Investigation of Healthcare-associated Transmission of Hepatitis C in an Unfamiliar Setting – Oklahoma, 2013

Arizona Infectious Diseases Conference

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State Epidemiologist

Hepatitis C Surveillance in Oklahoma

- Focus on capturing reports of acute disease
  - Symptoms and laboratory criteria
- Due to high volume of lab reports received, reporting requirements changed to "Hepatitis C in persons ≤ 40 years or in persons having jaundice or ALT ≥ 400 regardless of age with laboratory confirmation…"
- Chronic infection
  - Not assigned to public health nurses for follow up
  - Entered into Hepatitis C registry
  - Laboratory criteria alone
    - Antibody (past or current infection)
    - RNA (current infection)

Identification of Healthcare-associated Transmission Events

- Possible case cluster identified through case interviews
  - Individual acute hep C case investigations include standard question about recent medical/dental procedures
- Notification by a private healthcare provider of unusual increase
- Notification by licensure board of suspected breaches in infection control, injection safety or drug diversion

Previously Identified Healthcare-associated Transmission of HCV in Oklahoma

- Outpatient settings
  - Large outbreak of HCV and HBV associated with pain management clinic, 2002^
  - Small HCV transmission event in ambulatory surgery clinic, 2008

Comstock RD, et al. Inf Control & Hosp Epi. 2004;25:576-583.

Previously Identified Healthcare-associated Transmission in Dental Settings – United States

- No confirmed patient transmission events of HCV
- Two recognized transmission events of HBV (NM-2001*, WV-2009[b])
- One historic event of HIV (FL-1991)

* Redd JT, et al. *J Infect Dis* 2007;195:1311-1314

[b] Radcliffe RA, et al . *J Am Dent Assoc* 2013;144(10):1110-1118

Initial Investigation

- Positive anti-HCV lab result in an adult > 40 yrs old reported to OSDH
- Prompt from blood collection facility to pursue
  - F/U to gastroenterologist revealed elevated ALT , HCV viremia
- Case investigation found no traditional risk factors
  - Routine blood donor for several years
  - Seroconverted between April and August, 2012 donations
  - Hx of multiple dental visits during period of likely exposure
    - 3 different dental practices

Site Investigations

- 3-member site team evaluated infection control practices using CDC 's *Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care*

- Numerous "red flags" at oral surgical clinic

- Patient scheduler for past year obtained
  - Patient that preceded index case cross-matched on HCV surveillance database

March 12, 2013

March 18, 2013

Guide to Infection Prevention
For Outpatient Settings:
Minimum Expectations for Safe Care
http://www.cdc.gov/HAI/pdfs/guidelines/ambulatory-care-checklist-07-2011.pdf

Components of Checklist for Outpatient Settings

- Facility Policies and Practices
  - Infection Prevention training
  - Occupational health
  - Hand hygiene
  - PPE
  - Injection safety
  - Environmental cleaning
  - Sterilization and re-processing of reusable instruments/devices
- Personnel and Patient-care Observations

Checklist Items for Injection Safety

a) Medication vials are entered with a new needle and a new syringe, even when obtaining additional doses for the same patient

b) Medication administration tubing and connectors are used for only one patient

c) Multi-dose vials are dated when first opened and discarded within 28 days unless manufacturer specifies different date for that opened vial (shorter or longer)

d) Multi-dose vials to be used for more than one patient are kept in a centralized medication area and do not enter the immediate patient treatment area

e) All controlled substances are kept locked within a secure area

Excerpts from Complaint Affidavit

OK Board of Dentistry -- March 26, 2013

- Uncertified dental assistants routinely administering IV sedative drugs
- Lack of appropriate controlled drug inventory log; expired medications in cabinet and still being used
- Two sets of instruments
  - Instruments for known bloodborne pathogen-infected patients rinsed in undiluted bleach; pitted and corroded
- Failure to follow autoclave manufacturer's guidelines; no biological monitoring in 6 years

Decision for Large Scale Patient Notification

- Public health responsibility to notify persons who may have been exposed
  - Prevent further transmission of infectious disease
  - Identify infected persons to seek treatment & change lifestyle to protect liver health
- Requires careful planning, collaboration, and risk communication
- Expect criticism
  - Public
  - Dental profession

