agnostic view and played no role other than asking questions. "On a spectrum if 0 is nature and 100 is release—I am honestly at 50!" Farrar says he emailed to Fauci and Collins a day after the conference. But if that were honestly so, he fails to explain his switch from 50 to 0 when signing the *Lancet* letter a few days later.

According to *Spike*, it wasn't until March, "after the addition of important new information, endless analyses, intense discussions and many sleepless nights" that Andersen and his four fellow virologists "were ready to pronounce on the origins of the novel coronavirus." Why then was Andersen, the virologists' leader, ready to pronounce just 3 days after the conference that lab release was a conspiracy theory? Farrar's account does not match with the available facts.

Nor does Andersen's. In a June interview with the *New York Times*, he painted a picture that includes a change of mind on the possible engineering of the virus "in a matter of days, while we worked around the clock," and then that quick reversal being buttressed by drawn-out research.

"This is a textbook example of the scientific method, where a preliminary hypothesis is rejected in favor of a competing hypothesis as more data become available and analyses are completed," he said in a statement released by Scripps Research after his Jan 31 email to Fauci had become public. "I cautioned in that same email that we would need to look at the question much more closely and that our opinions could change within a few days based on new data and analyses—which they did," Anderson said in the *New York Times* interview. In that same interview, he also said that "more extensive analyses, significant additional data and thorough investigations to compare genomic diversity more broadly across coronaviruses led to the peer-reviewed study published in *Nature Medicine*."

These later data and analyses would not have been available three days after the conference, the date of Andersen's volte-face email to Daszak. And they would not have been available to Farrar as he signed the *Lancet* letter, which was published just 17 days after the teleconference.

More puzzling is Andersen's statement that in his preliminary studies "the genome of RaTG13, a SARS-related coronavirus found in bats, wasn't yet available." In fact its full sequence had been deposited by Shi in a data bank on January 24, 2020, a week before Andersen's report to Fauci, and Farrar says in *Spike* that he had seen the sequence by the time of the conference. RaTG13 is the closest known relative of SARS2, and the fact that it lacks the furin cleavage site found in SARS2 would have been a major reason for the Andersen group to suppose that this genetic element had been inserted into SARS2 in a lab.

Given his role in leading the February 1 teleconference, in presiding over the virologists' 180 degree change of views, and in arranging or influencing the *Lancet* and *Nature Medicine* letters, Farrar was evidently the driving force of the campaign to persuade the public that the SARS2 virus could not possibly have leaked from a lab. This was an unfortunate position for any

scientist to take, given that he was assuring the public of something he could not be sure was true.

Farrar now says in *Spike* that, although natural emergence is more likely, “nobody is yet in a position to rule out an alternative.” But his campaign sought very vigorously to do exactly that. “We stand together to strongly condemn conspiracy theories suggesting that COVID-19 does not have a natural origin,” Farrar and his cosignatories wrote in the *Lancet* on February 18, 2020. This lapse in scientific judgment reflects also on the other senior participants in the conference who saw what was happening but apparently took no steps to insist that scientific truth should take precedence over unjustifiable professions of certainty.

RELATED:

Caltech's David Baltimore discusses the debate over origins of SARS-CoV-2

The decision to quash any notion of lab escape seems to have brought relief all round. At least until the tide of opinion began to change a year later, Fauci and Collins didn't have to endure unpleasant questions about why they had been funding hazardous research in minimally safe conditions at the Wuhan Institute of Virology.

“I just wanted to say a personal thank you on behalf of our staff and collaborators, for publicly standing up and stating that the scientific evidence supports a natural origin for COVID-19 from a bat-to-human spillover, not a lab release from the Wuhan Institute of Virology,” Daszak emailed Fauci after a White House press briefing on April 17.

In August 2020 the NIAID announced it would award \$82 million over five years to 10 participants in its new network for detecting infectious diseases. Among the lucky winners: Daszak, Andersen, and his associate Robert Garry. The perturbing lab leak theory raised by Andersen and his colleagues on January 31, 2020 had been safely laid to rest. Farrar and his colleagues had succeeded in the one goal also pursued by the autocrats in Beijing, that of suppressing discussion of whether the SARS2 virus might have escaped from the Wuhan lab.

Beijing's way of squelching inquiry about the virus was, unintentionally, somewhat more obvious than the methods used in London. Chinese authorities tried so hard to stamp out information about the virus's origin that they left a rather clumsy trail of footprints pointing to where they didn't want people to go.

One of the more informative suppressions of data was the closure of China's main database on bat and other viruses. Zhengli Shi, China's leading expert on bat coronaviruses, told the BBC that it was taken off line because of numerous hacking attempts. It's conceivable that in January 2020, after the

pandemic broke out, people without authorized access might have tried to hack into the database. But in fact the database went off line on September 12, 2019. Who would have wanted to hack into a bat virus database back then? More likely, that is the date at which Chinese authorities realized they had a virus escape problem.

In February of last year, President Xi referred to the need to ensure biosafety and biosecurity, and the Chinese Communist Party followed by tightening up their biosafety rules in October 2020, accelerating a long planned revision. “To me, the fact that the CCP enacted a major series of laboratory biosafety regulations this past year is an indication that China’s political leadership believes that a lab accident is likely to have caused the pandemic,” says a biosurveillance expert who has monitored China’s disease outbreak reporting for the past two decades.

Major clues as to what happened are evident in Shi’s various pronouncements about the virus. The omissions and untruths in these statements are specific enough to outline the very body of facts the censors have sought to conceal.



Wuhan Institute of Virology researcher Shi Zhengli spoke about SARS during a Yixi event (comparable to a TED talk) on June 23, 2018. ([Yixi video](#))

In looking at Shi’s questionable statements, it’s only fair to keep in mind that they may have been compelled. Her train of deceptions began immediately after the genetic sequence of the SARS2 virus was published on January 10, 2020, by Yong-zhen Zhang of Fudan University, against the wishes of Chinese authorities who subsequently closed his lab for a time. Where did this strange new virus come from? Shi wanted or was told to establish SARS2’s

pedigree as a bat virus, with an ancestry analogous to that of SARS1, the bat virus that caused an epidemic in 2002. In an important paper published on February 3, 2020, Shi reported that the genome of SARS2 is 96 percent similar to that of a bat virus, RaTG13, “which was previously detected in [the bat species] *Rhinolophus affinis* from Yunnan province.”

Shi neglected to mention a salient difference between the two viruses, namely that SARS2 possessed a furin cleavage site and RaTG13 did not. Alina Chan, of the Broad Institute in Cambridge, has likened the omission to describing a unicorn by reporting all its horse-like features, but neglecting to mention the horn. Evidently the Chinese authorities were highly sensitive to the furin cleavage site’s presence.

Shi also failed to say when and where she had discovered the RaTG13 virus, surely important data for the closest known relative of SARS2. In fact, she had found RaTG13 in 2013, in an abandoned mine in Tongguan—the same place where six miners had fallen sick the year before. At that time, she analyzed just one of its genes and reported the virus under another name, BtCoV/4991. Daszak, the holder of her NIAID grant, told the London Times, perhaps on misinformation from Shi, that the virus was then thrown in a freezer and forgotten about until 2020. This was untrue—the virus was of much greater interest. Shi had analyzed its full genome, probably by 2018, but did not publish it. It was only when she needed a bat virus pedigree for SARS2 that Shi released information about the virus, which she now renamed RaTG13. The fact that BtCoV/4991 and RaTG13 were one and the same was discovered by Monali Rahalkar and Rahul Bahulikar, two internet-sleuthing researchers in Pune, India.

It’s not acceptable practice among scientists to report something already published under a different name as if were new. Shi’s February paper had the goal of portraying SARS2 as just another bat virus while concealing the true provenance of its closest known relative—a cave known to harbor lethal viruses.

When RaTG13’s connection to the Tongguan mine was pointed out, Shi still tried to conceal the lethality of the mine’s bat viruses, saying the miners had died of a fungus infection. This untruth was corrected when a master’s thesis by a Chinese doctor, Li Xu, was unearthed by the internet sleuth who calls himself TheSeeker268. The thesis reported that the miners had died of a SARS-related virus with symptoms identical to those of Covid-19 and with CT scans similar to those of Covid patients. The only evident difference between that virus’s effects and those of SARS2 is that the miners’ virus was not readily transmissible from one person to another.

The specificity of what Shi’s statements concealed—the furin cleavage site, RaTG13’s identity with BatCoV/4991, the latter’s origin in the mine where six

miners were infected, the death of the three miners from infection by a virus with symptoms very similar to those of SARS2—all point to the involvement of these elements in a scenario the Chinese authorities are determined to cloak. That scenario may have been the storage or generation of the SARS2 virus in Shi's lab from one of the many viruses recovered from the Tongguan cave. The Chinese government's persistent stonewalling and Shi's pattern of evasions do not amount to proof that the SARS2 virus escaped from her lab. But they seem less like the actions of innocent people and more like attempts to cover up a fatal accident, one that has caused the deaths of maybe 10 million people and counting.

Perhaps proof will one day emerge that the virus emerged naturally. If not, the likelihood that SARS2 escaped from a researcher's laboratory is an albatross that will hang round China's neck in perpetuity. China's only hope of release from this terrible encumbrance lies in opening its laboratory doors and either establishing its innocence or admitting its fateful error.

Cheers,

Peter

Peter Daszak
President

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USA

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Twitter: [@PeterDaszak](https://twitter.com/PeterDaszak)

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: Morens, David (NIH/NIAID) [E] (b)(6)
Sent: Sunday, August 15, 2021 6:26 PM

To: Jason Gale <j.gale@bloomberg.net>

Cc: (b)(6) Garry,
Robert F (b)(6)

Subject: RE: feedback on wild animals

Jason, not sure whose office politics is worse, but there is many a day I'd rather be in Australia, even if I had to drink that awful beer Fosters. (To quote Groucho Marx as he help up a glass of questionable beer: "last time I saw something like this, they had to shoot the horse").... But I do have fond memories of Australia, and

(b)(6), are out in (b)(6), the only large city there (if oy can call it that) I have never been, although it's high on my bucket list if this damn pandemic ever ends. (b)(6)

(b)(6)

David

David M. Morens, M.D.

