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PROMOTING INFECTION PREVENTION IN DIALYSIS FACILITIES

Hepatitis C Testing and Monitoring Algorithm

Approved by the Centers for Disease Control and Prevention (CDC)

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Despite dialysis facility policies to minimize the risk of infection, transmission of hepatitis C virus (HCV) remains a real risk for patients with chronic kidney disease (CKD). HCV-infected patients may develop chronic liver disease, and also may be at increased risk of developing diabetes mellitus and renal graft injury should an infected patient receive renal transplant. Strict attention to infection control practices and surveillance to detect hepatitis C can limit its spread within dialysis units. Antiviral regimens can cure HCV infection, leading to eradication of this virus among already infected hemodialysis patients. This algorithm is intended to help healthcare professionals involved in the care of hemodilaysis patients identify infected patients and refer them for antiviral therapy.

Once diagnostic testing for hepatitis C was introduced, it became clear that patients on maintenance hemodialysis (MHD) had a high prevalence of HCV infection and furthermore that hepatitis C acquisition was occurring in the outpatient dialysis setting. Despite screening of blood products, HCV infection has remained highly prevalent in the MHD population (1). In a multinational study in the period 1996-2002, the prevalence of hepatitis C in U.S. HD patients was 7.4% (2). A recent update from the period 2012-2015 indicates that the prevalence of hepatitisC in U.S. MHD patients is 7.3% (3). This suggests that with a U.S. dialysis population of approximately 450,000 patients that there may be 30,000 HCV infected patients on maintenance hemodialysis. Despite effective strategies to limit spread of hepatitis C among MHD patients (4), hepatitis C acquisition confirmed by epidemiologic investigation and phylogenetic analysis still occurs and typically reflects lack of attention to basic infection prevention measures such as injection safety, cleaning and disinfection of environmental surfaces, and hand hygiene(5). CDC was informed of about 36 cases of acute hepatitis C in MHD patients during 2014-2015 and issued an alert stressing the need to adhere to precautions to prevent hepatitis C spread in HD units and continuously assess and improve infection prevention precautions (6).

In the general population, efforts to identify HCV infected patients have typically focused on testing individuals with known risk factors for HCV infection including blood transfusion prior to 1991 and injection drug use (IDU)(7). Dialysis patients were also considered high risk because of the high prevalence of hepatitis C in this population Current recommendations for testing have also included so-called baby boomers, the population born between 1945 and 1965, due to a high prevalence of HCV infection (8). In patients on maintenance dialysis, an unexplained rise in alanine aminotransferases (ALT) levels should prompt testing for newly acquired HCV infection. However, serum ALT levels are typically abnormally low among persons on MHD, so that even an HCV infected patient may have levels within the “normal” range. Thus, HCV infection may be present even in MHD patients with aminotransferase levels within the normal range for reference laboratories, therefore surveillance for hepatitis C acquisition is also necessary in the MHD population.

In the CKD population hepatitis C testing is recommended as part of the evaluation of CKD, at entry to renal replacement therapy and every 6 months in patients on maintenance hemodialysis (see KDIGO guidelines https://kdigo.org/guidelines/hepatitis-c-in-ckd/ and CDC guidelines https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5005a1.htm).

For an HCV infected CKD patient there are a number of important consequences of infection including an increased risk of death (9,10). Cirrhosis and hepatocellular carcinoma have been implicated in this excess mortality. Another important consequence of HCV infection for a patient with CKD is the effect on potential candidacy for kidney transplantation. HCV infection has been shown to diminish graft and recipient survival following kidney transplant (11). HCV infected kidney transplant candidates with cirrhosis or focal hepatocellular carcinoma may not be eligible for isolated kidney transplant and may require consideration for combined liver/kidney transplant, a far more extensive procedure. There is also increasing evidence that HCV infection is not only implicated in causing renal disease, often mediated by cryoglobulinemia, but also may accelerate the course of CKD in general (12).

A number of highly efficacious, well-tolerated, all-oral regimens using direct-acting agents are licensed to treat HCV infection in patients with CKD (13, 14). (see HCVGuidelines.org for details)

Identification of HCV infected CKD patients will allow access to effective antiviral therapy which has already been shown to favorably affect outcomes in successfully treated patients(15) with reduction in all-cause mortality. In addition to the benefit for an individual HCV infected patient, successful antiviral treatment of HCV infected patients on MHD may potentially reduce the risk of transmission of hepatitis C in dialysis clinics.

Despite these considerations, preventing hepatitis C transmission in dialysis units requires meticulous precautions to prevent contamination from body fluids. Prompt identification of HCV infected patients is a key part of this strategy as outlined in the accompanying algorithm.