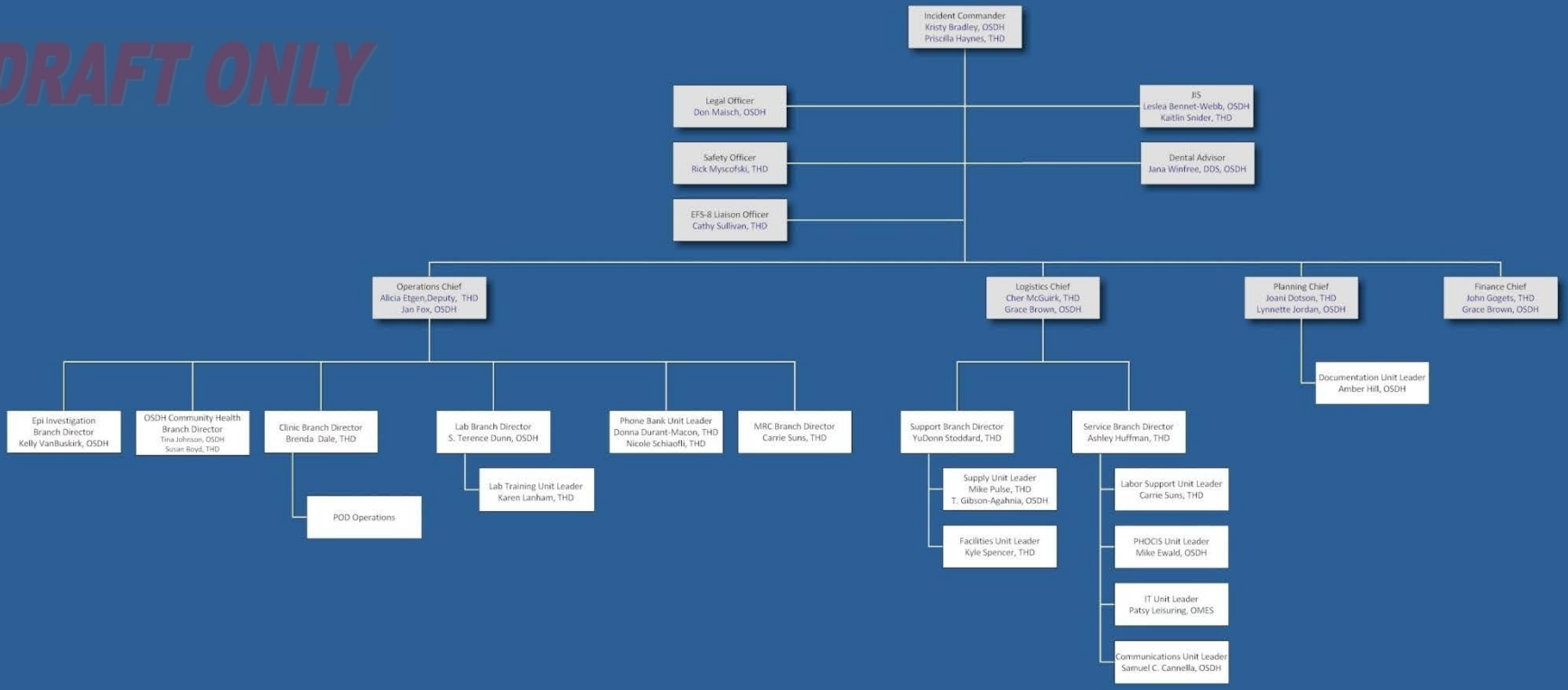
March 28, 2013

PRESS CONFERENCE

DENTAL HAI UNIFIED COMMAND

REVISION 2013.04.05

DRAFT ONLY



PUBLIC HEALTH & MEDICAL SYSTEMS EMERGENCY RESPONSE

Incident Objectives

- **Protect the public's health** by indentifying any persons who may have acquired HIV, HBV, or HCV due to improper infection control or injection safety practices at the dental facility.
- **Conduct an epidemiological investigation** to determine scope of the problem and define risk factors for HAIs linked to the dental practice.
- **Provide HIV, HBV and HCV testing** of the dental patient cohort in effective manner…
- **Effectively communicate test results** to all patients who receive testing, and provide appropriate recommendations for follow-up medical care…
- **Offer counseling and support resources** for persons affected by this incident.
- **Coordinate risk communication** and public releases of information related to this incident…
- **Track and document** all purchases, personnel time & effort and other resources dedicated to the incident response.

