

# **Hepatitis C: An Emerging Health Concern for Texans**

## **Executive Summary and Recommendations**

### *Summary*

Hepatitis C virus infects the liver and develops into a chronic illness in about 85% of infected persons. The virus usually does not cause any symptoms or signs when first transmitted; because of this, a majority of persons currently infected with hepatitis C may not know they carry this virus. Approximately 70% of chronically infected persons develop liver disease, which can manifest as cirrhosis and liver cancer. In the United States, estimates of the medical and work-loss annual costs of hepatitis C-related acute and chronic liver disease are over \$600 million.

The virus is transmitted in infected blood or blood products. Sexual and perinatal transmission are possible but infrequent. Since mid-1992 blood and blood products have been tested routinely for hepatitis C; being treated with these products now only very rarely results in transmission of this virus. However, approximately 6% of those who received transfusions, blood products or donated organs prior to the institution of routine testing (1990) are thought to be infected. Currently, the group at highest risk for hepatitis C infection are injecting drug users. Based on national prevalence data, the Texas Department of Health estimates that as many as 350,000 (about 1.8%) Texans are infected with the virus.

Diagnostic tests for hepatitis C infection are expensive and not routinely available through the public sector. Treatment is available but is lengthy (6-12 months), causes significant side effects, is costly and is not always successful.

### *Recommendations*

- 1) Seroprevalence studies in high risk populations and better surveillance systems for the general population are needed to estimate the current and future impact of hepatitis C in Texas.
- 2) Prevention counseling by trained staff and diagnostic testing should be available to persons at high risk for hepatitis C.
- 3) The department should build on - not supplant - its HIV/STD system of counseling, diagnosis and treatment referral to include hepatitis C.
- 4) Increased hepatitis C prevention efforts to reduce transmission risks are needed. These include risk reduction (needle exchange) programs and affordable drug and alcohol treatment programs and facilities.
- 5) Persons who have hepatitis C infection require a medical system which can provide definitive diagnosis and appropriate treatment.

Each recommendation is costly and millions of dollars are necessary to put a complete prevention and treatment program into effect. What must be realized is that ultimately the cost to society of not providing screening, counseling, and treatment will be much higher.

## Hepatitis C: An Emerging Health Concern for Texans

The purpose of this report is two-fold: to inform the reader about the epidemiology, testing and treatment of hepatitis C, and to provide an estimate of the additional resources that would be needed to allow a public health response to this epidemic in the State of Texas. Resources outlined in the second half of this document are a “best educated guess” estimate of new funds and staffing that would allow the Texas Department of Health (TDH) to adequately and proactively address hepatitis C infection in Texas in the areas of testing and counseling.

### *What is Hepatitis C?*

Hepatitis C (HCV) is a virus that causes hepatitis. Hepatitis is an inflammation of the liver, a vital organ in our bodies that has many functions. Symptoms of acute hepatitis, if present, may include fatigue, mild fever, flu-like illness, nausea and vomiting, stomach ache, and loss of appetite. Classic signs of hepatitis include yellow eyes and skin (jaundice), dark urine, and light-colored stools. However, many people have no symptoms. Infected people who are asymptomatic often don't find out that they are infected with this virus until they donate blood or until decades after the fact when they begin to experience symptoms due to liver damage.

- **Only about 30 to 40%** of persons with *acute* hepatitis C **develop symptoms** and **only 20 to 30%** have **jaundice**.
- **Up to 70%** of persons **may not even know** that they have acute hepatitis C.
- Hepatitis C has been called the “**silent killer**.”
- **The majority ( 85%)** of persons with acute hepatitis C virus infection **remain persistently infected**.
- **Liver disease** develops **in about 70%** of persons who become infected with this disease.
- Persons chronically infected with hepatitis C are at risk for **developing cirrhosis and liver cancer**.
- The Centers for Disease Control and Prevention estimates that **8,000 to 10,000 persons in the U.S. die each year from chronic liver disease that is hepatitis C-related**.
- **The costs of acute and chronic hepatitis C are considerable**. It is estimated that over **\$600 million are spent each year** in the U.S. on hepatitis C-related medical care and lost wages.

