Diagnosis and Prevention of HCV Infection in HD Patients

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Introduction

- 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.

Introduction

- 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.

SUPPLEMENT TO

kidney INTERNATIONAL

KDIGO 2022 CLINICAL PRACTICE GUIDELINE FOR THE PREVENTION, DIAGNOSIS, EVALUATION, AND TREATMENT OF HEPATITIS C IN CHRONIC KIDNEY DISEASE

KDIGO 2022 Clinical Practice Guideline for the Prevention, Diagnosis,

1.1.1: We recommend screening all patients for HCV infection at the time of initial evaluation of CKD (1C).

1.1.1.1: We recommend using an immunoassay followed by nucleic acid testing (NAT) if immunoassay is positive (1A).

Any CKD patient who has a risk factor for HCV infection should be tested.[1] Additionally, HCV testing is warranted for the evaluation of CKD because: (i) the prevalence of HCV infection may be higher in patients with CKD not yet on dialysis than in the general population[2,3]; (ii) HCV infection increases the risk of developing CKD[4]; and (iii) HCV infection can accelerate progression of CKD.[5–7]

The most usual strategy for diagnosis of HCV infection consists of initial screening with an inexpensive serological assay and, if the assay is positive, subsequent NAT. However, in high prevalence settings or very high risk groups, immediate NAT is an appropriate alternative.

1.1.2: We recommend screening all patients for HCV infection upon initiation of in-center hemodialysis or upon transfer from another dialysis facility or modality (1A).

1.1.2.1: We recommend using NAT alone or an immunoassay followed by NAT if immunoassay is positive (1A).

The prevalence of HCV infection in patients undergoing hemodialysis (CKD G5 on dialysis) is higher than in the general population[13,14] and has been associated with the number of years one has been on hemodialysis. Patient-to-patient transmission of HCV infection in outpatient hemodialysis centers has occurred repeatedly despite widespread knowledge of this risk and published guidelines for prevention. Identification of HCV transmission within a dialysis facility should prompt immediate reevaluation of infection control practices and determination of appropriate corrective action (see Chapter 3).[15–19] The majority of persons with

transfer from another dialysis facility or modality. In dialysis units with a high prevalence of HCV, initial testing with NAT should be considered. An anti-HCV–negative, HCV RNA–positive (i.e., NAT-positive) profile strongly suggests acute HCV infection.

Samples collected to test for HCV by NAT should be drawn before dialysis, because hemodialysis sessions reduce viremia level, although the mechanism remains unclear.[22]

1.1.3: We suggest screening all patients for HCV infection upon initiation of peritoneal dialysis or home hemo-dialysis (2D).

We recommend screening for HCV infection with immunoassay or NAT in in-center hemodialysis patients every 6 months (*1B*).

1.2.1.1: Report any new HCV infection identified in a hemodialysis patient to the appropriate public health authority (*Not Graded*).

1.2.1.2: In units with a new HCV infection, we recommend that all patients be tested for HCV infection and that the frequency of subsequent HCV testing be increased *(1A)*.

We recommend that hemodialysis patients with resolved HCV infection undergo repeat testing every 6 months using NAT to detect possible re-infection (1B).

Acute HCV infection should also prompt immediate evaluation of all other patients in the same facility to identify additional cases. The status of all patients should be reviewed at the time a new infection is identified, and all patients previously known to be uninfected should be retested for HCV infection. The frequency of repeat screening should also be increased for a limited time: for example, monthly testing for 3 months, followed by testing again in 3 months, and then resumption of screening every 6 months if no additional infections are identified.[17,20] This strategy can help to identify delayed seroconversions (from the same exposure period as the index case) or other cases resulting from recurrent breaches. Use of this strategy has led to the detection of additional new cases in several reported outbreaks.[19,29]

For anti-HCV–positive patients with chronic HCV infection who become HCV NAT–negative with a sustained virologic response (SVR) to HCV therapy, initiate NAT screening 6 months after documentation of SVR. SVR is determined based on results of NAT testing ≥ 12 weeks after the conclusion of therapy.

