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An Overview of

Hepatitis C Care and Treatment

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Screening for the hepatitis C virus (HCV) was integrated into services at San Diego County's STD clinics in September 1999 and expanded to the primary HIV counseling and testing site about a year later. Screening is offered to at-risk individuals, based on a risk assessment completed by the client or a counselor interview. For those who test HCV-positive and do not return to get their test results, a disease intervention specialist is assigned to the case for follow up. About 80 percent of clients who test HCV-positive receive their results. This is a significant accomplishment, given the hard-to-serve nature of the target population. Clients are primarily men, aged 20 to 45 years old, often with a history of substance use, unstable living situations, and no access to medical care.

When HCV-positive clients receive their test results, they receive counseling, focused on behavior change to reduce high-risk activities. They also receive information on how they can protect their health (e.g., limit or stop drinking alcohol, obtain a medical evaluation). Clients are also given a referral packet with general information on hepatitis A, B and C; a resource list of testing sites, health care providers, community-based clinics, clinical trials, support groups, and hepatitis-related organizations; and a glossary of related terms. Hepatitis A and B vaccinations are available to clients at the sites where HCV testing is available.

As with many health departments across the country, services end there. For clients who do not have private health insurance—which is the case for most of those who visit a public clinic—no resources are

available to provide health care in a coordinated way. San Diego County does not have a public hospital but does provide funds to community-based providers to deliver health care services free of charge or on a sliding scale. But, bottom line, HCV-infected clients confronted by this chronic and serious condition are on their own for obtaining the medical evaluation needed and any subsequent treatment indicated.

This document explores medical treatment and other services that are available currently for people living with hepatitis C. In addition, the efforts of two health departments, are profiled: the MA Department of Health's provider education program and California's Marin County treatment and case management program.

The challenges faced by San Diego County are not unique. Across the country, many health departments provide HCV testing to at-risk individuals. Unfortunately, clients who test positive for HCV have few, if any, options for further care. Some providers have argued that screening clients for HCV infection is pointless if those who test positive cannot be linked to medical services. Most agree, however, that clients need to know their HCV status. Data suggest that if clients know their HCV status, they are more likely to take steps to protect their health, such as limiting their intake of alcohol. They can also adopt safer behaviors that can prevent the spread of HCV to others.

Why are so few resources available to provide services to HCV-infected individuals? The federal government does not provide any funds to state and local health departments specifically for treating HCV. Categorical funding by the federal government addresses many related conditions, such as HIV, STDs, and substance abuse, but in most cases these funds cannot be used for HCV screening, evaluation, or treatment.

Diagnosis and Beyond

When persons are diagnosed with HCV infection, they might not immediately need treatment for the disease but they do, ideally, need to be under the care of a medical professional. Many HCV-infected people are asymptomatic, and subsequent medical evaluation does not always result in treatment. However, even without treatment, other steps can be taken to protect an HCV-infected person's health. These include:

- Screening for hepatitis A and hepatitis B infections and vaccination if they have not already been infected
- Testing to evaluate for chronic liver disease, which should be conducted regularly (patients with chronic active HCV infection and not on treatment should monitored twice a year)
- Providing referral to drug treatment if they are using illegal drugs
- Eliminating or reducing alcohol consumption and providing referral to alcohol treatment programs, if needed

People living with HCV may also need emotional support. Support groups, some with a specific focus, can help the newly diagnosed and also provide ongoing assistance in managing the disease.

Finally, newly diagnosed individuals should be counseled in how to prevent infecting others. For those who are active injection drug users, counseling should include how to adopt safer injection techniques. People with multiple sex partners should practice safer sex. HCV-infected individuals also should not donate blood, semen, organs, and other tissue or share toothbrushes, razors, or other personal care articles that might have blood on them.

Treatment of Hepatitis C

The most effective treatment for Hepatitis C is a combination of interferon, an antiretroviral drug, and ribavirin.

The most effective treatment is a combination of interferon, an antiretroviral drug, and ribavirin. Since 2001, pegylated interferon, which is long-acting and injected weekly, has been approved for treatment alone or in combination with ribavirin. Successful treatment can eradicate the virus. Treatment can also slow disease progression, improve histology, and reduce the risk of liver cancer. Combination therapy is most effective in patients with HCV genotypes 2 and 3, which represent about 25 percent of patients in the United States. The most common genotypes, 1a and 1b, which affect about 75 percent of patients in the United States, are currently considered to be the most difficult to treat.