CAPT, United States Public Health Service

Senior Advisor to the Director

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From: Jason Gale (BLOOMBERG/ NEWSROOM:) <j.gale@bloomberg.net>

Sent: Saturday, August 14, 2021 7:54 PM

To: Morens, David (NIH/NIAID) [E] (b)(6)

Cc: (b)(6) Garry,
Robert F (b)(6)

Subject: Re: feedback on wild animals

Thanks, David.

I just got off a video conf call with the current editor in NY (the one asking all the latest questions). He's very nice and I feel like he gets it. He thinks it's a fascinating story. Problem we have in journalism is that there are some people who aren't interested in actual journalism and telling stories; they want to climb to the top and manage people. I (b)(6)

(b)(6), but am so grateful that I still get to meet so many remarkable people, visit cool places and see all aspects of humanity.

A difficulty working for a NY-based organization is that it's assumed that all the best people are in NYC, so being in Melbourne (where I need to be (b)(6)

(b)(6)), is that folks consider Australia a backwater and, by association, I mustn't be all that important/valuable. But my new role as "global biosecurity czar" is helping somewhat. Ahhhhh... Office politics!

From: (b)(6) **At:** 08/15/21 09:03:03 UTC+10:00

To: Jason Gale (BLOOMBERG/ NEWSROOM:)

Cc: (b)(6)

(b)(6)

Subject: Re: feedback on wild animals

Jason, all I can say is that it must be harder to be a journalist than a scientist.... I had no idea someone at your level would get pushed back.

Usually i get from one to 4 reviewer responses to a ms. and three of those are out to lunch. Occasionally i get a reviewer who really understands the work: half of those are helpful, the other half are trashers.

Maybe it's like being in the government where i am: there is endless push back, but the push-backers are brainless idiots who don't know what they are talking about.

Do you ever get to a point where the editors leave you alone on the science? Or do they all think they are science geniuses? d

Sent from my iPhone
David M Morens
OD, NIAID, NIH

On Aug 14, 2021, at 16:05, Jason Gale (BLOOMBERG/ NEWSROOM:) <j.gale@bloomberg.net> wrote:

Thanks, Bob. In journalism, getting to the truth even when it's genuinely and actively pursued, can be a tortuous process!

----- Original Message -----

From: Robert F Garry (b)(6)

To: JASON GALE, (b)(6)

(b)(6)

At: 08/15/21 01:45:11 UTC+10:00

Looking forward to this important article. Truth is stronger than fiction.

From: Jason Gale (BLOOMBERG/ NEWSROOM:) <j.gale@bloomberg.net>

Sent: Saturday, August 14, 2021 6:41 AM

To: (b)(6)

(b)(6)

(b)(6); Garry, Robert F

(b)(6)

Subject: Fwd:Re:feedback on wild animals

External Sender. Be aware of links, attachments and requests.

Hi guys, in case you have nothing better to read over the weekend, this is some of the dialog I am having with editors in the U.S. Essentially, my response to questions from editor #6.

I thought I could claim victory when it looked like the story could be published this morning, but (b)(6) of Businessweek objected and thinks (b)(6) can make it better with another revision and an ETA of Tuesday. Sigh.

Jason

From: Jason Gale (BLOOMBERG/ NEWSROOM:) At: 08/14/21 16:36:58 UTC+10:00

To: Cristina Lindblad (BLOOMBERG/ NEWSROOM:) , Eric Gelman (BLOOMBERG/ NEWSROOM:)

Cc: Joel Weber (BLOOMBERG/ NEWSROOM:)

Subject: Re:feedback on wild animals

Hi.

Thanks for the feedback and the questions, which I have tried to answer in detail.

It's often easier to have a conversation over Nexi or the phone to explain nuanced information, or details that are clear to me, but might not be to someone coming at this fresh, but that's tricky with the time difference.

When you look back at what's happened here, it seems that in trying to deflect blame for the pandemic, which became increasingly vicious as the cataclysmic nature of the Covid-19 pandemic unfolded around March-April 2020, China tried to conceal a very obvious, very plausible source of the pandemic: it's flourishing wildlife trade (worth about \$90 billion in 2016).

It was an obvious cause of the pandemic because an almost identical scenario triggered an international outbreak caused by a very similar coronavirus (SARS) in 2003-04. But in attempting to cover up the wildlife trade, and making like there were never any wild animals being sold in Wuhan's wet markets, things began to backfire on China; questions were raised about the nearby lab studying these coronaviruses. The more geopolitical, heated and vicious the arguments and accusations became, the less cooperative China became. In response, the more intent/adamant some groups have become in their belief that China is covering up a lab-leak. It's become a vicious circle. If China isn't coming clean on the wild animals, what else is it trying to hide?? China's defensiveness means we may never get the cooperation needed to find the answers. If China had been honest and transparent about the wild animals in the wet markets, it might not be in this mess now.

Anyway, here are my response to your queries in green.

By the way, I wonder if the current headline:

Delayed Paper Gives Credence to Wuhan Market Covid Origin Story
doesn't convey much more than what we had 2 months earlier when
we reported Xiao's findings: China Markets Sold Mink, Civets,
Stoking Natural Origins Theory

Perhaps Obscured China Paper Scuppered Chance to Trace Covid
Origins

would hits "China", "Covid" and "Origins" in a way that won't
alienate people who already believe it was a lab-leak

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According to the report, minks, civets, raccoon dogs and other
mammals known to harbor coronaviruses were sold in plain sight
for years in shops across the city, including the now infamous
Huanan wet market, to which many of the earliest Covid cases
were traced. The evidence collected over 30 months by **Xiao Xiao**
a I'D NAME HIM HERE [[i don't know that naming a researcher no
one has ever heard of adds much]] researcher working at a lab
affiliated with China's Ministry of Education was hastily
drafted into a manuscript and submitted to a scientific journal
[Joel, we cannot name the first journal they delivered it to
because the authors decline to give us the name, saying it may
affect their future chances of being published] in February
2020, just weeks before the outbreak was declared a pandemic.

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While the study received wide attention when it was eventually
released by a different publisher [Publisher (Springer Nature)
and publication (Scientific Reports) are different. Might add
confusion DO YOU WANT TO ADD NAME HERE?], its long and torturous
journey to publication gave **Chinese officials an opportunity to
weave alternative narratives in which the virus may have come
from abroad, even from a U.S. Army biological research facility.**

[the stuff in bold is not contested and we go on to show how
that happened, documenting with links when available]I TWEAKED
WORDING HERE BUT THIS STILL ISN'T QUITE RIGHT. IF THE REPORT HAD
BEEN PUBLISHED EARLIER CHINESE OFFICIALS COULD STILL HAVE DONE
WHAT THEY DID--THEY COULD HAVE JUST SAID THE REPORT WAS SHODDY,
OR WHATEVER, AND THEY ALSO COULD HAVE JUST IGNORED IT. I
disagree. The evidence that Xiao et al provide was meticulously
documented and supported by photographs that would have been
difficult/impossible for China to dismiss (as older published
photos and media reports had been). What's more, Newman
understands that Xiao collected blood-sucking ticks from the
wild animals he studiously cataloged. His frozen tick samples
could be tested for blood/antibodies/virus, which could be

extremely helpful in identifying infected species PRIOR to December 2019. The WHO team knew nothing of this, so couldn't have asked China for this research or any results, had they actually done the research. The delay in the publication of Xiao's paper delayed the evidence that there were live animals sold in the Huanan market. The WHO researchers couldn't have asked about tests on wildlife that ostensibly were never there. Likewise, Chinese authorities couldn't have done the tests on animals that didn't exist. The problem is that in January and February 2020, it was widely assumed the animals HAD been there and that the necessary tests and tracing of animals (the sampling of animals on farms they were raised on, testing of farm workers, animal hunters, transporters and traders **had all been done** by researchers in China -- the very things that ultimately led to the discovery of the origins of SARS and of MERS viruses. **None of these things were done** (or at least, there is nothing publicly available to show that they were done) **because the animals "weren't there"**. Now that we all know they were there, China has lost considerable face. The issue has become so political that there is much less/no willingness to cooperate and conduct the additional research that the WHO-led team recommended. Ideally, Xiao's ticks should be studied, but it's doubtful that will now happen (I wouldn't be surprised if he's been ordered to incinerate them!) Hope this is clear.

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An international team of experts convened by the WHO traveled to Wuhan earlier this year to seek answers—a trip that might have yielded different results if the scientists had known about the work of Xiao Xiao, a virologist whose roles straddled epidemiology and animal research at the government-funded Key Laboratory of Southwest China Wildlife Resources Conservation and at Hubei University of Traditional Chinese Medicine. 'MIGHT HAVE YIELDED DIFFERENT RESULTS' SEEMS HIGHLY SPECULATIVE. WHAT RESULTS DID IT YIELD? I'D CUT THIS GRAF

As mentioned above, the WHO-convened team of researchers was told by market authorities, vendors and regular market visitors that there were no live animals sold in the Huanan market. That undermined completely the premise that the Huanan market was the kind of place where live animals from different species are stacked in cages, with urine and fecal material drips from one cage to the one below it, where there are splatters of blood and guts from animals, and lots of potential for the spread of diseases from one species to another (including Homo sapiens). Instead, the market (and one other one known to have been selling live wild animals in 2019) was presented as selling only

frozen wild animals and aquatic species and things unlikely to be the source of SARS-CoV-2. The WHO researchers were told there were frozen ferret badgers and other wildlife found in freezers. Some of the carcasses actually came from Yunnan, the province where the closest coronavirus related to SARS-CoV-2 was found in bats -- thus establishing a potential route from Yunnan to Wuhan in wildlife. That was actually important. When the researchers showed their Chinese counterparts photos of caged raccoon dogs taken in the Huanan market by Prof. Edward Holmes five or six years earlier, they were told by Chinese scientists that the photos may have been faked, and that the market had ceased selling such live animals anyway. The WHO researchers saw no evidence (empty cages, animal pelts, etc) to dispute what the Chinese scientists told them, although they did smell "animals" -- but were told they were smelling rotten meat, sewage etc. Three people associated with the WHO-led mission told me that they didn't believe the information they were given by anyone associated with the market. But since there was no evidence to the contrary, they were unable to push the Chinese scientists further on this. **The fact that the mission concluded that frozen, not live wild animals were sold in the market undermined the thesis that Covid resulted from an animal spillover.** And the absence of strong evidence pointing to a spill over from wild animals to humans made the lab-leak theory look, in relative terms, more plausible.

