



Minutes from the January 13, 2015

CDC Advisory Committee to the Director

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Advisory Committee to the Director Record of the January 13, 2015 Meeting

The Centers for Disease Control and Prevention (CDC) convened a meeting of its Advisory Committee to the Director (ACD) on January 13, 2015 via teleconference. The agenda included an update on the Ebola response; a presentation of proposed actions by the External Laboratory Safety Workgroup (ELSW), which the ACD approved; a presentation of proposed actions by the Public Health – Healthcare Collaboration (PHHCC) Workgroup, which the ACD approved; and a presentation of proposed actions by the State, Tribal, Local and Territorial (STLT) Subcommittee, which the ACD approved.

Welcome and Introductions

ACD Chair, Dr. Alan Greenberg, called the CDC ACD meeting to order at 11:00 am. He welcomed everyone and thanked Gayle Hickman for expertly coordinating the meeting. Ms. Hickman called the roll and determined that there was a quorum of ACD members. The following ACD members disclosed conflicts of interest:

- Dr. Alan Greenberg: The Department of Epidemiology and Biostatistics of George Washington University School of Public Health and Health Services receives indirect CDC funding through the District of Columbia (DC) Department of Health and the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF).
- Dr. Georges Benjamin: The American Public Health Association (APHA) receives a cooperative agreement and some small grants from CDC.
- Dr. Jewel Mullen: Connecticut Department of Public Health (CT DPH) and the Association of State and Territorial Health Officials (ASTHO) receive a number of grants from CDC.
- Dr. Nisha Botchwey receives CDC funds through her institution.

Director's Update

Dr. Thomas R. Frieden (Director, CDC) wished the group a Happy New Year and expressed his appreciation for their participation. He recognized that 2014 was busy, exciting, and stressful, but was ultimately rewarding. He said he thought the bottom line was that in 2015, CDC was poised for even more progress. He then offered an update on laboratory safety, the Ebola response, and other agency efforts.

CDC is very committed to improving laboratory safety at the agency. A lot has been done since the events of the spring and summer. An Associate Director for Laboratory Safety and Science (ADLSS) position was created and announced in November, for which recruitment is underway. The selected candidate will report directly to Dr. Frieden. That will provide a single point for coordination, oversight, and standardization throughout the agency. Dr. Rima Khabbaz has been leading the search process. In the meantime, Dr. Leslie Dauphin is leading the effort to form this new office.

Careful consideration is also being given to laboratory safety training. The Laboratory Leadership Service (LLS) is being created, which is anticipated to be analogous to the Epidemic Intelligence Service (EIS) and will combine core competency-based training focusing on the dual areas of safety and laboratory management. Dr. Frieden wants this to help CDC become a



national and global model for excellence in these areas. Consideration is also being given to training more broadly, including ways to establish a hands-on Biosafety Level (BSL)-3 training facility. While the agency does not currently have funding for a training facility, this is a goal.

Formal risk assessments have been completed of all of the 150+ laboratories at CDC, 54 of which work with select agents. All of those went through a moratorium on transfer until safety could be ensured. Unfortunately, there was a possible exposure incident in CDC's Ebola laboratory on December 22, 2014. That was recognized on December 23rd and was reported immediately. The investigation is underway. The one laboratory worker who may have been exposed was closely monitored for 21 days and did not develop Ebola. There was no possible exposure outside of the laboratory, and no exposure risk to other locations within CDC or to the public. However, this is a reminder that it is important to be vigilant and continue to focus efforts on safety.

In 2015, an external audit and certification process will be established using International Organization for Standardization (ISO) standards. Already, every laboratory that performs clinical testing undergoes external audit certification through the Clinical Laboratory Improvement Amendments (CLIA) process. Beginning this year, all other laboratories will be audited periodically by an external accreditation organization. Dr. Frieden thanked the new members of the ACD, Drs. Kanabrocki and Berns and their colleagues on the ELSW, who have done so much to give CDC good advice. He recognized that the ELSW, which is now associated with the ACD, is comprised of a superb set of people with highly complementary skills. CDC takes their recommended actions very seriously.

Regarding Ebola, Dr. Frieden recently returned from West Africa and completed his 21 days of monitoring. He wanted to see CDC's efforts first-hand. This is the largest global response in recent history. At the time of this meeting, CDC had over 200 people in West Africa engaged in the response. Thousands of people at CDC have worked on the response, and approximately 900 CDC staff have been in West Africa at one point or another. Thousands more are working overtime, nights, and weekends at CDC to keep the rest of the agency moving forward. There was a striking difference between Dr. Frieden's visit in August and September and his visit in late December. There has been significant progress in many areas, but there is still enormous heterogeneity between and within countries in terms of progress. There is also tremendous fragility because even a slight lapse in attention can result in a large cluster.

One of the efforts by CDC staff that has greatly impressed Dr. Frieden is the Rapid Isolation and Treatment of Ebola (RITE) strategy. They have determined that the quicker they can respond when there is a single case, suspected case, or cluster, the quicker Ebola can be stopped. They have conducted about 15 hotspot investigations. In almost all of these responses, they were able to stop the outbreak in two generations of spread. Some outbreaks were stopped within one generation of spread. Over the weekend, Dr. Frieden was speaking with CDC's team in West Africa. They have been honing their ability to engage in rapid response. They had a rumor of a case and within two hours, they were packed and ready to go. While that case was ruled out and they were able to stand down, the speed of the response has been the most important determining factor to success.



However, there are still tremendous problems. While in West Africa, Dr. Frieden met parents whose child had died, families who were reeling from the impact of Ebola, and survivors who are struggling to put their lives back together. A lot more needs to be done to move forward. Each of the three countries has different challenges. There has been remarkable progress in Liberia, which is now down to roughly one case per day compared to September and October when there were so many cases they could not even be counted. Liberia has shifted from the need to focus on the most basic issues such as safe burial and getting people into treatment units, to a current focus on identifying additional chains of transmission, preventing resurgence, searching for missing cases elsewhere in the country, and monitoring for imported cases from other countries.

Guinea provides a cautionary note for Liberia because there has been some complacency. Dr. Frieden met a nurse who six months into the epidemic inserted an intravenous line for a patient who had nausea and vomiting and contracted Ebola. She survived, but is now dealing with the stigma of survivors. He also observed very impressive efforts in Guinea. The call center there is as good as any he has seen throughout the world. It was stood up with funding from the CDC Foundation in about two weeks. They interviewed about 1000 people, hired 92 of them, put in an information system, leased an office, and got telephone lines working. They went from a hotline that was literally three people's personal cell phones to a hotline that handles 10,000 calls a day with a five-second wait on average and warm hand-offs of 150 calls per day, and is a key aspect of the response.

There also has been major progress in the forest area of Guinea. Dr. Frieden was in Macenta, where there was an Ebola epicenter. The French Red Cross set up an excellent treatment unit in Macenta, which had seven patients during Dr. Frieden's visit and is now empty. That type of service has led to an ambitious plan to reach zero cases in 60 days. They are at risk because there are still areas of resistance throughout the county, so 60 days may be overly ambitious. However, there has been a major change.

One of the game-changers in all three countries is the African Union, which has sent over 500 people. Roughly 100 of those individuals were trained in epidemiology by CDC. Dr. Frieden traveled to Liberia with one of them, a two-year field epidemiology training program graduate. One of the gaps is a lack of French-speaking public health experts in Guinea. CDC has turned to state and local health departments throughout the US and other partners to try to find people who can go to Guinea for three to six months.

Sierra Leone still has by far the most cases, but CDC is guardedly optimistic that if they continue with their response, they will achieve the kinds of reductions accomplished in Liberia. Nevertheless, Sierra Leone still has a long way to go. CDC has heard from the team that the major reductions in Liberia were very encouraging to the folks in Guinea, because they realized that they truly can make more progress.

