January 26, 2012

The University of Texas Medical Branch

Community Advisory Board Quarterly Meeting

David L. Callender, MD, MBA, FACS

President

Agenda

- Welcome — Dr. David Callender
  - News of the Day
  - UTMB's Strategic Plan
  - Campus Construction Update
- Institute for Human Infections and Immunity Update — Dr. Scott Weaver
- Galveston National Lab Update — Dr. Jim LeDuc

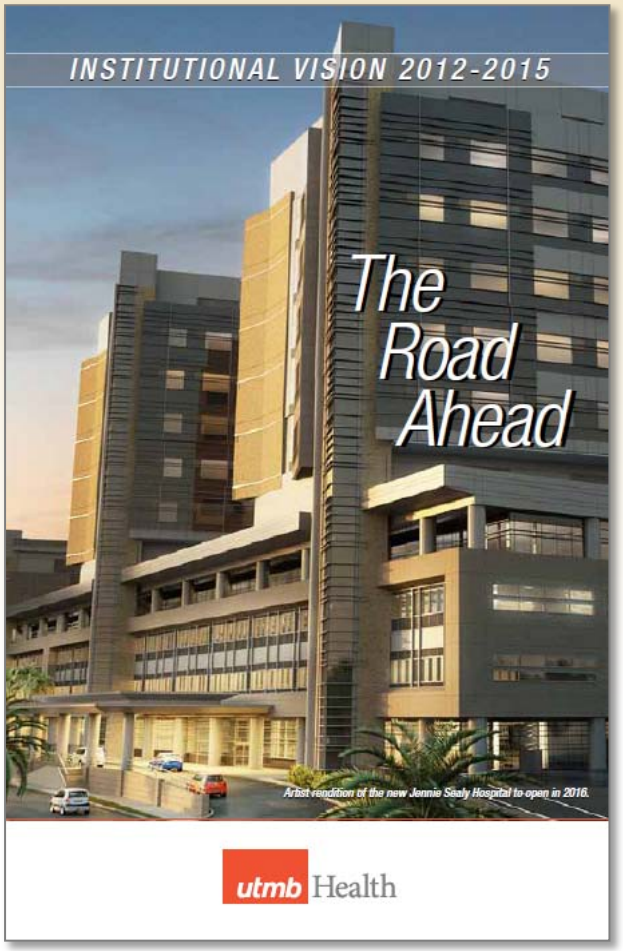
News of the Day

- Correctional care contract negotiations ongoing
- Indigent care making national and local headlines; UTMB will continue managing its charity care dollars ($130.9 million) to provide greatest benefit to most people
- UTMB named sole provider of telemedicine services for three U.S. Antarctic Program stations for five or more years

News of the Day (continued)

- UTMB's Integrated Medical Curriculum receives Texas Higher Education Star Award
- Three UTMB departments ranked in NIH top 10; 10 faculty in top 50; UTMB ranked 53rd among nation's medical schools
- UTMB participating in Brookings Institution collaboration to provide innovative, practical recommendations on U.S. health care

Our Strategic Plan



- A 3-year institutional plan
- Tied to mission-area planning
- Primary focus areas
  - People
  - Quality
  - Education
  - Research
  - Health System
  - Strategic Management & Growth
  - Financial Success
  - Community

Construction Update

- John Sealy modernization ongoing
- Children's "hospital within a hospital" to open in February
- L&D ribbon cutting set for Feb. 15
- Primary Care Pavilion to open in March
- Clinical Services Wing work to begin April
- Park-and-ride from Victory Lakes to start end of February

Update on Research

Scott C. Weaver, PhD

Director, Institute for Human Infections and Immunity

Scientific Director, Galveston National Laboratory

Dual Use Biodefense Research

"How do you balance the universal mandate for scientific openness against the fear that terrorists or rogue states might follow the researchers' work -- using it as catastrophic cookbooks for global influenza contagion?"

- Laurie Garrett, *Foreign Policy*

H5N1 Influenza Research Controversy

Consults

Experts on the Front Lines of Medicine

January 2, 2012, 4:28 PM

A Public Policy Expert Looks at the Bird Flu Threat

By LAURIE GARRETT

Laurie Garrett

Responding to experiments in the Netherlands and the United States in which scientists created a highly transmissible form of the potentially deadly H5N1 bird flu virus, the National Science Advisory Board for Biosecurity urged scientific journals not to publish details of the work out of fear that the information could be used by terrorists. Laurie Garrett, senior fellow for global health at the Council on Foreign Relations and a recipient of a 1996 Pulitzer Prize for her coverage of an Ebola epidemic, responds to questions about the public policy implications of bird flu and bioterrorism. Her latest book, "I Heard the Sirens Scream," offers a detailed account of the 2001 anthrax attacks and the bioterrorism policy actions that resulted.

