Hepatitis C virus (HCV), the most prevalent chronic blood-borne infection in the US, is a common cause of cirrhosis, hepatocellular carcinoma (HCC), and the need for liver transplantation. In NYC, the HCV-related death rate is now nearly equivalent to the rate for HIV-related deaths. The highest HCV-related death rates are among Latinos and non-Latino Blacks (Box 14-6).

Acute HCV infection is usually asymptomatic and therefore often not diagnosed. Of people with acute HCV, up to 75% to 85% will develop chronic infection. Five percent to 20% of patients infected with HCV will develop cirrhosis within 20 to 30 years, and 1% to 5% will die from liver cancer or end-stage liver disease.

Early identification and treatment of HCV improves clinical outcomes, reduces risk of transmission, and can reverse liver damage. Oral direct-acting antiviral agents (DAAs) have revolutionized HCV treatment by providing excellent cure rates (>90% in most patient populations) with a well-tolerated and relatively short treatment course.
ASSESS RISK AND TEST FOR HCV INFECTION

Ask all patients about risk factors for HCV and offer testing when indicated (Box 29,14-18). New York State law mandates that physicians, physician assistants, and nurse practitioners offer HCV testing to people born between 1945 and 1965 who are receiving inpatient or primary care services.19 Nationwide, almost 75% of HCV-related deaths occur in that cohort.20

Counsel patients with ongoing risk behaviors or exposures about the potential for HCV infection, regardless of their test results. For people who use drugs, it is especially important to provide risk reduction counseling and referral to harm reduction services, including syringe exchange programs, methadone programs, and buprenorphine providers (Box 3).

TEST WITH A SCREENING ASSAY

Current HCV antibody tests are sensitive, specific and readily available.7 A negative HCV antibody test result indicates that the patient likely has not been infected with HCV. However, if there is exposure within the past 6 months or if the patient is immunocompromised, perform an HCV RNA test.

BOX 1. HEPATITIS C INFECTION IN NEW YORK CITY4-6

- An estimated 146,500 adults (2.4%) had chronic hepatitis C virus (HCV) infection in 2010.
- There were 11,847 newly reported cases of HCV infection in 2016:
  - 43% were among people born between 1945 and 1965.
  - 86% were in patients living in areas of medium to very high poverty.
- In 2016, HCV-related death rates were higher in Latinos (8.9/100,000) and non-Latino Blacks (8.2/100,000) compared with non-Latino Whites (4.4/100,000).
- In 2015, 72% of people who injected drugs and were tested for HCV had current infection.
- While “baby boomers,” people born between 1945 and 1965, accounted for 43% of newly reported cases of HCV in 2016, the proportion of newly reported cases among those born after 1965 has increased since 2006, with the majority of newly reported cases in this younger age group occurring in women.
- During 2000-2010, 16% of NYC residents with HIV were known to be coinfected with HCV.

BOX 2. HEPATITIS C TESTING RECOMMENDATIONS*,9,14-18

Age cohort testing: Test once.
- All people born between 1945 and 1965

Risk behaviors: Test once. Retest if risk is ongoing.
- Injection drug use—even if only once in the remote past (test current injection drug users at least annually)
- Intranasal drug use

High-endemic countries: Test once.
- People who were born in or had invasive medical procedures or blood transfusions in areas of highest prevalence. The prevalence is ≥1.5% in several countries in Latin America, Eastern Europe, the former Soviet Union, and certain countries in Africa, the Middle East, and Asia. Prevalence is reported to be highest (approximately 10%) in Egypt. See CDC Travelers’ Health for more information.

Risk exposures. Test once. Retest if exposure is repeated.
- History of long-term hemodialysis
- Getting a tattoo or piercing in an unregulated setting
- Other injections without medical supervision (eg, silicone, cosmetics, hormones)
- Sharing any injection or medical equipment, including diabetic equipment
- Health care, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures to hepatitis C virus (HCV)-infected blood
- Children born to HCV-infected women. Do not test before the child is 18 months old.
- History of incarceration
- Recipients of transfusions or organ transplants if they
  - were notified that they received blood from a donor who later tested positive for HCV infection,
  - received a transfusion of blood or blood components or underwent organ transplantation before July 1992, or
  - received clotting factor concentrates produced before 1987.

