original paper

Hepatitis C among drug users: consensus guidelines on management in general practice

Dublin Area Hepatitis C Initiative Group

Abstract

Background Hepatitis C (HCV) is a common cause of morbidity among patients who attend general practitioners (GPs) in Ireland for methadone maintenance treatment.

Aims To describe the development and content of guidelines for the management of HCV among current or former opiate users in the Eastern Regional Health Authority area attending GPs for methadone treatment.

Methods The guidelines were produced in five stages: identification of key stakeholders; development of evidence-based draft guidelines; discussion of content; determination of 'Delphi'-facilitated consensus and review by a sample of GPs for whom the guidelines would be intended.

Results The guidelines contain advice for GPs on all aspects of care of patients at risk of HCV, including general and preventative care, care of other bloodborne and hepatotoxic viruses, and the factors to be considered and appropriate evaluation prior to referring a patient for assessment at a hepatology unit.

Conclusions GPs have an important role to play in the care of patients at risk of, or infected with, HCV.

Introduction

An estimated 62-81% of injecting drug users in the Dublin area have been infected with hepatitis C (HCV)[1,] which will be responsible for significant morbidity and mortality. According to a computer cohort simulation of the natural history of HCV carried out in a US population, Wong et al showed that between the years 2010 and 2019 the virus will be responsible for the loss of 1.83 million years of life in patients under 65 years at a cost of $10.7 billion in direct medical expenditure.[4]

GPs are increasingly involved in the care of drug users, with methadone maintenance treatment being provided in general practice.[5] GPs have a key role to play in the detection and management of HCV. Screening, counselling and identifying patients who will benefit from referral for antiviral treatment are strategies by which general practice might play an active role in minimising the harm resulting from HCV in coming years.

The management of HCV is unclear and clinical guidelines are a useful tool in improving the quality of care.[6] Guidelines should be evidence-based, feasible for primary care, relevant and acceptable to doctors, practice staff and patients.[7] Also they should be valid, reliable, reproducible, applicable to common clinical situations, flexible and clear; their development should be the product of a multidisciplinary team subject to clinical review.[11] The active participation of the intended recipients in the process is essential and leads to a greater sense of ownership among those expected to implement them.[910]

This study describes the development and content of guidelines for the management *of* HCV among current or former drug users attending general practice in the Eastern Regional Health Authority (ERHA) during 2001 and 2002.

Rigid adherence to guidelines such as these is often not possible in clinical practice, and may not be in the best interest of the patient or may not be in accordance with the patient's individual preferences.

Methods

Identification of key stakeholders

A multidisciplinary group was formed with representatives reflecting the range of medical and paramedical professionals involved in the care both of those who are at risk of becoming and those who have become infected with the HCV virus. Physicians working in each of the areas in which HCV impacts were invited to participate and to nominate other professionals who might have special insights.

Draft guideline development

A Medlinc literature search was performed using the search terms 'hepatitis C, 'HCV and 'non-A, non-B hepatitis[1] with the following terms: 'general practice'; 'family practice'; 'primary care'; 'guidelines'; 'protocols'; 'care'; and 'management'. The relevant articles were retrieved. Several professional organisations' publications were reviewed and protocols for the management of HCV reviewed.

The identified information was summarised under five categories: general aspects of care; care of other bloodborne viruses; screening for HCV; initial management of patients infected with HCV; and subsequent management of patients infected with HCV. This document was circulated to all group members and used as the basis of discussion and debate for subsequent meetings.

The group met on six occasions and the minutes of the meeting and proposed topics for discussion at subsequent meetings sent to each. Where consensus proved elusive, a modified 'Delphi' technique was used to help determine die beliefs of the majority of the group. This is a survey method designed to obtain the opinions of a group of experts. It utilises anonymity, iteration and controlled feedback, statistical group response and expert input," and has been used extensively by professional groups within medicine.[12]

Draft guidelines were sent to each member of the group, with an accompanying questionnaire inviting comments. Returned questionnaires were studied for common themes and suggested changes were incorporated into the subsequent draft of the guidelines. This process was repeated twice.