### ***Why is Hepatitis C a Major Health Problem?***

Hepatitis C can cause serious liver disease. Concern about this disease continues to increase because it is one of the leading causes of cirrhosis and liver cancer, and accounts for one-quarter to one-third of all liver transplants in the United States. Hepatitis C is also the most common chronic blood-borne infection in the U.S.

- Based on national estimates of the percent of the population who have been infected with hepatitis C, **more than 300,000 Texans are infected** with this virus, many of whom do not even know they are infected.
- In 1997, 376 cases of acute hepatitis C were reported to TDH for an overall rate of 1.9 cases per 100,000 **with Hispanics having the highest rate (2.2/100,000) among ethnic/racial groups.**
- Although each year several hundred new cases of acute hepatitis C are reported to the Texas Department of Health, **many cases go unreported because up to 70% of acute infections are unrecognized due to the silent nature of the disease.**

In September 1998, the U.S. Food and Drug Administration (FDA) released a guidance document for blood banks and their consignees (hospitals, transfusion services, physicians) that sets forth guidelines for the notification of consignees and blood recipients of donor test results for anti-HCV. Any hospital or transfusion service that is notified of the prior receipt of a unit of blood that potentially contained HCV should promptly notify the patient or their physician of record. FDA recommends that this notification process be completed within 18 months of the date of publication of the guidance document (September 1998).

### ***Is There a Vaccine or Other Drug to Help Prevent Infections with Hepatitis C?***

There are no vaccines or immune globulin products currently available to prevent the transmission of hepatitis C virus. The primary ways to prevent hepatitis C include the screening of blood, organ, and tissue donors; modification of high-risk practices; and the use of blood and body fluid precautions (avoidance of direct contact with blood and body fluids of an infected person through the use of gloves, gowns and other barrier methods).

### ***How is Hepatitis C Transmitted and Who is at Risk?***

A person infected with hepatitis C, either acutely or chronically, may infect other people, especially if no precautions are taken. The virus is found in the blood and is spread primarily by direct contact with blood and blood products. Studies have also shown that for every 100 mothers infected with hepatitis C, about five pass this infection to their infants. Hepatitis C may also be transmitted through sexual contact, especially among persons who have multiple sex partners, but the exact risk of sexual transmission is not yet well defined.

At risk groups for hepatitis C are the following:

- Persons notified that they received blood or blood products from a donor who tested positive for hepatitis C;
- ! Persons who received a blood transfusion or solid organ transplant (e.g., kidney, liver, heart) before July 1992 (Routine testing for HCV antibody began in 1990, and more sensitive testing became available during July 1992.);
- Persons with blood clotting problems who received treatment with a blood product made before 1987 (before effective procedures to inactivate viruses were available);
- Persons who ever injected street drugs, even once;
- Persons who were ever on long-term kidney dialysis; and
- Persons with accidental injuries due to needles or other sharp objects.

The virus may also be transmitted by sharing needles, toothbrushes, nail files, acupuncture needles and tattooing and body piercing instruments that may have blood on them. A small proportion of persons infected with this virus have no known history of exposure to blood or to drug use. The sources might be unapparent exposures, such as through cuts or wounds that come in contact with blood from an infected person. One mother of an infected teenager recalled that her child's only known exposure to another person's blood was when she became part of a "rough" group of kids when she was twelve. Part of the initiation was to become "blood" brothers and sisters. This rite involved cutting oneself and then touching cut and bleeding areas of the other members.

### ***What Screening Tests are Available and Who Should be Screened?***

The most widely available test for detection of antibody to hepatitis C (anti-HCV) is an enzyme immunoassay (EIA). A third version is now available that detects anti-HCV in 97% of patients with hepatitis C virus infection. Unfortunately, in groups of people which have low rates of infection, the rate of false positives for anti-HCV is high. All positive tests should be verified using a supplemental assay such as the Recombinant Immunoblot Assay (RIBA). The actual virus can also be detected through reverse transcriptase polymerase chain reaction (PCR) techniques that detect the genetic code of the virus. Results may vary considerably across laboratories, and therefore it is currently recommended that this type of test be used together with the more standard tests that detect anti-HCV antibodies.

The table on the following page provides the Centers for Disease Control and Prevention recommendations for populations who should be screened for hepatitis C. However, it is not unusual for recommendations to change as new data become available.

