



HEPATITIS C SEROCONVERSIONS AND ESRD REGULATIONS

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October 1, 2015

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Agenda



- Review frequently cited Federal and State deficiencies for ESRD facilities that had a Hepatitis C Seroconversion.

Cited Condition Level Deficiencies



- **V494.30** Infection Control - examples include:
 - Volume of standard level deficiencies cited.
 - Intravenous medication preparation performed at a dirty sink.

- **V 494.110** QAPI - example includes:
 - Failure to perform a root cause analysis after a Hepatitis C Seroconversion.

Cited Deficiencies Related To Staff Training & Staff Competency



- Staff members require education on infection prevention and control at orientation and, at a minimum, annually.
[8:43A-3.5(d)1], [494.30(a)1(i)]
- Staff members assigned as alternate administrator or day-to-day person responsible for infection prevention and control must be oriented to his/her position and demonstrate competency.
[8:43A-3.5(a)], [8:43A-12(b)1,5], V681

Cited Deficiencies Related To Hemodialysis Care



- Staff (visitors, other health care workers) perform hand hygiene before and after contact with patients and prior to performing procedures **[494.30(a)(1)(i),V113], [8:43A-24.4(b)]**
- Ensure that gloves are changed and hand hygiene is performed when moving from one patient to the next and before accessing clean supplies **[494.30(a)(1)(i),V113], [8:43A-24.4(b)]**
- Patient or visitor who held access sites, remove gloves and perform hand hygiene **[494.30(a)(1)(i),V113], [8:43A-24.4(b)]**

Cited Deficiencies Related To Hemodialysis Care



- Prepare medications in a clean area away from the dialysis station. **[494.30(a)(1)(i),V117]**
- Do not carry medication vials, syringes, alcohol swabs, or supplies in pockets. **[494.30(a)(1)(i),V119]**
- Items taken into the dialysis station are dedicated for use on a single patient (e.g. use of topical anesthetic spray for access prep). **[494.30(a)(1)(i),V116]**
- Supplies are stored in clean areas to prevent contamination from potentially infectious material. **[494.30(a)(1)(i),V119]**
- Clamps are cleaned of visible blood and disinfected in the open position. **[494.30(a)(1)(i),V116]**

Cited Deficiencies Related To Hemodialysis Care



- Equipment is disinfected before being returned to a common area or taken to another station (e.g. stethoscope, pH/conductivity meter, thermometer).
[494.30(a)(1)(i),V116]
- BP cuff and tubing, TV controls, the data entry station and counters around dialysis stations are wiped wet with disinfectant. **[494.30(a)(4)(ii),V122]**
- When the chair is vacated; have chair fully reclined, wet all external front facing and side chair surfaces, including down sides of seat cushion and top sides of table.
[494.30(a)(1)(i),V116], [494.30(a)(4)(ii),V122]

Cited Deficiencies Related To Hemodialysis Care



- Items taken into the dialysis station should be disinfected before used on another patient (e.g. laminates, clamps, clip boards). **[494.30(a)(1)(i),V116]**
- Disinfect machine top, front and side surfaces, dialysate hoses, Hansen connectors, and outside surfaces of dialysate concentrate containers **[494.30(a)(4)(ii),V122]**
- Wipe wet all surfaces of prime waste containers with disinfectant-soaked cloth/wipe. **[494.30(a)(4)(ii),V122]**
- Avoid cross contamination when handling blood samples. **[494.30(a)(1)(i),V117]**

Cited Deficiencies Related to Monitoring of Anti-HCV Negative Patients



- Screen all patients for possible HCV infection using anti-HCV and ALT test on facility admission. **[8:43A-24.4(b)]**
- For susceptible patients (i.e. anti-HCV negative), perform anti-HCV testing semiannually and ALT monthly. **[8:43A-24.4(b)]**
- Inform newly infected patients of the change in their HCV status and arrange for clinical evaluation/management. **[8:43A-24.4(b)], [494.90(b)(3),V559]**
- New Jersey Reporting Requirements for Communicable Diseases and Work-Related Conditions, July 2013, www.nj.gov/health/cd (e.g. Hepatitis C Seroconversion) **[NJAC, Title 8, Chap 57, Chap 58], [494.30(c),V145]**

