

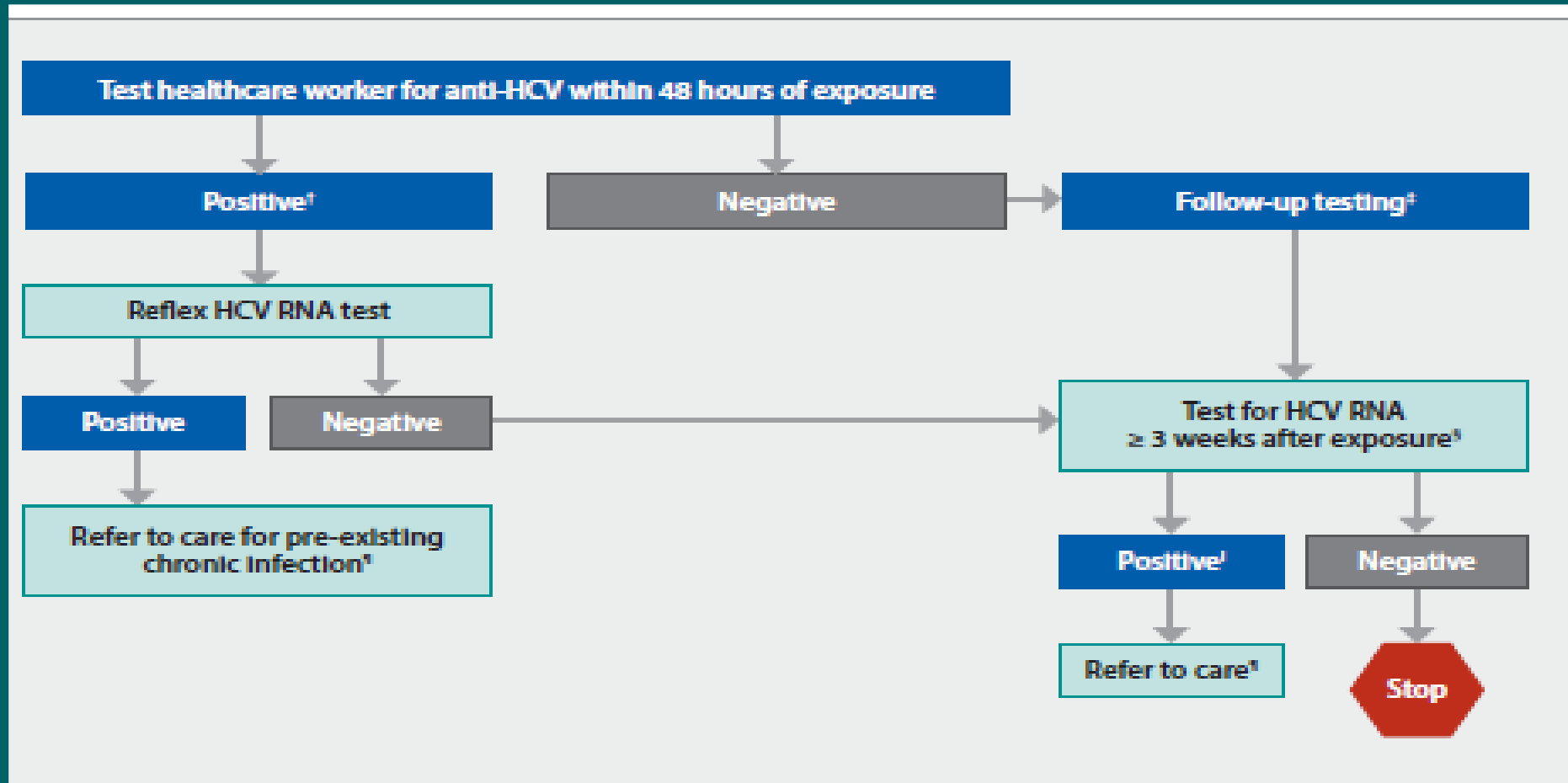
***Draft update:* Testing and Follow-up Information for Healthcare Personnel Potentially Exposed to Hepatitis C Virus**

Disclaimer: This document is a draft. The findings and conclusions in this draft report have not been formally disseminated by the Centers for Disease Control and Prevention and should not be construed to represent any agency determination or policy.

What is the purpose of this update?

- This draft guidance will provide updated CDC recommendations for laboratory testing and follow-up of healthcare personnel (HCP) who have been potentially exposed to hepatitis C virus (HCV) through an exposure to blood or body fluid.
- When published, this new guidance will supersede all previous guidance including the HCV testing algorithm formerly made available in 2016 on the CDC Division of Viral Hepatitis website, as well as the algorithm published earlier in MMWR in 2001.