Disease reduction is just one of many of CDC's efforts in the area of Ebola. In addition to implementation of current technology, the agency is also working on new diagnostics and a vaccine trial in Sierra Leone. Due to wonderful support from Congress with substantial resources, CDC can now put in systems that can better detect, respond to, and help prevent health threats. The emergency funding that was allocated to CDC and other parts of the United States (US) government was a game-changer that allows them to move forward with getting to



zero, staying at zero, and preventing future outbreaks in many parts of the world. Many parts of CDC worked long and hard to develop and prove the global health security concept in principle, which led to the commitment of Congress and the advocacy of the President. This recognizes CDC's ability to deliver on its commitments, and will be a major area for implementation in the future.

Of course, CDC is working on many other efforts in addition to laboratory safety and Ebola. The agency has had an increase in resources to address prescription opiate overdose. The agency has had very successful programs in tobacco control, is more broadly assessing issues pertaining to healthcare-associated infection (HAI) and antimicrobial resistance, and is considering opportunities for improvement of health in the US through the Million Hearts® program. Recruitment is underway for the Public Health Associate Program (PHAP) program. There will be 200 recruits this year and an additional 200 in 2016. The application process was opened for just one week because thousands of applications are submitted. The goal is to ensure that there is a broad and diverse range of interests in PHAP, which is an exciting program. PHAP is one of the several ways Dr. Frieden has tried to ensure that CDC's approach is as pragmatic as possible and is helping state and local health departments to become more effective in what they do. PHAP is a two-year service learning program through which the next generation of public health leaders is being trained. Many of these individuals have worked on the Ebola response and have been a tremendous asset. Dr. Frieden concluded that he is excited about what more CDC can accomplish in 2015.

Discussion Points

Recognizing that CDC has taken some very unfair hits publically even though the agency has done an excellent job, Dr. Farley inquired as to how ACD can be helpful to the agency in its overall Ebola response and laboratory safety issues.

Dr. Frieden responded that it is always helpful when people from outside of CDC speak up about CDC. When the agency says something about itself, it is considered self-interest. Advice is also beneficial. He was on the ACD when he was Health Commissioner in New York City. When he became CDC's Director, he suggested including people on the ACD from whom the agency wants advice. The agency truly wants ACD's advice on what it can be doing better or differently to be even more effective. In addition, it would be helpful for the members to let CDC know of anyone who speaks French and would like to go to Guinea for three to six months. He emphasized how much the agency appreciates the ACD help and support. He also recognized that meeting by teleconference was a pale reflection of an in-person meeting, but that it is better than no meeting. He stressed the importance of using this teleconference time to engage in as much open interchange, questions, and suggestions as possible.

Dr. Goldman thanked Ms. Villar and Dr. Frieden for having brought the nation through a period of near hysteria about the Ebola virus, and what she felt as a threat to herself as a Dean for her faculty to be able to go to West Africa to work for a while in the midst of the hysteria on her campus and among the trustees. It is fabulous that CDC successfully navigated a way for public health organizations and non-governmental organizations (NGOs) to go to West Africa to help in the response.

Dr. Bal agreed, emphasizing that the bad press CDC received was exceedingly unfair and that he was livid about this. Nevertheless, CDC moved forward efficiently and made great progress.



While pointing out that Dr. Frieden is likely to get his reward only in Heaven, Dr. Bal congratulated him on the tremendous job he did despite the hysteria and grandstanding.

Dr. Frieden emphasized that CDC's staff members have been phenomenal. The agency has the world's experts and the most dedicated people possible in terms of their commitment. Staff members have taken canoes through crocodile-infested waters to take laboratory specimens for outbreak investigations, camped in remote areas to deal with the response, and worked without a break for months on end. They do it because it is their work mission. It is hard sometimes to get their stories told as effectively as CDC wishes they could. The agency's communication staff does a great job, but these are "good news" stories that are not that interesting sometimes to others. For a random example, when Freetown had an explosion of cases, CDC had already been performing the laboratory testing for most of Sierra Leone and were told not to worry about Freetown because others would do it. However, when it became clear that this was not the case, the CDC Foundation provided a piece of equipment that was able to turn a routine laboratory into a high-throughput laboratory. CDC worked with the South African government and had this up and running within a week so that they could test 200 specimens a day versus 30. That was effective during the surge in Freetown. The CDC staff's willingness to do whatever it takes to stop the outbreak has been very inspiring, but it has also been very challenging. Ebola has moved so quickly in terms of the increases in cases and the change in the epidemiology, it has been a major challenge to the agency's system to make the impact that now appears to be occurring.

Dr. Greenberg thought the combination of the "steady-at-the-helm" response when the media frenzy was occurring and the magnitude of the response were remarkable. It reminded him of Dr. Satcher's words when he was Director, "Dedicated public health professionals quietly going about their work." Dr. Greenberg believes that at the end of the day, CDC will be judged on the effectiveness of its response and he emphasized the strong leadership that Dr. Frieden has shown in making sure that happens.

Dr. Lyon Daniel, CDC's Associate Director for Communication, expressed the agency's great appreciation of external third parties who help to validate the agency's efforts as well as the response and responders. There are opportunities for ACD members to use their voices and positions to be those third party validators. People read the comments at the bottom of news articles online, and many ACD members are interviewed in the media. She offered additional CDC information to anyone who may need it as background when making public statements.

External Laboratory Safety Workgroup Update

Dr. Joseph Kanabrocki, ELSW Chair, thanked Dr. Frieden, the CDC leadership, and members of the ACD for providing the ELSW the opportunity to report its observations and proposed actions concerning CDC laboratory safety programs. In particular, he expressed the ELSW's gratitude to Dr. Michael Bell, Dr. Leslie Dauphin, Elaine Baker, Sarah Wiley, and the many members of the scientific and administrative staff with whom the workgroup has had the pleasure to work. All of the staff with whom they have met have high regard for the agency and are truly proud of their affiliation with CDC. He also expressed appreciation to Gayle Hickman for her handling of administrative matters.



Speaking personally, Dr. Kanabrocki said he was very humbled by the opportunity to be appointed to the ACD for this very important work in terms of the CDC laboratory safety program review. He has been a member of the biosafety community for more than 20 years and can say with absolute confidence that the biosafety community looks to the CDC for leadership in the realm of biosafety. As many of the CDC employees do, the biosafety community holds the CDC in the highest regard. Everyone has the Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual on their desks and ready at their fingertips. The ELSW believes that it is critical for CDC to get this right, that the credibility of the agency is at stake, and that public confidence in the broader biosafety and life sciences community is at risk. In fact, this threatens most infectious disease scientists whose work is critical for the health of that same public whose support is also critical. The ELSW believes that CDC should become the state-of-the-art in laboratory safety and should be setting the standards for the rest of the world to follow. A comprehensive biorisk management program needs to be installed.

As the ELSW discussed its observations and formulated its proposed actions, an attempt was made to place them in an order of priority and rank them in terms of importance. However, that task proved to be difficult, if not impossible because all of these proposed actions are interdependent and each relies on the others for success. He asked everyone to keep this in mind as he presented the proposed actions.

Dr. Ken Berns, ELSW Co-Chair, echoed all of Dr. Kanabrocki's laudatory comments. He thought their interactions with everyone at CDC were incredibly positive. This is somewhat of a strange situation for him because he is primarily a laboratory research scientist with some administration layered on top of that, so he felt that he was probably viewing this from a slightly different angle than others. Interestingly, he was the Chair of the external advisory group when the first edition of the BMBL was published years ago and feels that he has come "full circle." Personally, he considers CDC to be as essential to national security as he does the Pentagon and believes that the agency should be held in the highest regard by the public.

Dr. Kanabrocki reviewed the ELSW's charge, which is to:

- Review and provide input into corrective actions for CDC's laboratories
- Prioritize implementation of additional safeguards across all CDC laboratories
- Identify potential weaknesses and necessary safeguards based on experiences of non-CDC laboratories
- Identify training and oversight needs to promote and sustain a culture of laboratory safety at CDC
- Identify ways to provide stronger safeguards for laboratories across the US
- Examine HHS laboratory protocols and report to the HHS Secretary through the ACD on whether current biosafety and biosecurity rules, processes, and procedures are appropriate; and whether implementation or execution of the current protocols is adequate
- Make suggestions for improving these protocols or their implementation

The ELSW is comprised of an outstanding group of members, which includes principal investigators (PIs) who have experience working with pathogenic microorganisms, public health officials, and biosafety professionals. This is a great team and all of the members have contributed mightily to this effort.