## Persons for Whom Routine HCV Testing is Recommended

<i>Persons who should be tested routinely for HCV infection based on their risk for infection</i>	<b>Average Anti-HCV Prevalence</b>
• Recipients of clotting factor concentrates before 1987	87%
• Injecting drug users	79%
• Persons with persistently abnormal alanine aminotransferase levels	15%
• Persons ever on chronic hemodialysis	10%
• Blood and solid-organ transplant recipients before 1992	6%*
• Persons notified that they received blood from a donor who later tested positive for HCV infection	No data
<i>Persons who should be tested for HCV-infection based on a recognized exposure</i>	
• Infants 12 months old born to HCV-infected women	(5% incidence)
• Healthcare, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-positive blood	(2% incidence)

\*Percentage positive who received blood transfusions or organ transplants before 1990.

## Persons for Whom Routine Testing for Hepatitis C is of Uncertain Need

• Persons with a history of multiple sex partners or sexually transmitted diseases	
More than 50 sex partners	9%
History of STDs	6%
• Recipients of transplanted tissue (eg, corneal, musculoskeletal, skin, ova, sperm)	
• Intranasal cocaine and other noninjecting illegal drug users	
• Persons with a history of tattooing or body piercing	
• Long-term, steady sex partners of HCV-positive persons	

## Persons for Whom Routine Testing for Hepatitis C Virus is NOT Recommended

• Health-care, emergency medical, and public safety workers
• Pregnant women
• Household (nonsexual) contacts of HCV-positive persons
• The general population

The cost of screening for hepatitis C varies by provider and laboratory. Based on a small survey of laboratories in Texas in the summer of 1998, cost to the patient for the EIA test ranged from \$75 to \$116, and cost for the RIBA ranged from \$176 to \$215. The TDH Bureau of Laboratories performs EIA testing for Medicaid patients at a cost of about \$20 per test.

### ***What is the Treatment?***

Several drugs are available to treat persons with chronic hepatitis C. A drug called interferon helps some persons with this chronic infection. The treatment must be given by injection, and has a number of side effects including flu-like symptoms. The medication may also interfere with the production of white blood cells (which help ward off infection) and platelets (which help blood to clot) by depressing the bone marrow. Periodic blood tests are required to monitor blood cells and platelets. While 50-60% of patients respond to treatment initially, lasting clearance of the virus occurs in only 10-20% of patients. Depending on patient response, length of treatment with interferon ranges from 6 to 18 months. Several cost-effectiveness studies have shown that a 6-12 month course of interferon treatment in patients with chronic hepatitis C increases life expectancy and that the costs per year of life gained compare favorably with other generally accepted medical interventions such as screening mammography or cholesterol reduction.

In June 1998, the U.S. FDA approved Rebetron combination therapy (interferon and ribavirin) for the treatment of chronic hepatitis C patients with liver disease who have relapsed following interferon therapy. Six months after treatment with this combination of interferon and ribavirin therapy, 46% of patients had undetectable virus levels. In December 1998, the U.S. FDA approved the combination therapy for treatment of chronic hepatitis C in patients with compensated liver disease previously untreated with interferon therapy. In addition to the side effects associated with interferon, ribavirin in the combination therapy can cause serious anemia (low red blood count). Ribavirin causes birth defects; therefore pregnancy must be avoided during treatment. Costs for a six-month treatment with the new Rebetron combination therapy are approximately \$6,400 to \$8,600, depending upon dosage. Because this therapy was just approved by the FDA in June 1998, no published studies are available on the cost effectiveness of this new drug regimen.

Some persons with hepatitis C require a liver transplant. Currently, one quarter to one third of all liver transplants in the U.S. are performed for end-stage hepatitis C disease. The cost of a liver transplant varies between surgeons, medical facilities, and regions of the U.S. The total cost of this procedure, including physician fees, hospital charges, and medications ranges between \$250,000 and \$500,000. After a person receives a liver transplant, annual costs for immunosuppressive drugs (which transplant patients will need to take the rest of their lives) and follow-up care can be up to \$29,000 per year.

## ***What is TDH Doing About Hepatitis C in Texas?***

TDH is actively involved in both professional and public education about hepatitis C.