Treatment is not recommended for all HCV-infected individuals with liver damage. Interferon should not be prescribed for people with serious psychiatric illness, unstable heart disease, or uncontrolled diabetes. Ribavirin should not be given to pregnant women and people with anemia, heart disease, stroke, or kidney disease.

Side effects of treatment can be severe, enough to cause some patients to stop treatment. Side effects from the two drugs include anemia and other blood disorders, heart disease, birth defects, depression, anxiety, insomnia, headache, fatigue, nausea, and muscle and joint aches. Severe side effects from interferon, which are rare, include thyroid disease, depression with suicidal thoughts, seizures, acute congestive heart and renal failure, vision loss, and lung problems. The side effects tend to lessen over the course of treatment.

The goal of treatment is a sustained virologic response (SVR). Therapy is considered to be successful if HCV remains undetectable six months after treatment ends. For patients with HCV genotype 1, the response rate to one year of combination therapy

The NIH Consensus Statement for the Management of Hepatitis C - 2002 was developed by an independent, non-advocate, non-Federal panel. The consensus meeting was convened to provide an update on a 1997 conference on the same topic. The 2002 Consensus Statement expands the scope of patients eligible for treatment to include those who use injection drugs, consume alcohol, suffer from co-morbid conditions such as depression, or are co-infected with HIV. The consensus statement addresses:

- Natural history of hepatitis C
- Appropriate approaches to diagnose and monitor patients
- Effective therapy for hepatitis C
- Which patients with hepatitis C should not be treated
- Recommendations that can be made to patients to prevent hepatitis C transmission

The consensus statement is available online at: http://consensus.nih.gov/cons/116/116cdc_intro.htm.

The American Association for the Study of Liver Diseases (AASLD), an association representing more than 2,400 physicians, researchers, and allied hepatology health professionals dedicated to advancing the science and practice of Hepatology, has also published practice guidelines on the diagnosis, management, and treatment of hepatitis C. These guidelines are available under the "Practice Guidelines" section of AASLD's Web site at http://www.aasld.org.

Other Treatment Resources

Treatment

Hepatitis Foundation International, http://www.hepfi.org/pages/liv_diagnosis.html

HIVandHepatitis.Com, http://www.hivandhepatitis.com/

National Institute of Allergy and Infectious Diseases, http://www.niaid.nih.gov/dmid/hepatitis/default.htm

Research

Hep C Research.com, http://www.hepcresearch.com/

Clinical Trials

ClinicalTrials.Gov
This NIH site provides information about federally and privately supported clinical research, http://www.clinicaltrials.gov

CenterWatch Clinical Trials Listing Service, http://www.centerwatch.com/patient/studies/cat79.html

of pegylated interferon and ribavirin is 40 to 45 percent. Data are limited on patients with genotype 4, but current studies suggest that one year of combination therapy is also needed to achieve similar response rates as those for genotype 1. Eighty percent of patients with genotypes 2 or 3 can achieve SVR with six months of combination therapy. For those who relapse after initial treatment, re-treatment might be an option.

Almost one half of all liver transplants in the United States are a result of HCV-related liver disease. Re-infection of the transplanted liver by HCV occurs at a high rate, but second transplants are rarely required.

The Treatment Dilemma

Given the unpleasant side effects, the cost of treatment (an estimated $10,000 to $15,000 a year for drug therapy—treating liver failure can cost $50,000 to $250,000), and the limited efficacy, some care providers and their patients consider other options. Patients must carefully weigh the likelihood that the disease will progress with the benefits and risk of therapy, especially since the progression is highly variable and unpredictable. For example, in a recent study reported in the *Journal of the American Medical Association* (JAMA), Harvard researchers noted that 30 to 70 percent of infected individuals may never progress to cirrhosis before dying from other causes.[1]

Some HCV-infected individuals opt to explore alternative or traditional therapies. Milk thistle, for example, is a popular herbal remedy. Some people who are taking medication for HCV believe it reduces side effects. There is no evidence that herbal remedies are effective, and some may actually be harm-

[1] Salomon JA, Weinstein MC, Hammitt JK, Goldie SJ. Cost-effectiveness of Treatment for Chronic Hepatitis C Infection in an Evolving Patient Population. *JAMA* 2003 290: 228-237.

ful. Patients should always consult their doctors before trying herbal therapies, since they can be toxic or react with other medications.