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Six months and two revisions later, the journal's publishers rejected the paper. "They did not think it would have widespread appeal," says Newman, who declined to name the publication [do you want us to say why he won't name it? I don't think it's necessary. There's no upside for scientists to make a publisher look bad (most journals are published by a handful of publishers)] "It caused us, especially our Chinese co-authors, concern that these data would not be taken seriously."

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The manuscript underwent a third revision to include data on China's pangolin trade networks (an earlier study, later contested, had implicated pangolins in the virus's spread to humans)WHO ASKED THAT THIS INFO BE INCLUDED? (I did, because we're trying to explain here why WHO missed the significance of Xiao's evidence. The WHO was slammed by other papers being submitted PLUS Xiao's paper had a weird title. That title seemed relevant to the authors back in January-February 2020, when

pangolins were considered a possible SARS-CoV-2-spreading culprit. But in October 2020, pangolins were off the hook, so the title would have seem irrelevant/unimportant at first glance at WHO). It was then sent to the online journal Scientific Reports.

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The China-based researchers had reason to be cautious. In February 2020, the China Center for Disease Control (CCDC lets not use "CCDC". It's not commonly used like the U.S. "CDC" is, and it's going to force readers to go back and figure out what the "CCDC" is) prohibited scientists working on Covid-relate

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CCDC Disease detectives arriving from Beijing (think this makes it clear that these are China's disease "feds" arriving) on the first day of 2020 ordered environmental samples to be collected from drains and other surfaces at the market. Some 585 specimens were tested, of which 33 turned out to be positive for SARS-CoV-2. "All current evidence points to wild animals sold illegally," China CDC Director George Gao and colleagues wrote in the agency's weekly bulletin in late January. All but two of the positive specimens came from a cavernous and poorly-ventilated section of the market's western wing, where many shops sold animals.

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~~The information void kindled a raging political debate that's already caused a trade war between China and Australia, as nations demand to know how Covid emerged.~~
Australia in April 2020 called for a global inquiry into the origins of the pandemic, including China's handling of the initial outbreak. Days later, then-U.S. Secretary of State Mike Pompeo used part of his Earth Day message to call on China to close its wet markets to "reduce risks to human health inside and outside of China."

Based on a discussion today with someone with knowledge of the WHO-led mission to Wuhan in Jan-Feb 2021, a significant catalyst for China's defensiveness is the emergence of **claims for reparations** that extended from the finger-pointing at China's wet markets. These surfaced in April 2020, and have continued as recently as June 2021 (when Trump pushed for it again at a rally in the Midwest)

SO IS THIS THE POINT AT WHICH CHINA, WHICH SEEMINGLY ACCEPTED THE WET MARKET HYPOTHESIS, BEGAN TRYING TO CREATE A DIFFERENT NARRATIVE? (I think it was incremental. I believe China was embarrassed that its citizens were still buying wild animals in wet markets to eat -- a well-known hazard for zoonotic disease transmission that China tried unsuccessfully to outlaw almost 20 years ago. But that embarrassment/humiliation morphed into rigid denial and obfuscation when governments began openly blaming the Chinese Communist Party and agitating for China to pay reparations for the pandemic. See these clips:

- USA Today: Blame the Chinese Communist Party for the coronavirus crisis: Coronavirus crisis proves communism is still a grave threat to the entire world. If Beijing had just been honest, the pandemic could be preventable. April 5, 2020
- Yahoo News: More than half of Americans think China should pay coronavirus reparations, poll shows April 9, 2020
- Voice of America: Americans Join Coronavirus Lawsuit to Make China Pay April 10, 2020
- Washington Post Opinion: China must pay reparations to Africa for its coronavirus failures April 16, 2020
- Reuters: In a first, Missouri sues China over coronavirus economic losses April 22, 2020
- Washington Post: Missouri is suing China over the coronavirus pandemic. It's the latest conservative gambit, April 22, 2020
- New York Post: Top German paper demands \$165 billion coronavirus reparations from China April 22, 2020
- Attorney General Fitch Prepares to Sue China on Behalf of Mississippians April 22, 2020
- Newsweek: Trump on U.S. Seeking Compensation From China Over COVID-19: 'We Have Not Determined the Final Amount' April 28, 2020
- The Guardian: Trump says China could have stopped Covid-19 and suggests US will seek damages April 28, 2020
- Intelligencer: Trump Thinks He Can Make China Pay for the Virus Like Mexico Paid for the Wall, April 30, 2020
- Washington Post: U.S. officials crafting retaliatory actions against China over coronavirus as President Trump fumes April 30, 2020
- Lawfare: Does China Really Owe the World Trillions of Dollars? May 7, 2020

- Fortune: Trump's demand that China pay coronavirus reparations evokes an ugly history May 8, 2020
- South China Morning Post: Why China won't be paying the West coronavirus reparations any time soon May 15, 2020
- Deccan Herald, India: Abhijit Bhattacharyya | Why China needs to pay reparations to the world June 4, 2020
- Why calls for reparations from China for coronavirus are an unfeasible distraction June 9, 2020
- Newsweek: Trump Demands China 'Pay Reparations' for COVID, Says \$10 Trillion Not Enough June 12, 2021

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Earlier the same day, the international research team visited Wuhan's larger Baishazhou market, where Xiao had regularly surveyed two sellers of live wild animals. Yet the group was told only frozen food, ingredients, and kitchenware were on offer there. Liang Wannian, an epidemiologist who led the Chinese experts collaborating with the WHO-convened team, says his group had no knowledge of Xiao's data either. [if the above information on what the delegation saw all comes from this same source, maybe we should include his name higher up (The source for the description of what the origins researchers saw on Jan. 31, 2021, comes from the official 120-page joint WHO-China report and its 193-page annexes, not from Liang. Since we are essentially accusing China of concealing the information that Xiao documented, we asked Liang at a press conference in late July 2021 when the Chinese team first knew about Xiao's findings -- that the Huanan market and three others in Wuhan were selling live animals permissive to SARS-CoV-2 infection -- and what research China has done subsequently as a follow-up on this information? Liang gave a very long-winded response in Chinese in which he said essentially "we didn't have that information in January-February 2021 when the research team was in Wuhan". I think it's important we keep this to demonstrate that we have tried to ascertain what China knew/has done and have given the Chinese researchers the opportunity to respond. In addition, I have emailed China CDC Director George Gao at least twice and not received any response.)]

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Among the earliest clusters of infections recorded in Wuhan, one involved three Covid cases among staff working at a stall in Huanan. One of the employees, a 32-year-old who fell ill on Dec. 19, traded goods back and forth between the Huanan and Baishazhou markets.

WHERE DOES THIS FACT COME FROM? NOT THE REPORT, RIGHT? WHEN DID IT FIRST BECOME KNOWN? This information was from the joint WHO-China report released in March 2021, however, the WHO-led researchers went to the Baishazhou market more as a demonstration by the China team of what a perfectly functioning large food market looks like. The WHO-led team was oblivious to Xiao's research that showed there were at least two stalls in Baishazhou that had been selling live wild animals for human consumption. So this detail and its significance was lost on the WHO researchers at the time.)

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A confirmed case linking two markets that sold wild animals is "very intriguing," says Stephen Goldstein, a research associate in evolutionary virology at the University of Utah in Salt Lake City. But tracing any contact the employee might have had with infected wildlife is impossible now that the animals are long gone. WOULD TIMELY PUBLICATION OF THE REPORT HAVE CHANGED THIS? It's unlikely that Xiao et al's paper would have been *published* soon after it was drafted in February 2020, but it could have been *released* as a pre-print ahead of publication and peer-review that same month. That would have **confirmed** what almost everyone had suspected: that there **was** a flourishing wildlife trade in Wuhan that provides a plausible pathway by which coronavirus-infected wildlife from Yunnan and beyond could have introduced the virus to the city, sparking the Covid outbreak. It's also possible that swift recognition of these potential wild-animal vectors could have allowed scientists to test them for the virus and for antibodies against the virus while they were still alive (perhaps not the ones from Huanan, but wildlife in the three other Wuhan markets). Because of the statements the Chinese authorities had been making in January and February that strongly supported the animal spill over theory, it was assumed that this research was being done. Of course, the pandemic was raging then, so it would have been challenging. But, because of the denial by Chinese researchers that wild animals were being sold in Wuhan wet markets before the pandemic, there was never that level of follow up. At least, if there was, it was never made public.)

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"It seems to me, at a minimum, that local or regional authorities kept that informationWHAT INFORMATION? (that Wuhan had a flourishing live wild animal business going on in its wet markets before the pandemic) quiet deliberately," Goldstein says. "It's incredible to me that people theorize about one type of cover-up, but an obvious cover-up is staring them right in the face."

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From: Peter Daszak
Sent: Sun, 15 Aug 2021 14:06:31 -0400
To: Jason Gale; Morens, David (NIH/NIAID) [E]
Cc: (b)(6); Garry, Robert F;
(b)(6)
Subject: RE: feedback on wild animals

Disappointing your editor doesn't get it yet.

All off-the-record, but please talk to your editor about how hard we argued with the China side re. whether live mammals were being sold or not. The fact that we couldn't state categorically in the WHO report that live mammals of species known to host SARS-CoVs were present in the market was used by the lab leak contingent to ridicule the evidence we did find – frozen ferret-badger & rabbit carcasses left behind after the cleanout. Anyone with half a brain could see what was going on here, but having that paper as evidence would have built a much stronger case in my opinion.

Also mention to your editors that the truth will out – there are papers coming down the pipeline that add weight to a bat-int.host-human pathway and zero for the lab leak BS. This article will be one of the few right now that gets on the right side of history – surely that matters?