The ELSW's activities to date include the following:

- July 18, 2014: Invitation from Dr. Frieden to ELSW members
- August 5 and 25, 2014: ELSW conference calls
- August 21, 2014: Request for CDC lab safety-related documents received
- August 25, 2014: *Culture of Lab Safety* Survey distributed to ~1500 CDC Employees and the data from the survey were provided to the ELSW for review
- September 15 – 17, 2014: In-person meeting at CDC, Atlanta, Georgia that included meetings with Dr. Bell, LSIW, CDC staff, and facility tours
- September 26, 2014: Teleconference with National Institutes of Health (NIH) Occupational Health & Safety staff members, Dr. Herbert Jacobi and Dr. Jeffrey Potts
- September 29, 2014: Teleconference
- September 30, 2014: Submission of Timeline to HHS Secretary Burwell
- October 3, 2014: Letter to NIH Director and Food and Drug Administration (FDA) Director
- October 5 & 20, November 9 & 24, and December 7 & 22, 2014: ELSW conference calls
- Oct. 22, 2014: ELSW receives response from Francis Collins, MD, PhD, Director NIH
- November 15, 2014: ELSW final recommendations sent to Dr. Frieden
- December 15, 2014: ELSW conference call with Debbie Wilson, DrPH, CBSP, RADM US Public Health Service, Director, Division of Occupational Health and Safety, Office of Research Services, NIH
- December 16, 2014: ELSW receives executive summary of LSW recommendations

Part of the ELSW's assessment was based on a CDC document review. CDC documentation received by ELSW included incident reporting; laboratory materials catalog; laboratory training programs; safety policies; internal organizations, standing committees, and committee charters; worker vaccination; and select agent instructions. ELSW areas of inquiry included project risk assessments, justification for high risk activities and programs, how compliance with risk mitigation proposed actions are monitored, CDC staff laboratory safety resources, reporting mechanisms, elements of the Personnel Reliability Program, and elements of the occupational health program.

The ELSW's observations and proposed actions are categorized into seven major focus areas, including: Leadership; Governance; Risk Assessments of Proposed Research Activities; Laboratory Safety Training; Incident Reporting; Environment, Safety, and Health Compliance Office (ESHCO) and Occupational Medicine; and Progress Reporting and Laboratory Accreditation. The observations and proposed actions are as follows:

- 1. Leadership Observations:** Leadership commitment toward safety has been inconsistent and insufficient at multiple levels. Safety, including lab safety, is viewed by many as something separate from and outside the primary missions of public health and research. Safety is not integrated into strategic planning and is not currently part of the CDC culture, enterprise-wide. Interviews and surveys demonstrated that many employees neither understand the agency's response to accidents nor how that information is communicated to the larger agency community outside the immediately affected labs. Disturbingly, the negative responses peak among those individuals who work in BSL-3 and BSL-4 laboratories, especially among those holding a Master's Degree. Individual divisions, teams and lab groups have taken it upon themselves to implement safety programs, but this is not



done in a consistent manner, nor is it done across the CDC. A clearly articulated CDC safety mission, vision or direction is lacking.

Proposed Action: Establish a CDC brand and communicate, from the top down, a “CDC Way” that is the performance of responsible science practiced in a consistently safe manner. This should be an expectation, and all persons are accountable. This should be a performance issue, but personal negative consequences should *only* be associated with failure to communicate incidents. As part of this effort, better mechanisms should be established for sharing information about safety incidents across CDC to promote transparency at all levels.

Proposed Action: Funding for laboratory safety programs and laboratory safety training should be established from a central funding source and should be considered a fundamental mission for the CDC. This responsibility should not be outsourced to contract organizations who, ultimately, cannot be held accountable.

Proposed Action: Create a position for a biomedical scientist in the Director’s office to lead this effort, which will also support the lab scientists.

- 2. Governance Observations:** Governance structures do not support maintaining a culture of shared responsibility and accountability across centers, nor the consistency of appropriate safety practices. This is, in part, a result of the organizational complexity of the CDC and the changing mission of the agency, which has evolved over the years. For example, ESHCO, the Institutional Biosafety Committee (IBC) and the Institutional Animal Care and Use Committee (IACUC) are outside the chain of command of centers and divisions.

Proposed Action: Establish governance structures that provide accountability and oversight authority to a central entity for laboratory safety and compliance committees such as the IBC and IACUC.

Proposed Action: Hold the central authority ultimately accountable for performance of responsible laboratory science, laboratory safety and the ESCHO, IBC, and IACUC should sit organizationally at the level of the Office of the Director (OD).

- 3. Risk Assessments Observations:** Risk assessments of proposed research activities are either not being done in a standardized manner or are not being done at all. Currently, the IBC only reviews recombinant deoxyribonucleic acid (rDNA) research.

Proposed Action: Broaden the scope of the IBC to include work with pathogenic microorganisms and biological toxins or establish a centralized, standardized mechanism for consistent and thorough review and risk assessment of proposed research activities.

Proposed Action: Risk assessments should be performed for experimental work being done at CDC. The benefits and risks of proposed experimental work should be documented before the work is undertaken.



- 4. Laboratory Safety Training Observations:** Laboratory safety training is inadequate. The organizational complexity of the CDC has contributed to a fragmented, inconsistent approach to laboratory safety training. The majority of training is now conducted on-line. Training is no longer under the domain of ESHCO. The CDC does not have its own hands-on directly observed centralized safety training program. Lab-specific training and competency observations are conducted at the program level and, therefore, the quality is not consistent. Observational competence occurs at the local lab level; however, except for clinical labs, competency skills mapping and refresher training are not consistent.

Proposed Action: Establish a standardized laboratory safety training curriculum across CDC.

Proposed Action: Establish standardized methods for competency skills mapping and refresher training.

Proposed Action: Establish a fellowship/internship program to train scientists to serve as laboratory safety professionals who serve as liaisons between the labs and ESHCO or other central lab safety entity.

Proposed Action: Responsibilities and facilities for laboratory safety training should be in-house.

- 5. Incident Reporting Observations:** The results of the *Culture of Laboratory Safety* survey indicate that a significant percentage of CDC staff have concerns about experiencing negative repercussions, either personally or more generally to the agency, as a result of reporting incidents involving exposures to pathogenic organisms or other hazardous materials. Some staff members working in select agent laboratories fear regulatory or other negative repercussions as a result of incident reporting. One example of this was the case report of the CDC accident involving highly pathogenic H5N1 that became public in June. Scientists interviewed all along the chain of command in that incident were concerned that there were violations of the Select Agent Rule, but there were no mentions of people being similarly concerned with biosafety. Other interviews with CDC staff also seemed to show a higher level of concern regarding select agent violations than biosafety violations. This finding suggests that at least in some laboratories, biosecurity requirements are being given priority over biosafety.

Proposed Action: Efforts to establish a culture of *responsible science* and *accountability* are of critical importance. This culture of responsible science will require prompt and accurate reporting of incidents or breaches in standard protocol without fear of reprimand or punishment. Not reporting should be considered a breach of responsibility. Reporting is important for facilitating the analysis of incidents and the establishment of corrective actions to mitigate repeat occurrences. Lessons learned from these activities should be shared with the community.

Proposed Action: In this culture of safety response, ensure that scientists operating safe laboratories are recognized for their work. Some CDC scientists feel that they have been doing their work safely and appropriately all along, but they were swept up in corrective or punitive actions that should not have applied to them.