Another important consideration is that few HCV-infected individuals are candidates for interferon-based therapies. In a study conducted at a county teaching hospital in Cleveland, Ohio, 72 percent of patients with HCV infection did not receive antiviral therapy because of failure to show up for appointments or tests (37 percent), severe co-morbid medical or psychiatric illness (34 percent), ongoing alcohol or drug abuse (13 percent), or preferences against treatment (11 percent). Another 28 percent of patients were treated, and 13 percent of these had a sustained viral response. Researchers concluded that most patients with HCV infection are not candidates for antiviral therapies, and alternative interventions should be sought for them.[2]

Providers are encouraged to make treatment decisions on a case-by-case basis.

These data are important to consider when weighing the advantages and disadvantages of implementing a treatment program for HCV-infected clients. Many medical clinics, correctional facilities, and hospitals are concerned that providing treatment services will bankrupt their program. In fact, numerous data, such as those in the study mentioned above, suggest that only a small percentage of clients would be eligible or willing to begin treatment, indicating that the costs of treatment could be manageable.

However, a growing number of studies are finding that many of these "ineligible" patients can be effectively treated if appropriate precautions are taken and if adequate supports for the patient are available. As this field continues to evolve and as HCV therapies rapidly improve, providers are encouraged to make treatment decisions on a case-by-case basis.

[2] Falck-Ytter Y, Kale H, Mullen KD, Sarbah, SA, Soerscu S, McCullough AJ. Surprisingly Small Effect of Antiviral Treatment in Patients with Hepatitis C. *Annals of Internal Medicine* 2002 136: 288-292.

Care for the Uninsured and Underinsured

Some options are available for providing health care to people who lack or have insufficient private health insurance. However, not everyone is eligible for these programs.

Medicaid

As the nation's major public health insurance program for low-income Americans, Medicaid finances health and long-term care services for 47 million people. The program is intended to cover the poorest and most vulnerable populations. It is often the only source of health insurance available for 35 million children and parents, and it provides acute and long-term care for 8 million people with disabilities. It also assists over 6 million low-income seniors and individuals with disabilities who receive Medicare.

To qualify for coverage, an individual must meet financial criteria and be a member of a "categorically eligible" group, such as low-income children, pregnant women, parents, the elderly, and people with disabilities. While federal law mandates coverage for some groups below specified income levels, states can extend eligibility beyond these minimum standards. As a result of this flexibility, coverage varies significantly across states.

States are required to provide certain services, including inpatient and outpatient hospital services, and receive federal matching funds for additional, optional services such as prescription drugs and clinic services. States also receive supplemental Medicaid payments to aid hospitals serving indigent patients.

State Medicaid programs face significant challenges, given the current fiscal crisis facing most states. Medicaid costs continue to rise, 13 percent in FY 2002, at a time when most states face huge budget deficits. States are limiting prescription drug spending, have frozen provider payments, and are reducing benefits and limiting eligibility.

For more information, visit the Centers for Medicare and Medicaid Services (CMS) web site at http://cms.hhs.gov

Ryan White CARE Act

The federal Ryan White CARE Act provides health care for people with HIV disease. Enacted in 1990, it fills gaps in care faced by those with low-incomes and little or no insurance. The Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau administers the program through hundreds of grantees, who serve 533,000 people each year.

The CARE Act includes four titles, and states are responsible for administering Title II. Title II funds assist states and territories in improving the quality, availability, and organization of health care and support services for individuals and families with HIV disease. The AIDS Drug Assistance Program (ADAP) is also funded under Title II. ADAP provides medications to low-income individuals with HIV disease who have limited or no coverage from private insurance or Medicaid.

Individuals who are co-infected with HIV and hepatitis can be treated under the CARE Act, as long as they meet the eligibility requirements, which vary from state to state.