Other conditions
- HIV infection (test at diagnosis, then test at least annually if patient uses intranasal or injection drugs, is pregnant, or is a man who has sex with men without a condom). Note that false-negative HCV antibody test results occur in some HIV-infected individuals.
- Sexually active people before starting preexposure prophylaxis (PrEP) for HIV and annually thereafter
- Solid organ donors (deceased and living)
- Unexplained chronic liver disease and chronic hepatitis, including elevated alanine aminotransferase levels

*Routine testing is not recommended for HIV-negative men who have sex with men, HIV-negative, monogamous sex partners of people with HCV infection, pregnant women without risk factors, nonsexual household contacts of people with HCV infection, or health care workers, unless there is a recognized exposure to HCV-infected blood or elevated liver enzymes.
test to detect early HCV infection prior to seroconversion (Figure).21

A positive HCV antibody test result either indicates a current or previous infection or is a false-positive result, which may occur more frequently in people at low risk for HCV infection7 (Figure).

FOLLOW A POSITIVE ANTIBODY TEST WITH A DIAGNOSTIC ASSAY

Use an FDA-approved quantitative or qualitative nucleic acid amplification test (polymerase chain reaction, or PCR) to confirm HCV infection in patients who test positive for HCV antibody9 (Box 422) or who may have recently been exposed to HCV. Be sure to explain why you are testing and what the results mean. Tests include

- Quantitative HCV RNA test:
  - Recommended to measure the presence of viral nucleic acid in blood,
  - Very sensitive and necessary to monitor antiviral treatment response,

- Use an FDA-approved quantitative or qualitative nucleic acid amplification test (polymerase chain reaction, or PCR) to confirm HCV infection in patients who test positive for HCV antibody9 (Box 422) or who may have recently been exposed to HCV. Be sure to explain why you are testing and what the results mean. Tests include

- Quantitative HCV RNA test:
  - Recommended to measure the presence of viral nucleic acid in blood,
  - Very sensitive and necessary to monitor antiviral treatment response,

- Prepare a diagnostic assay:
  - Use an FDA-approved quantitative or qualitative nucleic acid amplification test (polymerase chain reaction, or PCR) to confirm HCV infection in patients who test positive for HCV antibody9 (Box 422) or who may have recently been exposed to HCV. Be sure to explain why you are testing and what the results mean. Tests include

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  - Use an FDA-approved quantitative or qualitative nucleic acid amplification test (polymerase chain reaction, or PCR) to confirm HCV infection in patients who test positive for HCV antibody9 (Box 422) or who may have recently been exposed to HCV. Be sure to explain why you are testing and what the results mean. Tests include

- Quantitative HCV RNA test:
  - Recommended to measure the presence of viral nucleic acid in blood,
  - Very sensitive and necessary to monitor antiviral treatment response,
○ Not recommended for initial testing unless assessing acute HCV, false-negative HCV antibody test is suspected, or evaluating for HCV in an immunocompromised patient.

• Qualitative viral RNA test:
  ○ Less expensive than the quantitative RNA test and can be used to evaluate for active infection,
  ○ Very sensitive and can be used to monitor antiviral treatment response.

A positive HCV RNA PCR test indicates that the patient has a current infection.7

A negative HCV RNA PCR test following a positive antibody test indicates
  • a resolved or successfully treated infection,
  • a false-positive HCV antibody test result, or
  • acute HCV infection with intermittent viremia.23

### BOX 4. MANDATORY RNA TESTING TO CONFIRM HCV INFECTION22

- As of October 20, 2017, laboratories in New York City are required to routinely perform a confirmatory HCV RNA test if an antibody test is positive for HCV.
- Order the confirmatory RNA test at the same time as the antibody test.
- The confirmatory test must be performed on the same specimen that tested positive or on a second specimen collected at the same time as the initial specimen.