6. **ESHCO and Occupational Medicine Observations:** ESHCO is undervalued. ESHCO is seen by many staff scientists as an office with focus on *compliance* and is seen as an office with inadequate expertise in laboratory safety. For this reason, scientists in some divisions have little or no interaction with ESCHO. A related issue is that resources dedicated to the Occupational Medicine Program appear to be inadequate. It is critical that the Occupational Medicine Program serve to support on-site research programs as well as those abroad and that it become more integral to the health monitoring/reporting/response network associated with laboratory safety.

Proposed Action: Raise the stature of ESCHO in the CDC organization by staffing it with scientists with professional qualifications in research and/or laboratory safety as well as an understanding of requirements for compliance.

Proposed Action: Establish a fellowship/internship program to train scientists to serve as laboratory safety professionals. This training program should involve interns or fellows in the development and management of lab safety programs at the CDC as a central part of their training and professional development.

Proposed Action: Develop a division liaison program, where each division identifies individuals who can represent their needs to a centralized EHSCO committee.

Proposed Action: Expand the scope and capabilities of the Occupational Medicine Program to facilitate a more robust and active effort in monitoring employee health and in responding to laboratory incidents.

7. **Progress Reporting and Laboratory Accreditation Observations:** CDC is an incredibly capable organization and its value in promoting the health of our society cannot be lost. We are very concerned that the CDC is on the way to losing credibility. The CDC must not see itself as “special.” The internal controls and rules that the rest of the world works under also apply to CDC. There is need for a CDC systematic approach characterized by high-level leadership support and intervention. Accountability, personal accountability not only for our own actions but also in the actions of others, is essential. While human error is the fundamental cause of events like those challenging the CDC in recent months, it is also the reason why multiple layers of checks and balances and redundancy of controls must be built into the process of oversight and management system.

Proposed Action: The ELSW strongly encourages the CDC to track and to report on its progress in establishing programmatic elements and processes recommended in this ELSW report in some formal way (perhaps at the 3-month, 6-month, and 12-month marks) or to provide an explanation of why it was decided not to pursue specific proposed actions. This progress does not necessarily need to be reported back to the ELSW. It could be reported back to the new Director of Laboratory Safety and Science once hired, to the internal Laboratory Safety Improvement Workgroup (LSIW), or some other entity though there would be logic in briefing in back to the ELSW.



Proposed Action: The ELSW recommends that CDC laboratories go through an external review and accreditation process for all laboratories. The College of American Pathologists (CAP) could do this for the clinical labs. The CDC should pursue a similar accreditation for research labs, perhaps by commissioning this accreditation through the American Biological Safety Association (ABSA): <http://www.absa.org/aiachclap.html>

In terms of progress, the most recent incident involving Ebola showed a marked improvement in reporting and transparency. It was apparent that the incident was immediately reported up the chain of command and to the public. As Dr. Frieden noted, an ADLSS position was created and recruitment is underway. It also seems that many of the laboratory safety training efforts and establishment of a fellowship/internship program are underway.

Regarding next steps, the ELSW is beginning its review of the NIH Laboratory Safety Program-related documents. Bi-monthly conference calls will be held from January 2015 through December 2015, and the ELSW will conduct an on-site review of the NIH Laboratory Safety Program February 9-12, 2015. Proposed actions will be provided on the Laboratory Safety Program to the NIH Director in the March to April 2015 timeframe. The ELSW's review of the FDA is anticipated to begin in the April to May 2015 timeframe. Activities beyond this date will be dependent on further advice and requests from Drs. Frieden, Collins, and Hamburg.

Dr. Berns emphasized that biosafety is an issue that is not ever going to go away. Last summer, it was on the front pages. Then it was pushed back by emergence of Ebola. Of course, just before Christmas it came back involving Ebola. Therefore, biosafety must be addressed constantly. CDC is the premier institution in the country in terms of handling pathogens, so it is critical that the agency be viewed as being able to do this in safe manner. He and Dr. Kanabrocki are both members of the National Science Advisory Board for Biosecurity (NSABB), which is currently considering Gain-of-Function experiments. Drs. Berns and Kanabrocki are co-chairing a working group on that issue in terms of setting up a risk assessment. One of the primary arguments put forward is that laboratory accidents are inevitable and that this research is too dangerous to be done. That will lead to an interesting discussion regarding what the priorities need to be. It is imperative that CDC be viewed as a premier leader in this area. One of the issues that struck Dr. Berns in the ELSW's assessment of CDC was that training is done in a piecemeal fashion. He expressed his hope that there will be an opportunity for great improvement in this area, including hands-on BSL-3 and BSL-4 training, and that funds will be made available or found to enable this to occur.

Discussion Points

Given the comprehensive nature of these proposed actions, Dr. Greenberg asked Dr. Frieden whether CDC has the human and fiscal resources to respond to these proposed actions in a timely fashion.

Dr. Frieden thanked the ELSW for its excellent proposed actions. CDC agrees in principle with most of the proposed actions and is in the process of implementing many of these. Some of the proposed actions will take time to implement, while some can be implemented relatively quickly. Two categories will take more thought and action. Some of the organizational arrangements will be left to the new ADLSS. It seems appropriate for the inaugural person in that position to have input into this key issue. There are not yet resources for a hands-on BSL-3 training facility. Something similar was done for Ebola for people deploying to West Africa. Working with the



Federal Emergency Management Agency (FEMA) in its Anniston, Alabama facility, hundreds of people have been trained in a mock Ebola treatment unit. CDC would like to create a mock BSL-3 laboratory for state-of-the-art training, potentially at a nearby site rather than on one of the main campuses where space is so constrained and parking is such a problem. However, funding is not currently available for this effort. \$3 million dollars have been refocused for safety training so that employees do not have to take this out of their Individual Learning Accounts (ILAs). Implementation of some of the proposed actions involves federal government funding, which has not yet been identified. In terms of how the central entity works with respect to other committees and other laboratories, it will be important to consider the balance between making sure that they can provide supervision and oversight, as well as understanding that the laboratories do have differences. While standardization and minimal standards are needed, there are some uniquenesses between laboratories. There is a much greater need to standardize at least a process by which safety measures are implemented. The risk assessments are a very important issue. Regarding the issue of Gain-of-Function research mentioned by Dr. Berns, what these incidents emphasize to Dr. Frieden is that in research with dangerous pathogens, there are risks that can be minimized but it may be quite difficult to get to zero. There are benefits that may be theoretical but not definitive. This does not tell him that no one should be conducting Gain-of-Function research; however, it does tell him that the bar should be higher than it currently is for conducting such research. CDC is working very hard on the training and competency issues. He is quite excited about the laboratory leadership service, and agreed that this should not be outsourced. However, they do plan to outsource the external inspections of the agency's laboratories. They are working through the other proposed actions, and certainly agree with reporting periodically on the steps of implementation and providing that information transparently. They have been doing that so far and are committed to continuing to do that. The bottom line is that CDC agrees with the proposed actions, is implementing them, and is deeply appreciative of the ELSW's efforts and expert advice.

Dr. Bal praised the ELSW for its very well done, remarkably blunt report. Even with Hawaii's miniscule staff, it is like a dam. Every time they stick their finger in one hole and allocate resources into the holes that have developed, it is at the price of some of the required core work. The standard bureaucratic response is that funding cannot be comingled, but he has certainly done it for 44 years and is certain that all agencies do it. For example, manpower in chronic diseases may have to be moved to community diseases during an emergency. He noted that there is an expectation by Congress that CDC do all of this work, but will not give the agency more money. His career has been in chronic disease, which has always "taken a back seat." Given the acute need for dealing with pathogens like Ebola in the laboratory, no question, direct and indirect resources must come from somewhere. While "running the gauntlet" with Congress on things that they do not understand completely as they grandstand, perhaps it is a good time to mention needing more money to do more things.

