Presentation to the NASEM Committee on Reviewing the PHEMCE

Remarks from my NBSB experience with the PHEMCE, its accomplishments, and areas for improvement

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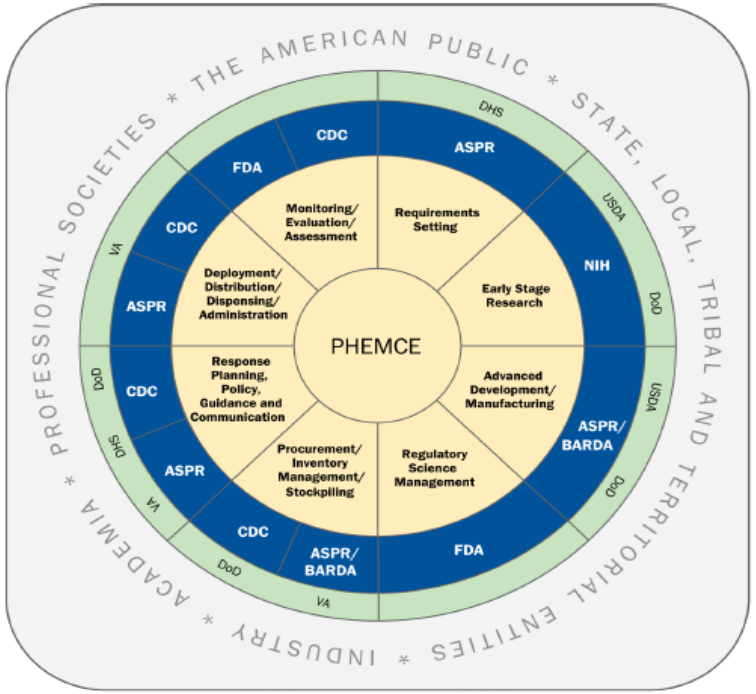
NBSB Composition and Mandate

- The National Biodefense Science Board (NBSB), is a federal advisory committee that provides expert advice and guidance on public health emergencies to the Secretary of the HHS/or designee
  - preventing, preparing for, and responding to adverse health effects of emergencies – biological, chemical, nuclear and radiological agents
  - on other matters related to public health emergency preparedness and response
  - on current and future trends, challenges, and opportunities presented by advances in biological and life sciences, biotechnology, and genetic engineering
- The board was created under the Pandemic and All-Hazards Preparedness Act of 2006, amended in the Pandemic and All Hazards Preparedness Reauthorization Act of 2013 (PAHPRA)
- NBSB consist of 13 Voting members and many ex-office members representing various departments of PHEMCE. Supported by a Federal Officer- our Connection to ASPR
- The Board reviews and considers information and findings received from the working groups of the Board

Q1. What should the PHEMCE be required to do?
What is the strategic and policy direction of the PHEMCE?

PHEMCE is a group of very large divisions of the government that are all under HHS
Each division has clear roles and responsibilities

Presented at the introductory meeting (August 6) by Chad Hrdina



- The work of PHEMCE led to a large, extensive and complete document:
  Homeland Security Presidential Directive 21 (HSPD 21)
  "Public Health and Medical Preparedness"
- Every aspect of how our nation will be prepared to meet a biological, chemical, nuclear or other threat is addressed in HSPD21
- Emergency exercises had been conducted on a large scale

Yet, in the face of SARS-CoV-2, we failed to protect the nation. What happened ?

Q1 Contd.

- In order for each division to perform effectively as defined, each division must be empowered to have FREEDOM to operate and the BUDGET to execute.
  - Complex divisions could function better as smaller units empowered to execute tasks
- There should be no political repercussions. Independence of Public health leaders to make public health decisions must be apolitical and spoken with a single voice. We cannot have different messages and shifting messages
- Process and actions should not be clouded by political and public opinion
- Public health must be maintained in this pandemic. Public health infrastructure is vastly deficient and needs to be re-built – Public health and local health doctors must work closely together
- In an emergency, funds are shifted to meet emergency needs – it has happened every time
- The policy and direction has become focused on the current pandemic- while all current programs (measles, HIV) and future epidemic/pandemic focus have lost funding and staffing
  - Both, must go on simultaneously

Q 1. Contd.

- It would be useful for the NBSB to be able hear of the policy decisions when they are made
- Input from the NBSB with its real life experience could be useful to PHEMCE
- ASPR and HHS should hear feed-back about our experience with the “last mile” of activities to meet emergencies

Q2. What should be the scope of the PHEMCE's mission?

- The current scope is very broad, but is appropriate
- The priority is health and safety of the nation- the basic budget/staffing should not be shifted to take care of the emergency
- PHEMCE should have reserve funds for emergencies. It should be sufficient to take care of 3-4 months of a pandemic scale emergency at which time it can be renewed by additional appropriations
- Development of countermeasures- Vaccines, therapeutics, diagnostics, devices are long term commitments
- Communication to the public must use a trusted non-political Public Health Leader
- One Health Concept is critically important. Global surveillance is required especially with the changing world landscapes
- Data base of current and potential future emergencies should be described and shared with all divisions
- Real exercises should be conducted by each unit. All divisions should work together
- Commitment to the regulatory path for assessment of treatments/vaccines/devices in a pandemic/emergency should not have any political influence

Q3. How can health equity principles be incorporated into the PHEMCE mission?