### BOX 5. WHAT TO TELL PATIENTS WHO HAVE CURRENT HEPATITIS C VIRUS INFECTION7,9,24-26

#### To prevent progression of liver disease
- Avoid alcohol; it can damage your liver. There is no safe amount of alcohol use if you have chronic hepatitis C virus (HCV) infection. If you need help in making this change, I can offer some resources.
- Do not miss any of your medical appointments, even if you don’t feel sick. It’s important that we monitor your liver health.
- Eat a healthy diet and exercise regularly. Maintaining a healthy weight may slow the progress of liver damage.
- Check with me before you take any medications, even over-the-counter medicines, herbs, or supplements. Some of these can damage your liver.
- HCV/HIV coinfection can speed up the progression of liver disease. If you have HIV, you should get treated and cured of HCV right away.

#### To prevent infection in others
- Don’t share anything that may have come in contact with your blood, such as toothbrushes, razors, needles, nail files, clippers, nail scissors, or washcloths.
- Explain to people with positive HCV antibody and negative HCV RNA that there is no laboratory evidence of current HCV infection.9 Repeat the HCV RNA test in 6 months if there is a high index of suspicion of infection.9,21

### COUNSEL HCV-INFECTED PATIENTS

Educate patients about preventing HCV transmission and the risks of alcohol use (Box 57,9,24-26) and direct them to support groups and counseling services (Resources for Patients).

Counsel patients who are overweight, obese, or who have metabolic syndrome about exercise, diet, and medication interventions to improve insulin sensitivity.9

### ASSESS HCV-INFECTED PATIENTS FOR TREATMENT

Evaluate all patients with current HCV infection for antiviral treatment, regardless of stage of fibrosis, prior treatment experience, or comorbidities such as substance use disorder or depression.

Determine the patient’s history, including past evaluation and treatment for HCV and assess for comorbidities, ongoing risk factors that could result in HCV transmission or reinfection, substance use or behavioral disorders, and medications (Box 67,9,24,27-32).

#### Special considerations

- HIV. Patients with HIV and HCV coinfection have accelerated rates of developing fibrosis and higher mortality from HCC.33,34

- Cover open cuts and sores with bandages.
- Throw away used bandages or menstrual pads in a plastic bag.
- Don’t donate blood, organs, semen, or other tissue.
- Clean blood spills with a mixture of 1 part household bleach and 9 parts water. Wear gloves when you clean up blood spills.
- There is no risk of transmission from casual contact like hugging or kissing.

#### To prevent sexual transmission of HCV

- HCV is rarely transmitted through sex in long-term monogamous heterosexual relationships.
- If you or a sexual partner are HIV positive, have a sexually transmitted infection (STI), or have multiple sex partners: use condoms to prevent sexual transmission of HCV.
- Avoid sex in which there is a risk of blood exposure (anal sex, sex during menstruation, rough sex).
- To protect against other STIs, including HIV, always use latex condoms, limit the number of sex partners, and see your doctor regularly.
Hepatitis B virus (HBV). Treatment of HCV can cause reactivation of HBV.\(^3\)

Metabolic syndrome, insulin resistance, type 2 diabetes, obesity. Patients with non-alcoholic fatty liver disease in particular have poorer outcomes.

Drug use or mental health conditions. Patients who have depression or use drugs\(^3\) can be treated for HCV. Provide multidisciplinary support if possible (see Resources for Providers for referral information).\(^3\)

### ASSESS FOR LIVER FIBROSIS AND CIRRHOSIS

Patients with all levels of fibrosis benefit from HCV treatment. Patients with decompensated cirrhosis treated with DAAs have high rates of sustained virologic response (SVR), defined as having undetectable HCV RNA 12 weeks\(^2\) following completion of treatment, and can have improvement in liver function tests.\(^9\)

- Assess the degree of liver fibrosis to help determine the treatment regimen and provide appropriate follow-up care. New noninvasive testing has replaced routine liver biopsy for the evaluation of fibrosis (Box 79,\(^3\)\(^8\)-\(^4\)\).
- In patients with advanced liver fibrosis, risk for HCC is lowered, but not eliminated, after treatment. Patients with advanced fibrosis or cirrhosis (Metavir stage 3 and greater) will need lifelong surveillance for HCC, even when SVR is achieved.\(^9\)
- For patients with advanced liver disease or cirrhosis, calculate prognostic indicators such as the Child-Turcotte-Pugh score and the Model for End Stage Liver Disease (MELD).\(^9\) If there is advanced disease or if you have any questions about treatment, refer to a specialist.