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: (b)(6)
Website: www.ecohealthalliance.org
Twitter: [@PeterDaszak](https://twitter.com/PeterDaszak)

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: Jason Gale (BLOOMBERG/ NEWSROOM:) <j.gale@bloomberg.net>
Sent: Saturday, August 14, 2021 7:54 PM
To: (b)(6)
Cc: (b)(6)

(b)(6)

Subject: Re: feedback on wild animals

Thanks, David.

I just got off a video conf call with the current editor in NY (the one asking all the latest questions). He's very nice and I feel like he gets it. He thinks it's a fascinating story. Problem we have in journalism is that there are some people who aren't interested in actual journalism and telling stories; they want to climb to the top and manage people. I (b)(6)

(b)(6), but am so grateful that I still get to meet so many remarkable people, visit cool places and see all aspects of humanity.

A difficulty working for a NY-based organization is that it's assumed that all the best people are in NYC, so being in Melbourne ((b)(6)

(b)(6)), is that folks consider Australia a backwater and, by association, I mustn't be all that important/valuable. But my new role as "global biosecurity czar" is helping somewhat. Ahhhhh... Office politics!

From: (b)(6) At: 08/15/21 09:03:03 UTC+10:00

To: Jason Gale (BLOOMBERG/ NEWSROOM:)

Cc: (b)(6)

(b)(6)

Subject: Re: feedback on wild animals

Jason, all I can say is that it must be harder to be a journalist than a scientist.... I had no idea someone at your level would get pushed back.

Usually i get from one to 4 reviewer responses to a ms. and three of those are out to lunch. Occasionally i get a reviewer who really understands the work: half of those are helpful, the other half are trashers.

Maybe it's like being in the government where i am: there is endless push back, but the push-backers are brainless idiots who don't know what they are talking about.

Do you ever get to a point where the editors leave you alone on the science? Or do they all think they are science geniuses? d

Sent from my iPhone
David M Morens
OD, NIAID, NIH

On Aug 14, 2021, at 16:05, Jason Gale (BLOOMBERG/ NEWSROOM:) <j.gale@bloomberg.net> wrote:

Thanks, Bob. In journalism, getting to the truth even when it's genuinely and actively pursued, can be a tortuous process!

----- Original Message -----

From: Robert F Garry (b)(6)

To: JASON GALE, (b)(6)

(b)(6)

At: 08/15/21 01:45:11 UTC+10:00

Looking forward to this important article. Truth is stronger than fiction.

From: Jason Gale (BLOOMBERG/ NEWSROOM:) <j.gale@bloomberg.net>

Sent: Saturday, August 14, 2021 6:41 AM

To: (b)(6)

(b)(6)

(b)(6)

Garry, Robert F

Subject: Fwd:Re:feedback on wild animals

External Sender. Be aware of links, attachments and requests.

Hi guys, in case you have nothing better to read over the weekend, this is some of the dialog I am having with editors in the U.S. Essentially, my response to questions from editor #6. I thought I could claim victory when it looked like the story could be published this morning, but (b)(6) of Businessweek objected and thinks (b)(6) can make it better with another revision and an ETA of Tuesday. Sigh.

Jason

From: Jason Gale (BLOOMBERG/ NEWSROOM:) At: 08/14/21 16:36:58 UTC+10:00

To: Cristina Lindblad (BLOOMBERG/ NEWSROOM:), Eric Gelman (BLOOMBERG/ NEWSROOM:)

Cc: Joel Weber (BLOOMBERG/ NEWSROOM:)

Subject: Re:feedback on wild animals

Hi.

Thanks for the feedback and the questions, which I have tried to answer in detail.

It's often easier to have a conversation over Nexi or the phone to explain nuanced information, or details that are clear to me,

but might not be to someone coming at this fresh, but that's tricky with the time difference.

When you look back at what's happened here, it seems that in trying to deflect blame for the pandemic, which became increasingly vicious as the cataclysmic nature of the Covid-19 pandemic unfolded around March-April 2020, China tried to conceal a very obvious, very plausible source of the pandemic: it's flourishing wildlife trade (worth about \$90 billion in 2016).

It was an obvious cause of the pandemic because an almost identical scenario triggered an international outbreak caused by a very similar coronavirus (SARS) in 2003-04. But in attempting to cover up the wildlife trade, and making like there were never any wild animals being sold in Wuhan's wet markets, things began to backfire on China; questions were raised about the nearby lab studying these coronaviruses. The more geopolitical, heated and vicious the arguments and accusations became, the less cooperative China became. In response, the more intent/adamant some groups have become in their belief that China is covering up a lab-leak. It's become a vicious circle. If China isn't coming clean on the wild animals, what else is it trying to hide?? China's defensiveness means we may never get the cooperation needed to find the answers. If China had been honest and transparent about the wild animals in the wet markets, it might not be in this mess now.

Anyway, here are my response to your queries in green.

By the way, I wonder if the current headline:

Delayed Paper Gives Credence to Wuhan Market Covid Origin Story doesn't convey much more than what we had 2 months earlier when we reported Xiao's findings: China Markets Sold Mink, Civets, Stoking Natural Origins Theory

Perhaps Obscured China Paper Scuppered Chance to Trace Covid Origins

would hits "China", "Covid" and "Origins" in a way that won't alienate people who already believe it was a lab-leak

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According to the report, minks, civets, raccoon dogs and other mammals known to harbor coronaviruses were sold in plain sight for years in shops across the city, including the now infamous Huanan wet market, to which many of the earliest Covid cases were traced. The evidence collected over 30 months by **Xiao Xiao** a I'D NAME HIM HERE [[i don't know that naming a researcher no one has ever heard of adds much]] researcher working at a lab

affiliated with China's Ministry of Education was hastily drafted into a manuscript and submitted to a scientific journal [Joel, we cannot name the first journal they delivered it to because the authors decline to give us the name, saying it may affect their future chances of being published] in February 2020, just weeks before the outbreak was declared a pandemic.

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While the study received wide attention when it was eventually released by a different publisher [Publisher (Springer Nature) and publication (Scientific Reports) are different. Might add confusion DO YOU WANT TO ADD NAME HERE?], its long and torturous journey to publication gave **Chinese officials an opportunity to weave alternative narratives in which the virus may have come from abroad, even from a U.S. Army biological research facility.**

[the stuff in bold is not contested and we go on to show how that happened, documenting with links when available] I TWEAKED WORDING HERE BUT THIS STILL ISN'T QUITE RIGHT. IF THE REPORT HAD BEEN PUBLISHED EARLIER CHINESE OFFICIALS COULD STILL HAVE DONE WHAT THEY DID--THEY COULD HAVE JUST SAID THE REPORT WAS SHODDY, OR WHATEVER, AND THEY ALSO COULD HAVE JUST IGNORED IT. I disagree. The evidence that Xiao et al provide was meticulously documented and supported by photographs that would have been difficult/impossible for China to dismiss (as older published photos and media reports had been). What's more, Newman understands that Xiao collected blood-sucking ticks from the wild animals he studiously cataloged. His frozen tick samples could be tested for blood/antibodies/virus, which could be extremely helpful in identifying infected species PRIOR to December 2019. The WHO team knew nothing of this, so couldn't have asked China for this research or any results, had they actually done the research. The delay in the publication of Xiao's paper delayed the evidence that there were live animals sold in the Huanan market. The WHO researchers couldn't have asked about tests on wildlife that ostensibly were never there. Likewise, Chinese authorities couldn't have done the tests on animals that didn't exist. The problem is that in January and February 2020, it was widely assumed the animals HAD been there and that the necessary tests and tracing of animals (the sampling of animals on farms they were raised on, testing of farm workers, animal hunters, transporters and traders **had all been done** by researchers in China -- the very things that ultimately led to the discovery of the origins of SARS and of MERS viruses. **None of these things were done** (or at least, there is nothing publicly available to show that they were done) **because the animals "weren't there"**. Now that we all know they

were there, China as lost considerable face. The issue has become so political than there is much less/?no willingness to cooperate and conduct the additional research that the WHO-led team recommended. Ideally, Xiao's ticks should be studied, but it's doubtful that will now happen (I wouldn't be surprised if he's been ordered to incinerate them!) Hope this is clear.

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An international team of experts convened by the WHO traveled to Wuhan earlier this year to seek answers—a trip that might have yielded different results if the scientists had known about the work of Xiao Xiao, a virologist whose roles straddled epidemiology and animal research at the government-funded Key Laboratory of Southwest China Wildlife Resources Conservation and at Hubei University of Traditional Chinese Medicine. 'MIGHT HAVE YIELDED DIFFERENT RESULTS' SEEMS HIGHLY SPECULATIVE. WHAT RESULTS DID IT YIELD? I'D CUT THIS GRAF

As mentioned above, the WHO-convened team of researchers was told by market authorities, vendors and regular market visitors that there were no live animals sold in the Huanan market. That undermined completely the premise that the Huanan market was the kind of place where live animals from different species are stacked in cages, with urine and fecal material drips from one cage to the one below it, where there are splatters of blood and guts from animals, and lots of potential for the spread of diseases from one species to another (including Homo sapiens). Instead, the market (and one other one known to have been selling live wild animals in 2019) was presented as selling only frozen wild animals and aquatic species and things unlikely to be the source of SARS-CoV-2. The WHO researchers were told there were frozen ferret badgers and other wildlife found in freezers. Some of the carcasses actually came from Yunnan, the province where the closest coronavirus related to SARS-CoV-2 was found in bats -- thus establishing a potential route from Yunnan to Wuhan in wildlife. That was actually important. When the researchers showed their Chinese counterparts photos of caged raccoon dogs taken in the Huanan market by Prof. Edward Holmes five or six years earlier, they were told by Chinese scientists that the photos may have been faked, and that the market had ceased selling such live animals anyway. The WHO researchers saw no evidence (empty cages, animal pelts, etc) to dispute what the Chinese scientists told them, although they did smell "animals" -- but were told they were smelling rotten meat, sewage etc. Three people associated with the WHO-led mission told me that they didn't believe the information they were given by anyone associated with the market. But since there was no evidence to

the contrary, they were unable to push the Chinese scientists further on this. **The fact that the mission concluded that frozen, not live wild animals were sold in the market undermined the thesis that Covid resulted from an animal spillover.** And the absence of strong evidence pointing to a spill over from wild animals to humans made the lab-leak theory look, in relative terms, more plausible.

