# Report:

# CDC Board of Scientific Counselors,
# Office of Infectious Diseases
# January 23, 2017 Meeting
# May 3-4, 2017 Meeting

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Nov 1-2, 2017

CLIAC Meeting

# BSC/OID Meeting [Jan 23, 2017] Included Reports:

- Food Safety Modernization Act Surveillance Working Group
  - Report from  Dec 2016 Meeting

- External Review of  CDC's Advanced Molecular Detection Program
  - Report from Dec 2016 Meeting

# BSC/OID Meeting [May 3-4, 2017] Included Reports:

- Food Safety Modernization Act Surveillance Working Group
- Report on ID Laboratory Working Group
- National Center for Immunization and Respiratory Disease
- Division of HIV/STD/TB HIV/STI
- Center for Emerging and Zoonotic Infections
  - Vectorborne Diseases
- Remarks from CDC Acting Director

# Food Safety Modernization Act (FSMA) Surveillance Working Group Dec 5-6, 2016 Meeting Updates

Harry Chen, MD, Chair

FSMA Surveillance working group mandated Nov 2011, charge provide advice & recs to CDC, FDA & HHS on: 1) Improvements of FB illness surveillance, 2) Develop & submit annual report to HHS secretary

- Dec 2016 Meeting Topics:
  - CIDT Influence on Foodborne Illness detection , OB Surveillance & Response
  - Progress with the Interagency Food Safety Analytics Collaboration (IFSAC)
  - Genomic Testing (ie WSG) potential impact on foodborne OB investigation & response

# FSMA-Working Surveillance Group
# Culture Independent Diagnostic Tests (CIDTs)

- Monitor CIDTs to help move towards development of a new consensus on the a “gold standard for enteric disease testing”

- Plan for maintaining culture based testing
  - Culture will always be needed to monitor the emergence of new and emerging threats as well as to detect AR genes and patterns of resistance

- Work to better understand how surveillance and OB investigations should be modified for CIDT
  - Better understand the impact of CIDTs on foodborne disease estimates and trends

# Interagency Food Safety Analytics Collaboration (IFSAC): A Collaboration among CDC, FDA & USDA

Goals 2017-2121 Strategic Plan:

- Goal 1: Improve the use and quality of new and existing data sources to conduct analyses and develop estimates of foodborne source attribution
- Goal 2: Improve analytic methods and models
- Goal 3: Enhance the use and communication about IFSAC products

IFSAC Projects:

- Template for annual tri-agency attribution update and dissemination
- Norovirus in shellfish using IFSAC attribution fraction methodology
- Evaluation of dataset utility for identifying food contamination points
- Analysis of Campylobacter attribution
- Estimation of complex (multi-ingredient) food attribution
- Evaluation of temporal trends in food categories implicated in outbreaks
- Update of *Salmonella* enteritis attributable fractions

# Whole Genome Sequencing (WGS)

- Improvements over PFGE
- PulseNet transitioning from PFGE to WGS
- PFGE will gradually be phased out starting in 2018
- WGS Capacity: expanding across PulseNet Laboratories
- Costs associated with Licenses of analysis software [$250K/100 annual license] & Bioinformatician in each PulseNet Lab [$8.4M annually to staff across PulseNet Labs]
- Improved Metrics
  - Listeria used as model
- WGS is routine part of FDA OB response & compliance/surveillance activates

# Whole Genome Sequencing (WGS)

- Improve coordination between agencies
- Planning for resources required to implement and respond to WGS data
  - Including investigating a large number of OBs
- Improved monitoring, including new metrics
  - Assess WGS impact on food industry and disease prevention

# Annual Report: 2016 Key Topics

- Engage industry
- Reviewing IFSAC
- Enhancing foodborne trace back investigations
- Improving integrated food safety centers of excellence
- Expanding foodborne antimicrobial resistance surveillance

# Report from Food Safety Modernization Working Group
## Update May 3-4, 2017

- **FoodNet:** ( 10 state HD, USDA-FSIS & FDA). Active Surveillance Network
- **Changes to FoodNET since 2009**: Addition of routine surveillance for positive culture -independent (CIDT) reports. Routine collection of exposure data (CEA).
  - **Special Studies**: STEC non O:157 surveillance.
- **CIDTs complicate data gathering and trending.**
  - More ordering – sooner results = more testing.
  - Increased sensitivity.
  - More pathogens reported.
  - More co-detection.
  - Decrease in culture-confirmed cases.
  - These changes make it challenging to determine the burden of disease & impact surveillance.
- **Amount of change due to CIDTs needs to be assessed.** Update incidence rates to allow for CIDT effect to determine appropriate goals.
- **New Tool: FoodNet Fast:** Interactive tool to display data on graphs, maps, and tables for select pathogens transmitted commonly through food.
  - Custom searches and download data from FoodNet, which covers about 15% of the United States population.
  - www.cdc.gov/foodnetfast
- **National OB reporting Systems**