We suggest that patients have serum alanine amino-transferase (ALT) level checked upon initiation of in-center hemodialysis or upon transfer from another facility (2B).

1.2.2.1: We suggest that hemodialysis patients have ALT level checked monthly (2B).

Preventing HCV transmission in hemodialysis units

We recommend that hemodialysis facilities adhere to standard infection control procedures including hygienic precautions that effectively prevent transfer of blood and blood-contaminated fluids between patients to prevent transmission of blood-borne pathogens (see Table 1) (*1A*).

We recommend regular observational audits of infection control procedures in hemodialysis units (*1C*).

We recommend *not* using dedicated dialysis machines for HCV-infected patients (*1D*).

We suggest *not* isolating HCV-infected hemodialysis patients (*2C*).

Table 2 | Recent reported HCV prevalence in hemodialysis patients

Country	*N*	Year of testing	HCV prevalence (%)	Source
Australia-New Zealand	393	2012	3.8	DOPPS 5[152]
Belgium	485	2012	4.0	DOPPS 5[152]
Brazil	798	2011	8.4	Rodrigues de Freitas[153]
Canada	457	2012	4.1	DOPPS 5[152]
China	1189	2012	9.9	DOPPS 5[152]
Cuba	274	2009	76	Santana[154]
Egypt	—	2007–2016	50	Ashkani-Esfahani[155]
France	501	2012	6.9	DOPPS 4[152]
Germany	584	2012	4.5	DOPPS 5[152]
Gulf Cooperation Council	910	2012	19.3	DOPPS 5[152]
India	216	2012	16	NephroPlus
	1050	2013	11	
	3068	2014	8	
Iran	—	2006–2015	12	Ashkani-Esfahani[155]
Iraq	—	2008–2015	20	Ashkani-Esfahani[155]
	7122	2015	10	

Infection control practices (“hygienic precautions”) particularly relevant for preventing HCV transmission

- Proper hand hygiene and glove changes, especially between patient contacts, before invasive procedures, and after contact with blood and potentially blood-contaminated surfaces/supplies
- Proper injectable medication preparation practices following aseptic techniques and in an appropriate clean area, and proper injectable medication administration practice

Infection control practices (“hygienic precautions”) particularly relevant for preventing HCV transmission

- Thorough cleaning and disinfection of surfaces at the dialysis station, especially high-touch surfaces
- Adequate separation of clean supplies from contaminated materials and equipment

Table 3 | Factors and lapses in infection control practices associated with transmission of HCV infection in dialysis units

- Preparation of injections in a contaminated environment (including at patient treatment station)
- Reuse of single-dose medication vial for more than 1 patient
- Use of mobile cart to transport supplies or medications to patients
- Inadequate cleaning or disinfection of shared environmental surfaces between patients
- Failure to separate clean and contaminated areas
- Failure to change gloves and perform hand hygiene between tasks or patients
- Hurried change-over processes
- Low staff-to-patient ratio

Infection control practices

- It should be emphasized that blood contamination of environmental surfaces and equipment both at the patient treatment station and outside the immediate treatment area can be present, even in the absence of visible blood.
- HCV RNA has been detected on external surfaces of dialysis machines, a dialysate connector, on a shared waste cart, and in hand washings of dialysis personnel.

Infection control practices

- Blood that is visible or not visible to the naked eye, as evidenced by chemical tests, has also been detected on dialysis treatment station surfaces that underwent routine cleaning procedures following an outbreak of HCV.
- HCV can persist in an infectious state for at least 16 hours, and potentially much longer, on surfaces at room temperature.
- Hand hygiene also plays an important role in prevention of nosocomial transmission.

Infection control practices

- Lack of adherence to standard practices, such as hand-washing and glove use and removal practices, has been documented in several audits.
- In most HCV outbreaks in US hemodialysis centers reported to the CDC, multiple lapses in infection control were identified, involving practices such as hand hygiene and glove use, injectable medication handling, and environmental surface disinfection.