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Six months and two revisions later, the journal's publishers rejected the paper. "They did not think it would have widespread appeal," says Newman, who declined to name the publication [do you want us to say why he won't name it? I don't think it's necessary. There's no upside for scientists to make a publisher look bad (most journals are published by a handful of publishers)] "It caused us, especially our Chinese co-authors, concern that these data would not be taken seriously."

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The manuscript underwent a third revision to include data on China's pangolin trade networks (an earlier study, later contested, had implicated pangolins in the virus's spread to humans)WHO ASKED THAT THIS INFO BE INCLUDED? (I did, because we're trying to explain here why WHO missed the significance of Xiao's evidence. The WHO was slammed by other papers being submitted PLUS Xiao's paper had a weird title. That title seemed relevant to the authors back in January-February 2020, when pangolins were considered a possible SARS-CoV-2-spreading culprit. But in October 2020, pangolins were off the hook, so the title would have seem irrelevant/unimportant at first glance at WHO). It was then sent to the online journal Scientific Reports.

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The China-based researchers had reason to be cautious. In February 2020, the China Center for Disease Control (CCDC lets not use "CCDC". It's not commonly used like the U.S. "CDC" is, and it's going to force readers to go back and figure out what the "CCDC" is) prohibited scientists working on Covid-relate

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~~CCDC~~ Disease detectives arriving from Beijing (think this makes it clear that these are China's disease "feds" arriving) on the

first day of 2020 ordered environmental samples to be collected from drains and other surfaces at the market. Some 585 specimens were tested, of which 33 turned out to be positive for SARS-CoV-2. "All current evidence points to wild animals sold illegally," China CDC Director George Gao and colleagues wrote in the agency's weekly bulletin in late January. All but two of the positive specimens came from a cavernous and poorly-ventilated section of the market's western wing, where many shops sold animals.

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~~The information void kindled a raging political debate that's already caused a trade war between China and Australia, as nations demand to know how Covid emerged.~~

Australia in April 2020 called for a global inquiry into the origins of the pandemic, including China's handling of the initial outbreak. Days later, then-U.S. Secretary of State Mike Pompeo used part of his Earth Day message to call on China to close its wet markets to "reduce risks to human health inside and outside of China."

Based on a discussion today with someone with knowledge of the WHO-led mission to Wuhan in Jan-Feb 2021, a significant catalyst for China's defensiveness is the emergence of **claims for reparations** that extended from the finger-pointing at China's wet markets. These surfaced in April 2020, and have continued as recently as June 2021 (when Trump pushed for it again at a rally in the Midwest)

SO IS THIS THE POINT AT WHICH CHINA, WHICH SEEMINGLY ACCEPTED THE WET MARKET HYPOTHESIS, BEGAN TRYING TO CREATE A DIFFERENT NARRATIVE? (I think it was incremental. I believe China was embarrassed that its citizens were still buying wild animals in wet markets to eat -- a well-known hazard for zoonotic disease transmission that China tried unsuccessfully to outlaw almost 20 years ago. But that embarrassment/humiliation morphed into rigid denial and obfuscation when governments began openly blaming the Chinese Communist Party and agitating for China to pay reparations for the pandemic. See these clips:

- USA Today: Blame the Chinese Communist Party for the coronavirus crisis: Coronavirus crisis proves communism is still a grave threat to the entire world. If Beijing had just been honest, the pandemic could be preventable. April 5, 2020

- Yahoo News: More than half of Americans think China should pay coronavirus reparations, poll shows April 9, 2020
- Voice of America: Americans Join Coronavirus Lawsuit to Make China Pay April 10, 2020
- Washington Post Opinion: China must pay reparations to Africa for its coronavirus failures April 16, 2020
- Reuters: In a first, Missouri sues China over coronavirus economic losses April 22, 2020
- Washington Post: Missouri is suing China over the coronavirus pandemic. It's the latest conservative gambit, April 22, 2020
- New York Post: Top German paper demands \$165 billion coronavirus reparations from China April 22, 2020
- Attorney General Fitch Prepares to Sue China on Behalf of Mississippians April 22, 2020
- Newsweek: Trump on U.S. Seeking Compensation From China Over COVID-19: 'We Have Not Determined the Final Amount' April 28, 2020
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- Newsweek: Trump Demands China 'Pay Reparations' for COVID, Says \$10 Trillion Not Enough June 12, 2021

In response, Geng Shuang, a spokesman for China's Foreign Ministry, denied "wildlife wet markets" existed in the country. Government researchers CAN WE BE MORE SPECIFIC? Twenty-two researchers from mostly nationally-funded laboratories (I think it's the Chinese equivalent of the NIH in the U.S.) and institutes attached to the Chinese Academy of Sciences) now dismiss the market hypothesis completely. "SARS-CoV-2 could not

have possibly evolved in an animal market in a big city and even less likely in a laboratory," they wrote in a paper released last month ahead of publication WHERE/WHEN WILL IT BE PUBLISHED? It was released as a "pre-print" on a Chinese academic repository ahead of publication that appears to be managed/owned by the Chinese Academy of Sciences. Papers are usually released in pre-print form before they have been accepted for publication or peer-reviewed as a way of expediting public access to the information. In this case, there is no information to suggest if, where or when the paper will be published.

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A more recent paper BY WHOM? (China CDC's Gao and eight other scientists mostly from the Chinese of Academy of Sciences' institutes) contends that the virus may have been imported from multiple locations worldwide, including parts of Europe where mink are raised in areas inhabited also by horseshoe bats known to harbor coronaviruses. "The official narrative changed not because the evidence changed," says Robert Garry, a professor of microbiology and immunology at Tulane University's School of Medicine in New Orleans "A spillover from a wet market was what caused SARS, and, embarrassingly for China, those wet markets were never shut down." Garry is the co-author of one of the earliest papers on the origins of Covid but wasn't involved in the research on Wuhan's markets.

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I DON'T REALLY UNDERSTAND WHAT POINT THIS GRAF IS TRYING TO MAKE. This is intended to demonstrate the kind of gaslighting that has occurred. Some of the WHO-led researchers are veterinarians and zoologists -- they know what animals smell like, and could smell their lingering presence a year later, but were told essentially that it was impossible that they were smelling animals because **there "were no live animals there".**) The researchers noted a mixed smell of animals and disinfectant in some areas of the market, but they were told by the market's manager that they were probably smelling the lingering stench of rotten meat and sewage, according to a joint WHO-China report. [should we add "according to Laing Wannian etc here? Liang Wannian was the leader of the Chinese research team collaborating jointly with the WHO-led research team. The source for the above description are in the annexes to the official joint WHO-China report released at the end of March 2021.]

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A confirmed case linking two markets that sold wild animals is "very intriguing," says Stephen Goldstein, a research associate in evolutionary virology at the University of Utah in Salt Lake City. But tracing any contact the employee might have had with infected wildlife is impossible now that the animals are long gone. WOULD TIMELY PUBLICATION OF THE REPORT HAVE CHANGED THIS? It's unlikely that Xiao et al's paper would have been *published* soon after it was drafted in February 2020, but it could have been *released* as a pre-print ahead of publication and peer-review that same month. That would have **confirmed** what almost everyone had suspected: that there **was** a flourishing wildlife trade in Wuhan that provides a plausible pathway by which coronavirus-infected wildlife from Yunnan and beyond could have introduced the virus to the city, sparking the Covid outbreak. It's also possible that swift recognition of these potential wild-animal vectors could have allowed scientists to test them for the virus and for antibodies against the virus while they were still alive (perhaps not the ones from Huanan, but wildlife in the three other Wuhan markets). Because of the statements the Chinese authorities had been making in January and February that strongly supported the animal spill over theory, it was assumed that this research was being done. Of course, the pandemic was raging then, so it would have been challenging. But, because of the denial by Chinese researchers that wild animals were being sold in Wuhan wet markets before the pandemic, there was never that level of follow up. At least, if there was, it was never made public.)

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From: Peter Daszak
Sent: Tue, 17 Aug 2021 08:37:54 -0400
To: Morens, David (NIH/NIAID) [E]; Jason Gale
Cc: (b)(6); Garry, Robert F;
(b)(6)
Subject: RE: feedback on wild animals
Importance: High

Very much enjoying your piece out today Jason!

<https://www.bloomberg.com/news/features/2021-08-17/where-did-covid-come-from-report-on-infected-wuhan-wild-animals-sheds-new-light>

Delayed Wuhan Report Adds Crucial Detail to Covid Origin Puzzle

A study documenting the trade in live wild animals at Wuhan wet markets stayed unpublished for more than a year.



Wuhan Huanan Wholesale Seafood Market, December 31, 2019.

Photo illustration by 731; Photo: Oriental Images

By

Jason Gale

August 17, 2021, 12:01 AM EDT

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The origin story of Covid-19 remains a mystery mired in contentious geopolitical debate. But a research paper that languished in publishing limbo for a year and a half contains meticulously collected data and photographic evidence supporting scientists' initial hypothesis—that the outbreak stemmed from infected wild animals—which prevailed until speculation that SARS-CoV-2 escaped from a nearby lab gained traction.

According to the report, which was published in June in the online journal Scientific Reports, minks, civets, raccoon dogs, and other mammals known to harbor coronaviruses were sold in plain sight for years in shops across the city, including the now infamous Huanan wet market, to which many of the earliest Covid cases were traced. The data in the report was collected over 30 months by Xiao Xiao, a virologist whose roles straddled epidemiology and animal research at the government-funded Key Laboratory of Southwest China Wildlife Resources Conservation and at Hubei University of Traditional Chinese Medicine.

In May 2017, Xiao began surveying 17 shops at four Wuhan markets selling live wild animals. He was trying to find the source of a tick-borne, Lyme-like disease that had spread in Hubei province years earlier. He kept up monthly visits until November 2019, when the discovery of mysterious pneumonia cases that heralded the start of the Covid pandemic brought his visits to an abrupt end.