For more information, visit the HRSA HIV/AIDS Bureau Web site at http://hab.hrsa.gov, or visit NASTAD's Web site at http://www.nastad.org/res_public_policy.asp?menu=res. Click on "Funding Profile" listed under the "State Federal HIV/AIDS Funding Profiles." A copy of the AIDS Drug Assistance Program (ADAP) Monitoring Report can also be viewed at http://www.nastad.org/ADAP/.

The Veterans Health Administration

The Veterans Healthcare System, which serves eligible U.S. veterans, offers hepatitis C screening, treatment, and supportive services to its patients. Visit http://www.hepatitis.va.gov/ for more information on the VA's hepatitis C program.

Indigent Care

Indigent care programs are available in some communities. In most, these constitute a public hospital or programs carried out by community-based programs, such as programs providing care to homeless individuals. These programs are often not designed to provide the kind of ongoing care a person with chronic hepatitis needs.

Resources on the Uninsured and Underinsured

Kaiser Family Foundation

KFF's supports the Kaiser Commission on Medicaid and the Uninsured, which studies the challenge of providing health care to those without coverage.
http://www.kff.org

Treatment and Support Continuum

Combination therapy for HCV is expensive. For someone who is uninsured or underinsured, even the most basic care might be unaffordable. Some service providers, including state and local health departments, have been reluctant to promote hepatitis screening programs because of the lack of options for treatment if a person is infected. They argue that there is no point in telling a person that they are positive if follow-up medical care cannot be offered.

That argument overlooks opportunities to provide essential services to this population. While funding for many of the activities listed below might not be available now, these services should be considered as part of the continuum of care for people living with HCV. State and local health departments should explore ways to integrate these services, as much as possible, into services targeting populations at risk for HCV.

Referral for Medical Evaluation

For those who are HCV infected, regular tests to monitor the health of the liver are essential.

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- ***Liver function tests*** are performed to measure the levels of enzymes and other substances. When the liver is inflamed or damaged, certain enzymes will be released or the level of some substances will change. Common liver function tests include albumin, total protein, the enzymes ALT and AST, alkaline phosphatase, and bilirubin. If these tests indicate liver damage, a liver biopsy should be performed.

- A ***liver biopsy*** is a diagnostic tool to determine the severity of liver disease and the stage or degree of fibrosis in patients who have hepatitis C. Before a biopsy, an ultrasound and/or a CT

scan may be performed. Ultrasound can assess the size, structure, and vascular supply of the liver. CT scans confirm the findings of ultrasound and, by measuring the size and texture of the liver, can be used to detect tumors. Biopsies can identify the site of a lesion and can also assess the degree of liver damage. The utility of a liver biopsy in patients infected with HCV genotypes 2 or 3 is currently a topic of debate. Because of the high likelihood of achieving SVR in these patients through combination drug therapy, many providers elect to bypass the liver biopsy and begin drug therapy without assessing the severity of liver disease.

- ***Other tests*** that should be provided during the initial medical evaluation include a complete blood count (cbc), a viral load test, and a genotype test.

Hepatitis C has been linked to many other medical conditions. Some are severe, especially during the later stages of liver disease, such as kidney damage and liver cancer. Case reports suggest that a number of autoimmune conditions might also be associated with hepatitis C. Medical conditions that have been linked to hepatitis C include Sjogren's syndrome, rheumatoid arthritis, vasculitis, thyroid disease, scleroderma, fibromyalgia, and type II diabetes. The severity of these conditions supports the importance of access to regular medical care for people living with hepatitis C.

Referrals for Other Services

People infected with HCV may also benefit from referral to other services. Hepatitis C disproportionately affects some populations, including current and former injection drug users, individuals who have been incarcerated, people with mental illness, and people of color. Some of these populations may live somewhat chaotic lives and face various challenges.

Some programs, especially harm reduction programs such as syringe exchange, have found that screening for hepatitis can provide a "point of access" to this population. Many people at risk have sought out screening, having heard of the risk of HCV. Others have been identified when they accessed services, such as STD services. Their engagement in care can provide an opportunity to link them to other services.

Most importantly, people with HCV should be referred to substance abuse treatment if they are still using drugs or need treatment for alcohol abuse. If people are still injecting drugs, they can be exposed to other blood-borne viruses such as HIV and hepatitis B virus or they can get re-infected with HCV. Since alcohol can accelerate liver damage in people with HCV infection, those who are infected should reduce or abstain from alcohol use. For those who are addicted, alcohol reduction or cessation may not be possible without treatment.