# Report from Food Safety Modernization Working Group
## Update May 3-4, 2017

- **Themes for FY18**
  - Periodic foodborne Surveillance System Reviews
  - Enhancing data integration between agencies with updates
  - Addressing Challenges with imported food
  - Addressing orphan illnesses
  - Measuring the impact of FSMA
  - Addressing food allergy & anaphylaxis
  - Improving root cause identification and analyses
  - Building state capacity and associated performance measures.

# AMD Program – External Review, Dec 2016
# Gregory L. Armstrong, MD, Director Office of AMD

- $30M/yr program est FY2014 [now yr 4]

- Technology program focused on:
  - Bringing NGS & bioinformatics to bear against PH threats in the US
  - Facilitating adoption of other, related technologies into PH

- Working off initial yr 5 strategic plan

- Starting to plan for yr 6 & beyond

# AMD External Review

- Objectives
  - Review AMD progress yrs 1-3
  - Propose adjustments to plans yrs 4-5
  - Review & comment on tentative priorities yr 6 & beyond
- Areas of Focus
  - General:
    - Amplifying impact of program, evaluate vulnerabilities & gaps promoting partnerships
  - Specific:
    - Priorities, translation of AMD progress into PH, workforce development, building capacity in state & local PH depts
- Recommendations & Plans

# AMD External Review: Recommendations & Plans

- Leadership
  - Succession planning, steering committee with lab & epi leadership at CDC, enlist outside expertise
  - Options to expand AMD office, engaging ASLS, ADES & IDLWG
- Priorities
  - Spending on projects with PH impact to leverage strengths of CDC & state PH, improve evaluation of programs, define impact
  - Update process by which AMD projects are selected & funded to improve alignment with PH priorities.
- Translation of PH impact
  - AMD capacity coming online, need to engage epidemiologists, integrate genomic and epi data, improve tools to analyze and visualize data, coordinate applications used by state & local PH
  - Epi training & engagement, funding one integration project, collaborations , wet-lab & analysis options (3 options)

# AMD External Review: Recommendations & Plans

- Workforce development
  - Promote collaboration with academia, expand training [APHL, CSTE, EIS & LLS fellowships]
  - Continued collaboration with Georgia Tech, expanded epi training, regional bioinformatics resources,  APHL & CSTE meeting sessions, LLS & EIS to include AMD training
- Capacity in State/local PH
  - Earlier engagement , Promote innovation to states, develop higher level of capacity in regional labs, expand bioinformatics fellow placement into state labs, expand AMD day
  - Reengage with EIP, CARB program to pilot higher level of sequencing in one lab, AMD day to expand to 2 days & increase funding for more state participation
- Other
  - IT infrastructure [including assisting states with IT issues], establish NGS QC standards, surge capacity at CDC, potential for outsourcing of sequencing, bioinformaticians with translational skills

# Report on ID Laboratory Working Group

- **AMD**
  Need resources to keep making progress.
  - Leadership team may be too small and vulnerable to turnover.
  - Need to integrate epidemiology into laboratory component.
  - Synergy with academia and industry.
  - Bioinformatics, and issues with CDC IT policies inhibiting development.
- **CIDT**
  Impact on PH surveillance; Impact on PH laboratories.
- Impact highest when CIDT replace rather than supplement culture-based techniques; currently primarily stool / GI pathogens.
- This is an ongoing and growing issue; what mechanisms to use to address it?
- Mentioned: The larger issue that laboratory (or other…) testing / activities performed for public health purposes are not CMS reimbursable. This makes effective surveillance activities extremely difficult to maintain.

# National Center for Immunization and Respiratory Disease

- Mumps increased from 5833 in all of 2016 to 2570 by week 16 for 2017. CDC provided laboratory support for testing.
- General laboratory capacity-building in global health; packaging and shipping training, laboratory scale-ups during outbreaks (e.g. meningitis in the meningitis belt).
  - International reagent resource to cover respiratory pathogens: 'FTD33 kit' for multiplex RT-PCR assays. Distributed to central laboratories in 11/17 high-risk countries.
- Training and career development; career development pathways needed for laboratory staff to correspond with epidemiology pathway at CDC.
  - Need ideas for this.

