Managing Vaccine Supply Disruptions and Shortages in the US:

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Monitoring

- CDC purchase vaccines to vaccinate eligible children and adults with routinely recommended vaccines

- The contracts have a requirement for manufacturers to provide advanced notice of vaccine supply issues to CDC when possible (e.g., a manufacturing problem that is expected to lead to decreased vaccine availability)

- This requirement often provides CDC with visibility to anticipated supply issues
Pediatric Vaccine Stockpile Program

- The law that created the United States’ Vaccines for Children program (VFC) authorized CDC to purchase vaccine stockpiles of routinely recommended pediatric vaccines as part of the VFC program.
- Using VFC funding, CDC procures and manages stockpiles for use in outbreaks of vaccine-preventable diseases and vaccine supply disruptions.
- Stockpiles are dynamic storage and rotation stockpiles (vendor-held), to ensure vaccine viability and reduce waste.
- Target size for each stockpile is defined as a six month supply of VFC vaccine usage.
Communication/Planning

- Once notified by a manufacturer about a supply disruption, CDC seeks permission to share confidential information with manufacturers of alternative vaccines for contingency planning.

- CDC meets regularly to plan with/update key stakeholders, including provider and public health organizations, US FDA, CDC staff.

- CDC maintains a webpage to communicate about vaccine supply shortages and disruptions (https://www.cdc.gov/vaccines/hcp/clinical-resources/shortages.html)
Controlled Vaccine Ordering

- CDC implements controlled vaccine ordering in the public sector in the following circumstances:
  - Adequate but tight supply (no redundancy)
  - Supply is not sufficient to meet the ACIP-recommended schedule

- Controlled ordering works by placing limits on how much vaccine each jurisdiction can order; limits are calculated to ensure that each jurisdiction receives a fair share of available vaccine

- Manufacturers may also implement ordering controls in the private sector; the approach used varies by manufacturer
Interim Vaccine Recommendations

- If insufficient vaccine is available to fulfill ACIP’s recommended routine vaccine schedules, interim vaccine recommendations may be issued by CDC.

- An interim vaccine recommendation is a temporary change in the recommended vaccine schedule made to conserve limited supply and/or ensure protection of persons at highest risk.

- Interim recommendations may temporarily target limited vaccine to high risk individuals and/or reduce the number of doses offered in a multi-dose series.
Example: Adult Hepatitis A Vaccine, 2017

- Large outbreaks of Hepatitis A among adults in several US cities resulted in increased demand for vaccine, well beyond routine usage.

- While this did not result in a true vaccine shortage, supplies were constrained.

- Because CDC’s vaccine stockpile program only includes pediatric vaccines, release of stockpiled vaccine was not an option to mitigate the supply constraint.
Example: Adult Hepatitis A Vaccine, II

- Several other actions were taken by CDC to manage the supply constraints:
  - Technical assistance to public health officials in affected jurisdictions to support targeting vaccine in response to local epidemiology
  - Collaboration with manufacturers to understand options for managing private sector ordering and increasing national supply
  - Implementation of ordering controls in the public sector to support outbreak response and maintain vaccine availability nationally
  - Modification of CDC’s adult vaccine contracts to support the purchase of additional public sector Adult Hepatitis A vaccine
Outbreak Related Cases of Hepatitis A in California

- San Diego
- Santa Cruz
- Los Angeles
- Other Jurisdictions

*Episode date used if onset unknown.

Number of Cases

Week Ending Date of Onset*

*Episode date used if onset unknown.
California Hepatitis A Outbreak – March 2017-Present

- San Diego noted increases in HepA cases beginning March 2016.
- 688 cases (1/12/18); Investigations revealed history of:
  - 33% homeless and substance abuse
  - 16% other homeless
  - 11% - substance abuse
- Coinfection with HBV (4%); HCV (14%)
- DVH laboratory confirmed outbreak strain: IB
  - 688 cases
    - 449 (65%) hospitalizations
    - 21 (3%) deaths

https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Immunization/Hepatitis-A-Outbreak.
California Outbreak Response

- CDC Epi-AID in May 2017
- Incident Command Structure (ICS) implemented and Public Health Emergencies declared at State level and in San Diego and Los Angeles Counties
- San Diego requested technical assistance from Housing and Urban Development
- Mass vaccination events
  - Foot teams to encampments
  - Jails/detention centers
  - Social service providers
  - Medical providers
- Handwashing stations installed and additional public toilets made available in San Diego
Confirmed Hepatitis A Case Onset by Week for the Michigan Outbreak for cases referred Aug 1, 2016 to Feb 20, 2018

WEEK OF ILLNESS ONSET

- Primary-Confirmed Cases
- Secondary-Confirmed Cases

*If illness onset was not identified first lab collection date was used in place

Cases likely to increase due to 15-50 day incubation period and reporting delays
Michigan hepatitis A outbreak—October 2016-Present

- Increases were noted in October 2016
- CDC field team provided technical assistance
- DVH laboratory confirmed outbreak by identifying same strain circulating among cases
- As of 2/20/18:
  - 760 cases HBV 2.4%; HCV 27%
    - 50% history of substance abuse
    - 615 (80.9%) hospitalization
    - 25 (3.3%) deaths
Michigan Outbreak Response

- State level ICS
- CDC field team in October 2017
- Received and distributed $7.2 million allocation from the state for response
- Focused vaccination efforts of local health departments and providers
  - Collaboration with HIV/STI Division for outreach to MSM
  - Collaboration with Michigan Primary Care Association
  - Collaboration with drug treatment centers
Hepatitis A vaccine doses administered and reported to the Michigan Care Improvement Registry for adults ≥18 years of age for the top ten facility types by week, November 5, 2017 – February 17, 2018
Vaccine allocation

- As available vaccine supplies have increased and outbreaks have slowed, public vaccine supply strategy is evolving:
  - Support for affected jurisdictions is ongoing
  - Ordering controls have been adjusted to increase vaccine availability for unaffected jurisdictions, to facilitate routine vaccination activities and make vaccine available for response to smaller scale outbreaks without CDC consultation

- CDC and vaccine manufacturers are continuing to carefully monitor demand and usage for adult Hepatitis A vaccine
Current Hepatitis A vaccine supply

- **One month since vaccine availability increased**
  - No indication that increased supply is insufficient
  - Vaccine seasonality: low ordering in the winter, which hinders the comparison between now and the fall months

- **Supply is not unlimited**
  - CDC continues to review state plans for large-scale prevention campaigns

- **Continued CDC assistance to direct hepatitis A vaccination to outbreak risk populations in MI and other states.**