Public Health Response Timeline, 2013

- March 12 - Dental practice site investigations begin
- March 18 – Joint site investigation with Board of Dentistry
- March 20 – Oral surgeon voluntarily surrenders dental license
- March 22 – ICS activation
- March 28 – Press Conference at Tulsa Health Department
- March 29 – Patient notification mailings and blood draw clinics operational
- April 8 – Tulsa Health Dept scales back clinic hours
- April 18 – Situational update media release announces first round of positive lab results
- June 28 -- Dental patient testing ended; epidemiologic study ongoing

METHODS

Epidemiologic Investigation

- **Patient serosurvey**
  - Testing at PHL: HIV 1/2, Hep B surface Ag, anti-HCV
  - HCV+ specimens forwarded to commercial lab for quantitative PCR and genotyping
- **Record review and patient questionnaire**
  - Abstract dental medical records and CDS drug log
  - Questionnaire administered to patients since 2011
  - Data entry into separate “PHIDDO” module
- **Genotype cluster analysis**
  - Evaluate patient encounters of all HCV-infected patients since 2011

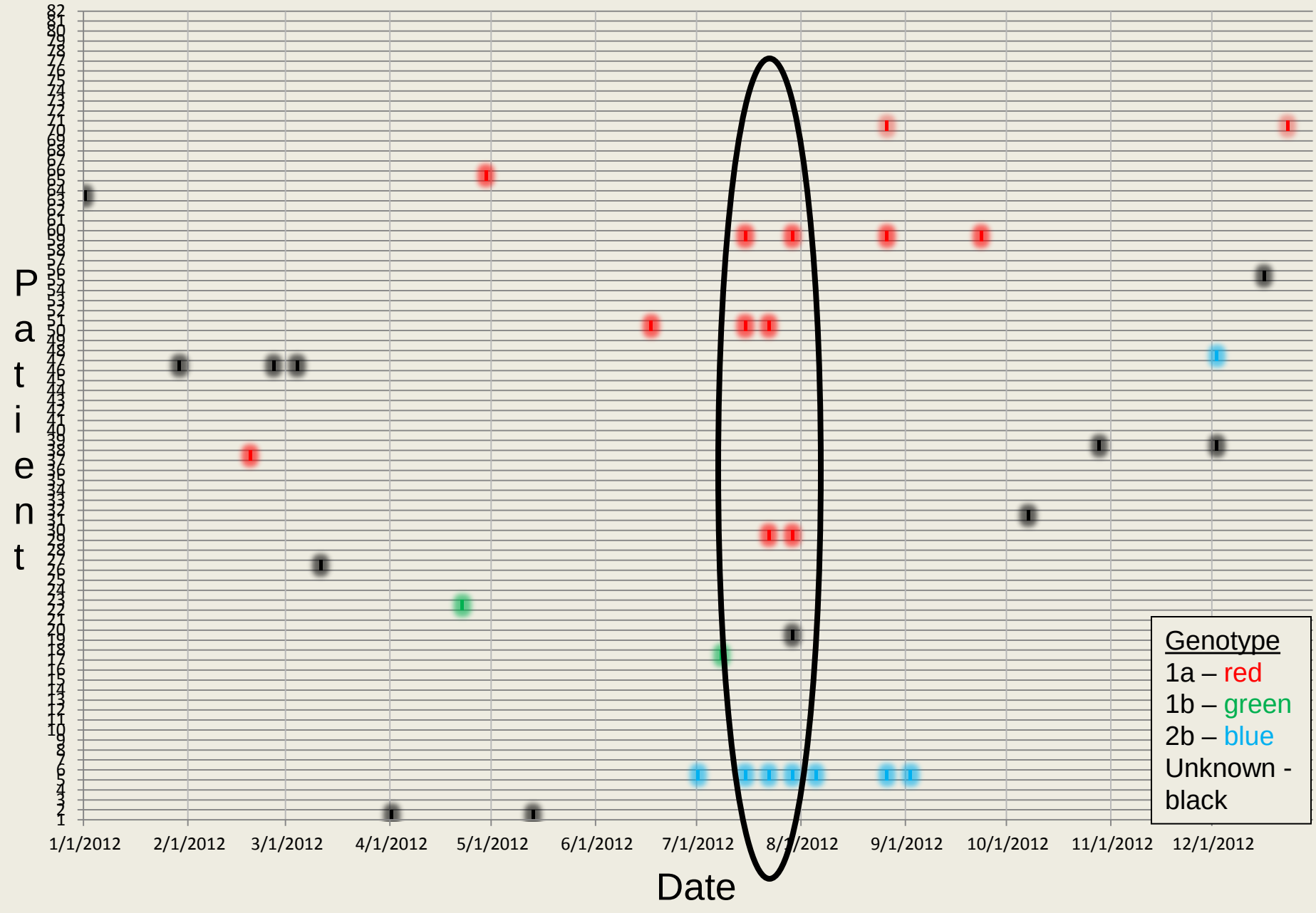
Findings

- 5,810 patient notification letters mailed
- 4,208 former dental patients tested through Public Health Lab; unknown number through private HCP
  - ✓ 4 HIV-positive
  - ✓ 6 HBV-positive
  - ✓ 96 (2.3%) HCV-positive
- 60 (62%) newly identified HCV infections
- 100% homology of index case & source case specimens by quasispeciation (genotype 1a)
- No linkage found with 3 HIV patient specimens

