

CMS PERSPECTIVE 2009 A/H1N1 OUTBREAK



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CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Public Health Emergency Declared!!

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Topics for Discussion

- Coordination w/ CDC, FDA & APHL
- CMS' actions
- CMS Recommendations & Final Thoughts
- CMS Plans for the Fall



Request from APHL to CMS

- Postpone routine surveys of State Public Health Laboratories (PHL)
- Prevent interruption & delays of urgent, high volume H1N1 testing

Approval of EUA by FDA

- FDA approved Emergency Use Authorization (EUA) test for 1 year or until emergency ceases
- CDC developed test for PHL use
- FDA notified CMS of approval/guidance
- Only FDA approved test for A/H1N1

Approval of EUA by FDA

- Real Time PCR swine flu panel test for H1N1 'presumptive diagnosis'
- Confirmatory viral culture testing performed at CDC
- FOCUS (Quest) also developed a test which FDA granted EUA in July

Coordination with CDC

- CDC developed protocol for EUA test validation & coordinated w/ CMS
- Few positive samples existed to perform validation & QC
- Testing personnel must complete training prior to testing-per FDA
- Laboratory developed tests (LDT) must meet CLIA/State requirements

CMS Actions

- Forwarded pertinent CDC/FDA H1N1 testing information to CMS regional offices (RO), States (SA) & accrediting organizations (AO)
- Developed & transmitted a policy memo to delay PHL surveys unless:
 - Immediate jeopardy or
 - Complaint alleged

CMS Actions Con't.

- Due to potential test kit shortage, made PT discretionary for one event or until further notice to facilitate adequate kit supply for patient testing
- Communicated w/ CMS management w/ information, issues & resolutions
- CMS mgt. coordinated w/ HHS

CMS Actions Con't.

- Participated on joint call w/ CDC re 'Interim Test Guidance for H1N1" 7/09
- Monitored CDC LOCs updates, as necessary
- Informal survey in July indicated that almost all testing performed in PHLs.
- Participated in CDC/APHL H1N1 meeting 9/1/09

CMS Recommendations

- Testing laboratories should:
 - Standardize equipment, procedures for QC, test validation, training, in advance
 - Include pre & post analytical information
 - Coordinate these w/ CMS for CLIA compliance, in advance
 - Those w/ high volumes should network w/ lg. clinical laboratories in emergencies

CMS Recommendations

- Testing laboratories should:
 - Coordinate w/ each other to balance/stagger resources & workload
 - Have a plan & involve all affected parties in its design!

CMS Recommendations

- All parties should collaborate to:
 - Develop a testing triage & clinical protocol including PT, QC & test validation
 - Work w/ manufacturers to ensure adequate test kit & reagent inventory
 - Ensure w/ FDA that QC material is approved & perf. spec. developed
 - Identify surplus technical resources who can be deployed quickly to supplement workforce shortages

CMS Final Thoughts

- Overall, good communication & coordination & response time!
- Successful outcomes.
- Whew!!

CMS CLIA Plan for Fall

- Includes external plan for testing, surveys, program resources
- Also includes internal plans to prioritize & accomplish program work & minimize staff exposure
- Sampling of external plan action items includes--

CMS CLIA Plan for Fall

- Collaborate w/ CDC/APHL/FDA on testing triage protocol to focus resources, minimize kit consumption, test TAT
 - Monitor test volumes & locations
 - Facilitate mechanisms to expedite testing or re-locate it
 - Check competency of laboratory staff
 - Develop standard QC, PT, test valid.

CMS CLIA Plan for Fall

- Suspend surveys, as appropriate
- Institute simple, effective communication mechanism w/ all affected parties; use regularly!
- Prioritize problems; mitigate risk
- Facilitate enrollment of new labs & personnel qualification verifications
- Provide updates on CMS/CLIA website

CMS CLIA Plan for Fall

- Solicit assistance from professional organizations which may have additional resources
- Prioritize workload for SA/RO to minimize exposure, but ensure test quality w/ effective oversight

Where to Find Info:

- CMS CLIA Web site:
 - www.cms.hhs.gov/clia/
 - NEW FEATURE: A/H1N1 Updates & Links--2009-10
 - Brochures, state contacts, application, guidelines
- CMS Central Office, Baltimore
 - 410-786-3531
- Judy Yost's email:
 - Judith.yost@cms.hhs.gov



THE END!!

Stay safe & healthy until we see
you again!