2016 testing algorithm (superseded)



¹If it is not possible to test source for HCV RNA, then test for antibodies to HCV (anti-HCV) and screen HCW exposed to anti-HCV positive source. Note that persons with acute infection may test HCV RNA positive but anti-HCV negative.

²In a nationally representative population sample with low (1%) HCV infection prevalence, 22% of anti-HCV positive results were determined to be false-positive. An additional 10% had indeterminate results in a confirmatory assay; most were likely to be false-positive. Among the subset of persons testing anti-HCV screening reactive and subsequently HCV RNA negative, 50% of the anti-HCV tests were false-positive.³

³Anti-HCV testing at ≥ 6 months with reflex to HCV RNA test, if positive, could also be done.

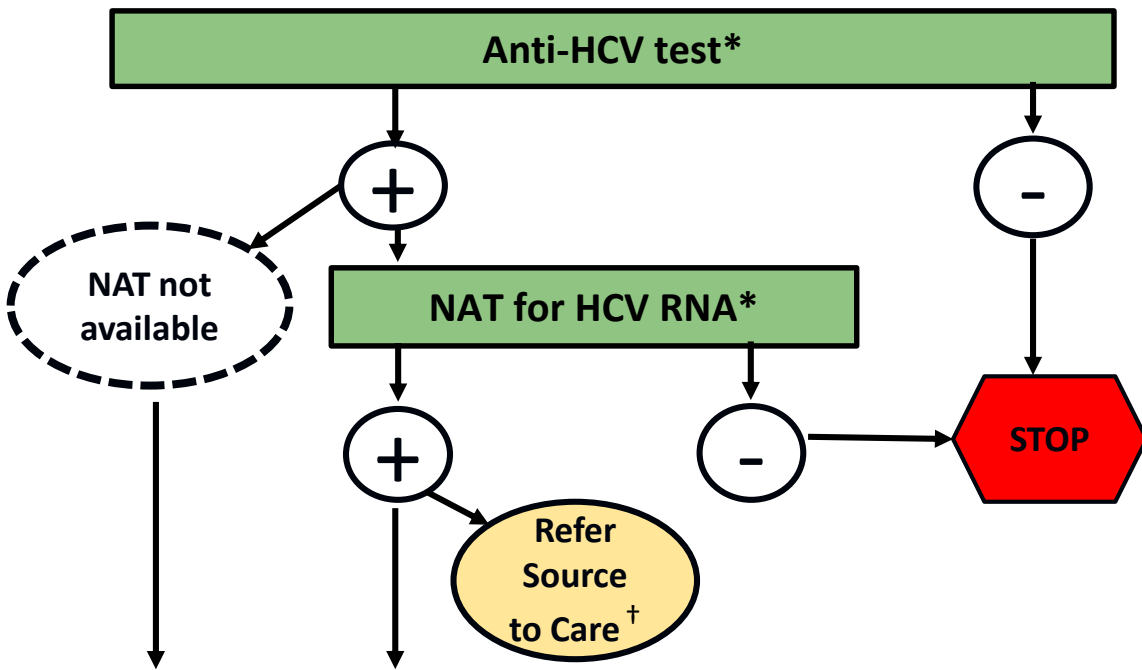
What has been updated in this report?

- Post-exposure testing of the exposed HCP updated to include HCV antibody (anti-HCV) testing 4-6 months after exposure, not included in the 2016 algorithm, based on current understanding of early HCV infection viral dynamics.
 - Periods of aviremia have been described primarily in the literature when older HCV RNA testing methodologies were used, although relevance to use of newer highly sensitive RNA testing is unclear
- Treatment of acute HCV infection now recommended in updated guidance (11/6/19) from professional organizations, see www.hcvguidelines.org
- Source testing updated in consideration of the increasing incidence of acute HCV infection among growing numbers of persons who inject drugs
 - If the source is known or suspected to have recent behavioral risks for HCV (for example, injection drug use), or if risk cannot be reliably assessed, initial source testing should include a test for the HCV virus (a nucleic acid test, or NAT, for HCV RNA)