The Washington Post

A flu virus risk worth taking

By Anthony S. Fauci, Gary J. Nabel and Francis S. Collins

1-1-12

Sciencexpress — Letter

Pause on Avian Flu Transmission Research

Ron A. M. Fouchier,[1]* Adolfo García-Sastre,[2] Yoshihiro Kawaoka,[3] Wendy S. Barclay,[4] Nicole M. Bouvier,[5] Ian H. Brown,[6] Ilaria Capua,[7] Hualan Chen,[8] Richard W. Compans,[9] Robert B. Couch,[10] Nancy J. Cox,[11] Peter C. Doherty,[12] Ruben O. Donis,[13] Heinz Feldmann,[14] Yi Guan,[15] Jaqueline Katz,[16] H. D. Klenk,[17] Gary Kobinger,[18] Jinhua Liu,[19] Xiufan Liu,[20] Anice Lowen,[21] Thomas C. Mettenleiter,[22] Albert D. M. E. Osterhaus,[23] Peter Palese,[24] J. S. Malik Peiris,[25] Daniel R. Perez,[26] Jürgen A. Richt,[27] Stacey Schultz-Cherry,[28] John Steel,[29] Kanta Subbarao,[30] David E. Swayne,[31] Toru Takimoto,[32] Masato Tashiro,[33] Jeffery K. Taubenberger,[34] Paul G. Thomas,[35] Ralph A. Tripp,[36] Terrence M. Tumpey,[37] Richard J. Webby ,[38] Robert G. Webster[39]

News & Opinion

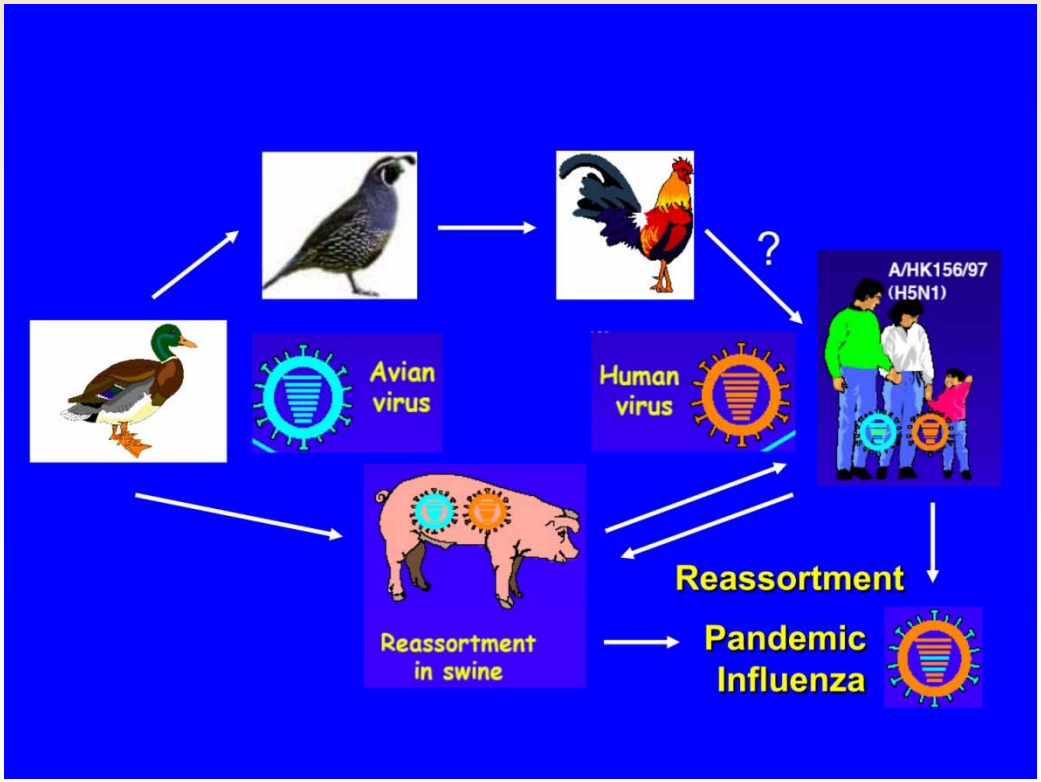
A Call to Stop H5N1 Research

Three dozen researchers have signed a letter promising to halt dangerous bird flu research for 2 months to initiate safety discussions.

By Sabrina Richards | January 23, 2012

Emergence of New Influenza Virus Strains

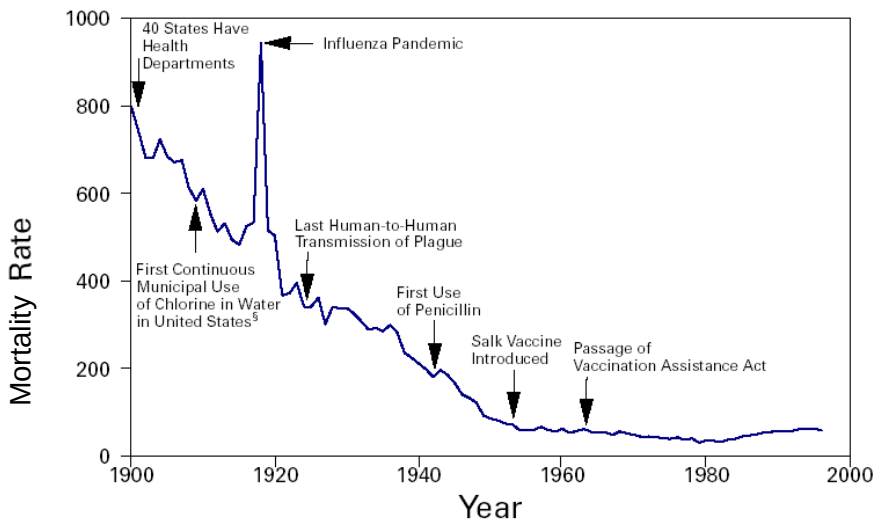
- **Antigenic drift**: The same virus strains change slightly each year through mutations that help them to escape immunity in people exposed previously to the same serotype.
- **Antigenic shift**: Two different influenza virus serotypes infect the same host (bird, pig, human etc.) and shuffle their gene segments to produce a novel combination to which most people have no immunity.