Cited Deficiencies Related To Assessment & Plan of Care

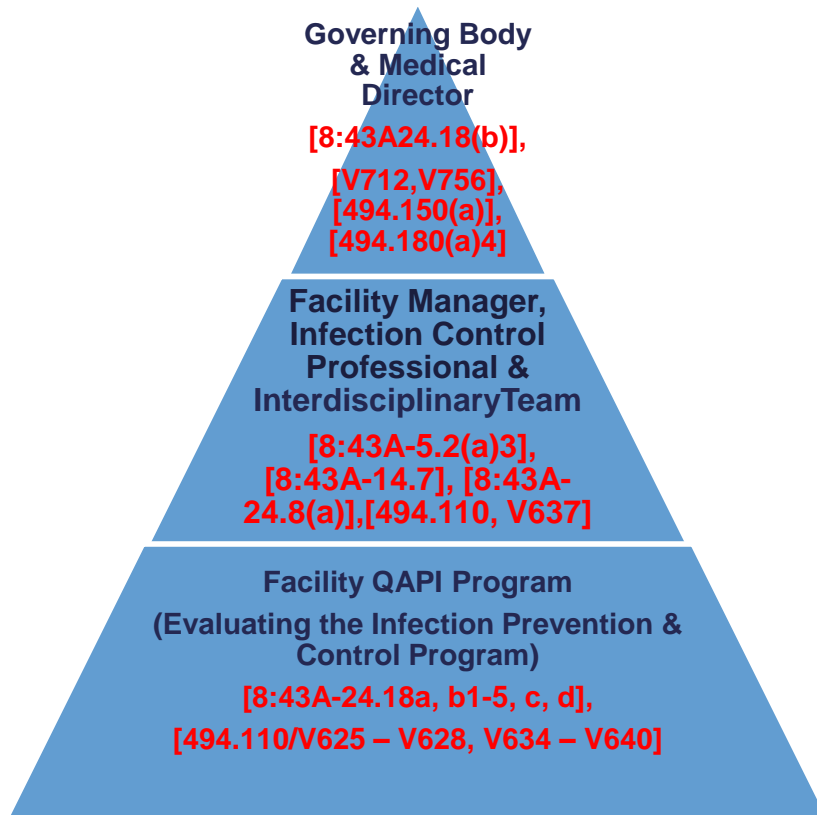


- Psychosocial Services - The social worker performs a re-assessment and modifies the plan of care to address psychosocial issues. **[NJ 8:43A-24.13(b,c)], [494.80(a)(7),V510], [494.90(a)(6),V552]**
- IDT modifies the plan of care when expected outcomes are not achieved (e.g. monthly ALT is above acceptable range). **[NJ 8:43A-24.4(b)], [494.90(b)(3),V559]**

Cited Deficiencies Related to QAPI



Regulatory Requirements - QAPI



- Measure, analyze and track outcomes. Develop plans and take actions when goals are not met.
**[NJ 8:43A-24.4(b)],
[494.110(a)(2)(ix), V637]**
- Is a root cause analysis performed after a Hepatitis C serconversion has been confirmed? **[NJ 8:43A-24.4(b)], [494.110(a)(2)(ix), V637]**

References



- **N.J.A.C. Title 8, Chapter 43A Standards For Licensure Of Ambulatory Care Facilities**
 - **Part 494 Conditions For Coverage For End-Stage Renal Disease Facilities**