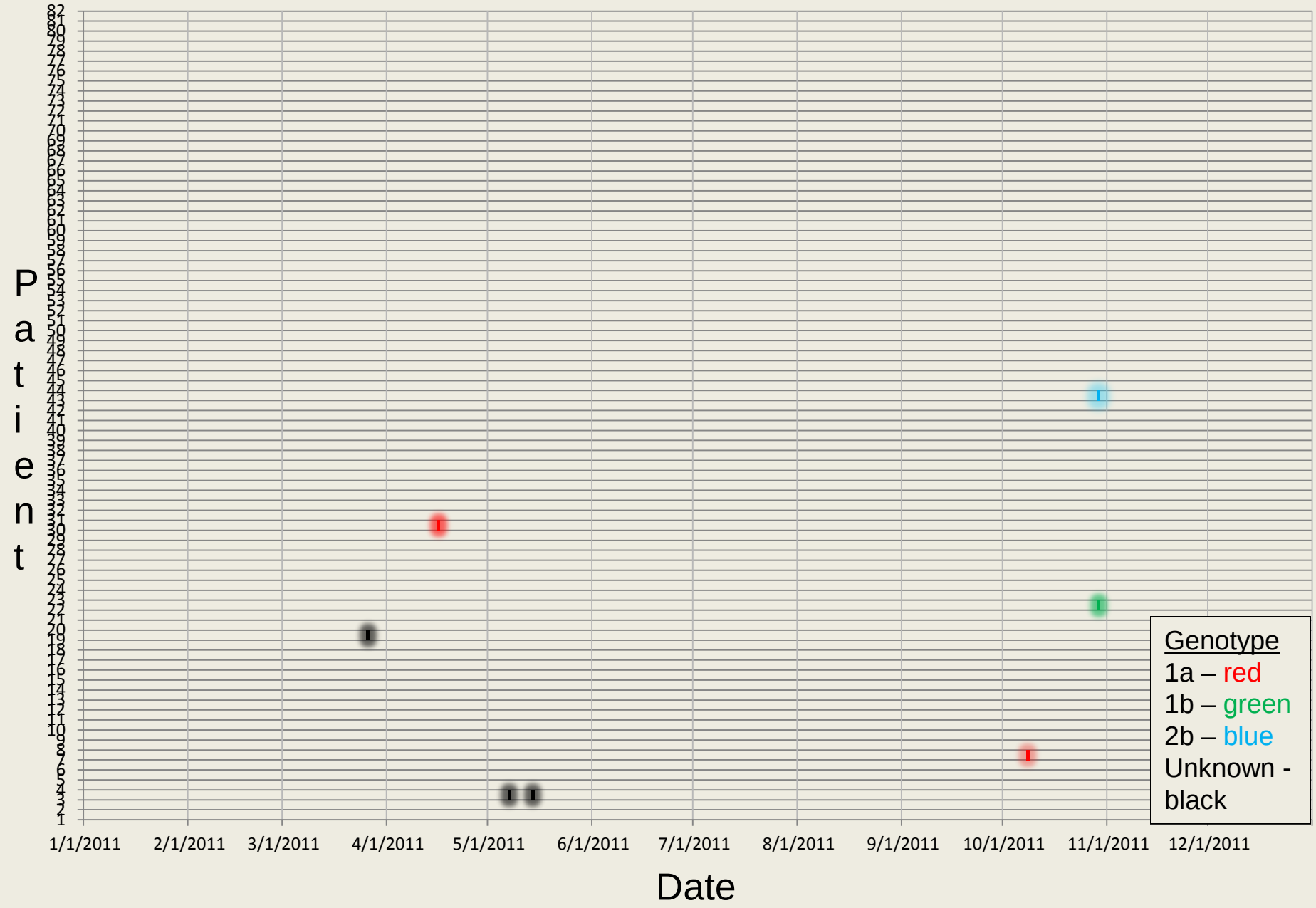
HCV Results: Timing and Risk Factors

- 90 dental patients with hepatitis C
  - 19 - HCV diagnosis prior to first Harrington dental visit
  - 63 – HCV diagnosis after first dental visit
  - 8 – unknown relationship between test result and dental visits
- Among 63 with diagnosis following dental procedures at Harrington's clinic:
  - ✓ 32 (51%) reported high risk behaviors (IDU, incarceration)
  - ✓ 26 (41%) reported low or no risk behaviors
  - ✓ 5 (8%) declined interview or lost to follow up

