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Recent Regulatory Changes to HCV Diagnostics

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TREATMENT ACTION GROUP

Virtual Learning Collaborative

March 23, 2022

Learning Objectives

- **Explain recent changes to FDA approval requirements for HCV diagnostics**
- **Understand the regulatory status of point of care molecular diagnostics for viral hepatitis**
- **Discuss diagnostics the context of HCV elimination efforts: New York State + City**
- **Share advocacy efforts & resources**

Downclassification Explained

- **FDA classifies diagnostics according to:**
 - **Complexity/training required**
 - **Patient impact: “actionable results”**
- **Class I, II, III – less stringent → most**
 - **Different fees + no of samples (?)**
- **Nov 2021 FDA order: Class III → II**

“The two types of HCV diagnostic tests being reclassified are nucleic acid-based HCV ribonucleic acid (RNA) devices intended for the qualitative or quantitative detection or genotyping of HCV RNA and certain HCV antibody devices intended for the qualitative detection of HCV.”

<https://www.fda.gov/news-events/press-announcements/fda-brief-fda-issues-final-orders-reclassifying-certain-hepatitis-c-diagnostic-tests-class-iii-class>

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Downclassification Explained

Context:

- **FDA typically 5-6 yrs behind European Medicines Agency**
- **FDA regulates viral hepatitis dx within the same branch as HIV, which has historically been cautious**
- **Point of care RNA platforms/assays with EMA and WHO PQ approval are commercially available outside US**
- **Product developers must submit for approval**
- **NVHR+TAG webinar:** <https://nvhr.org/resources/hcv-point-of-care-diagnostics/>

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TAG Pipeline Report

| | | | | |
|-------------------------------|---|--------------|-----------------------------|--|
| Xpert® HCV VL FS assay | 100 µL, capillary blood, fingerstick Tertiary POC, harm reduction settings | Cepheid (US) | CE-IVD; Not FDA-approved | |
|-------------------------------|---|--------------|-----------------------------|--|

- The VL fingerstick assay was a modified version of the HCV RNA assay.
- Xpert® HCV VL fingerstick test for HCV RNA quantification demonstrates high sensitivity: 100.0% (95% CI, 93.9–100%) and specificity: 100.0% (95% CI: 96.6–100%).
- Time to results <1 hour; this reduces wait times and can prevent patients lost to follow up.
- Median time to results depends on RNA level; this study among 1426 participants showed faster results for people with detectable HCV RNA (32 minutes) versus people with undetectable HCV RNA (57 minutes).
- Screening tool that can be used for HCV RNA detection in high-prevalence settings, particularly in hospital emergency departments and services for people who inject drugs and/or people who experience homelessness.

(as of 2020)

https://www.treatmentactiongroup.org/wp-content/uploads/2020/08/pipeline_HCV_diagnostics_2020.pdf