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DIALYSIS ASSOCIATED HEPATITIS C REPORTING IN NEW JERSEY

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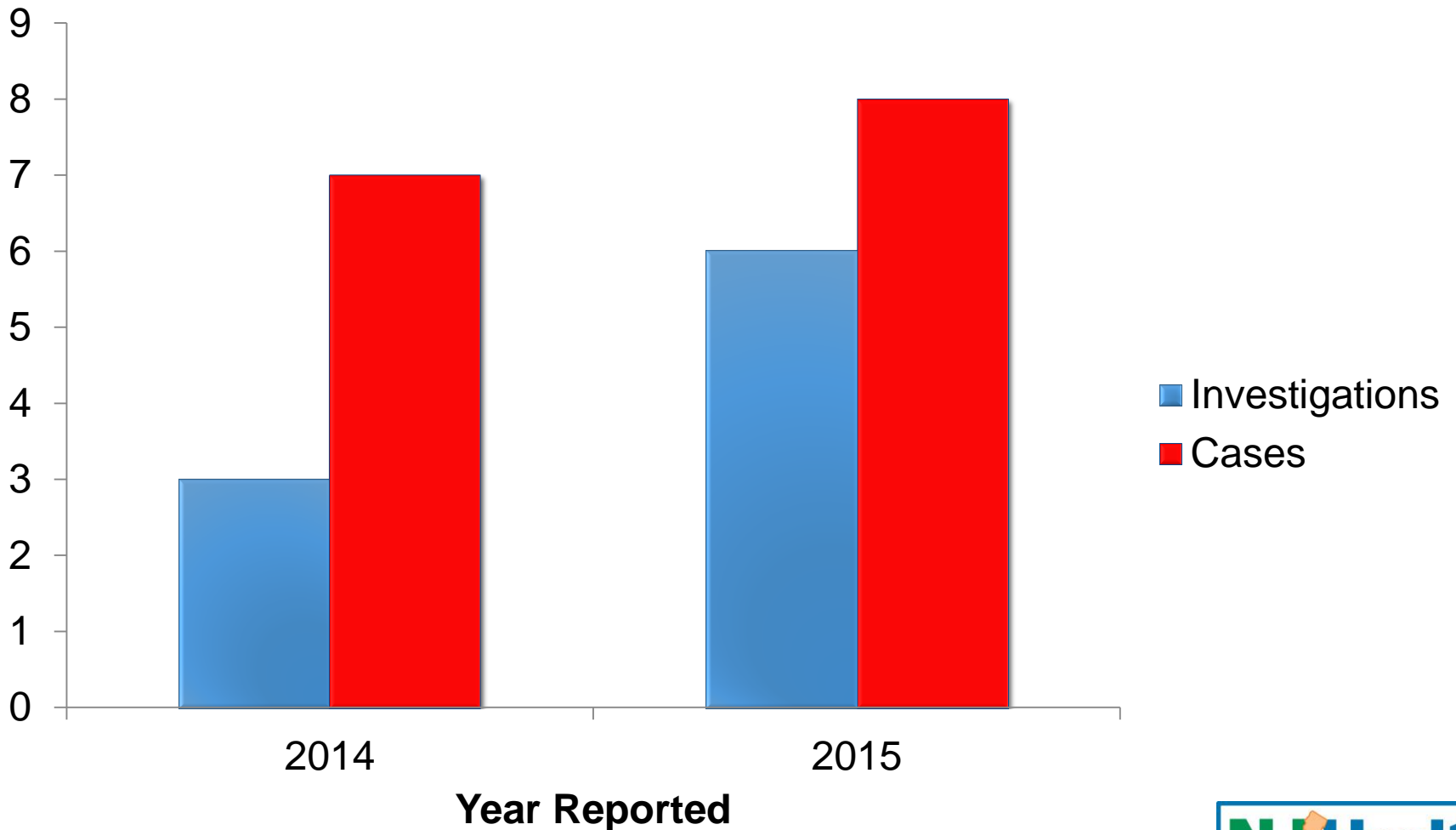
Communicable Disease Service

New Jersey Department of Health

Reporting Regulation

- New Jersey Administrative Code 8:57-1.6
- Hepatitis C is directly reportable to NJDOH within 72 hours through CDRSS by laboratory
- A Dialysis Hepatitis C seroconversion is considered an HAI outbreak
- All outbreaks, even suspected, are reportable by PHONE from physicians or facility administrators

New Jersey HCV Seroconversions 2014-2015



Outbreak steps

- Roles of Local Health Department, Regional Epidemiologist, and Subject Matter Expert
- Lab review
- Initial investigation for risk factors, other exposures
- Conference call with all stakeholders
- Collect specimens for testing at CDC
- Referral to Division Health Facility Survey & Field Operations

New Jersey Dialysis Seroconversion Investigation Example

- 2 seroconversion patients reported to NJDOH
 - HCV negative January 2014
 - HCV positive June 26, 2014
- Asymptomatic
- No traditional risk factors