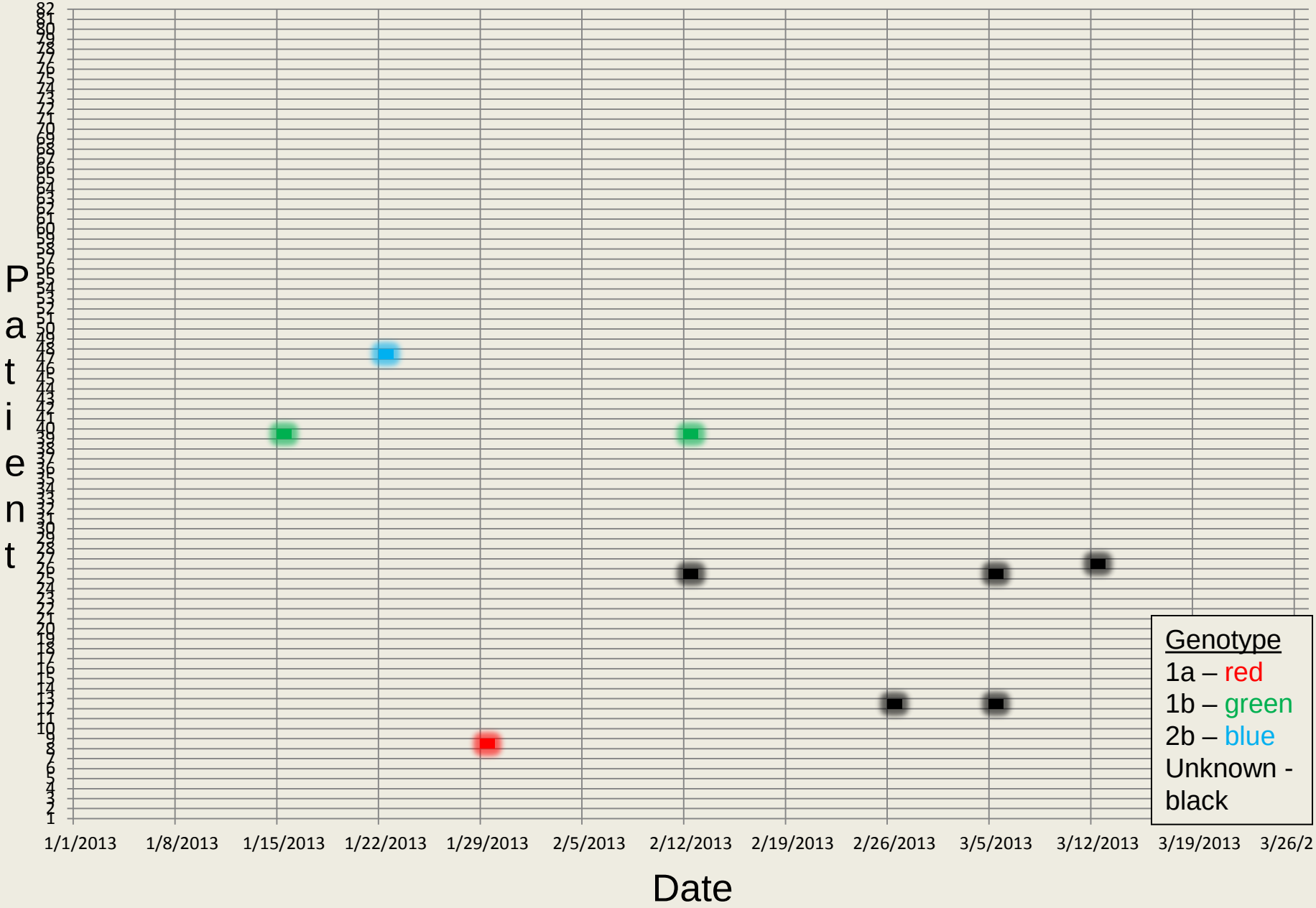
Exposures to dental clinic for all positive HCV infections during 2012



Exposures to dental clinic for all positive HCV infections during 2011



Exposures to dental clinic for all positive HCV infections during first three months of 2013



Findings of Investigation

- First documented case of HCV patient-to-patient transmission in an oral healthcare setting
- Receipt of higher dosages of 3 separate IV medications (propofol, Brevital®, metoclopramide) associated with higher likelihood of newly diagnosed HCV infection
  - Case cohort study of 1,021 patients (Mar 1, 2012 – Mar 20, 2013)
  - Not statistically significant at $p < 0.05$
- Obstacles to large retrospective investigation
  - Large proportion of former dental patients with unk status
  - Characteristics of HCV infection

Possible Mode of Transmission

- Contaminated instrumentation
- Dental healthcare worker to patient
  - Oral surgeon and 3 dental assistants complied with request for testing; all negative tests
- Contaminated multi-dose vials of anesthetic drugs
  - Propofol known to support growth of many organisms*
  - 20 ml multi-dose vials of propofol routinely used
  - Index case and source case received 400 mg and 300 mg compared to usual dose of 200 mg

*Anesth Analg 1999;88:209-212. J Hosp Infect 2010;76:225-230.

Sterilization Monitoring in Dental Facilities

- Routine monitoring of sterilization procedures through a combination of methods:
  - Mechanical
    - Assess time, temp and pressure by observing displays/gauges
  - Chemical
    - heat sensitive tape to prove parameters met (doesn't prove sterilization achieved)
  - Biological
    - Use of indicators (spore test) directly determine presence of most resistant microorganisms (*Bacillus spp*)

http://www.cdc.gov/OralHealth/infectioncontrol/faq/sterilization_monitoring.htm

Frequency of Spore Testing

- At least weekly (routine)
- Whenever new packaging material or tray is used
- After training new personnel
- After autoclave/sterilizer repair
- After any change in loading procedures
- With any load containing implantable device