### TREAT HCV INFECTION

Offer treatment to all patients with HCV infection, including and especially those who use drugs or have advanced fibrosis or cirrhosis, complications of cirrhosis, or HIV coinfection.

**Explain the treatment goal**

The goal of antiviral treatment is cure (SVR), which is associated with long-term improvement in biochemical markers; reduction of liver fibrosis and inflammation, and reduced mortality.\(^4\)\(^1\)-\(^4\)\(^2\) SVR reduces all-cause mortality and risks of liver transplantation and HCC in patients with advanced fibrosis and cirrhosis.\(^9\)

### BOX 6. INITIAL ASSESSMENT AND MANAGEMENT OF PATIENTS INFECTED WITH HEPATITIS C VIRUS\(^7\),\(^9\)-\(^2\)\(^4\)-\(^2\)\(^7\)-\(^3\)\(^2\)

- Collect details of past staging of liver fibrosis and hepatitis C virus (HCV) treatment.
- Identify all conditions that may accelerate liver damage (eg, HIV, hepatitis B virus (HBV), diabetes, obesity, metabolic syndrome, steatosis, and alcohol use disorder) or complicate treatment (eg, cardiac disease, hematologic disorders, autoimmune disorders).
- Screen for behavioral health disorders, including depression and substance use (see Detecting and Treating Depression in Adults and Addressing Alcohol and Drug Use—An Integral Part of Primary Care).
- Assess all medications used, including over-the-counter medications (eg, acetaminophen and NSAIDs) and alternative or herbal therapies for potential hepatotoxicity and potential for drug interactions with antivirals.
- Identify risk factors for HCV infection that might lead to transmission or reinfection.
- Determine family history of liver disease that might complicate HCV infection (eg, hemochromatosis, alpha-1 antitrypsin deficiency).
- Conduct a complete physical examination, including assessment for chronic liver disease and extrahepatic manifestations of HCV infection (mixed cryoglobulinemia, renal syndrome, lymphoproliferative disorders, porphyria cutanea tarda, Sjögren syndrome, neuropathies).
- Assess for complications of advanced liver disease (gastrointestinal bleeding, ascites, hepatic encephalopathy) that would require referral to a hepatologist.
- Order initial laboratory tests:
  - liver chemistry, international normalized ratio (INR), renal profile, CBC with differential,
  - quantitative HCV RNA (to establish baseline) and HCV genotype (to determine optimal regimen—send for resistance testing if indicated),
  - hepatitis A total antibody, hepatitis B serologies (including hepatitis B core antibody, hepatitis B surface antigen, hepatitis B surface antibody),
  - HIV.
- Vaccinate against:
  - hepatitis A and B if patient is susceptible,
  - influenza annually,
  - pneumococcus (PPSV23) in patients with cirrhosis.

*For other recommended vaccines, see Vaccine Information for Healthcare Providers.*

- Assess stage of liver fibrosis (Box 7).

\(^{a}\)For adolescents and young adults, check the Citywide Immunization Registry [CIR] for the patient’s immunization history. To register, visit the CIR Web site or call 347-396-2400 for more information. You must report immunizations administered to people aged <19 years, and you are encouraged to report immunizations given to patients aged ≥19 years, with patients’ verbal consent, to the CIR.
Discuss the advantages of treatment

Become familiar with current antiviral treatments and refer to a specialist if you are not prepared to manage HCV infection. See Resources for Providers for online clinical training options, detailed guidance on managing patients with HCV infection, and medication assistance programs.

For patients who initially decline treatment, revisit the issue periodically. The patient’s circumstances may change (eg, insurance coverage) or new medications may become available.

Select treatment

Determine the optimal treatment regimen according to the viral genotype (GT). HCV is now classified into 7 major GTs and more than 67 subtypes. In the US, approximately 75% of HCV infection is due to GT 1 (subtype 1a is more common than 1b), roughly 20% due to GT 2, and fewer cases due to GT 3. GTs 4, 5, 6, and 7 are rarely identified as causes of infection in the US.

People can be infected with multiple genotypes and can also be reinfected with the same or a different genotype after spontaneous resolution or successful treatment of infection. Antibodies to HCV are not protective against future infection with HCV.