Infection control practices

- Receiving dialysis next to, rather than sharing the same dialysis machine with, an HCV-infected patient has been found to be a risk factor for HCV acquisition.
- In outbreak investigations with phylogenetic viral sequencing analysis, transmission is sometimes documented from an infected patient to a subsequent patient treated at the same station on the next shift, and also from an infected patient to patients treated in nearby stations during the same or subsequent shifts, which indicates transmission independent of the machine.

Infection control practices

- Hurried and incomplete disinfection of external machine surfaces and other surfaces at the station (e.g., side table, dialysis chair, blood pressure cuff, or prime waste container) are lapses commonly identified in these outbreaks.
- In some investigations, transmission involving the dialysis machine was essentially ruled out.
- In several studies included in the systematic reviews of HCV transmission, nosocomial spread was documented despite the existence of a policy of dedicated machines.

Table 5| Steps to initiate concurrently and undertake following identification of a new HCV infection in a hemodialysis patient (Adapted from CDC Health Alert[25])

A. Report the infection to appropriate public health authority.
   - Assess risk factors of the affected patient in conjunction with public health.

B. Determine HCV infection status of all patients in the hemodialysis unit.
   - Test all patients treated in the center for HCV infection (Chapter 1) unless they are already known to have active infection. Follow-up and testing of patients who were treated in the center and those subsequently transferred or discharged may be warranted.

C. Conduct a thorough root cause analysis of the infection and address infection control lapses.
   - Perform rigorous assessments of staff infection control practices to identify lapses. This should minimally include assessments of hand hygiene and glove change practices; injectable medication preparation, handling, and administration; and environmental cleaning and disinfection practices.
   - Share findings with all staff members and take action to address lapses. Staff education and retraining may be necessary.
   - Consider hiring a consultant with infection prevention expertise to provide recommendations for improvement of practices and work flow and/or to help implement actions to address identified lapses.
   - Conduct regular audits to ensure improved adherence to recommended practice.
   - Demonstrations of cleaning adequacy such as use of Glo Germ (Moab, UT) or luminol might be helpful for staff education.

D. Communicate openly with patients.
   - Inform all patients of the reason for additional HCV testing and the results of their HCV tests.
   - If transmission within the center is suspected or confirmed, inform all patients of this. Patients should also be made aware of steps being taken to assess and improve practices.

Strategies to support adherence to infection control recommendations in hemodialysis centers

- It is important for the designers of dialysis units to create an environment that makes infection control procedures easy to implement.
- Adequate handwashing facilities must be provided, and the machines and shared space should make it easy for staff to visualize individual treatment stations.
- Certain jurisdictions specify the area around a hemodialysis machine.

Strategies to support adherence to infection control recommendations in hemodialysis centers

- The unit should ensure that there is sufficient time between shifts for effective decontamination of the exterior of the machine and other shared surfaces.

Strategies to support adherence to infection control recommendations in hemodialysis centers

- The unit should locate supplies of gloves at enough strategic points to ensure that staff has no difficulty obtaining gloves in an emergency.
- When selecting new equipment, ease of disinfection should be considered.

Strategies to support adherence to infection control recommendations in hemodialysis centers

- There are indications from the literature that the rate of failure to implement hygienic precautions increases with understaffing.
- Understaffing has been associated with hepatitis C outbreaks.
- Certain jurisdictions specify a specific nurse-to-patient ratio (e.g., 1:4 in France).
- Formal healthcare training of all staff should be required (e.g., in the US, technicians provide most direct hemodialysis care but lack standardized training).

Strategies to support adherence to infection control recommendations in hemodialysis centers

- Dialysis units that are changing staff-to-patient ratios, or introducing a cohort of new staff, should review the implications on infection control procedures and educational requirements.

Strategies to support adherence to infection control recommendations in hemodialysis centers

- Resource problems should be handled by carrying out a risk assessment and developing local procedures.
- For example, if blood is suspected to have penetrated the pressure-monitoring system of a machine but the unit has no on-site technical support and no spare machines, an extra transducer protector can be inserted between the blood line and the contaminated system so that the dialysis can continue until a technician can attend to the problem.

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