Dr. Frieden replied that the fact is, CDC does not have all of the resources they wish it had. The budget really does not have flexibility. After having spent a few years at the beginning of his time as Director trying to increase flexibility, a very wise person in Washington finally turned to him and said, "That's a very good strategy if you want your budget cut." Sometimes, what may seem to be a good idea is not. He hopes not to see one program at CDC gain at the expense of others. While the agency does have resource needs, they will do whatever they can within their existing resource envelope and do whatever they can to increase that envelope as well in the areas that need work. He has engaged in a lot of work on non-communicable disease as well.



One reason he had some freedom to focus on non-communicable disease when he was in New York City was that the city was doing such a phenomenal job in communicable disease control work. CDC has a phenomenal infectious disease prevention and control programs. Anytime there is an issue like Ebola or laboratory safety, it reminds them that they have to get that part of the house implemented as totally and effectively as possible because that is the first expectation that the public and policymakers have of the agency.

Vote: ELSW Proposed Actions

Dr. Bal moved that the ACD adopt the ELSW's proposed actions in their entirety.
Dr. Botchwey seconded the motion. The motion carried unanimously with no abstentions.

Dr. Frieden thanked Sherri Berger, who has overseen this process and has done a phenomenal job, her staff, and everyone else who has worked on this effort. He acknowledged that often in the administrative and operating offices are the "behind the scenes" folks who make progress possible, but who often do not receive the recognition they merit. In an agency that is averse to taking credit for what it does, it is a part of the agency that is least likely to be recognized.

Ms. Hickman then indicated that the minutes of the ELSW workgroup must be approved by the ACD.

Vote: ELSW Minutes

A motion was made and seconded for the ACD to approve the minutes of the ELSW.
The motion carried unanimously with no abstentions.

Public Health – Health Care Collaboration Workgroup Update

Dr. Georges Benjamin, Co-Chair, PHHCC, reported that since the last ACD meeting in April 2014, the PHHCC Workgroup has been finalizing considerations for the ACD to increase public health and health care systems collaboration in a post-health reform context. The PHHCC Workgroup is comprised of an amazing and robust group of people from the healthcare community, academia, business, and the public health community.

The charge of the PHHCC Workgroup is to identify key opportunities to increase connections between public health, healthcare systems, and other community stakeholders to improve population health outcomes, health care delivery and reduce health care costs. The workgroup sought input that would be feasible for CDC; promote improvements that respond to the current economic environment and optimally yield a large-scale public health and health care impact; and have an identifiable outcome beyond additional processing (e.g., another committee).



The PHHCC Workgroup focused on the following:

- ❑ Supporting a more coordinated health system that links clinical care, social and behavioral health services, and public health to achieve greater impact;
- ❑ Fully leveraging the Affordable Care Act (ACA) requirements that non-profit hospitals conduct community health needs assessments (CHNA) and community health improvement planning (CHIP) to improve community health;
- ❑ Aligning performance measurement and improved public health and clinical data system interoperability with federal and non-federal, national and state stakeholders to increase health system accountability; and
- ❑ Developing guiding principles to support active engagement between state and local public health, the health care system, and other community stakeholders.

Proposed Action #1: Support a more coordinated health system that links clinical care, social and behavioral health services, and public health to achieve greater impact.

#1 Activities:

1. Support the expansion of new payment and delivery models.
 - Seek opportunities to link population health with models that incorporate the social determinants of health.
 - Synthesize and translate the evidence documenting improved outcomes and reduced costs.
2. Support efforts by experts in clinical care, social services, behavioral health, public health, and law to describe the structure, operations, and workforce needed to sustain new payment and delivery models.
3. Define the health impact and cost savings realized from specific high-value prevention and public health interventions.
 - Coordinate guidance around preventive services with key stakeholders.
4. Build capacity to implement, evaluate, and sustain programs and policies that promote cross-sector linkages.

Proposed Action #2: Fully leverage ACA requirements for non-profit hospitals to conduct community health needs assessments (CHNA) and community health improvement planning (CHIP) to improve community health. Support a more coordinated health system that links clinical care, social and behavioral health services, and public health to achieve greater impact.

#2 Activities:

1. Develop mechanisms that incentivize multiple hospitals within a single jurisdiction to conduct their CHNAs and CHIPs jointly and engage health departments.



2. Address potential practical, policy, and legal barriers to joint planning and implementation.
3. Promote alignment between community health planning and community financing.

Proposed Action #3: Align performance measurement and improved public health and clinical data system interoperability with federal and non-federal, national, and state stakeholders to increase health system accountability.

#3 Activities:

1. Performance Measures:
 - Prioritize existing measures; propose retirement of measures where applicable.
2. Data Systems:
 - Promote use of census tract-level data, rather than zip-code level data, that can describe “real time” place based, neighborhood level health status.
3. Data Interoperability:
 - Support efforts to update the clinical data capture process.
 - Promote a patient-centered data architecture.
 - Promote examples of community-wide patient portals and regional data hubs with public health entities as “data curators” and analytic partners.

Proposed Action #4: Develop guiding principles to support active engagement between state and local public health, the health care system, and other community stakeholders.

#4 Activities:

1. Promote a unified and aligned health agenda across sectors with place-based health improvement as the explicit goal.
2. Utilize state and local public health expertise, common data tools, and shared analyses, and a place-based epidemiologic approach to assist health care systems in measuring health and health disparities at the whole-community level.
3. Partner with health care systems to conduct health, economic and budgetary analyses.
4. Promote strengthened partnerships between local public health and health care purchasers and providers.
5. Support the development of a multi-sector workforce with skills and competencies to effectively build and sustain a health system.



Pending approval by the ACD and CDC's Office of the Associate Director for Policy (OADP), the PHHCC workgroup will reconvene within six months to determine the next steps.

Discussion Points

Dr. Frieden expressed appreciation to the workgroup for their advice. This is an area in which CDC is working intensively and believes there is real opportunity for progress, and in which there has been some progress. However, it is very difficult to determine how to leverage the healthcare system for more progress overall in the community. The typology and proposed actions are all important. There is a major focus on CDC's interactions with the Centers for Medicare and Medicaid Services (CMS), which is thought to be an incredibly important and potentially productive partnership. A diligent effort is being made to identify success stories that will lead to others taking up more effective systems. Data are very important, given that progress can be driven through data in very important ways. The challenge of getting this right is that it should not be underestimated, given that this is a very tough area in which to work effectively. Dr. Frieden looks forward to working within CDC to implement ACD-supported proposed actions. He invited Mr. Auerbach, the lead for coordinating throughout CDC on this topic, to provide additional comments.

Mr. Auerbach emphasized that the agency views this as a very important area of work that is likely to result in some significant benefits. CDC looks forward to reporting back to the PHHCC Workgroup in a few months regarding the work that has taken place in support of final ACD recommendations.

Dr. Bal indicated his intent to abstain from voting, given that he thought Proposed Action #2, Activity 1, would not result in Activity 3. The beauty of CHNA is the requirement for it to be community-based. Incentivizing multiple hospitals, as has been done in Hawaii, results in linking them up with a report that means nothing. There is no mention of the fact that one major incentive is the Form 990 Schedule H1 and H2 requirements to develop a CHNA plan every three years. Across the country, uniformly with few exceptions, is the failure to follow the spirit of the requirements. He suggested previously that CDC provide technical assistance to help the Internal Revenue Service (IRS) develop rules to evaluate Form 990 Schedules H1 and H2. He indicated that he would send a note to CDC to detail his concerns. While he said he knew nothing about laboratories, he emphasized that he loved their report because it basically addressed the good, the bad, and the ugly and how to fix it. That degree of frankness from an advisory group that is not internal to CDC is something the ACD should model themselves after. In other words, if CDC receives valid technical advice from an outside group, either a workgroup or a subcommittee, CDC can basically say, "This is what the technical gurus said should be done." If it is politically not feasible as some of the proposed actions might not be, at least the onus is on the technical group not CDC [Note: Post-meeting, Dr. Bal submitted his detailed comments, which are included in this document as Attachment #3].

Vote: PHHCC Report

Dr. Fleming moved that ACD approve the PHHCC Report. Dr. Botchwey seconded the motion. The motion carried unanimously with one abstention.