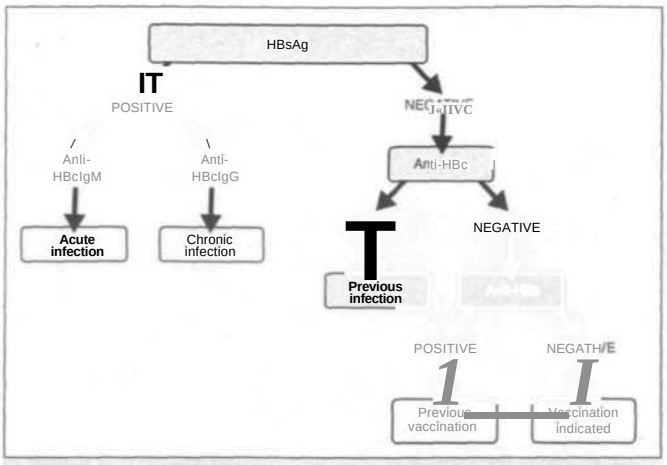

Figure 1. Diagnostic algorithm for Hepatitis B.

Guideline review

Prior to dissemination of the guidelines, a purposive sample of GPs was given the guidelines and interviewed regarding their content and implementation. This process resulted in minor **additions and** alterations to the guidelines as described."

Guidelines on management of hepatitis C among drug users in general practice

General aspects of care

Advice on safe drug use

Injecting drug use is the main risk factor for HCV infection.[1,2] GPs have an important role in encouraging patients to refrain from any drug use and promoting safe drug using practices. Patients should be advised not to share syringes, needles or other drug-related paraphernalia.[14,11]

Transmission through sexual contact

The risk of sexual transmission from having intercourse with somebody with chronic hepatitis C is low."'" There are no recommendations for change in sexual practices for those in monogamous relationships[14] but condom use is strongly encouraged for those with multiple partners.[1518IV]

Vertical transmission

The prevalence of mother to child transmission is 0-6%.[I1UO23] Transmission is associated with high levels of maternal HCV-RNA[24] and co-infection with HIV." Data on transmission are limited, but indicate no difference between vaginal deliver}' and delivery by Caesarean section.[4-1n] HCV infection should not be a factor in determining mode of delivery, except where the patient is also HIV positive.[14] The risk of transmission during breastfeeding is low."[1]

Care of other bloodborne and hepatotoxic viruses

Hepatitis B infection

The course of liver disease in patients infected with HCV and either hepatitis B (HBV) or hepatitis A (HAV) is more aggressive.[1029] All patients at risk of HCV should be tested for the presence of, or immunity to, HBV infection (see Figure 1)[10] and HAV infection.

The presence of Hep B surface antigen (HBsAg) in the serum indicates acute infection or chronic carrier status. The person may or may not be infectious. The presence of anti-hepatitis B core antibody (Anti-HBc) indicates previous exposure to the hepatitis B virus and may or may not have active infection. Acute infection is indicated by the presence of high levels of IgM antibody. Chronic infection is usually indicated by the presence of IgG antibody. Occasionally, IgM antibody can be **found** in patients with chronic infection.

In people with chronic infection (HBsAg positive and Anti-HBc IgG positive), the presence of HBeAg indicates an actively replicating (infective) virus, and therefore that the patient is unlikely to clear the virus from his or her system. This is probably the best marker for ongoing viral activity.

Immunisation guidelines for Ireland recommend that HBV vaccine be given as three doses at 0, 1 and 6 months (see Figure 2)." In high risk cases, the vaccine should be given at 0, 1 and 2 months.

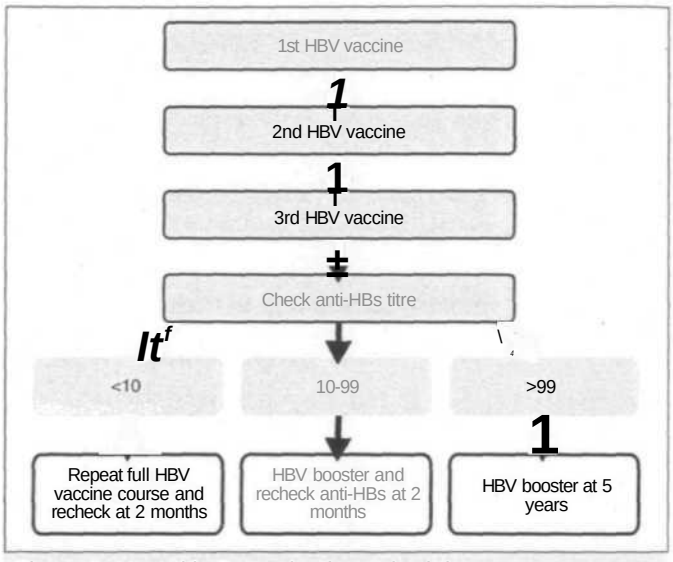

Figure 2. Hepatitis B vaccination schedule.