Persons with severe mental illness are 11 times more likely than the population at large to have HCV.

Persons with severe mental illness are 11 times more likely than the population at large to have HCV.[1] Their mental illness might affect their ability to access treatment. These individuals should be linked to appropriate services for their condition.

[1] Rosenberg SD, Goodman LA, Osher FC, Swartz MS, Essock SM, Butterfield MI, Constantine NT, Wolford GL, Salyers MP. Prevalence of HIV, Hepatitis B and Hepatitis C in people with severe mental illness. *Am J Public Health* 2001; 91: 31-37.

Treating HCV in People with Mental Illness

The high prevalence of HCV in people with mental illness is a serious challenge for health care providers. Hepatitis C treatment is associated with significant mental-health-related side effects, for which people with a history of mental illness, including substance use, may be at increased risk. Treatment options currently available, interferon monotherapy and interferon and ribavirin combination therapy, can result in serious psychiatric side effects including psychosis, depression, suicide, and substance use relapse.

Early treatment guidelines, developed in 1997 by an NIH consensus panel, recommended that people with mental illness and those who continue to use illicit substance not be offered treatment for HCV. This recommendation stemmed from the belief that substance users were more prone to adherence lapses and that the psychiatric side effects posed too great of a threat to people with mental illness. The treatment guidelines were revised in 2002, and treatment is now recommended for people with mental illness and for active drug users.

Studies have indicated that between 40 to 80 percent of drug users adhere to treatment, with the type of illicit drug used and the regularity of use being major determinants for adherence. Other factors can also play a role in adherence. People with mental illness and illicit drug users may have chaotic, unstable lives with many challenges. Inadequate social support and housing can affect adherence. Factors that can enhance adherence include the quality of the clinician-patient relationship, the treatment regimen, clinical setting, and the treatment of co-morbid conditions such as mental illness and substance abuse.

Other populations affected by HCV might be poor and unfamiliar or distrustful of the mainstream health care system. Linking them to necessities, such as food and housing, might help to build their confidence in “the system” and serve to link them to a range of services. If they do not already have access, linking people to health coverage, such as Medicaid, is also crucial.

Individuals with a history of incarceration are also disproportionately affected by hepatitis C. These individuals might benefit from a range of services including housing, employment, and legal aid. Those who are still incarcerated might be in need of discharge planning services that link them to services outside of the correctional facility.

Secondary Prevention Services

Once a person is infected, secondary prevention measures prevent or slow disease progression. People with HCV infection can take two significant steps to protect their health.

- ***Get vaccinated***
  Since hepatitis A and hepatitis B can exacerbate hepatitis C, people infected with HCV should be screened to determine if they have been exposed to hepatitis A or hepatitis B. If they have not already been infected, they should be vaccinated for both. The hepatitis A vaccine is given in two doses, 6 to 18 months apart. The hepatitis B vaccine is usually given in three doses over a six-month period. Follow-up is often needed to ensure that all doses of the vaccines are received.

- ***Cease or reduce consumption of alcohol***
  People with HCV should ideally abstain from alcohol use, since consumption of alcohol can speed the onset of liver disease. If a person cannot stop using, any reduction in alcohol use is beneficial. Individuals with drinking problems may need to be referred to substance abuse treatment programs.

People living with HCV should also be educated about other steps they can take to protect their liver. They should consult with a physician or pharmacist when taking prescription or over-the-counter medications, since many drugs are metabolized in the liver. Ibuprofen and acetaminophen in large doses can harm the liver. Following a healthy diet and reducing stress are also important. Some people living with HCV explore alternative therapies.

Supporting the Adoption of Safer Behaviors

People infected with HCV should be counseled on how to prevent transmitting the virus to others. This is especially important if the person continues to inject drugs. Numerous resources are available that discuss safer injection practices. While injection drug use is the main transmission mode, HCV-infected individuals should also be educated about other means of exposure, such as household, sexual contact, and occupational exposure.

