Clinicians Connect

Role of FDA in Reducing Cases of Syphilis and Congenital Syphilis

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Agenda

- Penicillin G Benzathine Shortage

- Tests for Syphilis

Drug Shortages and FDA

- FDA defines a shortage as a period of time when the demand for a drug in the US exceeds its supply

- Drug shortages can occur for a variety of reasons:
  - Manufacturing and quality problems
  - Delays
  - Demand
  - Discontinuation

FDA's Authority in Drug Shortages

- What we can require:
  - Notification by manufacturers of:
    - Supply disruptions
    - Delays
    - Discontinuations
    - Certain manufacturing changes

- What we cannot require:
  - A company to report an increase in demand that might lead to shortage
  - A company to make a drug
  - A company to make more of a drug
  - A distributor report on how much of a drug is distributed and which purchasers will be given priority

Penicillin G Benzathine Shortage

- Only one FDA approved penicillin G benzathine injectable suspension (Bicillin L-A) product marketed
- Shortage began April 26, 2023 due to demand outpacing supply
- Increased demand of Bicillin L-A due to increased rates of syphilis
- FDA reached out to other international regulatory agencies
- Most countries also identified Pfizer as their source for Bicillin L-A

Temporary Importation

- Importation explored when there is a shortage where U.S. approved manufacturers not able to meet demand and there are no adequate substitutes
- Last resort to meet critical patient need
- Identify a drug supplier for temporary importation
  - Consult with companies producing for the US market to see if they produce for other markets
  - Reach out to regulators in other countries with robust regulatory standards (e.g. EU, UK, Canada, Australia., etc.)
  - Once a supplier is identified, we evaluate their suitability for supplying the US market
- Confirm import will not cause shortage in other countries

Current State of Penicillin G Benzathine Shortage

- Current state of penicillin G benzathine injection supply (as of 11/12/24):
  - 600,000 IU unavailable
  - 1,200,000 IU available
  - 2,400,000 IU limited availability

- Extencilline (temporary import)
  - 1,200,000 IU available
  - 2,400,000 IU available

- Lentocilin (temporary import)
  - 1,200,000 IU available

https://dps.fda.gov/drugshortages

Resolution of a Drug Shortage

- FDA considers a shortage resolved when:
  - Manufacturers can meet total national historical demand
  - all backorders filled
  - distributors have plenty of stock to satisfy orders
  - the company has a healthy safety stock

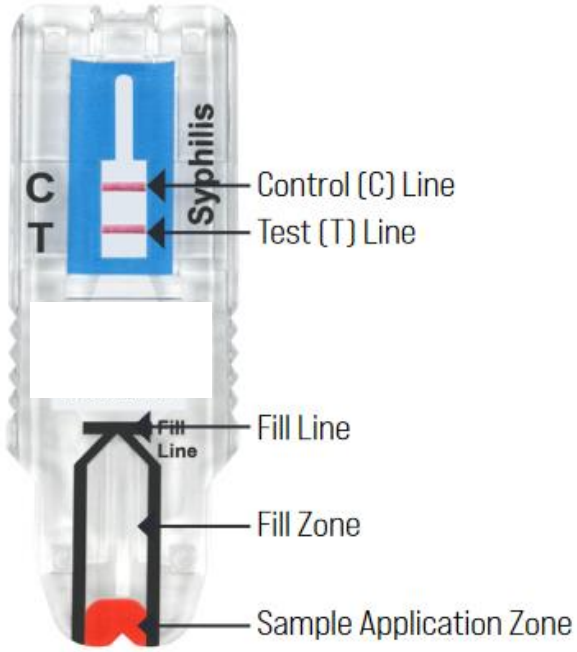
Point of Care and Over-the-Counter Testing for Syphilis

- FDA has cleared two CLIA-waived point-of-care (POC) tests and one over-the-counter (OTC) test for syphilis which:
  - Use whole blood from a fingerstick
  - Detect antibodies to *Treponema pallidum*
  - Can provide rapid test results
  - Increase access to testing

- Main differences between syphilis POC/OTC tests and lab-based serologic syphilis tests:
  - Time to result
  - Syphilis POC/OTC tests must be confirmed, using laboratory-based tests

Over-the-Counter Test for Syphilis

- One FDA-cleared test is available
- Provides results in 15 minutes
- Detects antibodies to *Treponema pallidum*
  - A positive result needs a 2nd (non-treponemal) lab-based test to make diagnosis of active syphilis infection
  - A positive test alone cannot distinguish between new infection and re-infection
- Increases access to testing
- Allows for testing in privacy, overcoming stigma associated with STIs
- Increases awareness of STIs among general population
- FDA clearance of OTC tests encourages manufacturers to develop new tests



Top Things to Know From FDA

- FDA has been working to mitigate the penicillin G benzathine drug shortage

- Syphilis POC tests and OTC tests screen for antibody to *T. pallidum* and a positive result requires follow-up testing

Thank you!