- NBSB's past recommendation addressed standardized training with local modifications - for all hospitals and for community leaders irrespective of race/region/income
- These communities need to be involved with exercises. **We have fire drills but no epidemic/pandemic drills**
- Funding should be provided to diverse communities to enable participation in drills and to that ensure trusted leaders are engaged
- Paths to equipping and getting countermeasures to remote areas must be practiced
- Education and unified communication to all must be in clear understandable and non-scientific
- Building trust is an on-going process. Trust is even more important while dealing with less privileged people. Trust in government has been destroyed.
  - Training must us the trusted leaders of each community

Q4. What is the value that the PHEMCE can and should provide?

- PHEMCE value is in planning and being prepared for emergencies, including
  - Wide and expert surveillance to detect pathogens; unknown pathogens can be detected by genome-sequencing methods in patients with fevers of unknown origin
  - Modelling of data to see how the disease can spread
  - Leadership role in public-health guidance and communication
  - Development of therapies and vaccines. mRNA vaccine work started 20 years ago.
  - Distribution of the countermeasures
- PHEMCE must have the resources to provide support to communities/hospitals
- Prepare for shifting populations and environments
- Being informed and ready to act in real-time based on global surveillance information
- Global data access, pathogen/sequence access. Needs cooperation between nations. And WHO.
- Streamlined communication and decision processes are needed as delays can be dangerous
- Logistics of testing, treating and vaccinating all types of communities

Q5. Who should be the primary recipient of the PHEMCE's analysis and advice?

- Report goes to who commissioned the work
- The question is – Will there be buy-in by the Head of HHS, ASPR, and the heads of each division?
- Will the recommendations be accepted and how will they be acted upon?
- Action points relevant to each division must be developed and shared with all managerial level staff in that division.
- This must be followed up with achievement/deliverable milestones
- Feed-back should be provided- How were the recommendations addressed?

Q6. How should the PHEMCE be organized to meet its mission and have the authority to act?

- The current organization and distribution of responsibilities are acceptable
- Directors should be non-political appointments with freedom and budget to operate.
- Leadership changes because of Presidential changes are not useful for continuity- **Science does not work on a 4-year political cycle**
- There is no room for complacency. PHEMCE was resting on its laurels for Ebola, Zika, Influenza, SARS-CoV, MERS..**and then came SARS-CoV-2!**
- Topics of importance could be proposed to the NBSB (and other Boards) which could provide valuable input. Feedback is essential.

Q7. How can programs and budgets be aligned and coordinated to support the PHEMCE mission?

- Planning, communication between divisions
- Identify shared priorities- build momentum from these priorities
- Identify the participants for each cluster of activity- empower them and hold them accountable to milestone driven budgets
- Shared data bases can eliminate redundancies
- Decrease bureaucracy
- Reserve Budget for emergencies should be separate from the annual budget
- Like in a business, budgets should be managed with discipline.
  - Tight, milestone driven, success driven, accountable

Q8. How can PHEMCE be organized to ensure improved transparency and communication and consistent decision making?

- Listen to staff. Are there open Division meetings?
  - Meetings must be followed by feed-back and action
- People with different opinions must be recognized and their ideas considered
- Rationale for decisions should be explained at the time the decisions are made
- Ability to act quickly must be encouraged
- Emergency exercises must include members of all divisions.
- “One PHEMCE”, scientifically driven culture, must be nurtured

Q9. How can PHEMCE be organized to ensure efficient and effective business operations?

- Access to senior management
- Faster decision making
- Appropriately size each division/fewer decision makers. Leaner and more empowerment in organizations. Stream-lined decision making.
  - Use a BARDA model (? DoD) where the decisions are made in real time, access to senior decision makers is possible and easy
- Better to be over-prepared than under-prepared
- Use Boards (like the NBSB) and other committees to hear what works and what does not
- Company-government contracts must be set up prior to emergencies but must be closely monitored
- Leaders of each unit of PHEMCE should be career and not political appointees

Q10. What are lessons learned from the ongoing COVID-19 pandemic?

- **There is a massive failure of execution by government and markets while scientists were prepared** (vaccines)
- A stable public health infrastructure is urgently needed
- Adequate supplies are required - strong and duplicated supply chains are needed
  - Manufacturing in 2-3 parts of the world, including in the U.S., to ensure raw materials and supplies
  - We cannot count on private industry – Govt must use the Defense model of building the supply chain
- Too much regulation can be harmful – e.g., diagnostics: Why could hospital labs not run the PCR test described by the WHO in a pandemic?
- Public health should be driven by science and not from economic/political/public opinion pressures
- We need every effort to counter misinformation online and in the news
  - Ignorance *Vs*. Science

Q10. Contd. What are lessons learned from the ongoing COVID-19 pandemic?

- Leverage intellectual know-how and payments provided to companies to obtain vaccines/therapies at a fair price
- Communication should be with a single voice which is steady. Should not be political.
- Surveillance, world wide. Plan for the worst scenario/ be ready with real exercises
- Learn from what worked from small local groups , e.g., Duke, Stanford, Indiana Universities
  - on surveillance, testing, quarantining, disease modeling
  - Global data access, pathogen/sequence access. Cooperation between nations, and with the WHO.
- Need to develop broad spectrum therapeutics/ fast access to vaccines and therapeutics
- Every persons health data needs to be accessible electronically to heath care professionals.
- *Beware of future complacency after COVID*

Thank you!

Questions?