Support Groups

As with many life threatening illnesses, people living with HCV might want to share their experiences with others who are confronting similar challenges. Support groups, often conducted by organizations by and for people living with HCV, are available in various communities across the country. Many of these groups are run by volunteers with extremely limited resources. Depending on the resources available and the size of the community, an array of support groups might be tailored to meet the needs of various populations such as those who are infected but asymptomatic, are in treatment, or are treatment nonresponders.

Support groups can play a key role in maintaining the health of people with HCV. Peers can help support people in abstaining from alcohol and can provide comfort when they are experiencing the unpleasant side effects of treatment. Knowing that someone else has gone through what they are going through can be an ongoing motivator.

Case Management

As has been learned from the HIV epidemic, case management can make a significant difference in

Massachusetts: Multiple Approaches for Educating Providers about HCV

Imagine being diagnosed with a life-threatening illness and then, when you go to the doctor, finding that he or she knows as little about the condition as you do. State and local health departments regularly hear from frustrated people living with HCV that providers know little about how to evaluate and treat HCV infection. In response, many health departments have initiated programs to educate health care providers about HCV. As with other HCV-related needs, funds to carry out these activities are extremely limited.

In 1999, when the Massachusetts Department of Public Health (MDPH) initiated a viral hepatitis program, educational activities targeting health care providers were a major component. Materials were developed for health care providers over several years. These included an educational audio tape for primary care providers, a pocket-sized HCV screening algorithm for primary care providers, a manual on integrating hepatitis C into HIV services, posters, and a resource mailing to nursing professionals containing basic information on HCV and strategies for talking to patients about drug use and sex. MDPH also has held several one-day, regional conferences for providers. All these efforts are financed by state funds.

In developing the materials, MDPH took several steps to ensure that they addressed the needs of the target population. Focus groups were conducted to determine what information providers would find most valuable, and business reply cards were included with many of the resource mailings. MDPH also formed the Hepatitis C Advisory Committee, made up of various stakeholders including organizations representing health care providers. The advisory committee provides ongoing advice to MDPH.

Using multiple approaches, both the written materials and the conferences, provides flexibility and enables MDPH to reach a wider audience, since people prefer different education methods. For example, MDPH is revising the surveillance process for HCV—providers will now report cases, instead of local health departments—and MDPH is planning a series of conferences for the coming year that will educate providers about the new reporting requirements. Conferences enable MDPH to provide information in a timely way. Publications can quickly become dated, and funds may not be available to update publications as new issues arise.

Reaching health care providers, especially physicians, can be challenging. Even when CME credits are provided, getting physicians to attend can be difficult due to the demands on their time. Also, physicians are inundated with information. In their formative research, MDPH learned that the appearance of documents targeting physicians is very important. To be noticed, materials must be designed and printed well. Unfortunately, producing this type of document is expensive.

Primary care providers in particular are a key target audience for MDPH. MDPH has found that many primary care providers do not identify HCV as an issue that they need to address. Their approach to patients with HCV has often been to refer them to a specialist, rather than manage the illness themselves.

MDPH has found that it is often easier to reach nursing professionals and physician assistants, who may have more time for patient education efforts. Central to MDPH's efforts in reaching nursing professionals is a focus on occupational exposure. MDPH's research found that nursing professionals felt very vulnerable to HCV and wanted more information on how to protect themselves in the workplace.

Despite their efforts, MDPH continues to hear from consumers and advocacy groups that more provider education is needed. According to Dan Church, Hepatitis C Coordinator for MDPH, providers need to be educated on an ongoing basis—to reach the broadest provider audience and to keep providers updated as information changes. Better surveillance data are also needed to document the impact of HCV. Currently, many providers may not recognize the problem and therefore, do not feel a need to respond. Unfortunately, funding to enhance surveillance efforts is limited.

An important part of provider education is involving people living with HCV. MDPH works to educate patients so that they can encourage their providers to learn more. An MDPH-developed video and supplemental booklet for newly diagnosed individuals includes a list of questions that patients should discuss with their physicians. This way, patients at least know what questions need to be addressed, making the education process more efficient for the provider and highlighting the issues raised.