Vote: PHHCC Minutes

A motion was made and seconded for the ACD to approve the PHHCC Minutes. The motion carried unanimously with no abstentions.

State, Tribal, Local and Territorial Subcommittee Update

Dr. David Fleming, Chair, STLT Subcommittee, presented the STLT Subcommittee’s proposed actions that grew out of the work of the three Think Tanks. These Think Tanks explore priority issues identified by the STLT Subcommittee which specifically respond to the changing roles of STLTs in the evolving health system. The three current Think Tanks include the following:

- Public Health Finance (Chair: Terry Cline)
- Public Health Surveillance (Chair: Bechara Choucair)
- Social Determinants of Health (SDOH) (Chair: Jose Montero)

STLT Subcommittee proposed actions for consideration by the ACD grew out of deliberations from these three Think Tanks.

Public Health Finance

Background: The STLT Subcommittee recognized the need to identify opportunities to strengthen financing for public health services in light of funding shifts in federal and STLT budgets, and requested that the ACD consider two issues:

1. **Preventive Health and Health Services (PHHS) Block Grant:** Offers an opportunity to advance this purpose but must be fully accountable and transparent about their investments and accomplishments. This is one of the few sources of flexible funding and has been somewhat of a “political football.” Funding for this was doubled by Congress during the last session. This grant is politically vulnerable because it is flexible.
2. **Foundational Capabilities:** As work to define foundational capabilities for all PH agencies nears completion, it is critical to understand how they will be sustained over time.

Proposed Action 1: Preventive Health and Health Services Block Grant: To improve the accountability and transparency of the PHHS Block Grant, CDC should:

- A. Strengthen CDC business practices and administration of PHHS Block Grant
- B. Communicate current PHHS Block Grant achievements
- C. Develop a plan to measure progress and impact of the PHHS Block Grant



Proposed Action 2: Potential opportunities to finance public health foundational capabilities: In the next 12 months, CDC should conduct an assessment of the factors and strategies that support the financing of foundational capabilities including identification of new and existing opportunities.

Public Health Surveillance

Background: The STLT Subcommittee strongly endorses CDC surveillance strategy. Goals related to state, territorial, local, and tribal entities are to:

1. Enhance the accountability, resource use, workforce and innovation for surveillance at CDC and in support of STLT agencies
2. Accelerate the utilization of emerging tools and approaches to improve the availability, quality, and timeliness of surveillance data
3. Through cross-cutting agency initiatives, improve surveillance by addressing data availability, system usability, redundancies, and incorporation of new information technologies in major systems or activities

Proposed Action 1: CDC Surveillance Strategy: In support of successful implementation of the CDC Surveillance Strategy, CDC should:

- A. NOT significantly modify or change the plan for at least 2 years to ensure progress and consistency
- B. Ensure that the CDC Surveillance Strategy work is connected to existing efforts defining the Health Department of the Future, and integration of healthcare and public health

Proposed Action 2: Data Standards Harmonization: CDC should formalize a roadmap process for adoption and implementation of harmonized data standards within 16 months. The roadmap should balance flexibility and prescriptiveness in harmonizing standards, and consider the role of funding in supporting the use of harmonized standards.

- This is consistent with CDC Surveillance Strategy, Goal 3: *Through cross-cutting agency initiatives, improve surveillance by addressing data availability, system usability, redundancies, and incorporation of new information technologies in major systems or activities.*

Proposed Action 3: Workforce Plan for Public Health Informatics and Surveillance: CDC should support development of a workforce plan for public health informatics and surveillance and should consider including training for the existing workforce as a first priority, and expanding the workforce for skillsets that do not exist.

- This is consistent with CDC Surveillance Strategy, Goal 1: *Enhance the accountability, resource use, workforce and innovation for surveillance at CDC and in support of STLT agencies.*



Social Determinants of Health

Background: ACD adopted recommendation (4/24/14) to help STLTs access non-health data sources to better understand/address social determinants of health.

Proposed Action: Assist STLTs in Understanding/Modifying SDOH: CDC should support expansion of approaches like the Community Health Status Indicators tool (CHSI) that assist health departments to better understand and modify SDOH in their jurisdictions. Special attention should be paid to the timeliness of data and to their direct application to actions that improve the health of the population.

- This is consistent with CDC Surveillance Strategy, Goal 2: *to accelerate utilization of emerging tools and approaches to improve the availability, quality, and timeliness of surveillance data.*

Discussion Points

Dr. Richardson thanked Dr. Fleming and his group for the outstanding work that they continue to do, and said she thought the proposed actions were excellent. The Health Disparities Subcommittee (HDS) is already collaborating with the STLT Subcommittee on the third content area from the Social Determinants of Health Think Tank. During the last HDS meeting, the HDS and STLT Subcommittee seemed to be converging on several of the same priorities that emerged in this report. Although there was not time for a report from the HDS during this ACD meeting, she requested that she and Dr. Fleming plan to discuss how they might be able to create more synergy in their work where interests of both subcommittees overlap.

- Dr. Fleming said he would be happy to discuss this with Dr. Richardson to further the collaboration between the two subcommittees.

Dr. Frieden requested further information either from the subcommittee or the staff on the concept and the plan related to supporting foundational capabilities.

- Dr. Fleming responded that a significant amount of work has been done by CDC and others to flesh out the specific details of these capabilities. The problem in the past has been discussion in vague terms about what needs to occur to finance them. This is not so much about fleshing out the capabilities, but is rather to consider, given the existing financing streams, whether there are ways to incorporate financing to assure these capabilities as part of the way of doing work. This includes assessing existing financing sources to determine whether there is a way to make it possible for people to allocate more stable resources to these streams. One example is that in the Prevent Block Grant guidance that was distributed, there was explicit reference to being able to use Prevent Block Grant funds to pay for foundational capabilities. Perhaps there are other examples at CDC. It is also important to recognize the momentum that is gaining at the state and local levels in brainstorming with the public health community to determine whether there are additional financial opportunities beyond the existing sources that could be targeted toward these capabilities. Dr. Monroe added that determining costs of the foundational capabilities is critical for STLTs.



Vote: STLT Subcommittee Recommendations for Proposed Actions

Dr. Palacio moved that ACD approve adoption of the recommendations for proposed actions from the STLT Subcommittee. Dr. Richardson seconded the motion. The motion carried unanimously with no abstentions.

Public Comments

No public comments were offered during this meeting.

Concluding Remarks / Adjournment

Dr. Frieden thanked everyone for their time on the call, as well as for the time they have all spent among themselves and with CDC staff. He emphasized that the ACD is an advisory committee to the director, and that he really does appreciate their advice and takes it seriously. Reflecting on the past two years, there have been times when recommendations by the ACD, workgroups, and subcommittees have been adopted and have become policy and impacted programs at CDC.

Dr. Greenberg thanked Carmen Villar and Gayle Hickman for organizing this teleconference. He indicated that the next in-person ACD meeting is scheduled for Thursday, April 23, 2015 in Atlanta.

Dr. Fleming recognized the difficulty in conducting meetings via teleconference and congratulated CDC for arranging and Dr. Greenberg for facilitating this call masterfully.

With no additional comments, questions, or business posed, the meeting was officially adjourned at 12:58 pm.



Certification

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the January 13, 2015 meeting of the Advisory Committee to the Director of CDC are accurate and complete.