Monitor response

Gauge clinical response by comparing quantitative HCV RNA with a pretreatment baseline measurement. See the American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) guidelines for detailed monitoring at www.hcvguidelines.org.

Summary

Early identification and treatment of HCV infection improves clinical outcomes, reduces risk of transmission, and can reverse liver damage. Evaluate all patients for risk factors and test everyone at risk, including all patients born between 1945 and 1965, for HCV antibody, with reflex to HCV RNA PCR to determine the current infection status.

Educate and counsel patients with current HCV infection about the risks of using alcohol and sharing drug use equipment; offer appropriate vaccinations against hepatitis A and B; and assess their liver function and stage of disease. Ensure that patients with current HCV infection have a plan to start treatment; refer to a specialist if you are not prepared to manage and treat HCV infection.

Guidance for hepatitis C treatment is changing frequently with the advent of new therapies and other developments. See the AASLD/IDSA Practice Guidelines at www.hcvguidelines.org for the most up-to-date treatment recommendations.

HEPATITIS C VIRUS IN PREGNANT WOMEN

Pregnancy outcomes

- Pregnancy does not appear to adversely affect the course of chronic hepatitis C virus (HCV) infection, but HCV infection may lead to poor pregnancy outcomes, including intrahepatic cholestasis of pregnancy, gestational diabetes, low-birthweight infants, and prematurity.
- Ribavirin-containing HCV antiviral therapies are contraindicated in pregnancy and in male sex partners of pregnant women, due to ribavirin’s embryocidal and teratogenic effects.

Perinatal transmission

- The risk of perinatal HCV transmission is 4% to 6% and as high as 20% in women who are HCV/HIV coinfected.
- As many as 4,000 new HCV infections occur in US children annually, largely from mother-to-infant transmission.
- All children born to women with HCV infection should be tested for HCV, regardless of symptoms. Screen with an HCV antibody test at or after age 18 months, since earlier antibody testing may detect maternal antibodies.
- Refer children with detected HCV viremia to a pediatric gastroenterologist or infectious disease specialist for evaluation and possible treatment.

No intervention has proven to be successful in preventing mother-to-infant transmission. Treat HCV in women of childbearing age before a pregnancy is planned.

Box 7. Assessment of fibrosis and cirrhosis

- Standard labs and imaging: can be normal until advanced cirrhosis
  - AST, ALT, total bilirubin, albumin, INR, platelet count
  - Ultrasound: can be used to confirm cirrhosis, evaluate portal hypertension, screen for HCC
- Serum liver fibrosis markers:
  - AST to platelet ratio, FIB-4
  - Hepascore® or FibroSURE® (marketed as FibroTEST® in Europe)
- Fibroelastography: noninvasive measurements of liver “stiffness”
  - Transient ultrasound elastography:
    - Transient elastography (Fibroscan®), shear wave elastography
  - Magnetic resonance elastography
- Liver biopsy: indicated when noninvasive markers are discordant, inconclusive, or not available, and when there is concern for concurrent liver disease in addition to hepatitis C virus.

Note: Noninvasive studies have been shown to be best for differentiating minimal versus advanced fibrosis or cirrhosis, but are less accurate in staging patients with mid-level disease.

AST, aspartate transaminase; ALT, alanine transaminase; INR, international normalized ratio; HCC, hepatocellular carcinoma; FIB-4, fibrosis-4.
COVERING THE COST OF HEPATITIS C CARE

For patients with health insurance
• Testing, evaluation, and treatment for hepatitis C virus (HCV) infection are usually covered.
• Patients need prior authorization for all HCV medications; this may involve multiple steps and advocacy on behalf of the patient.

For patients who are uninsured or underinsured
• Federally qualified health centers (low cost) and public hospitals (lowest cost) in NYC provide medical care on an income-based, sliding-scale fee.
• All pharmaceutical companies have patient assistance programs that provide medication at no cost to people who do not qualify for health insurance. Many companies also have copay assistance programs.
• The New York State Department of Health HepCAP program offers
  ◦ free HCV evaluation and treatment related physician visits, laboratory testing, and liver cancer screening,
  ◦ assistance in applying for free medication through patient assistance programs.

See hepfree.nyc/health-care-access-meds for more information on free and low-cost care options.