For more information on the Massachusetts Department of Public Health program, contact Dan Church, Hepatitis C Coordinator, at 617/983-6800 or Daniel.Church@state.ma.us. For copies of the health care provider resources developed by the Massachusetts Department of Public Health go to: http://www.masshepc.org.

ongoing treatment of a chronic condition, especially for populations facing many challenges in their lives. These people are usually at increased risk of being lost to care because the task of accessing all the services they need, and the bureaucracy associated with doing so, can be extremely daunting, if not impossible. Case managers can assess what services are needed and help the client obtain these services. Through ongoing interaction with the client, the case manager can assess whether client needs are being met and can help address new needs as they arise. Case management can also help support adhering to treatment and adopting and maintaining safer behaviors.

Unfortunately, few case management models are available for treating HCV-infected individuals—primarily because of the lack of resources to develop and implement these services.

Marin County: Integrating HCV Services Into an Existing HIV Program

Marin County is a small suburban county 30 minutes north of San Francisco. Although the per capita income is one of the highest in the country, 8.1 percent of Marin residents are without health insurance coverage. The County's Hepatitis C Program primarily serves those who are uninsured or underinsured and have the least access to health care.

Five years ago, the County of Marin Department of Health and Human Services initiated HCV screening activities linked with medical consultation services. These services were integrated into existing HIV/AIDS program. Integration into the HIV/AIDS program was the most logical choice, since it allowed the health department to build on existing infrastructure and staff resources, as well as established links with community-based providers. Because of limited resources, HCV services would not have been

possible if they were provided on a stand-alone basis. According to Craig A. Lindquist, MD, Medical Director of the Marin Specialty Clinic, “The greatest challenge is funding—HCV services will always be difficult to provide without dedicated funding for such services. To provide HCV services, you really need the commitment of the local health department and the local and state government. Hepatitis C must be recognized as a public health issue and made a priority in the community to bring the services needed.”

Screening

The HCV Screening Program provides screening, risk-reduction counseling, testing, and referral of infected clients for medical evaluation. Integrating the HCV Screening Program into the county’s HIV Testing and Outreach Program was the most logical and cost-effective approach to providing HCV testing and counseling. HIV counseling staff, already experienced in obtaining demographic and risk behavior data, facilitated HCV client referral to medical care. To prepare staff for incorporating HCV services, 12 hours of training were provided. Training included basic information about liver physiology, epidemiology, disease transmission of HCV, HCV-antibody testing, and HCV treatment. Counselors also received training in risk-reduction techniques for clients with ongoing risk behaviors and information on how HCV-infected clients can slow disease progression.

A risk assessment questionnaire specifically addresses HCV and collects data on demographics, possible HCV risk factors, and other information that can be used to counsel clients on protecting their health. The HCV-specific questionnaire facilitates the counseling sessions and decreases the time needed to perform HIV and HCV risk assessments. Test results are provided to clients at a scheduled follow-up appointment two weeks later, and reminder notices are sent to those who miss their appointments.

Initially, HCV testing was conducted once a week at the public health laboratory. Over time, the program has been expanded and now provides outreach and on-site testing at more than 20 locations, including residential drug treatment centers, homeless shelters, and locations where services are provided to high-risk populations such as drug users, the homeless, and the mentally ill.

The program now provides outreach and on-site testing at more than 20 locations.

Targeted HCV testing has been highly successful. From January 1999 to December 2002, 30 percent of clients tested by the program were infected with HCV. Of the clients who tested positive, 83 percent reported a history of injection drug use, and 45 percent reported injecting drugs within the past year.

Specialty Clinic Services

The Marin County HIV/AIDS Program provides medical care to HIV-infected clients at the county HIV/AIDS Specialty Clinic. Clients who test positive for HCV are referred to the Specialty Clinic's HCV Consulting Clinic. About two-thirds of the patients at the HCV Consulting Clinic are referred through outreach efforts. The remaining patients are referred by other providers in the community, including local medical providers, substance abuse treatment programs, homeless shelters, and the community-based family practice clinic that treats mostly Medicaid and uninsured patients. Other patients are self- referred.

HCV-infected patients have their first appointment with the HCV clinical coordinator, who compiles the patient's medical history, documentation of HCV infection, and any available lab results. Noninvasive tests including liver function, viral load, and ultrasound are administered. The clinical coordinator also provides basic HCV education and an overview of the clinical services. Given the complexity of the treatment, this overview increases patients' awareness of the process so that they are better prepared.