New Jersey Dialysis Seroconversion Investigation Example

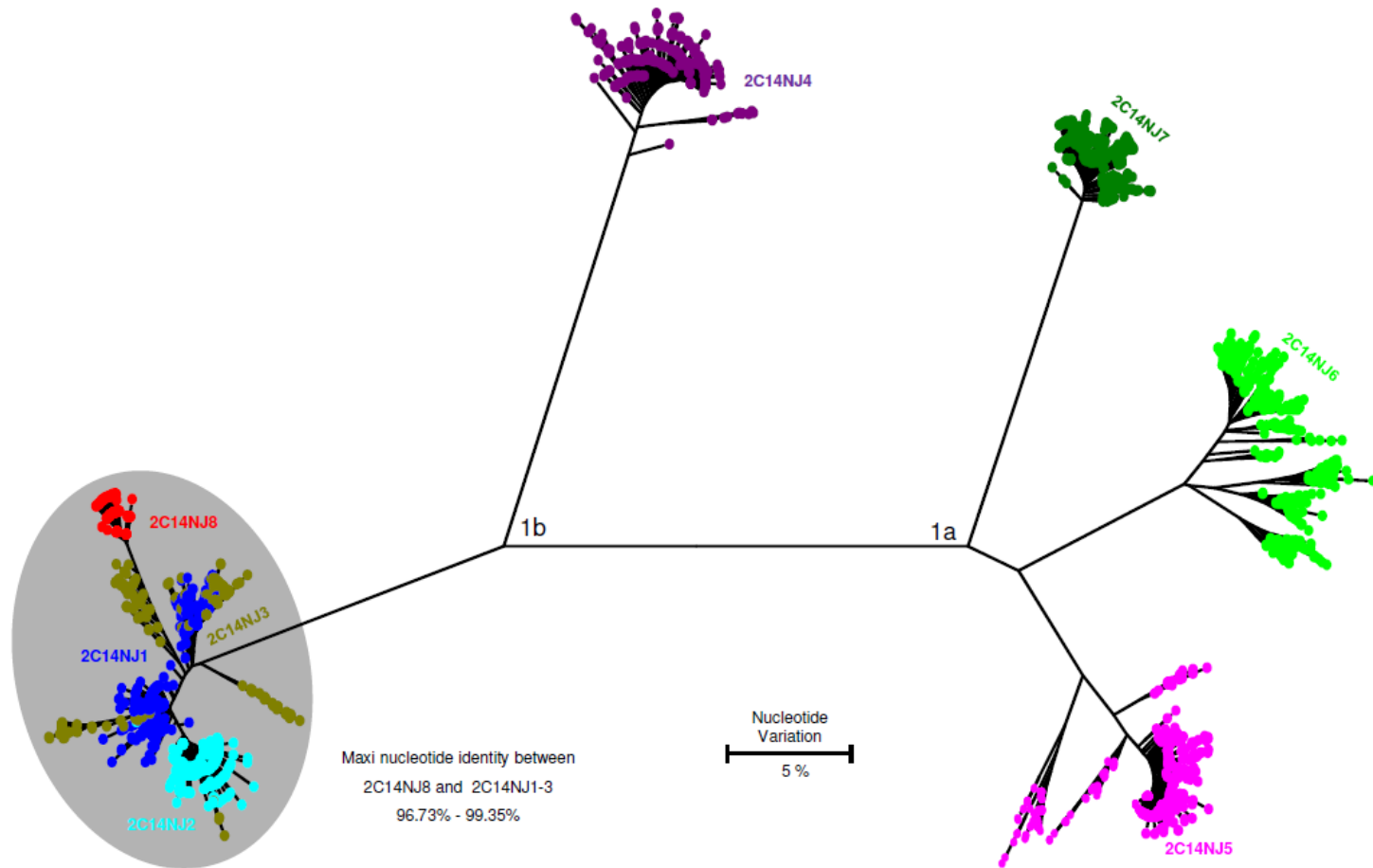
- Initial investigation and conference calls with facility and local health department
- Samples from 2 seroconversions and 5 known chronic cases sent to CDC
- Facility reported to Health Facility Survey & Field Operations
- Unannounced site visit planned for 8/7/14

New Jersey Dialysis Seroconversion Investigation Example

- July 2014- HCV negative population testing once a month
- September 2014- two additional seroconversions
 - Collected and sent to CDC for matching

2C14NJ E1-HVR1 Quasispecies Sequences

(E1-HVR1 region, 306 bp in length, only unique sequences are shown, Updated 11/5/2014)



Issues in Reporting

- HCV seroconversions reported days, weeks, or months late
- Communication gaps occur between labs and facilities
 - Delays in HCV antibody tests
 - ALT monitoring not maintained
- Some labs do not specifically mention dialysis on reports to Local Health Department

Possible Solutions

- First day HCV testing upon entry to facility, don't wait for June/January mandatory testing
- ALT spike, standing order for reflex testing
- Antibody positive but s/co <11, issue reflex testing
- Red flag system for labs

Facility Relationship with NJDOH

- Communicable Disease Service is not the licensing division
- Our goal is to work with facilities to help reduce disease transmission
- If you have any questions relating to communicable disease transmission and reporting please ask!

Thank you!

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