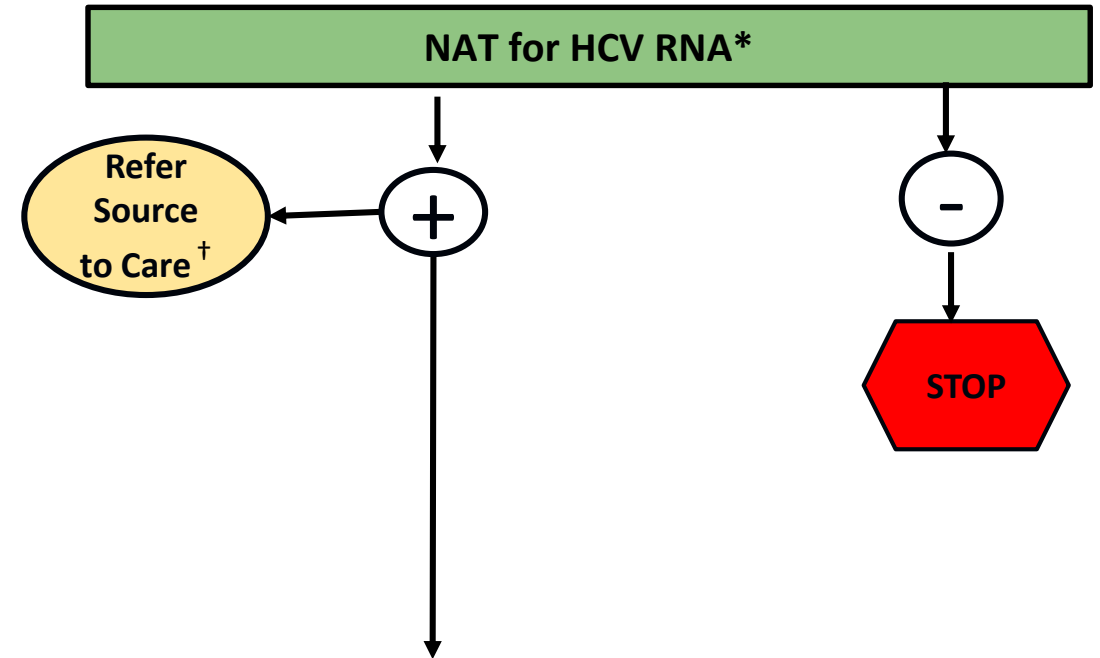
Test the Source

Note: If source known or suspected to have recent behavioral risk for HCV such as injection drug use, or if risk cannot be reliably assessed, initial testing of the source should include a NAT for HCV RNA.

Option A. Test for antibody against HCV ([anti-HCV]) with reflex to a nucleic acid test (NAT) for HCV RNA if positive



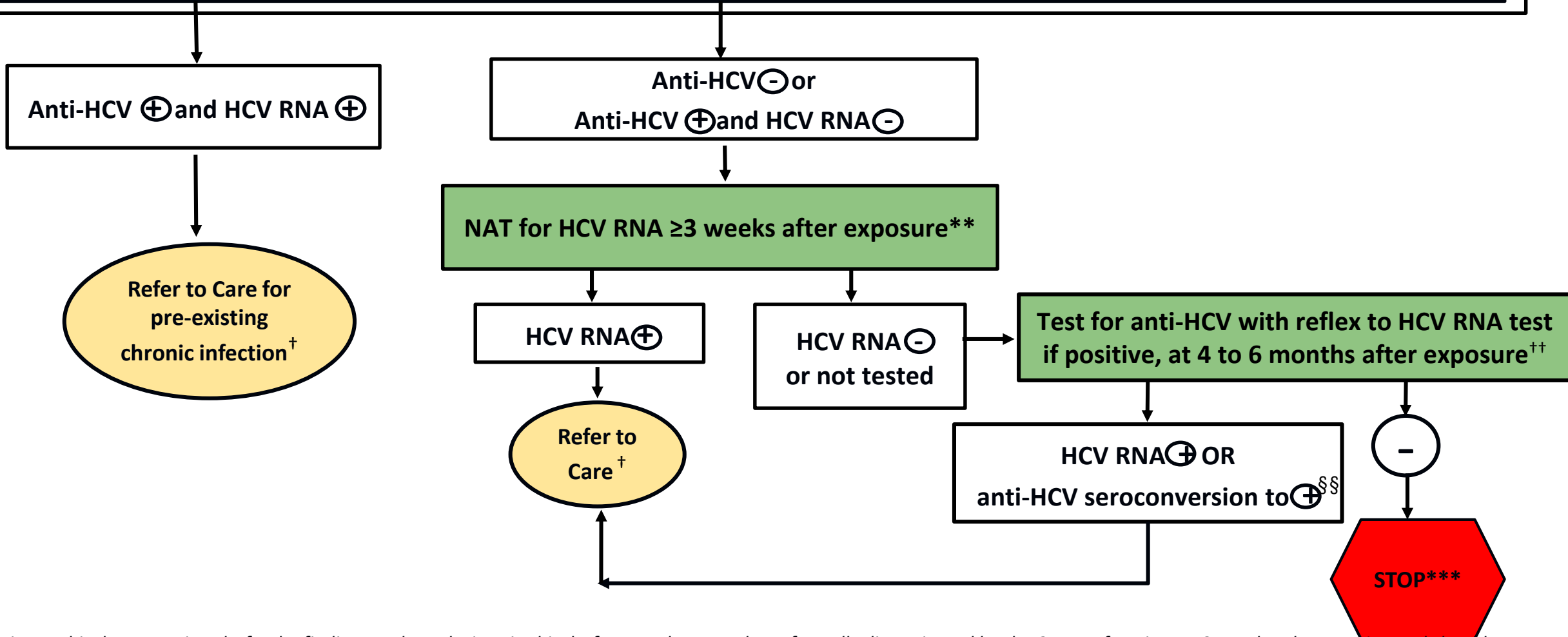
Option B. Initial testing using NAT



Test the Healthcare Provider (HCP) if source positive for anti-HCV or HCV RNA or source HCV infection status unknown