The Importance of Staff Training

All specialty clinic medical and nursing staff are trained in the evaluation and medical management of HCV through medical in-services with local hepatologists, attendance at HCV education conferences, and consultation with a tertiary care-level hepatologist. Educational sessions cover management of HCV, extra-hepatic manifestations of HCV, recommendations for treatment of nonresponders or relapsers, HIV/HCV co-infection, and criteria for referral to transplant evaluation.

HCV infection is a complex disease to treat. Also, since HCV is an emerging disease, new information on treatment is continuous. Provider education must be ongoing, and time must be allotted for staff training.

Treatment is provided based on HCV treatment protocols and is coordinated by a treatment team, consisting of a nurse practitioner (NP) and the HCV clinical coordinator. The NP and the HCV clinical coordinator meet with the patient and describe the treatment process, train the patient in self-injection, and describe potential side effects and how to manage them. If complications result during treatment, the treatment team consults with the supervising physician.

Linkage to Case Management and Primary Care

All patients are required to have an outside source of primary care, since the specialty clinic's HCV program does not have the capacity to provide this care. The HCV clinical coordinator assists patients with establishing primary care.

Before the first medical appointment, patients are referred to a social worker to assess their ability to pay for care. Patients who do not have some form of coverage, either private insurance, Medi-Cal, or the county's insurance, are referred to a case manager. The health department contracts with two community-based organizations (CBOs), an AIDS service organization and a methadone clinic, to provide these services. Case managers work with patients to determine their eligibility, help them apply for benefits, and educate them about HCV infection and treatment options.

The link to the CBOs is an important part of the program. These organizations serve as resources in

various areas and are experienced in working with the patient population. Given their existing ties to the patient population and the range of services that they offer, the CBOs are well-positioned to play a complementary role in the care provided by the specialty clinic's HCV Consultation Clinic. To ensure the ongoing availability of these services, the health department recognized the need to provide resources to support the CBOs' efforts. On the advice of the health department, the county's Board of Supervisors allocated funds to support the two contracts.

Lessons Learned

Staff identified a variety of challenges in the program's implementation and ongoing operation:

Patient education should be built into the process from the earliest stages.

- ***Importance of HCV Patient Education***
  Patient education should be built into the process from the earliest stages. Patients not only need to know about the course of the disease, how to slow progression of liver disease, and how to prevent spreading the disease to others, but they also need to know about evaluation and treatment. Providing patients with information on what they can expect prepares them for future steps and limits the time that must be devoted to patient education in medical appointments.

- ***Co-morbidity of Mental Health and/or Substance Use Issues***
  The population served by the specialty clinic presents with various mental health and substance use issues. Of the clinic's patients, 59 percent continue to drink alcohol after diagnosis, and 22 percent report having injected drugs within a year of being evaluated. Depression is the most common mood disorder, found in 71 percent of patients reporting a history of psychiatric disease. More severe psychiatric illness has also been reported. These co-occurring conditions can

significantly affect patient care, and staff must devote significant energy to move patients along in the evaluation process. Active drug use among patients is a serious issue. It requires links with community-based substance abuse treatment programs to facilitate the evaluation of chronic HCV infection.

- ***Medical Complexity of Patients***
  Many patients also suffer from other chronic diseases, such as hypertension or other cardiovascular disorders, smoking-related illnesses, and diabetes. These health problems were either known or identified in the initial evaluation, and patients were referred to care for these conditions. Additional evaluations can delay HCV treatment and in some cases, patients were lost to followup.

- ***Staff Communication***
  HCV infection is a complex condition to treat. The phlebotomist plays a key role in collecting information from the various staff and compiling it in the clinical folder. Since the evaluation process is already lengthy—multiple appointments over three to four months—all the information needed should be available at each subsequent appointment. Any breakdown can result in needless appointments, which may result in patients being lost to care. Ensuring that the process stays on track requires ongoing staff focus and communication.

For More Information: A detailed description of Marin County's HCV program is available in the ***Journal of the Association of Nurses in AIDS Care***, Vol. 14, No. 5, Supplement to September/ October 2003, 95S-107S. Information is also available from Suzan Stringari-Murray, ACRN, MS, ANP, Marin County Health and Human Services, Specialty Clinic/HCV Consultation Clinic at sstringari@co.marin.ca.us or 415/499-7377.