As the virus started to explode, Xiao recognized the potential significance of his data. In January of 2020, he collaborated with Zhou Zhaomin, a researcher at a wildlife resources laboratory affiliated with China's Ministry of Education, and three seasoned scientists from the University of Oxford's Wildlife Conservation Research Unit, on a manuscript that was submitted to a journal the following month. (They declined to name the publication). "We'd imagined that the journal we sent it to would say, 'Fantastic! Of course we want these data out as quickly as we can. The World Health Organization would be absolutely thrilled to receive this information,'" says Chris Newman, a British ecologist who is one of the paper's co-authors. But it was rejected. "They did not think it would have widespread appeal," says Newman. Had the study been made public right away, the search for the origins of the virus might have taken a very different course. Not only did the study contain conclusive evidence that live animals were being sold for human consumption at the epicenter of the outbreak, but Newman says he assumes Xiao collected blood-sucking ticks from the wild animals he studiously cataloged. The blood meals of frozen tick samples could be examined for traces of the coronavirus, which would be extremely helpful in identifying infected species prior to December 2019. Xiao didn't respond to emails requesting comment.

In the first months of the epidemic, local researchers asserted that the new coronavirus resembled a spillover from animals, reminiscent of the emergence of the virus that caused severe acute respiratory syndrome (SARS) in wet markets in Guangdong

almost 20 years ago. They also readily acknowledged the presence of “a variety of live wild animals” at Wuhan markets.



Raccoon dog, Wuhan wet market, 2013.

Photo illustration by 731; Photo: Animal Equality

The Huanan market was shuttered in the early hours of Jan. 1, 2020, and its 678 stalls emptied and sanitized. In the middle of the month CNN broadcast unverified footage reportedly recorded in early December showing caged deer, marmots, and raccoon dogs there. Photographs of a menu board advertising the price and availability of exotic animals circulated online.

Disease detectives arriving from Beijing on the first day of 2020 ordered environmental samples to be collected from drains and other surfaces at the market. Some 585 specimens were tested, of which 33 turned out to be positive for SARS-CoV-2. “All current evidence points to wild animals sold illegally,” China Center for Disease Control Director George Gao and colleagues wrote in the agency’s weekly bulletin in late January. All but two of the positive specimens came from a cavernous and poorly-ventilated section of the market’s western wing, where many shops sold animals.

“We have found out which stalls on the seafood market in Wuhan had the virus,” Tan Wenjie, a researcher at China CDC’s viral disease control and prevention

institute, was quoted telling the state-owned China Daily newspaper days later. “It is an important discovery, and we will investigate which animal was the source.”

How Researchers Missed Clues in Wuhan

How Researchers Missed Clues in Wuhan

China temporarily banned the wildlife trade. The decision became permanent a month later and widened to prohibit human consumption of terrestrial wild animals.

A WHO-China joint mission to Wuhan to examine China’s response to the outbreak in February 2020 reported that an effort was under way to collect detailed records on the source and type of wildlife species sold at the Huanan market and the destination of those animals after the market was closed. But there’s no public record of that ever happening.

“Unfortunately, the apparent lack of direct animal sampling in the market may mean that it will be difficult, perhaps even impossible, to accurately identify any animal reservoir at this location,” Zhang Yongzhen and Edward Holmes, the scientists who published the first genetic sequence of SARS-CoV-2, wrote in a commentary published in the journal *Cell* in March 2020.

As other nations began blaming the Chinese Communist Party for the pandemic, the government grew defensive. It may have been embarrassed that its citizens were still eating wild animals bought in wet markets—a well-known path for zoonotic disease transmission that China tried unsuccessfully to outlaw almost 20 years ago.

Australia in April 2020 called for a global inquiry into the origins of the pandemic, including China’s handling of the initial outbreak. Days later, then-U.S. Secretary of State Mike Pompeo used part of his Earth Day message to call on China to close its wet markets to “reduce risks to human health inside and outside of China.”

In response, Geng Shuang, a spokesman for China’s Foreign

Ministry, denied “wildlife wet markets” existed in the country. Government researchers now dismiss the market hypothesis completely. “SARS-CoV-2 could not have possibly evolved in an animal market in a big city and even less likely in a laboratory,” said a paper released in July, written by 22 researchers from mostly government-funded laboratories attached to the Chinese Academy of Sciences.

A more recent paper by government-affiliated scientists contends that the virus may have been imported from multiple locations worldwide, including parts of Europe where mink are raised in areas inhabited also by horseshoe bats known to harbor coronaviruses. “The official narrative changed not because the evidence changed,” says Robert Garry, a professor of microbiology and immunology at Tulane University’s School of Medicine in New Orleans. “A spillover from a wet market was what caused SARS, and, embarrassingly for China, those wet markets were never shut down.” Garry is the co-author of one of the earliest papers on the origins of Covid but wasn’t involved in the research on Wuhan’s markets.

Since he was not connected to a law enforcement agency, Xiao was granted “unique and complete access to trading practices,” he and his colleagues wrote. Seven of the shops he surveyed were in the Huanan market, which has been linked to two of the earliest documented cases of Covid-19. On each visit, Xiao asked vendors what species they had sold over the preceding month, documenting both their numbers and prices.

Xiao checked the animals for injuries and disease, noting that almost a third bore trapping and shooting wounds consistent with being caught in the wild, and that none of the shops displayed an origin or quarantine certificate, making the commerce “fundamentally illegal,” according to the study.

His animal logs included masked palm civets and raccoon dogs—both involved in the 2003 SARS outbreak—and other species susceptible to coronavirus infections, such as bamboo rats, minks, and hog badgers. Of the 38 species Xiao documented, 31 were protected.



A closed seafood wholesale market in Wuhan on Jan. 23, 2021.

Photo illustration by 731; Photo: AP Photo

Anyone caught violating China's wild animal conservation law faces fines and up to 15 years of imprisonment. But enforcement was lax, as evidenced by the fact that many of the Wuhan shops displayed their wares openly, "caged, stacked and in poor condition," Xiao observed in the report. Xiao estimated that 47,381 wild animals were sold in Wuhan over the survey period. These were luxury food items priced at up to \$25 a kilogram (\$11 per pound)—or more than four times costlier than pork, China's main meat staple.

The initial manuscript was revised twice following feedback by a reviewer, and after more than six months of exchanges, was rejected.

The researchers revised the manuscript a third time and included data on China's pangolin trade networks (an earlier study, later contested, had implicated pangolins in the virus's spread to humans). In October 2020 they sent it to Scientific Reports.

Springer Nature, the publisher of Scientific Reports, forwarded a copy swiftly to the WHO as part of an agreement with the agency, says Ed Gerstner, Springer Nature's director of journals, policy, and strategy. But the publisher emailed the paper, titled "Pangolin Trading in China: Wuhan's Alibi in the Origin of Covid-19," to a generic address at the WHO that functions as an inbox for unpublished research where it languished amid tens of thousands of submissions flooding the agency.

Springer Nature also sent a copy to Maria Van Kerkhove, the organization's technical lead for Covid-19. Van Kerkhove says there were so many submissions related to the pandemic that she didn't look at it right away, and she regrets there was no direct follow-up from the journal or by the authors. "It's a shame this important information was not shared directly with the mission team while the team was in Wuhan and visited the markets," she said in an email. "This paper would certainly have added great value."

Newman says his Chinese co-authors never told him why they didn't take their data directly to the WHO, but it's possible they were more comfortable writing a report on market surveys for publishing in a journal, he says.

The China-based researchers would have had reason to be cautious. In February 2020, the China CDC prohibited scientists working on Covid-related research from sharing their data and required them to receive permission before conducting any studies or publishing the results. Days later, a special panel convened by China's top executive body to oversee coronavirus research took control of all publication work related to the pandemic for "coordinated deployment."

An international group of experts convened by the WHO to research the origins of Covid traveled to Wuhan earlier this year—a trip that might have yielded different results if the scientists had known about Xiao’s work.

By the time the team visited the Huanan market in the afternoon of Jan. 31—more than a year after its closure—little remained to assist the kind of epidemiological sleuthing that led SARS investigators to Himalayan palm civets, raccoon dogs, and Chinese ferret-badgers sold in live-animal markets in Guangdong almost two decades ago.

The researchers noted a mixed smell of animals and disinfectant in some areas of the market, but they were told by the market’s manager that they were probably smelling the lingering stench of rotten meat and sewage, according to the official joint WHO-China report released in March 2021.

Chinese officials briefing the visitors told them 10 Huanan shops had been found to be selling frozen “domesticated” wild animals, including bamboo rats—some sourced from Yunnan province, where scientists found a coronavirus that most closely matches SARS-CoV-2 in horseshoe bats. But no live animals had been seen before the market was closed, the official said.

The researchers saw nothing to dispute that. They were invited to quiz two Wuhan residents whom they were told had shopped there regularly for 20 and 30 years and who, according to the report, said they “had never witnessed any live animals being sold.”

Earlier the same day, the international research team visited Wuhan’s larger Baishazhou market, where Xiao had regularly surveyed two sellers of live wild animals. Yet when the researchers were there they were told that only frozen food, ingredients, and kitchenware were on offer. Liang Wannian, an epidemiologist who led the Chinese experts collaborating with the WHO-convened team, says his group had no knowledge of Xiao’s data either.

Among the earliest clusters of infections recorded in Wuhan, one involved three Covid cases among staff working at a stall in Huanan. One of the employees, a 32-year-old who fell ill on Dec. 19, traded goods back and forth between the Huanan and Baishazhou markets.

A confirmed case linking two markets that sold wild animals is “very intriguing,” says Stephen Goldstein, a research associate in evolutionary virology at the University of Utah in Salt Lake City. But tracing any contact the employee might have had with infected wildlife is impossible now that the animals are long gone. As for the existence of a flourishing live wild animal business, “It seems to me, at a minimum, that local or regional authorities kept that information quiet deliberately,” he says.

“It’s incredible to me that people theorize about one type of cover-up, but an obvious cover-up is staring them right in the face.”

U.S. intelligence agencies will report their own findings on Covid’s origins later this month. But with only circumstantial evidence remaining, the world may now never know what caused the outbreak. “It is unclear why earlier initiatives within China to locate source animals for SARS-CoV-2 were curtailed, and now appear unfortunately to have stopped,” says Tulane’s Garry. “Instead, the focus is on highly implausible origin scenarios. If we continue to place politics over science, humanity will again be unprepared for the next emergence of a pandemic virus.”