March 22, 2015

Date

Alan Greenberg, MD, MPH
Chair, Advisory Committee to the
Director, CDC



Attachment #1: Attendance

ACD Members Present

Dileep G. Bal, MD, MS, MPH

District Health Officer
Hawaii State Health Department

Georges C. Benjamin, MD, FACP, FNAPA, FACEP (E), Hon FRSPH

Executive Director
American Public Health Association

Kenneth I. Berns, MD, PhD

Distinguished Professor Emeritus
Molecular Genetics and Microbiology College of Medicine
University of Florida

Nisha D. Botchwey, PhD, MCRP, MPH

Associate Professor
School of City and Regional Planning
College of Architecture
Georgia Institute of Technology

Thomas A. Farley, MD, MPH

Joan H. Tisch Distinguished Fellow in Public Health
Hunter College

David W. Fleming, MD

Vice President for Public Health Impact
PATH

Lynn R. Goldman, MD, MS, MPH

Michael and Lori Milken Dean of Public Health
George Washington University

Alan Greenberg, MD, MPH (ACD Chair)

Professor and Chair
Department of Epidemiology and Biostatistics
George Washington University Milken Institute School of Public Health

Anthony B. Iton, MD, JD, MPH

Senior Vice President
Healthy Communities
The California Endowment



Joseph Kanabrocki, PhD, CBSP
Associate Vice President for Research Safety
Professor of Microbiology
The University of Chicago

Jewel M. Mullen, MD, MPH, MPA
Commissioner and State Health Officer
Connecticut Department of Public Health

Herminia Palacio, MD, MPH
Director, Human Capital and Leadership Teams
Robert Wood Johnson Foundation

Lynne D. Richardson, MD, FACEP
Professor and Vice Chair of Emergency Medicine
Professor of Health Evidence and Policy
Mount Sinai School of Medicine

CDC Participants

Ileana Arias, PhD
Principal Deputy Director

John Auerbach, MBA
Associate Director for Policy

Ursula E. Bauer, PhD, MPH
Director, National Center for Chronic Disease Prevention and Health Promotion

Katherine Lyon Daniel, PhD
Associate Director for Communication

Leslie Dauphin, PhD
Interim Director of Laboratory Safety

Kelly Dawson, MPH
OHSC-ORISE Fellow, Office of Health System Collaboration
Office of Associate Director for Policy

Thomas R. Frieden, MD, MPH
CDC Director

Corinne Graffunder, DrPH, MPH
Deputy Associate Director for Policy

Gayle Hickman
Committee Management Specialist, ACD
Advance Team, Office of the Chief of Staff



Michael F. Iademarco, MD, MPH (CAPT, USPHS)

Director, Center for Surveillance, Epidemiology and Laboratory Services, OPHSS

Harold W. Jaffe, MD, MA

Associate Director for Science

Rima Khabbaz, MD

Deputy CDC Director

Office of Infectious Diseases

Judy Lipshutz, MPH

Public Health Analyst

Office for State, Tribal, Local and Territorial Support

Jonathan (Jono) Mermin, MD, MPH (CAPT, USPHS)

Director, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Judith A. Monroe, MD, FAAFP

Deputy CDC Director, Office for State, Tribal, Local, and Territorial Support

Designated Federal Officer, STLT Subcommittee

Laura Seeff, MD

Senior Director for Health Systems, Office of Health System Collaboration

Office of the Associate Director for Policy

Carmen Villar, MSW

Chief of Staff

Designated Federal Officer, Advisory Committee to the Director

Sarah Wiley

Interim Designated Federal Officer, External Laboratory Safety Workgroup

Public Health Analyst, Office of the Director, Office of Infectious Diseases

General Public

Stephanie Wallace

Writer/Editor, Senior Technical Writing Lead

Cambridge Communications, Training, & Assessments (CCTA)



Attachment #2: Acronyms Used in This Document

Acronym	Expansion
ABSA	American Biological Safety Association
ACA	(Patient Protection and) Affordable Care Act
ACD	Advisory Committee to the Director
ADLS	Associate Director for Laboratory Safety
ADLSS	Associate Director for Laboratory Safety and Science
ASTHO	Association of State and Territorial Health Officials
BSL	Biosafety Level
CAP	College of American Pathologists
CDC	Centers for Disease Control and Prevention
CHIP	Community Health Improvement Plan
CHNA	Community Health Needs Assessment
CLIA	Clinical Laboratory Improvement Amendments
CMS	Centers for Medicare and Medicaid Services
DFO	Designated Federal Officer
EIS	Epidemic Intelligence Service
ELSW	External Laboratory Safety Workgroup
ESHCO	Environment, Safety, and Health Compliance Office
FDA	(United States) Food and Drug Administration
FEMA	Federal Emergency Management Agency
HAI	Healthcare-Associated Infection
HDS	Health Disparities Subcommittee
HHS	(United States Department of) Health and Human Services
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
ILA	Individual Learning Account
ISO	International Organization for Standardization
IRS	Internal Revenue Service
LLS	Laboratory Leadership Service
LSIW	Laboratory Safety Improvement Workgroup
NCCDPHP	National Center for Chronic Disease Prevention and Health Promotion
NGO	Non-Governmental Organization
NIH	National Institutes of Health
NSABB	National Science Advisory Board for Biosecurity
OADP	Office of the Associate Director for Policy
OD	Office of the Director
OSTLTS	Office of State, Local, Territorial and Tribal Support
PHAP	Public Health Associate Program
PHHCC	Public Health – Health Care Collaboration (Workgroup)
PPHF	Prevention and Public Health Fund
PHHS	Preventive Health and Health Services
rDNA	Recombinant Deoxyribonucleic Acid
RITE	Rapid Isolation and Treatment of Ebola
STLT	State, Local, Tribal, and Territorial



Attachment #3: Dr. Bal's Comments Regarding PHHCC Proposed Actions:

From: Bal, Dileep (CDC doh.hawaii.gov)

Sent: Wednesday, January 14, 2015 08:27 PM Eastern Standard Time

To: Greenberg, Alan (CDC gwu.edu); Villar, Carmen S. (CDC/OD/OCS); Benjamin, Georges (CDC apha.org)

Cc: Graffunder, Corinne (CDC/OD/OADP); Seeff, Laura (CDC/OD/OADP); Stange, Paul V. (CDC/OD/OADP) (CTR); Hickman, Gayle J. (CDC/OD/OCS); aiton@calendow.org <aiton@calendow.org>; goldmanl@gwu.edu <goldmanl@gwu.edu>; Bal, Dileep (CDC doh.hawaii.gov)

Subject: FW: An old Indian's ode to ---- CHNA, COMMUNITY BENEFIT and COMMUNITY BUILDING

Aloha Alan and Carmen et al,

My compliments for an excellent ACD meeting by conference call. Those are rather difficult to do with 50 people on the line for a couple of hours.

As I promised, I am sending you some comments I have on the agenda item that addressed the Proposed Actions from the Public Health-- Care Collaboration (PHHCC) Workgroup to the CDC Advisory Committee to the CDC Director, Chaired by Georges Benjamin with Corinne Graffunder as the Designated Federal Official. The report was fine except for a couple of things in my opinion. The attachment above entitled Tab 3A is the cause for my concern. Within it Proposed Action 2 (Fully leverage ACA requirements for non-profit hospitals to conduct community health needs assessments (CHNA) and community health improvement planning (CHIP) to improve community health) is the one I wish to address. Its Activities are listed as --

- a) Develop mechanisms that incentivize multiple hospitals within a single jurisdiction to conduct their CHNAs and CHIPs jointly and engage health departments.
- b) Address potential practical, policy, and legal barriers to joint planning and implementation.
- c) Promote alignment between community health planning and community financing.

Obviously I have no problem with the proposed action itself but Activity (a) in my view will not result in Activity (c) and is actually difficult to do & probably illegal as Activity (b) clearly states.

Hawaii is a poster child or case study on how if all the hospitals in a state, undertake to do this jointly, they abdicate their responsibilities for doing the CHNA and instead come up with a transparent fig leaf that is a poor substitute for meeting the letter and spirit of the CHNA provisions of the Affordable Care Act. In addition to not meeting the IRS Form 990, Schedule H1 and H2 requirements, by outsourcing this activity, most of the hospitals have not built an inherent system capacity to even understand this provision of the ACA, let alone implement it. Tragically many of the hospitals in the USA have adopted a similar "avoidance as a coping mechanism stance" and now 3 years later we are going into the next CHNA report cycle and we are seeing preparations for the same Kabuki Theater as we saw in 2013, in Hawaii and elsewhere in the nation. Of course there are very many forward thinking hospital systems,



helped by progressive health departments (like David Fleming's) in the mainland, who are doing very many of these things right. Regrettably they are in a minority.