Algorithm Process

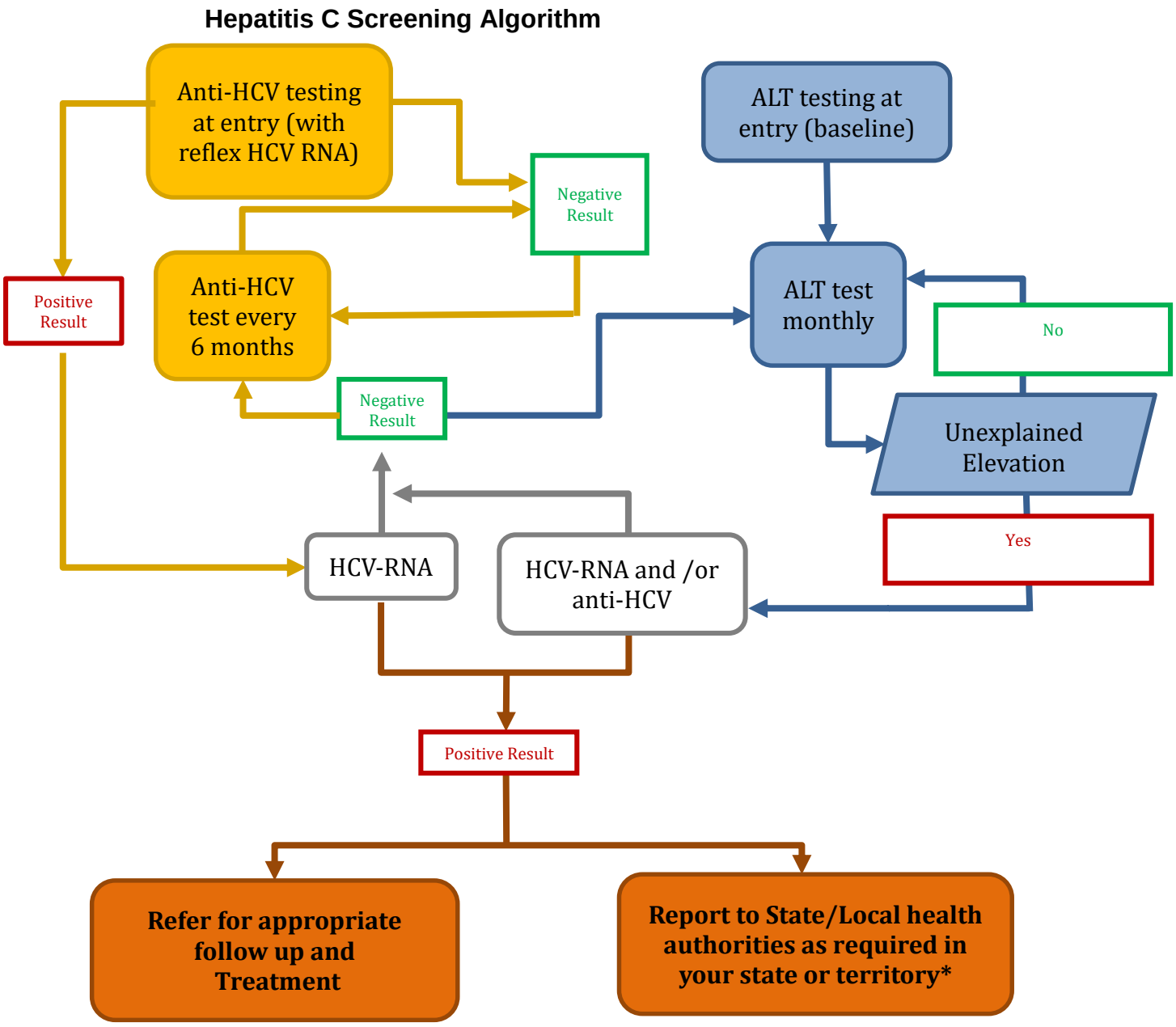
1. Upon entry to the dialysis facility, the patient will undergo HCV antibody (anti-HCV) testing (with reflex HCV RNA testing) and have ALT tested to determine their baseline value
    a. After the initial testing, anti-HCV will be tested every 6 months for patient with negative anti-HCV
    b. After the initial testing, ALT will be tested monthly

2. Results
    A. Results of the anti-HCV test
        a. Positive results-test for HCV-RNA
            i. If HCV-RNA is positive, refer for followup and treatment and report to state/local health authorities as required by the individual state/territory
            ii. If the anti-HCV is positive, but HCV-RNA is undetectable (e.g., after treatment with a sustained response or after a resolved infection) repeat HCV-RNA testing every 6 month (instead of anti-HCV testing)
        b. Negative results-continue anti-HCV testing every 6 months

    B. Results of ALT
        a. If unexplained elevation is detected,-test for HCV-RNA and anti-HCV

            i. If HCV-RNA/anti-HCV is negative, continue to test anti-HCV every 6 months and ALT monthly
            ii. If HCV-RNA/anti-HCV is positive, refer for followup and treatment and report to state/local health authorities as required by the individual state/territory. If one or more seroconversion (i.e., patient is newly anti-HCV positive and previously tested negative) or acute case occurs, this should be reported to the health department as a suspected healthcare-associated infection.

        b. If unexplained ALT elevation is NOT detected-no immediate hepatitis C testing warranted, continue routine testing



testing path

Treatment and Referral path

If the anti-HCV is positive, but the HCV RNA test is negative (e.g., after treatment with a sustained virologic response) the anti-HCV testing is replaced with HCV RNA testing. A change in HCV infection status (i.e., new infection or seroconversion)

should be reported to the state or local healthcare-associated infection (HAI) program.

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