Cheers,

Peter

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EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: Morens, David (NIH/NIAID) [E] (b)(6)
Sent: Sunday, August 15, 2021 6:26 PM
To: Jason Gale <j.gale@bloomberg.net>
Cc: (b)(6) Garry,
Robert F (b)(6)
Subject: RE: feedback on wild animals

Jason, not sure whose office politics is worse, but there is many a day I’d rather be in Australia, even if I had to drink that awful beer Fosters. (To quote Groucho Marx as he help up a glass of questionable beer: “last time I saw something like this,

they had to shoot the horse”).... But I do have fond memories of Australia, and (b)(6), are out in (b)(6), the only large city there (if you can call it that) I have never been, although it’s high on my bucket list if this damn pandemic ever ends. (b)(6)

(b)(6)

David

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From: Jason Gale (BLOOMBERG/ NEWSROOM:) <j.gale@bloomberg.net>

Sent: Saturday, August 14, 2021 7:54 PM

To: Morens, David (NIH/NIAID) [E] (b)(6)

Cc: (b)(6); Garry,
Robert F (b)(6)

Subject: Re: feedback on wild animals

Thanks, David.

I just got off a video conf call with the current editor in NY (the one asking all the latest questions). He's very nice and I feel like he gets it. He thinks it's a fascinating story. Problem we have in journalism is that there are some people who aren't interested in actual journalism and telling stories; they want to climb to the top and manage people. I (b)(6) (b)(6), but am so grateful that I still get to meet so many remarkable people, visit cool places and see all aspects of humanity.

A difficulty working for a NY-based organization is that it's assumed that all the best people are in NYC, so being in Melbourne ((b)(6))

(b)(6), is that folks consider Australia a backwater and, by association, I mustn't be all that important/valuable. But my new role as "global biosecurity czar" is helping somewhat. Ahhhhh... Office politics!

From: (b)(6) **At:** 08/15/21 09:03:03 UTC+10:00

To: Jason Gale (BLOOMBERG/ NEWSROOM:)

Cc: (b)(6)

(b)(6)

Subject: Re: feedback on wild animals

Jason, all I can say is that it must be harder to be a journalist than a scientist.... I had no idea someone at your level would get pushed back.

Usually i get from one to 4 reviewer responses to a ms. and three of those are out to lunch. Occasionally i get a reviewer who really understands the work: half of those are helpful, the other half are trashers.

Maybe it's like being in the government where i am: there is endless push back, but the push-backers are brainless idiots who don't know what they are talking about.

Do you ever get to a point where the editors leave you alone on the science? Or do they all think they are science geniuses? d

Sent from my iPhone

David M Morens
OD, NIAID, NIH

On Aug 14, 2021, at 16:05, Jason Gale (BLOOMBERG/ NEWSROOM:) <j.gale@bloomberg.net> wrote:

Thanks, Bob. In journalism, getting to the truth even when it's genuinely and actively pursued, can be a tortuous process!

----- Original Message -----

From: Robert F Garry (b)(6)

To: JASON GALE, (b)(6)

(b)(6)

At: 08/15/21 01:45:11 UTC+10:00

Looking forward to this important article. Truth is stronger than fiction.

From: Jason Gale (BLOOMBERG/ NEWSROOM:) <j.gale@bloomberg.net>

Sent: Saturday, August 14, 2021 6:41 AM

To: (b)(6)

(b)(6)

(b)(6) Garry, Robert F

Subject: Fwd:Re:feedback on wild animals

External Sender. Be aware of links, attachments and requests.

Hi guys, in case you have nothing better to read over the weekend, this is some of the dialog I am having with editors in the U.S. Essentially, my response to questions from editor #6. I thought I could claim victory when it looked like the story could be published this morning, but (b)(6) of Businessweek objected and thinks (b)(6) can make it better with another revision and an ETA of Tuesday. Sigh.
Jason

From: Jason Gale (BLOOMBERG/ NEWSROOM:) At: 08/14/21 16:36:58 UTC+10:00

To: Cristina Lindblad (BLOOMBERG/ NEWSROOM:) , Eric Gelman (BLOOMBERG/ NEWSROOM:)

Cc: Joel Weber (BLOOMBERG/ NEWSROOM:)

Subject: Re:feedback on wild animals

Hi.

Thanks for the feedback and the questions, which I have tried to answer in detail.

It's often easier to have a conversation over Nexi or the phone to explain nuanced information, or details that are clear to me, but might not be to someone coming at this fresh, but that's tricky with the time difference.

When you look back at what's happened here, it seems that in trying to deflect blame for the pandemic, which became increasingly vicious as the cataclysmic nature of the Covid-19 pandemic unfolded around March-April 2020, China tried to conceal a very obvious, very plausible source of the pandemic: it's flourishing wildlife trade (worth about \$90 billion in 2016).

It was an obvious cause of the pandemic because an almost identical scenario triggered an international outbreak caused by a very similar coronavirus (SARS) in 2003-04. But in attempting to cover up the wildlife trade, and making like there were never any wild animals being sold in Wuhan's wet markets, things began to backfire on China; questions were raised about the nearby lab studying these coronaviruses. The more geopolitical, heated and vicious the arguments and accusations became, the less cooperative China became. In response, the more intent/adamant some groups have become in their belief that China is covering up a lab-leak. It's become a vicious circle. If China isn't coming clean on the wild animals, what else is it trying to hide?? China's defensiveness means we may never get the cooperation needed to find the answers. If China had been honest and transparent about the wild animals in the wet markets, it might not be in this mess now.

Anyway, here are my response to your queries in green.

By the way, I wonder if the current headline:

Delayed Paper Gives Credence to Wuhan Market Covid Origin Story
doesn't convey much more than what we had 2 months earlier when
we reported Xiao's findings: China Markets Sold Mink, Civets,
Stoking Natural Origins Theory
Perhaps Obscured China Paper Scuppered Chance to Trace Covid
Origins

would hits "China", "Covid" and "Origins" in a way that won't
alienate people who already believe it was a lab-leak

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According to the report, minks, civets, raccoon dogs and other mammals known to harbor coronaviruses were sold in plain sight for years in shops across the city, including the now infamous

Huanan wet market, to which many of the earliest Covid cases were traced. The evidence collected over 30 months by **Xiao Xiao** a I'D NAME HIM HERE [[i don't know that naming a researcher no one has ever heard of adds much]] researcher working at a lab affiliated with China's Ministry of Education was hastily drafted into a manuscript and submitted to a scientific journal [Joel, we cannot name the first journal they delivered it to because the authors decline to give us the name, saying it may affect their future chances of being published] in February 2020, just weeks before the outbreak was declared a pandemic.

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While the study received wide attention when it was eventually released by a different publisher [Publisher (Springer Nature) and publication (Scientific Reports) are different. Might add confusion DO YOU WANT TO ADD NAME HERE?], its long and torturous journey to publication gave **Chinese officials an opportunity to weave alternative narratives in which the virus may have come from abroad, even from a U.S. Army biological research facility.**

[the stuff in bold is not contested and we go on to show how that happened, documenting with links when available]I TWEAKED WORDING HERE BUT THIS STILL ISN'T QUITE RIGHT. IF THE REPORT HAD BEEN PUBLISHED EARLIER CHINESE OFFICIALS COULD STILL HAVE DONE WHAT THEY DID--THEY COULD HAVE JUST SAID THE REPORT WAS SHODDY, OR WHATEVER, AND THEY ALSO COULD HAVE JUST IGNORED IT. I disagree. The evidence that Xiao et al provide was meticulously documented and supported by photographs that would have been difficult/impossible for China to dismiss (as older published photos and media reports had been). What's more, Newman understands that Xiao collected blood-sucking ticks from the wild animals he studiously cataloged. His frozen tick samples could be tested for blood/antibodies/virus, which could be extremely helpful in identifying infected species PRIOR to December 2019. The WHO team knew nothing of this, so couldn't have asked China for this research or any results, had they actually done the research. The delay in the publication of Xiao's paper delayed the evidence that there were live animals sold in the Huanan market. The WHO researchers couldn't have asked about tests on wildlife that ostensibly were never there. Likewise, Chinese authorities couldn't have done the tests on animals that didn't exist. The problem is that in January and February 2020, it was widely assumed the animals HAD been there and that the necessary tests and tracing of animals (the sampling of animals on farms they were raised on, testing of farm workers, animal hunters, transporters and traders **had all been done** by researchers in China -- the very things that

ultimately led to the discovery of the origins of SARS and of MERS viruses. **None of these things were done** (or at least, there is nothing publicly available to show that they were done) **because the animals "weren't there"**. Now that we all know they were there, China has lost considerable face. The issue has become so political that there is much less/no willingness to cooperate and conduct the additional research that the WHO-led team recommended. Ideally, Xiao's ticks should be studied, but it's doubtful that will now happen (I wouldn't be surprised if he's been ordered to incinerate them!) Hope this is clear.

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An international team of experts convened by the WHO traveled to Wuhan earlier this year to seek answers—a trip that might have yielded different results if the scientists had known about the work of Xiao Xiao, a virologist whose roles straddled epidemiology and animal research at the government-funded Key Laboratory of Southwest China Wildlife Resources Conservation and at Hubei University of Traditional Chinese Medicine. 'MIGHT HAVE YIELDED DIFFERENT RESULTS' SEEMS HIGHLY SPECULATIVE. WHAT RESULTS DID IT YIELD? I'D CUT THIS GRAF

As mentioned above, the WHO-convened team of researchers was told by market authorities, vendors and regular market visitors that there were no live animals sold in the Huanan market. That undermined completely the premise that the Huanan market was the kind of place where live animals from different species are stacked in cages, with urine and fecal material drips from one cage to the one below it, where there are splatters of blood and guts from animals, and lots of potential for the spread of diseases from one species to another (including Homo sapiens). Instead, the market (and one other one known to have been selling live wild animals in 2019) was presented as selling only frozen wild animals and aquatic species and things unlikely to be the source of SARS-CoV-2. The WHO researchers were told there were frozen ferret badgers and other wildlife found in freezers. Some of the carcasses actually came from Yunnan, the province where the closest coronavirus related to SARS-CoV-2 was found in bats -- thus establishing a potential route from Yunnan to Wuhan in wildlife. That was actually important. When the researchers showed their Chinese counterparts photos of caged raccoon dogs taken in the Huanan market by Prof. Edward Holmes five or six years earlier, they were told by Chinese scientists that the photos may have been faked, and that the market had ceased selling such live animals anyway. The WHO researchers saw no evidence (empty cages, animal pelts, etc) to dispute what the Chinese scientists told them, although they did smell "animals"

-- but were told they were smelling rotten meat, sewage etc. Three people associated with the WHO-led mission told me that they didn't believe the information they were given by anyone associated with the market. But since there was no evidence to the contrary, they were unable to push the Chinese scientists further on this. **The fact that the mission concluded that frozen, not live wild animals were sold in the market undermined the thesis that Covid resulted from an animal spillover.** And the absence of strong evidence pointing to a spill over from wild animals to humans made the lab-leak theory look, in relative terms, more plausible.