The hepatitis B vaccine contains the surface antigen, which induces the production of anti-HBs antibody so that if the host is subsequently exposed to the virus, the immune system recognises this event and already has formed antibodies. The presence of anti-HBs antibody docs not differentiate between previous vaccination or previous infection with the virus. A positive anti-HBc antibody indicates that the patient **has** previously been exposed to the virus.

It should not be offered if the patient is suffering from an acute febrile illness, is hypersensitive to the vaccine or is allergic to aluminium. It should be used with caution in cases of cardiac or pulmonary insufficiency, thrombocytopenia, bleeding disorder or where the patient is on warfarin or heparin. Facilities for the management of anaphylaxis should be in place in the event of a serious hypersensitivity reaction. The vaccine should only be administered if there is a doctor on site.

Hepatitis A infection[10]

This is the most common cause of viral hepatitis worldwide. It is transmitted by the faeco-oral route. It usually causes a mild self-limiting illness, manifesting as jaundice, diarrhoea, vomiting and flu-type symptoms but in HCV positive patients it can cause fulminant hepatitis.

Anti-HAV IgM indicates acute infection. The presence of anti-HAV IgG indicates viral clearance. Chronic HAV infection rarely occurs. Patients with HCV whose hepatic status suddenly becomes compromised should be tested for HAV infection.

Vaccination against HAV improves prognosis in patients with HCV. A negative anti-HAV IgG indicates that the patient has never been exposed to the virus and needs vaccination. Vaccination is recommended for intravenous drug users with chronic liver disease, persistent HBV or HCV infections.

HIV infection

Recently, the importance of HCV-HIV co-infection in predicting a poorer prognosis has been highlighted.[32 M] It is recommended that HIV screening should be offered at the same time as screening for HCV and, where appropriate, referral for specialist care offered.

Screening for HCV

Testing for HCV (see Figure 3)

All those at risk of hepatitis C (including injecting drug users) should be offered testing.[24-5] Furthermore, any patient with signs or symptoms suggestive of hepatitis or requesting testing should be tested for die virus. Where a recent test has been performed by another agency, or where it is not possible to obtain a blood sample, it may be appropriate to request the result of previous tests from the National Virus Reference Laboratory which will release this information to doctors upon receipt of a consent form signed by the patient.

Recent generations of EIAs used to detect anti-HCV antibodies have good sensitivity and specificity. If positive, the laboratory will use RIBA assay or another EIA to confirm the presence of anti-HCV.

Pre-test discussion

Having identified risk behaviours, clinical features of hepatitis or where a patient requests HCV testing, it is important to counsel the patient using an approach used in testing for HIV infection.[15*6] This includes explaining the benefits and risks of HCV testing, reassurance about confidentiality, education on reduction of risk of transmission, discussing the risk for co-infection with HIV or HBV and, if appropriate, offering testing and ensuring the appropriate support is available, especially in the event of a positive result.

Information should be given on hepatitis C, with emphasis on the indolent nature of the illness. Patients should be told that not everyone with HCV antibodies will have continuing infection or will develop liver disease.[14-17]

Post-test discussion

The need to give the results personally should be emphasised during the pre-test discussion.[18] Where possible, results should be given by the person who initially discussed the test widi the patient.

Positive result

Delivery of a positive result can be a serious emotional shock to die patient. Support should be pro\ided and the patient allowed time to recover. It may be possible to give important information, such as the need for further assessment and monitoring, but this should be reinforced at subsequent consultations.

Although prognostic information cannot be exact at this early stage, it is useful to point out the often indolent course of HCV and that monitoring may be the only management required. Patients with concerns about transmission should be advised that the risks of vertical[24-5] and sexual[14161617] transmission are low. It is recommended that the sharing of razor blades and toothbrushes be avoided. The presence of HCV antibody does not protect against re-infection and therefore patients should be advised against continued risk activity.