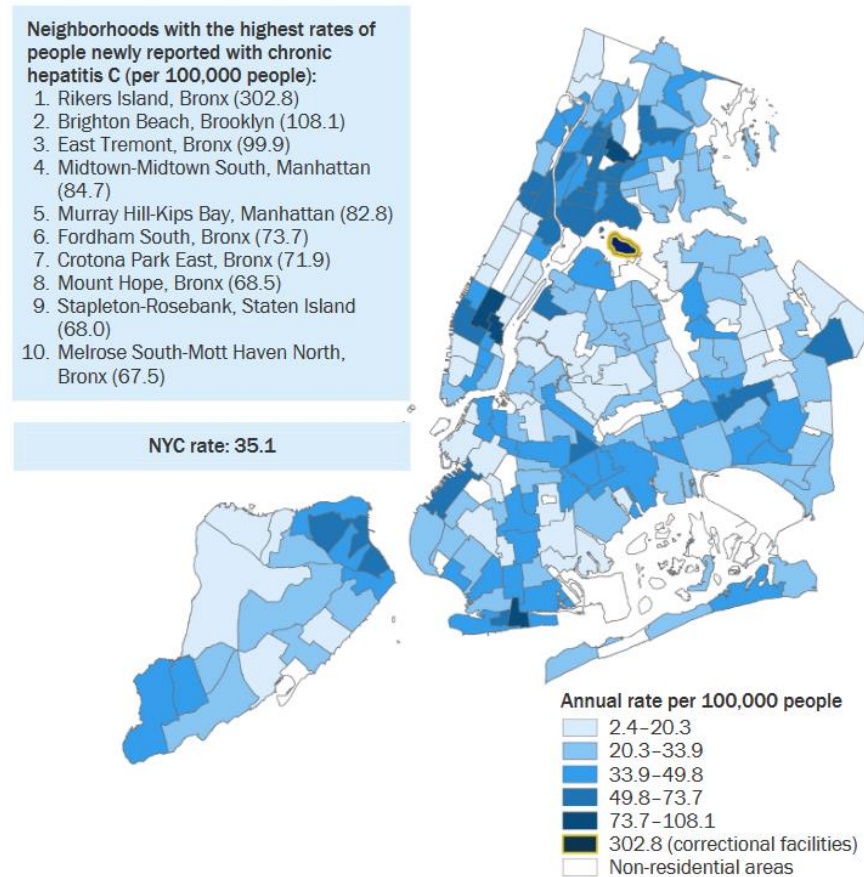
NYS+C case study

- **Elimination planning brought together NYC+State DOH surveillance & data teams**
- **At the time, NYC reflex testing & reporting negative RNA results**
- **Technology sharing & collaboration to integrate & scale data systems**
- **DBS pilot study in rural upstate NY**
 - **Sample analysis at Wadsworth Center, informed by CDC developed lab assay**
 - **Sample handling problem solved on the ground**
 - **Well suited where lack of transportation & few providers/labs are barriers to care**

Data for advocacy

Chronic Hepatitis C: Geographic Distribution

Figure 19. Rate of people newly reported with chronic hepatitis C in NYC by NTA,²³ 2020



» For full data and map of NTAs, see Appendices 6 and 12.

Heatmaps w/ SES overlays can be powerful tools for advocacy

» Achieving a Hep Free NYC

Hepatitis C in NYC: Opportunities for Elimination

91,000

Estimated number of people with current hepatitis C infection in NYC*

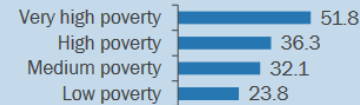
40%

Estimated percentage of NYC residents with chronic hepatitis C who are undiagnosed

*For information about how the hepatitis C prevalence estimate is calculated, see Appendix 1.

Hepatitis C can be cured, making elimination of the disease a reality, but 40% of NYC residents with hepatitis C remain undiagnosed.

Rate of hepatitis C infection per 100,000 people by neighborhood poverty level



Close to half of people ages 18 to 34 newly reported with hepatitis C* reported injection drug use (IDU).



The rate of hepatitis C infection in very high-poverty neighborhoods is more than twice the rate in low-poverty neighborhoods.

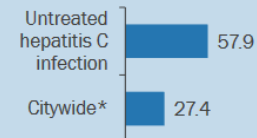
*Reported through enhanced surveillance

Hepatitis C can be cured, yet 40% of NYC residents diagnosed with hepatitis C remain untreated.

40%

Estimated percentage of people diagnosed with chronic hepatitis C who have not initiated treatment