HEPATITIS C QUIZ

1. Which one of the following medical conditions is considered an indication for routine hepatitis C virus (HCV) screening?
   A. History of hepatitis B infection
   B. Insulin-dependent diabetes mellitus
   C. Renal failure on chronic hemodialysis
   D. Chronic anemia

2. Which one of the following measures would be most important to counsel for in an effort to prevent household transmission of HCV?
   A. Do not share razors
   B. Do not mix clothes when washing laundry
   C. Do not use the same toilet
   D. Do not share eating utensils

3. Which of the following tests are necessary before treating patients with HCV infection?
   A. HCV genotype
   B. Stage of liver fibrosis
   C. Hepatitis B virus
   D. All of the above

   Answers: 1- C; 2-A; 3-D


RESOURCES FOR PROVIDERS

New York City Department of Health and Mental Hygiene
• Hepatitis Healthcare Provider Resources: www1.nyc.gov/site/doh/providers/health-topics/hepatitis.page
• Alcohol & Drug Use Resources: www1.nyc.gov/site/doh/providers/health-topics/alcohol-and-drugs.page
• City Health Information archives: www1.nyc.gov/site/doh/providers/resources/city-health-information-chi.page
  ◦ Addressing Alcohol and Drug Use—An Integral Part of Primary Care
  ◦ Detecting and Treating Depression in Adults
  ◦ Improving Medication Adherence
  ◦ Improving the Health of People Who Use Drugs
  ◦ Buprenorphine—An Office-Based Treatment for Opioid Use Disorder

Online Hepatitis C Clinical Training and Guidelines
• American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA) Practice Guidelines. Recommendations for Testing, Managing, and Treating Hepatitis C: www.hcvguidelines.org/
• AASLD. LiverLearning (CME available): liverlearning.aasld.org/aasld
• University of Washington School of Medicine/International Antiviral Association (USA) Hepatitis C Online Course (CME and CNE available): www.hepatitisc.uw.edu
• Clinical Care Options–HCV (CE available for doctors, nurses, and physician assistants): www.clinicaloptions.com/hepatitis
• University of Liverpool. HEP Drug Interaction Checker: hep-druginteractions.org
RESOURCES FOR PATIENTS

Hepatitis C Information
- New York City Health Department. Hepatitis C: www1.nyc.gov/site/doh/health/health-topics/hepatitis-c.page
- US Department of Veterans Affairs. Hepatitis C: www.va.gov/patient/hcv
- Centers for Disease Control and Prevention. Viral Hepatitis: www.cdc.gov/hepatitis/HCV

Support for People with Hepatitis C
- American Liver Foundation: hepatic.liverfoundation.org; and National Hepatitis Helpline: 800-GO-LIVER (800-465-4837)

NYC Hepatitis Testing, Vaccination, and Medical Care Site Locator
- NYC HealthMap: a816-healthpsi.nyc.gov/NYCHealthMap
- NYC Hepatitis Testing, Vaccination, and Medical Care Site Locator: www1.nyc.gov/site/doh/health/health-topics/hepatitis-c/consumers/prevention/needles_syringes/index.htm

Harm Reduction and Syringe Access
- Injection Drug Users Health Alliance. www.IDUHA.org

Mental Health Concerns and Substance Use Assistance and Referrals
- NYC Well: nycwell.cityofnewyork.us/en/; text WELL to 65173; call 888-NYC-WELL (888-692-9355); call 711 (relay service for deaf/hard of hearing), interpreters available in 200 languages

Drug and Alcohol Treatment
- Substance Abuse and Mental Health Services Administration (SAMHSA) Behavioral Health Treatment Services Locator: 800-662-HELP (x4357), 800-487-4889 (TTY), www.findtreatment.samhsa.gov
- Buprenorphine Treatment Practitioner Locator: www.samhsa.gov/medication-assisted-treatment/physician-program-data/treatment-physician-locator

12-Step/Self-Help Groups
- Alcoholics Anonymous (AA): 212-870-3400 or www.aa.org
- New York City Al-Anon: 212-941-0094 from 8 AM to 6 PM, Monday–Friday; www.nycalanon.org; or e-mail: info@nycalanon.org (support for families and friends of people struggling with alcohol use)
- Narcotics Anonymous (NA): 212-929-6262 or nycna.org

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