Conducting Research in Public Health Emergencies

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ASPR brings together policy, science, and response

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H1N1 highlighted the challenges of doing scientific research in face of a pandemic

We saw real successes…

- ✓ Rapid characterization of the H1N1 virus
- ✓ Determining the vaccine dose for children
- ✓ Identifying priority groups for vaccination and treatment
- ✓ Surveillance for antigenic drift
- ✓ In vitro and non-human animal pathogenesis and therapeutic evaluations
- ✓ Standardized data collection using existing adult and pediatric critical care research networks

…and real shortcomings

- Delays in human subjects review limited real-time data sharing and analysis
- Funding mechanisms affected study design and caused delay
- Modeling's value and limitations were not well understood or communicated to policymakers and public; scientific competition led to public confusion
- Important research questions were not considered until it was too late to act on them
- Limited biospecimen collection

We faced many of the same challenges in other disasters

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2010 Haiti earthquake

- "Real time" collection and analysis of data would have allowed more granular clinical guidelines on treating complex fractures in austere environments

2010 Gulf oil spill

- Could not determine effects of oil/ dispersants on human health
- Needed to know how to prevent behavioral health sequelae

2011 Japan nuclear disaster

- Limited number of experts
- Limited lab capacity
- Inconsistent guidance
- Unanswered questions re human health effects

After-actions identified need for "scientific research in response"

- **Evidence-basis to inform preparedness**
- **Making decisions with the best available science**
  - Process for expert analysis and advice should be formally integrated into command structure
- **Strategic science coordination**
  - Aims to prioritize knowledge gaps and rapidly and effectively execute research to resolve critical questions for the "next time"
- **Need mechanisms to address public concerns:**
  - Just-in-time messages (development and vetting)
  - Prevent "epidemics of fear"

Policies must enable scientific research in response

- **US has over 138 clinical research networks that can support collaborative research**
- **The expertise is there but bureaucratic, logistical, and financial obstacles can impede needed, strategic science**
- **In theory, some of these networks can be used to support collaborative clinical research in a radiological emergency**
- **Policy Pilots:**
  - PHERRB
  - Terms and Conditions
  - Research data sets

How can we build on progress to create robust science response?

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Components	Making it operational
Rostered experts in research design, technology, and topical areas of concern	Identify and roster experts; plan for 'ready reserve' of citizen-scientists and clinicians
Scientific research is part of core response plans	Make formal part of planning documents and incident command structure
Identification of knowledge gaps and research questions	Explicitly review, prioritize and recommend which research to pursue
Generic and scenario-specific templates and protocols	Pre-approved core survey documents; pre-scripted clinical protocols; minimum data set
Rapid review mechanisms for human subjects research	Advance approval, national review board for emergencies
Rapid funding	Implement administrative mechanisms to enable
Registries and networks for studies	Pre-prepared registries
Involvement of affected communities	Establish mechanisms to directly engage community to discuss concerns; share findings

Progress establishing science response

- **Improved traction** for 'science response' concept
- **Formed a national IRB**; now addressing barriers to its rapid use
- **Partially rostered experts**
- **Piloted process for rapid identification of research priorities**, using MERS-CoV as an example
- **RFP for 'warm-base' clinical research networks** awarded

- **NIEHS developing template environmental response protocols, now exercise tested**

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