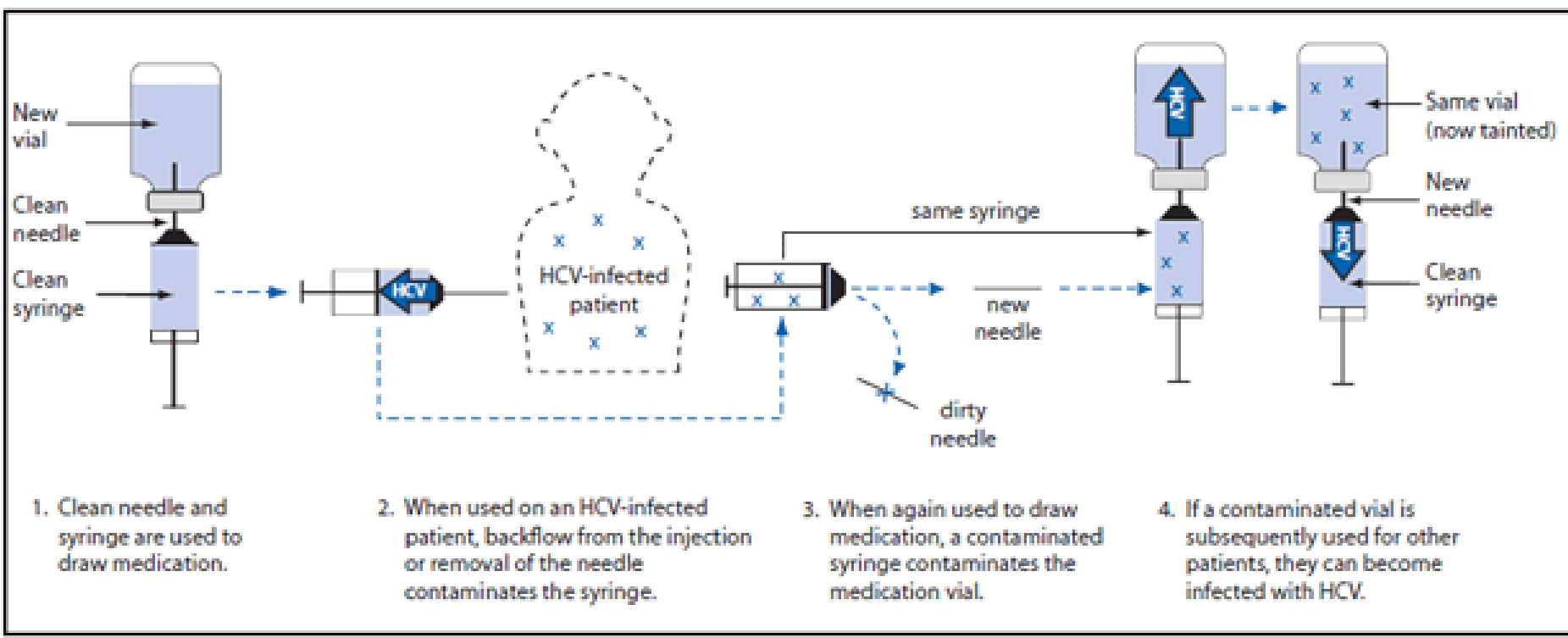
Persisting Problems with Unsafe Injection Practices in the U.S. Healthcare System

- Increasing number of outbreaks attributed to unsafe injection practices
  - 49 outbreaks since 2001
  - 21 involved HBV/HCV; 28 involved bacterial BSIs
  - 90% in outpatient settings; pain mgmt clinics, cancer clinics

- Burden of patient notification to undergo testing for bloodborne pathogens
  - Estimated 150,000 patients notified during 2001-2012

CDC. MMWR 2013;62:423-425

Unsafe Injection Practices and Circumstances Leading to HCV transmission at Endoscopy Clinic – Las Vegas, NV, 2007



CDC.MMWR 2008;57:513-517

One and Only Campaign

http://www.oneandonlycampaign.org/campaign_resources

Blood Donor Seroconversion as HAI Sentinel Event

- Since 2008, repeat blood donors who converted from HBV or HCV negative to NAT-confirmed positive were sentinel indicators for 4 HAI transmission outbreaks/events:
  - Outpatient cardiac clinic, NC
  - Hospital, CA
  - Pain management clinic, SC
  - Oral surgical clinic, OK