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Six months and two revisions later, the journal's publishers rejected the paper. "They did not think it would have widespread appeal," says Newman, who declined to name the publication [do you want us to say why he won't name it? I don't think it's necessary. There's no upside for scientists to make a publisher look bad (most journals are published by a handful of publishers)] "It caused us, especially our Chinese co-authors, concern that these data would not be taken seriously."

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The manuscript underwent a third revision to include data on China's pangolin trade networks (an earlier study, later contested, had implicated pangolins in the virus's spread to humans)WHO ASKED THAT THIS INFO BE INCLUDED? (I did, because we're trying to explain here why WHO missed the significance of Xiao's evidence. The WHO was slammed by other papers being submitted PLUS Xiao's paper had a weird title. That title seemed relevant to the authors back in January-February 2020, when pangolins were considered a possible SARS-CoV-2-spreading culprit. But in October 2020, pangolins were off the hook, so the title would have seem irrelevant/unimportant at first glance at WHO). It was then sent to the online journal Scientific Reports.

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The China-based researchers had reason to be cautious. In February 2020, the China Center for Disease Control (CCDC lets not use "CCDC". It's not commonly used like the U.S. "CDC" is, and it's going to force readers to go back and figure out what the "CCDC" is) prohibited scientists working on Covid-relate

- USA Today: Blame the Chinese Communist Party for the coronavirus crisis: Coronavirus crisis proves communism is still a grave threat to the entire world. If Beijing had just been honest, the pandemic could be preventable. April 5, 2020
- Yahoo News: More than half of Americans think China should pay coronavirus reparations, poll shows April 9, 2020
- Voice of America: Americans Join Coronavirus Lawsuit to Make China Pay April 10, 2020
- Washington Post Opinion: China must pay reparations to Africa for its coronavirus failures April 16, 2020
- Reuters: In a first, Missouri sues China over coronavirus economic losses April 22, 2020
- Washington Post: Missouri is suing China over the coronavirus pandemic. It's the latest conservative gambit, April 22, 2020
- New York Post: Top German paper demands \$165 billion coronavirus reparations from China April 22, 2020
- Attorney General Fitch Prepares to Sue China on Behalf of Mississippians April 22, 2020
- Newsweek: Trump on U.S. Seeking Compensation From China Over COVID-19: 'We Have Not Determined the Final Amount' April 28, 2020
- The Guardian: Trump says China could have stopped Covid-19 and suggests US will seek damages April 28, 2020
- Intelligencer: Trump Thinks He Can Make China Pay for the Virus Like Mexico Paid for the Wall, April 30, 2020
- Washington Post: U.S. officials crafting retaliatory actions against China over coronavirus as President Trump fumes April 30, 2020
- Lawfare: Does China Really Owe the World Trillions of Dollars? May 7, 2020
- Fortune: Trump's demand that China pay coronavirus reparations evokes an ugly history May 8, 2020
- South China Morning Post: Why China won't be paying the West coronavirus reparations any time soon May 15, 2020
- Deccan Herald, India: Abhijit Bhattacharyya | Why China needs to pay reparations to the world June 4, 2020
- Why calls for reparations from China for coronavirus are an unfeasible distraction June 9, 2020
- Newsweek: Trump Demands China 'Pay Reparations' for COVID, Says \$10 Trillion Not Enough June 12, 2021

In response, Geng Shuang, a spokesman for China's Foreign Ministry, denied "wildlife wet markets" existed in the country. Government researchers CAN WE BE MORE SPECIFIC? Twenty-two

researchers from mostly nationally-funded laboratories (I think it's the Chinese equivalent of the NIH in the U.S.) and institutes attached to the Chinese Academy of Sciences) now dismiss the market hypothesis completely. "SARS-CoV-2 could not have possibly evolved in an animal market in a big city and even less likely in a laboratory," they wrote in a paper released last month ahead of publication WHERE/WHEN WILL IT BE PUBLISHED? It was released as a "pre-print" on a Chinese academic repository ahead of publication that appears to be managed/owned by the Chinese Academy of Sciences. Papers are usually released in pre-print form before they have been accepted for publication or peer-reviewed as a way of expediting public access to the information. In this case, there is no information to suggest if, where or when the paper will be published.

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A more recent paper BY WHOM? (China CDC's Gao and eight other scientists mostly from the Chinese of Academy of Sciences' institutes) contends that the virus may have been imported from multiple locations worldwide, including parts of Europe where mink are raised in areas inhabited also by horseshoe bats known to harbor coronaviruses. "The official narrative changed not because the evidence changed," says Robert Garry, a professor of microbiology and immunology at Tulane University's School of Medicine in New Orleans "A spillover from a wet market was what caused SARS, and, embarrassingly for China, those wet markets were never shut down." Garry is the co-author of one of the earliest papers on the origins of Covid but wasn't involved in the research on Wuhan's markets.

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I DON'T REALLY UNDERSTAND WHAT POINT THIS GRAF IS TRYING TO MAKE. This is intended to demonstrate the kind of gaslighting that has occurred. Some of the WHO-led researchers are veterinarians and zoologists -- they know what animals smell like, and could smell their lingering presence a year later, but were told essentially that it was impossible that they were smelling animals because **there "were no live animals there".**) The researchers noted a mixed smell of animals and disinfectant in some areas of the market, but they were told by the market's manager that they were probably smelling the lingering stench of rotten meat and sewage, according to a joint WHO-China report. [should we add "according to Laing Wannian etc here? Liang Wannian was the leader of the Chinese research team collaborating jointly with the WHO-led research team. The source

for the above description are in the annexes to the official joint WHO-China report released at the end of March 2021.]

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Earlier the same day, the international research team visited Wuhan's larger Baishazhou market, where Xiao had regularly surveyed two sellers of live wild animals. Yet the group was told only frozen food, ingredients, and kitchenware were on offer there. Liang Wannian, an epidemiologist who led the Chinese experts collaborating with the WHO-convened team, says his group had no knowledge of Xiao's data either. [if the above information on what the delegation saw all comes from this same source, maybe we should include his name higher up (The source for the description of what the origins researchers saw on Jan. 31, 2021, comes from the official 120-page joint WHO-China report and its 193-page annexes, not from Liang. Since we are essentially accusing China of concealing the information that Xiao documented, we asked Liang at a press conference in late July 2021 when the Chinese team first knew about Xiao's findings -- that the Huanan market and three others in Wuhan were selling live animals permissive to SARS-CoV-2 infection -- and what research China has done subsequently as a follow-up on this information? Liang gave a very long-winded response in Chinese in which he said essentially "we didn't have that information in January-February 2021 when the research team was in Wuhan". I think it's important we keep this to demonstrate that we have tried to ascertain what China knew/has done and have given the Chinese researchers the opportunity to respond. In addition, I have emailed China CDC Director George Gao at least twice and not received any response.)]

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Among the earliest clusters of infections recorded in Wuhan, one involved three Covid cases among staff working at a stall in Huanan. One of the employees, a 32-year-old who fell ill on Dec. 19, traded goods back and forth between the Huanan and Baishazhou markets.

WHERE DOES THIS FACT COME FROM? NOT THE REPORT, RIGHT? WHEN DID IT FIRST BECOME KNOWN? This information was from the joint WHO-China report released in March 2021, however, the WHO-led researchers went to the Baishazhou market more as a demonstration by the China team of what a perfectly functioning large food market looks like. The WHO-led team was oblivious to Xiao's research that showed there were at least two stalls in Baishazhou that had been selling live wild animals for human

consumption. So this detail and its significance was lost on the WHO researchers at the time.)

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A confirmed case linking two markets that sold wild animals is "very intriguing," says Stephen Goldstein, a research associate in evolutionary virology at the University of Utah in Salt Lake City. But tracing any contact the employee might have had with infected wildlife is impossible now that the animals are long gone. WOULD TIMELY PUBLICATION OF THE REPORT HAVE CHANGED THIS? It's unlikely that Xiao et al's paper would have been *published* soon after it was drafted in February 2020, but it could have been *released* as a pre-print ahead of publication and peer-review that same month. That would have **confirmed** what almost everyone had suspected: that there **was** a flourishing wildlife trade in Wuhan that provides a plausible pathway by which coronavirus-infected wildlife from Yunnan and beyond could have introduced the virus to the city, sparking the Covid outbreak. It's also possible that swift recognition of these potential wild-animal vectors could have allowed scientists to test them for the virus and for antibodies against the virus while they were still alive (perhaps not the ones from Huanan, but wildlife in the three other Wuhan markets). Because of the statements the Chinese authorities had been making in January and February that strongly supported the animal spill over theory, it was assumed that this research was being done. Of course, the pandemic was raging then, so it would have been challenging. But, because of the denial by Chinese researchers that wild animals were being sold in Wuhan wet markets before the pandemic, there was never that level of follow up. At least, if there was, it was never made public.)

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"It seems to me, at a minimum, that local or regional authorities kept that information WHAT INFORMATION? (that Wuhan had a flourishing live wild animal business going on in its wet markets before the pandemic) quiet deliberately," Goldstein says. "It's incredible to me that people theorize about one type of cover-up, but an obvious cover-up is staring them right in the face."

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