Influenza (Flu) Virus: History of and Risk for Catastrophic Pandemics

- Normal “seasonal” flu kills about 3,000-49,000 Americans annually, 90% of them are >65 years of age; overall mortality rate is <0.01%. Vaccination is usually effective.
- H1N1 “swine” flu had a slightly lower mortality rate than typical “seasonal flu.” It spread widely because it was a new variant with limited human immunity.
- Two particularly virulent flu strains have emerged during the last century:
  - 1918 “**Spanish Flu**” with 2-3% mortality distributed in all age groups; killed an estimated 50 million persons.
  - H5N1 “**Bird Flu**” arose in 1997 in Asian birds with **>50% human mortality** distributed in all age groups; **fortunately there has been no widespread human-to-human transmission.**

Infectious Disease Mortality, U.S.



➔There is a major concern for the potential for avian H5N1 to mutate or reassort into a form that can spread easily among humans through coughing or sneezing.

Recent, Controversial Flu Experiments

- Two groups of scientists reported orally the creation of mutant H5N1 bird flu strains that can be transmitted between ferrets merely breathing the same air, possibly an indicator that the virus could also spread easily among humans.
- Experiments were conducted in biosafety level 3 enhanced (BSL-3E) labs.
- This work raises the concern that an H5N1 influenza strain could emerge that combines the human transmissibility of seasonal flu with the high mortality of bird flu.
- A debate has arisen as to whether this research should be published, especially the methods and exact mutations that made the bird flu strains more transmissible, and whether BSL-3E is adequate containment for these strains.
- The U.S. National Science Advisory Board recommended that the conclusions should be published, but not the details that could enable replication of the experiments by those who would seek to do harm.
- Discussions are underway to find ways to limit the availability of the details to individuals with a demonstrated, legitimate scientific need.
- A 60 day moratorium on similar experiments was recently agreed upon by most major flu researchers.

Recent UTMB Research on H5N1 Flu

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Superior efficacy of a recombinant flagellin:H5N1 HA globular head vaccine is determined by the placement of the globular head within flagellin

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ABSTRACT

Transmission of highly pathogenic avian influenza (HPAI) between birds and humans is an ongoing threat that holds potential for the emergence of a pandemic influenza strain. A major barrier to an effective vaccine against avian influenza has been the generally poor immunopotency of many of the HPAI strains coupled with the manufacturing constraints employing conventional methodologies. Fusion of flagellin, a toll-like receptor-5 ligand, to vaccine antigens has been shown to enhance the immune response to the fused antigen in preclinical studies. Here, we have evaluated the immunogenicity and efficacy of a panel of flagellin-based hemagglutinin (HA) globular head fusion vaccines in inbred mice. The HA globular head of these vaccines is derived from the A/Vietnam/1203/04 (VN04; H5N1) HA molecule. We find that replacement of domain D3 of flagellin with the VN04 HA globular head creates a highly effective vaccine that elicits protective HAI titers which protect mice against disease and death in a lethal challenge model.

Flu research, like all other infectious disease research at UTMB, must be approved by the Institutional Biosafety Committee composed of UTMB scientists, environmental health and safety specialists, and community representatives.

CDC Select Agent Inspection January 9-20, 2012

All BSL-2 and BSL-3 laboratories that work with select agents were inspected, with reviews of:

- Inventories of virus and bacterial samples and strains
- All training and access records
- Security and biosafety protocols and systems
- Knowledge and training of personnel
- Facilities operations and maintenance

Overall, excellent outcome with no major deficiencies identified.

GNL Update

James W. LeDuc, PhD

Director

Galveston National Laboratory

Topics in Biosecurity Symposium #4

- **Session 4:**

November 7, 2011

Special guests:
Dr. Dale Klein, Assoc. Vice Chancellor for Research, UT System

Stewart Simonson, General Counsel, Futures Group. He was the first appointee to HHS assistant secretary for public health emergency preparedness.

Topics in Biosecurity Symposium #5

- **Session 5:**

December 2, 2011

Special guest:
George W. Korch Jr., PhD

Sr. Science Advisor to the Asst. Secretary for Preparedness and Response, U.S. Department of Health & Human Services

Co-Chair, Federal Experts Security Advisory Panel (FESAP)

An International Perspective

- Biological Weapons Convention Meeting

  Geneva, Switzerland
  December 2011

- NAS Report "*Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories*"