- In the past year, staff have talked to various health professional groups across the state concerning hepatitis C, its prevention, and counseling of persons infected with this virus.
- TDH has developed a bilingual (Spanish/English) pamphlet on hepatitis C; over 10,000 of these were distributed the past year to clinics, health professionals, and the general public. The demand continues to be very high for this information, and TDH has received requests for copies of the pamphlet from all across the U.S.
- TDH is working with the Texas Medical Association (TMA) to identify the educational needs and materials that could be used to help educate physicians about hepatitis C.
- TDH hosted one of the Centers for Disease Control and Prevention and Hepatitis Foundation International live satellite video conferences in November 1997 on “Hepatitis C: Diagnosis, Clinical Management, and Prevention.” The Department also helped publicize this offering across the state and provided information on other downlinks around Texas.
- As part of its quarterly CME Conference on Perspectives in Public Health in September, TDH offered sessions on the “Epidemiology of Hepatitis C” and “Ethical Issues in Public Health Population Screening: Partner Notification/Contact Tracing.” The December 1998 conference provided a session on hepatitis C treatment.
- TDH continues to work with local health departments on conducting surveillance for acute hepatitis C and in providing materials and information for counseling persons who either have or are at risk of contracting hepatitis C.

Staff in the Department continue to provide several hundred consultations each year, primarily to persons with hepatitis C, their families, and coworkers on the nature of the illness, how its spread can be prevented, and what persons with the disease can do to help maintain their health.

Staff in TDH Bureau of HIV/STD are currently exploring mechanisms for integrating hepatitis C screening and counseling into their clinic operations. A significant portion of the HIV-infected population (particularly those with a history of injecting street drugs) may be coinfecting with hepatitis C.

The TDH Associateship for Disease Control has established a Hepatitis C Working Group, cochaired by Dr. Stanley, Chief of the Bureau of HIV/STD Prevention, and Dr. Brender, Epidemiologist in the Bureau of Communicable Disease Control, to address issues surrounding the hepatitis C epidemic in Texas. It is anticipated that, with the federally mandated lookback process being undertaken by blood banks and hospitals across the nation, demands for counseling, testing, and referral for care for hepatitis C will increase significantly in the state of Texas and will impact our HIV and STD clinics

as well as other publicly funded clinics. Currently the public sector cannot meet these needs without eliminating other services. The working group is assessing the anticipated impact of this epidemic on the public health clinics and establishing plans and anticipated costs necessary to meet these increased demands. The working group represents a broad collaboration between TDH, TMA, blood bank representatives, Austin/Travis County Health and Human Services Department, American Red Cross, and the Hep C Connection.

***What is Needed to Address Public Health Issues Related to Hepatitis C and What Resources Does TDH Require to Meet the Needs?***

Resources are needed at both the state and local levels to meet the needs for public and professional education, testing, and counseling related to hepatitis C, and a system to refer infected persons for care. The recent publication of the CDC's *Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease*. (MMWR, October 16, 1998 / Vol. 47 / No. RR-19) has underscored the need for public health agencies to mount a concerted effort to meet the challenge posed by hepatitis C. Although these recommendations apply equally to private and public health providers, the guidelines specifically call upon public health HIV counseling and testing sites and STD clinics to implement hepatitis C primary prevention and screening and to provide linkages to sources of treatment. These types of public health facilities already have a steady flow of patients/clients who comprise many of the hepatitis C high-risk populations. The following discussion will be limited to the resources needed at TDH to provide education, screening, testing, and referral services.

**Public education:** We need a wider effort to alert Texans who are in the high risk groups about hepatitis C, the need for testing, prevention of transmission, and management of this chronic disease. Currently, very few federal or state dollars have been allocated for this significant health problem. The identification of resources to launch and maintain such a public education effort is a major challenge. Private organizations such as the Hep C Connection and the Texas Medical Association (TMA) have indicated they are willing to join with TDH in a partnership to see that this task is accomplished.

**Professional education:** Hepatitis C is a recently discovered disease and its diagnosis and treatment are evolving. Physicians, especially those in primary care, and other health professionals need more information and education about hepatitis C. Part of this educational effort could be accomplished through TDH partnering with professional organizations such as the Texas Medical Association and county medical associations.