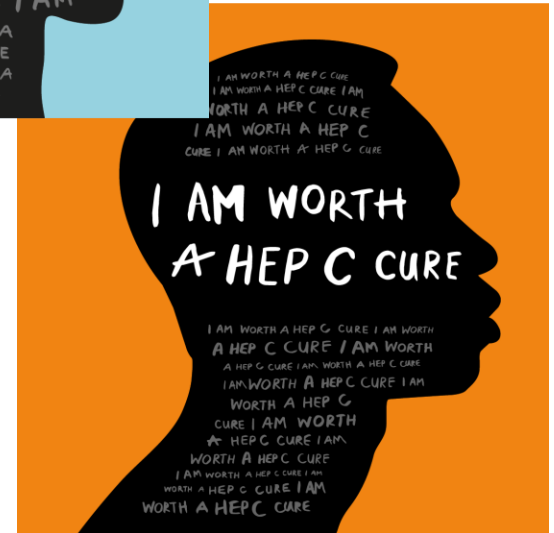
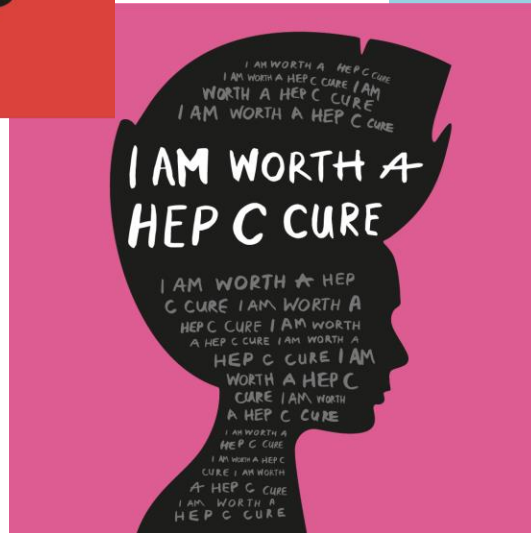
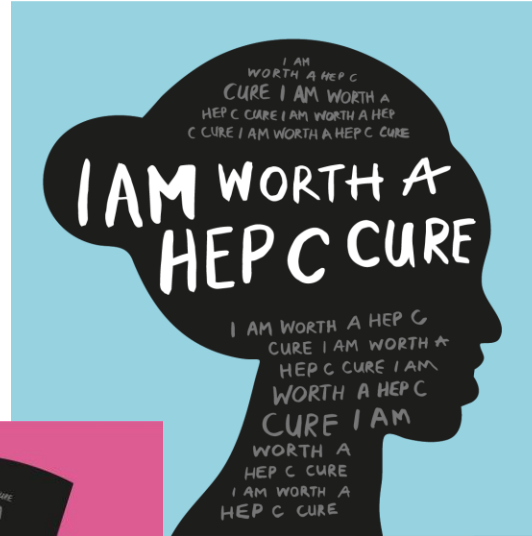
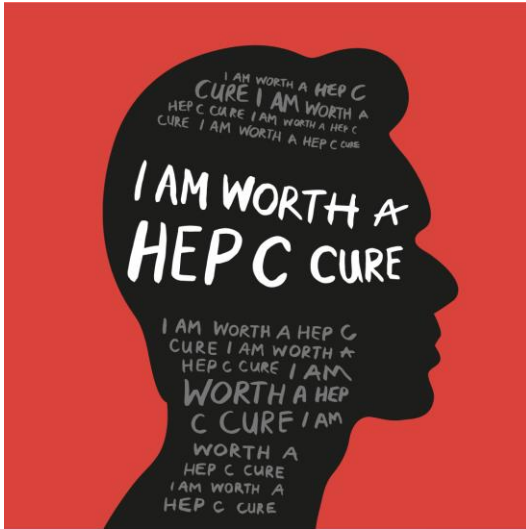
Percentage of people who died prematurely in 2017



The percentage of people with hepatitis C who die prematurely (occurring before age 65) is two times higher than all premature deaths in NYC.

*Including hepatitis C infection

SES, stigma & discrimination



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Join the Viral Hep Dx Working Group!

The Viral Hepatitis Diagnostics Working Group (WG) is an informal network of community advocates, providers, researchers, and technical specialists meeting monthly to develop and advance advocacy to expedite and expand access to confirmatory point of care (POC) diagnostics for viral hepatitis in the US.

Email: annette.gaudino@treatmentactiongroup.org or adrienne@nvhr.org

Final takeaway: leverage elimination planning coalitions and processes to expand testing and surveillance

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Additional resources

- **NYS AI CEI:** <https://ceitraining.org/courses/>
- **HepCure Webinar series:**
<https://hepcure.org/provider/#a-webinars>
- **HepElimiNATION:** <https://eliminatehep.org/>
- **NYC Viral Hep Elimination Plan:**
<https://www1.nyc.gov/assets/doh/downloads/pdf/cd/viral-hepatitis-elimination-plan.pdf>

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Questions & Discussion

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