# H7N9 Influenza Focused Discussion

- Risk assessment for new influenza viruses; 10-factor Influenza Risk Assessment Tool (IRAT).
- H7N9 is the highest scoring virus now; highest since 2013. IRAT 6.5ish, severity 7.0.
- Mostly occurring in coastal China; but expanding range now. Competent for some wild bird species; potential for global spread. Producing vaccine strains for stockpiling.
- **Also providing emerging strains to diagnostics companies for (yearly) recertification and for prospective assessment of diagnostics.**
- **Is there a regulatory pathway for adding an emerging virus to a multipathogen respiratory panel under EUA?. Per FDA rep to OID, the answer is yes; EUA is a flexible pathway and adding an EUA to an approved panel is a possible thing.**

# Division of HIV/STD/TB
# HIV/STI

- **Highest levels ever** of STD; NG, CT, Syphilis.
  - Concentrated in young gay and bisexual men.
  - Syphilis rates continue to increase, up 19% 2014-15; also ↑50% in congenital syphilis.
- CDC 'Call to Action' on syphilis incl:
  - new lab guidelines
  - new diagnostic technologies
  - specimen repository.

# Division of HIV/STD/TB
# TB

- Current data:  2016 lowest # of cases ever, 9287; but is the graph leveling off again?  Elimination threshold is 1/million; our current rate in 3/100K.
- Importance of LTBI.  Estimated that 86% of US active TB is reactivation of LTBI. **Modeling suggests that better detection / treatment of LTBI has biggest impact of all plausible interventions.**
- Advantages of IGRAs in key populations.  BCG-immunized; no need for 2nd visit.
- Recent USPHTF recommendation for routine testing of adults at risk for LTBI.
- **NHANES survey in 2011-12 tested by TST/IGRA.  TST(+) 4.7%; IGRA (+) 5%; both positive 2.1% (!).  Prevalence estimate between 3.7 and 8.2 million patients nationwide with LTBI.**
- **For both TB and GC/CT, small number of cases is a barrier to economic development of CLIA-waived molecular tests.**

# Update from Center for Emerging and Zoonotic Infections

- **Foodborne Diseases: Campylobacter down, STEC, Yersinia, Cryptosporidium up. STEC and Yersinia detected particularly by CIDT.**
- **Cipro-resistant Shigella: test as S per CLSI, but no clinical response. Resistance sometimes plasmid-based (!). Plasmid-enhanced rate of chromosomal mutations in gyrA.**
- C. auris: Highly transmissible person-to-person in HCF; highly drug-resistant; urgent CDC alert to facilities to look for it. So far 93 organisms , 61 cases, 32 colonized. **Not well-identified by current biochemical or MALDI databases.**
- CDC Call for Innovative Proposals to Combat AR
  **New diagnostics**
  International transmission interventions
  Domestic transmission interventions
  Microbiome disruption
  AR pathogens in water & environment
  Med safety and Abx Stewardship
- **CDC AR Isolate Bank for diagnostics / drug developers**, researchers, public health. CDC AR Map.
- **Advanced Molecular Detection**
  Convert PulseNet from PFGE to WGS in 86 labs by end of 2018; HIV TRACE software for states
  Plan to use NGS to adopt to CIDT; and to provide much deeper information about pathogens.
  Use in other areas, TB, STI, Legionella, Influenza, etc…
- Workforce development for microbiologists and epidemiologists re advanced molecular diagnostics.
  Bioinformatics and bioinformatician support.

# Vectorborne Diseases

- Beyond Zika….
  - Arboviral disease branch Colorado, Bacterial Colorado, Dengue in Puerto Rico, Rickettsial Zoonoses Georgia.  Handles more distinct pathogens than any other division.
- **Trends**
  - **Accelerating emergence of mosquito-borne diseases in Western hemisphere Increasing number of tick-borne dzs in US; increasing incidence / range Decreasing resilience to deal with above.**
  - **YF and Dengue introduced to West Hemisphere with slave-trade; then no new introductions until 20$^{th}$ century, WNV; then CHIKV, then Zika =>  a trend!!!!**
- **Inadequate diagnostics; needed to detect outbreaks earlier and manage them better.**

# Remarks from CDC Acting Director

- **Opioid epidemic a current priority; implications for BBP.**
- **Budget:  2017 in place, 2018 is to be intensely debated, partners are vital to that issue.**
- CDC as a defense agency.  Public health as investment rather than as expense.  ROI for public health efforts.
- **Antimicrobial resistance a priority**

# Thank You

Questions?

# General Query and Issues

- What's the pathway for communications and advice between CLIAC and the BSC-OID?

- OID budget has been stable through FY 2017; query was made how to support CDC in the budget process.