**Resources for screening:** Demand for hepatitis C screening is expected to increase precipitously with the notification of blood recipients of their potential risk of infection and the attendant media attention to hepatitis C. Currently, for three risk groups, there is a large unmet need in Texas for public health screening of those who have poor access to private medical care:

- Transfusion recipients,
- Past and current injecting drug users,
- Persons at recognized sexual risk.

People found to be HCV-infected also need to be referred for care. Those seeking screening and referral at TDH clinics usually do not have health insurance, are not part of any public medical assistance plan, or are underinsured; a small percentage are on Medicaid.

The following estimates were based, in part, on CDC estimates of the percentage of the people in the U.S. who fall into the groups having elevated risk for becoming infected with hepatitis C, and a CDC estimate of hepatitis C prevalence among those risk group members<sup>1</sup>. CDC estimates were applied to Texas statistics on population, insured-uninsured, Medicaid, and poverty using certain assumptions. Assumptions, methods, and more detailed analyses are available upon request from TDH.

### Estimated Five-Year Costs for Public Sector Hepatitis C Screening in Texas

Risk Group	Population	Public Sector Population	Hepatitis C Prevalence (%)	Low-range 5-year costs (\$)	High-range 5-year costs (\$)
Injecting drug users	1,099,748	78,482	--	9,120,715	19,153,520
Current	99,977	43,990	79.0	-----	-----
Past	999,771	34,492	39.5	-----	-----
Transfusion recipients	1,357,661	95,248	6.0	2,913,063	12,420,806
50 or more sex partners	-----	71,075	4.0	1,954,975	8,978,131
<b>Total</b>				<b>13,988,753</b>	<b>40,552,457</b>

*\*Costs were based on the lowest and highest findings in the survey of laboratory costs, mentioned above.*

Although the estimated costs for screening are somewhat startling at first glance, it should be remembered that the costs would be distributed over a five-year period, most likely somewhat lower in the first year, as the program began, and then peaking in the third and fourth years. The expense of RIBA testing of patients with positive EIA results drives up the costs for high-prevalence groups. Another item to note and remember is that as hepatitis C testing becomes more common and as time passes, market forces are likely to bring the costs of test kits down.

**Counseling:** Notification of past transfusion recipients of their need for testing (as set forth in the September 1998 U.S. FDA guidance document) will likely increase the demands for counseling and testing for hepatitis C in Texas. Already, local health departments have relayed to TDH that their staff are often overwhelmed by the number of persons who have hepatitis C who request and need counseling. TDH staff have experienced similar demands. The availability of timely and appropriate counseling can help prevent transmission of hepatitis C (primary prevention) as well as help persons

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<sup>1</sup> Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease. *MMWR*, October 16, 1998 / Vol. 47 / No. RR-19

with chronic hepatitis C lower their risk of disease progression (secondary and tertiary prevention). Thus, it is imperative to put the infrastructure in place to meet this need for counseling and referral. The plan below draws largely upon the expertise in training that currently exists in the Bureau of HIV and STD Prevention and its public HIV counseling and testing sites and STD clinics. The total amount estimated covers an additional three FTEs (or long-term contracts with individuals to perform these tasks), training, educational materials, and supplies.

The suggested training and education plan is modeled after the counseling programs for HIV and other STDs that exist in the Bureau of HIV/STD Prevention. These programs have proven effective in meeting the needs for counseling, risk reduction, and prevention in the affected populations. The Bureau of HIV/STD Prevention maintains a registry of trained counselors who have successfully completed one and two week courses in HIV and STD counseling. Of the more than 1400 individuals listed in the Registry, over 600 currently provide counseling in TDH-funded clinics. The fundamental principle of the present plan is to give further training on HCV prevention, counseling, and testing to local health department and community-based organization staff already handling these tasks for HIV and STDs; these counselors are already seeing many individuals in the high-risk HCV populations. We would take a two-tiered approach to training; first training all currently active counselors (approximately 630) and staff as *hepatitis generalists* and then further training a special cadre of *hepatitis specialists*. Several approaches to training counselors and staff could be used, and are outlined briefly below.