I actually became aware of the potential for CHNA to be done correctly through early discussions within the ACD in 2012, and became immersed in studying it and doing it correctly in Hawaii, as my 2013 email below to Tom Frieden illustrates. It is entitled: An old Indian's ode to ---- CHNA, COMMUNITY BENEFIT and COMMUNITY BUILDING. Two years later -- plus ça change, plus c'est la même chose.

Three years ago, I proceeded to work with our local Wilcox Hospital CEO and all the consumer, advocate and governmental constituencies on Kauai, especially our Mayor, School Superintendent and College Chancellor. We had some help from CDC and a bunch of other mainland partners including the Federal Reserve Bank of San Francisco and the Public Health Institute. The product of our health department coordinated efforts is shown in the first two links below, and Wilcox Hospital's IRS filing is I believe the only adequate one among Hawaii's non-profit hospitals, regarding the CHNA provisions.

By June 2014, the KCHII partners and the community developed the Kauai Community Health Improvement Plan, charting a course for action. In August 2014, an island-wide conference was held to showcase the Kauai Community Health Improvement Plan and to kick-off the plan's implementation strategies. The Kauai Community Health Improvement Plan is available online at three websites: County of Kauai Mayor's Office; Kauai District Health Office; and Wilcox Memorial Hospital websites. These links are:

CHNA: <http://health.hawaii.gov/kauai/files/2013/07/KAUAI-CHNA-July-2013.pdf>

Appendix: <http://health.hawaii.gov/kauai/files/2013/07/KAUAI-CHNA-APPENDIX-A-C-July-2013.pdf>

Kauai Community Health Improvement Plan:
http://www.kauai.gov/Portals/0/Mayor/KauaiPlan_June2014_reformatted_July28.pdf

In addition, a physician colleague of mine Paul Esaki and I, wrote a guest editorial on this subject in the major paper in Hawaii which you can see as the first attachment above. The final two attachments above are very well-documented and lucid technical and lay articles describing how broken this all is and some suggested fixes.

Let me hasten to add that all this information and more is well known to the CDC cognoscenti in this subject area, obviously including Corinne Graffunder, Laura Seeff, Paul Stange and others.

My specific question is whether CDC is helping the IRS write the regulations especially mandating the H2 requirements and describing what kinds of "upstream interventions" could result in the best ROI (i.e. the best downstream health outcomes). If so, what is being done and if not, why not, because your CDC folk are intimately familiar with all the nuances of the issue while the IRS folk are not. It would indeed be a crying shame if this revolutionary provision of the ACA was not enforced despite the President's vision in having such a specific requirement in the law.



Finally I am happy to discuss this with Corinne Graffunder, Laura Seeff and their staff and/or be available to work with Georges Benjamin's workgroup, if you so wish.

Hau'oli Makahiki Hou! (A Happy New Year!) &

Ke Akua pu me 'oukou - (God be with you all.)

Cheers,

Dileep

Dileep G. Bal, M.D., M.S., M.P.H.
District Health Officer
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3040 Umi Street
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Dileep.G.Bal@doh.hawaii.gov

From: Bal, Dileep G.

Sent: Friday, April 05, 2013 12:56 PM

To: Dr. Thomas Frieden (CDC) <TFrieden2@cdc.gov> (TFrieden2@cdc.gov)

Cc: Monroe, Judith A. (CDC/OSTLTS/OD); Rosenbaum, Sara (CDC gwumc.edu); Bauer, Ursula (CDC/ONDIEH/NCCDPHP) (iws8@cdc.gov); Rein, Andrew S. (CDC/OD/OADP);

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Subject: FW: An old Indian's ode to ---- CHNA, COMMUNITY BENEFIT and COMMUNITY BUILDING

Aloha Tom et al,

This is to thank Judy, Sara, Andrew, David and others at CDC, who contributed greatly towards my education about CHNA and the need for systematic public health and public input in this process. Basically the hospitals in Oahu, decided to band together and do a centralized statewide CHNA for their convenience and to ensure uniformity. The need for community and public health input was paid lip service, and some minimal "key informant surveys" were conducted as a fig leaf of compliance with the law. I was furious and with the head of our local hospital conducted my own CHNA process much to Honolulu's chagrin. I received some help from the Public Health Institute in California which I coincidentally currently chair. We followed the letter and the spirit of the law which included involvement of every community constituency and are still conducting island wide focus groups.



Having set up an appropriate process I wrote the above guest editorial with a local physician Paul Esaki and created a bit of a stir. Although my comments were clearly made as a private citizen, our Director and Department are in substantial agreement with my comments, though they had no prior knowledge of them. I am especially appreciative of our Director's support, but will continue to express my opinion, when asked, as a private citizen. A plethora of mainland organizations and authorities are in agreement with our intellectual position, including some prestigious progressive hospital systems.

Paul's and my main concern regarding CHNA, is that hospitals across our nation need to understand that we are a nation of laws not mere men! ACA (the Affordable Care Act), is the law of the land, like it or not. Furthermore, it is our considered and informed opinion that all Hawaii's hospitals, with the exception of Wilcox Hospital, could be deemed to be in substantial non-compliance with the law, for multiple reasons including procedural concerns and early indications that their IRS filings may be wanting. They still have a chance to remedy the latter by adding Community Building activities to their Form 990 (Schedule H2) filings with the IRS. In fact we have provided them with a convenient method for so doing if they should choose to take it. This would fund the upstream stuff Ursula wants funded.

The main difference between the Wilcox/ Kauai CHNA and the others in Hawaii is the community involvement. In Kauai there is a sense of ohana that is tangible and instead of looking at this as a federal mandate, the head of our only 501 c(3) hospital and I chaired an island wide effort. However, the other islands in our beloved state did not have that same privilege because the community leaders were not fully aware let alone involved (beyond a perfunctory phone survey!) and the population at large not even consulted directly. On Kauai we are currently conducting the labor-intensive focus groups across the island. Also funding for our efforts has been a shared responsibility with Wilcox Hospital and the Health Department underwriting all the front end costs, with the County generously funding some of our future on-going implementation efforts. Thus we meet the letter and spirit of what Congress and President Obama intended with this legislation, as we are a locally driven effort, spanning every constituency within and outside the hospital with active collaboration and a joint commitment to implement whatever we collectively decide. We will not always agree nor perhaps should we. But everyone will know that their opinion was sought and respectfully considered as part of a truly participatory process.

Also, after 8 years in Hawaii I have developed a primal dislike for Oahu centric decision making (out of Honolulu), that is presented as a fait accompli to neighbor islands. (I am sure Tom and Tom have had similar opinions about arbitrary if not capricious actions from Albany!) In my view this was a particularly gratuitous example of that syndrome, which was doubly egregious, as in my view it was a clear violation of federal law. My guest editorial was a source of some embarrassment to my co-chair (as it complimented her and roundly criticized her Honolulu bosses) but I staunchly defended the intellectual and legal basis for my actions and the fulfillment of the greater good, by informing the public of how the other islands are being seriously short changed by this CHNA process.



As my Kauai colleagues whimsically remind me on occasion, a series of Kings Kamehameha never conquered the island of Kauai. Well nothing has changed and we do get a high, out of intentionally ignoring Honolulu. I must confess to some vicarious satisfaction in simultaneously defending public health interests and tweaking the noses of the biggest hospital systems in Hawaii, who were arrogantly not fulfilling the letter or spirit of the CHNA law and regulations under the mistaken belief that nobody would notice.

I hope Tom that CDC will set up technical assistance to help health departments in other states and counties that lack the information and ability to force their hospitals to do what is right. Public health folk must stop being a doormat in this CHNA process!

Enough said!

Much Aloha to every one of you and Mahalo again to Judy, Andrew, David and Sara for their early help. (Judy would you mind distributing my editorial to other ACD members. Mahalo.)

Cheers,

Dileep

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