Moorman AC, et al. *Transfusion* 22 Apr 2015. DOI:10.1111/trf.13132

Recommended Policy Changes

- Dental Assistants - Improved oversight (permit within 30 days of employment)
- Add category for Dental Technician (dental assistant in training)
- Infection Control continuing education requirements for dental personnel
- Periodic unannounced inspections of dental facilities (enhanced compliance)

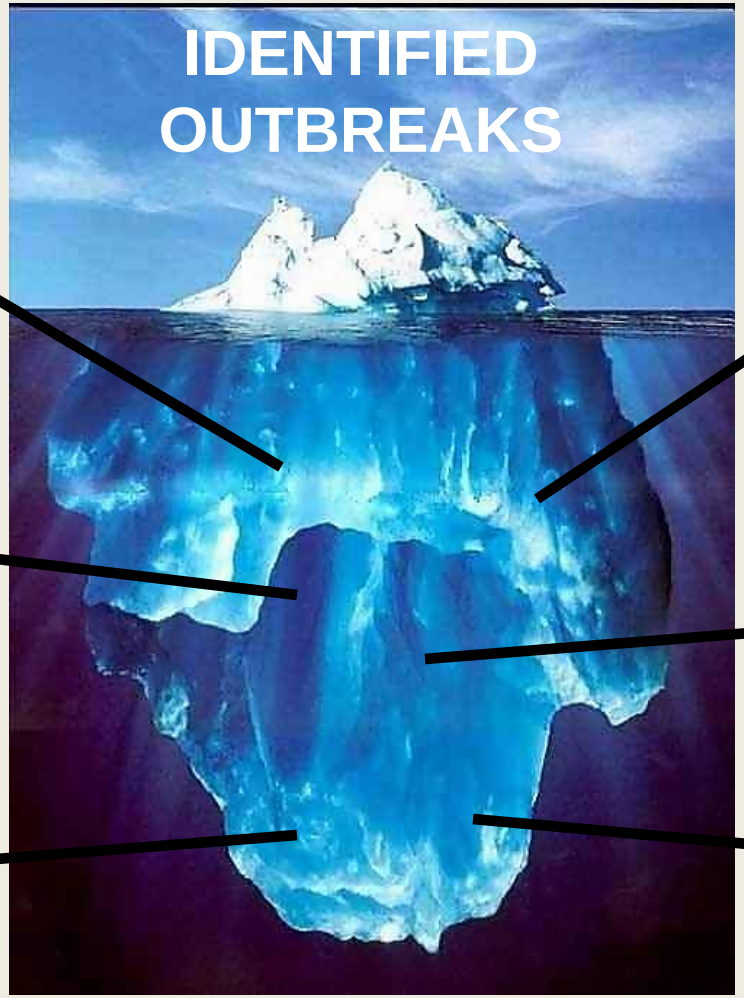
Revisions to the OK Dental Practice Act
effective July 1, 2013

- Creation of a new level of Dental Assistant, the Oral Maxillofacial Surgery Assistant
- Requirement of permits for all Dental Assistants
- Increase the maximum number of FTE employees at the Board of Dentistry agency from 5 to 10
  - will include more dental investigators;
- Addition of the following act that constitutes grounds for penalties: *practicing dentistry in an unsafe or unsanitary manner or place, including but not limited to repeated failures to follow Centers for Disease Control (CDC) or Occupational Health Safety Administration (OSHA) guidelines*

O.S. Title 59, Chapter 7, Section 328.1-328.56

HCV Transmission in Dental Settings: Rarely Occurring or Rarely Identified?

- Asymptomatic infection
- Under-reporting of cases
- Under-recognition of healthcare as risk



- Difficulty identifying single **healthcare** exposure
- Barriers to investigation
- Resource constraints

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Public Information Outreach

- Hotline staffed by Tulsa Health Department
  - 3,467 calls fielded
- Media conference followed by press releases
  - Total of 23 Situation Updates
- Extensive international/national/state/local interest and coverage
  - 39 countries outside of U.S.
  - 9,129 news stories documented by TVEyes Media Monitoring Suite