**Estimated costs of hepatitis C training for counselors, public education, and better surveillance:** The following resources are needed to improve the surveillance and reporting of HCV infections, support professional and public education about HCV, and provide training about HCV for HIV and STD counselors. Once counselors are trained, they will be able to provide the appropriate counseling to persons who test positive for hepatitis C or who are at high-risk of contracting this virus. This counseling can help patients understand how they can prevent further spread of the virus, how they can protect their liver from further harm, and the importance of medical follow up to evaluate the extent of their disease and the need for treatment.

<b>Category</b>	<b>Annual Cost</b>
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*Staff*

Additional staff (placed within the Bureau of Communicable Diseases) is needed at this time to plan, implement, and coordinate public and professional education and information, help improve surveillance, and provide consultations to both the public and health professionals on hepatitis C. Better surveillance is important to identify new cases and determine disease incidence and trends; to determine risk factors for infection and disease transmission patterns; and to estimate disease burden. These consultative, public information, and surveillance needs could be best met by a Nurse IV.

Salary	\$33,900
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Training efforts carried out by the Bureau of HIV and STD Prevention would require one full time Trainer Specialist IV to develop and modify curricula, train over 630 generalists and specialists, develop and conduct training of trainers, and evaluate counselors and trainers. A sizable travel budget is included to cover the extensive travel involved with this position.

Salary	\$35,132
Travel	\$12,000

Due to the significant development and dissemination of materials combined with the planning, registering, training and tracking of participants statewide, the Training Branch within the Bureau of HIV and STD Prevention would also require at least one additional full time Administrative Technician II. This position would provide secretarial support, including word processing, telephone duties, assistance with materials, duplication and distribution, filing, mailouts, creation and maintenance of computerized registries and general clerical support as needed.

Salary	\$21,852
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***Printing and Postage***

There continues to be a high demand for the TDH pamphlet on hepatitis C. The Bureau of Communicable Diseases does not have sufficient funds to reprint this pamphlet and has in the past asked other Bureaus to contribute to the printing costs. The cost estimate below covers the printing of 100,000 pamphlets per year. These pamphlets are also distributed by local health departments. TDH staff mail out materials about hepatitis C on a daily basis. Currently the costs of these mailings come out of the general operating budget.

Printing costs	\$16,000
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***Travel***

Current staff receive numerous requests to give presentations on hepatitis C throughout the state. Because of budget restraints, it has been necessary for the requesting entity to pay for travel outside of Austin. Some of the requesting groups, however, do not have the resources to pay for this travel. Travel money is also needed for staff to work with local health departments to help improve their surveillance of hepatitis C.

Travel	\$5,000
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Total cost of staff, travel, printing, postage	\$123,884
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**First Year Costs for TDH Staffing, Counselor-Training, and Education Program**

<b>Type of Training</b>	<b>Costs(\$)*</b>
<b>HCV Mail-outs to HIV Counselors</b>	
With verification and/or testing	3,500
<b>Annual HIV/STD Conference</b>	
Contract with instructor/speaker to train at generalist and specialist levels	1,500
<b>Videotapes or Teleconferencing</b>	
Videotapes	56,000
<b>Self-Paced Course</b>	
For specialists only—first two years only	24,000
<b>Adding Hepatitis Training to Current Trainings in the Bureau</b>	100,000
<b>Development of Hepatitis C Curriculum</b>	225,000
<b>Staff, Travel, Printing, and Postage</b>	123,884
<b>Total</b>	<b>533,884</b>

\*Costs for the second year of the Program would be \$249,384 and then \$225,384 per year thereafter.

***Summary***

The number of infected Texans and the anticipated serious health effects of hepatitis C infection establish this newly emergent infectious disease as a serious public health concern. Without effective intervention, deaths from hepatitis C-related conditions will triple in the next 10 to 20 years. Screening and counseling persons at high risk of hepatitis C are important interventions to prevent the spread of this virus in the general population. Education of persons infected with hepatitis C virus can result in lifestyle changes that help prevent further progression of liver disease. The Texas Department of Health does not possess the resources to adequately address this emerging public health threat; diversion of resources currently allocated to the control of other communicable diseases would adversely affect the health of Texans. A new commitment to the fight against this newly recognized infectious disease is needed.