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Initially test HCP for anti-HCV with reflex to HCV RNA test if positive as soon as possible after the exposure (baseline testing), may be simultaneous with source testing[§]



Anticipated Q&A, updated guidance

What is recommended for HCP exposed to blood or body fluids from an anti-HCV positive but HCV RNA negative source?

- HCP exposed to blood or body fluids from a source who tests anti-HCV positive but HCV RNA negative are not currently recommended for follow-up testing.
 - However if there are concerns regarding specimen integrity including handling and storage conditions that may have compromised test results, or if at any time clinical signs of HCV infection appear in the HCP, follow-up testing may be warranted.
 - To the best of our knowledge we are unaware of any transmissions to HCP from anti-HCV positive, HCV RNA negative source. Most published descriptions of HCV-exposed HCP focus on source anti-HCV test results rather than tests for HCV RNA. However, data are available from one European case-control study of HCP who became anti-HCV positive after exposure to an anti-HCV positive source during 1991-2002, which demonstrated that among the small number for whom source HCV RNA status was known (n=37, 62% of HCP who became anti-HCV positive), all sources had been HCV RNA positive.

HCP tested under the 2016 algorithm

- Do HCP who were tested under the 2016 algorithm with a single HCV RNA test at ≥ 3 weeks after exposure need to be re-tested for anti-HCV now, as they did not have the currently recommended anti-HCV test at 4-6 months post-exposure?
 - CDC now recommends the 4-6 month post-exposure anti-HCV test out of an abundance of caution because of the potential for periods of intermittent aviremia during acute infection described in several earlier publications, primarily when older HCV RNA testing methodologies were used. Relevance to use of newer highly sensitive RNA testing is unclear.
 - CDC is not aware of infections missed by the abbreviated HCV RNA-based testing schedule made available in 2016, which was prompted by marked improvements in HCV RNA testing methodologies which have greater test sensitivity. Our assessment based upon sparse data is that the risk to persons tested under the 2016 guidance is minimal, but not zero.
 - CDC does not recommend notification and re-testing of persons tested under this past algorithm.
 - However, for any person who has signs or symptoms of viral hepatitis, or for those who wish absolute certain confirmation that transmission did not occur from the past exposure, a test for anti-HCV with reflex to RNA could be considered.

When is baseline testing of the source for HCV viral RNA recommended?

- If source known or suspected to have recent behavioral risks for HCV (for example, injection drug use) or if risk cannot be reliably assessed, initial testing of the source should include a test for the HCV virus
 - HCV RNA becomes detectable as early as 1-2 weeks after exposure. Anti-HCV does not become detectable until on average 8-11 weeks after exposure, although this may be delayed among persons with immunosuppression, such as that which occurs with HIV infection.
- The incidence of acute HCV infection is increasing in the United States, primarily related to injection drug use
 - 3.7-fold rise in cases reported to CDC between 2010 - 2017
 - Window period infections (testing anti-HCV negative but HCV RNA positive) identified among 5.3% of HCV RNA-positive deceased organ donors who had recent behavioral risk factors for viral hepatitis during 2014-2017.
 - These data suggest the possibility that in some healthcare settings HCP may be exposed to source patients with early HCV infection prior to development of detectable HCV antibody.

Is there currently recommended post-exposure prophylaxis (PEP) for HCP potentially exposed to HCV, to prevent infection?

- HCV PEP is not recommended for HCP who have occupational exposure to blood and other body fluids.
 - Recent estimates indicate that about 0.2% of HCP percutaneous exposures to HCV antibody positive blood or body fluids resulted in transmission. Thus routine PEP use for all such exposures would treat approximately 1000 individuals for every two who might become infected.
 - The effectiveness and duration of treatment required for HCV PEP has not been established. A pilot trial of a two-week DAA PEP regimen was initiated in 2019 for HCP who experience hollow-bore needle exposure to an HCV RNA positive source, factors that may be associated with increased transmission risk. Although this study will not have sufficient statistical power to determine the impact of PEP on seroconversion rates, this is the first DAA PEP study for HCP.
 - In contrast with the other bloodborne pathogens (hepatitis B virus and HIV) for which PEP is recommended, if HCV transmission does occur, currently available direct acting antiviral therapy is highly effective in eradicating both acute and chronic HCV infections.

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Thank you!

- Questions?