It is important to emphasise that the presence of antibody to HCV alone is evidence of previous exposure to the virus, not evidence of chronic infection and that an HCV-PCR test is required to determine the presence of active viraemia.

Negative result

If potential exposure to the virus has occurred within the previous six months, repeat testing should be offered. If continued potential exposure to the virus is an issue, then repeat testing should be offered at intervals of 12 months.

Initial management of patients infected with HCV (see Figure 4)

General advice

After diagnosis, initial advice should include how patients can reduce the risk of developing further liver injury.[24] This includes reducing alcohol consumption,[IS.19J5.39.40] abstaining from further injecting drug use (or engaging in safe drug-using practices)/[7] adopting a healthy diet,[41] vaccination against HAV and HBV[30] and avoiding hepatotoxic medication. Where an analgesic or an antipyretic is required, paracetamol should be the drug of first

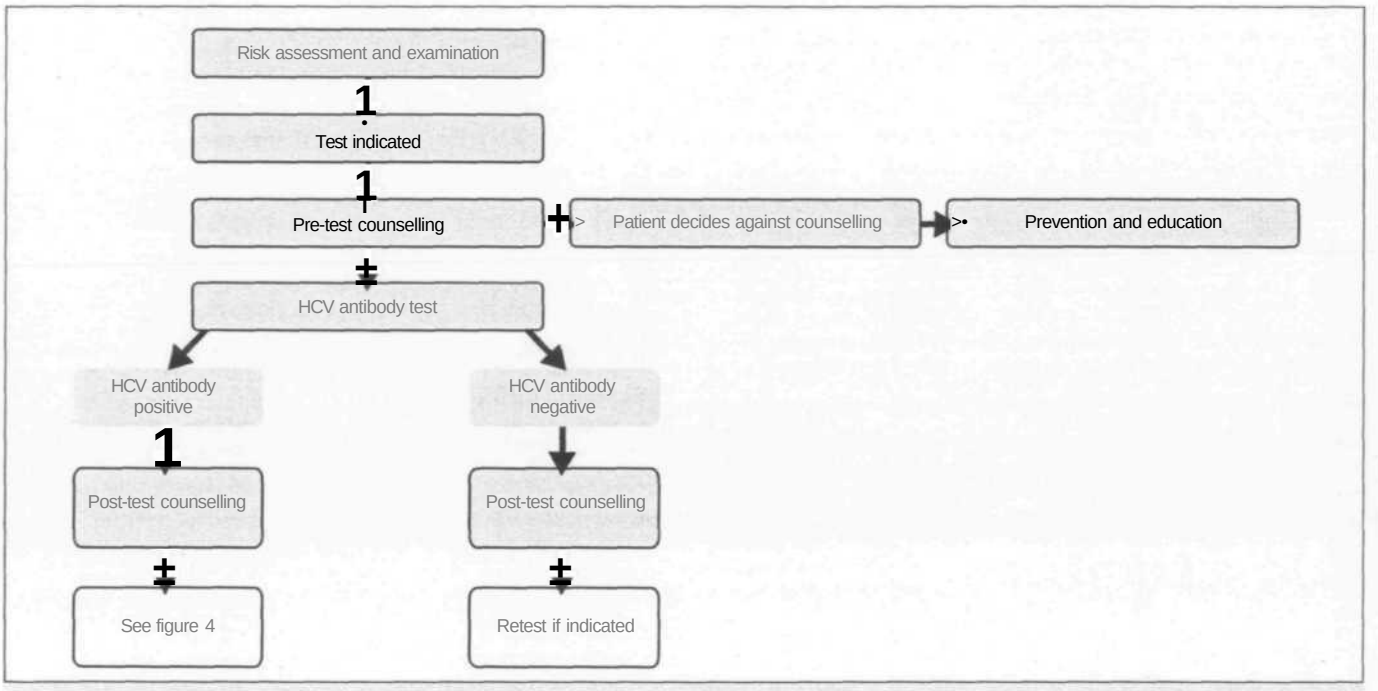

Figure 3. Screening for hepatitis C — diagnostic algorithm. (Based on Royal Australian College of General Practitioners/Australian National Council on AIDS and related diseases algorithms.)[46]

choice. Patients should be encouraged to consult with their GP early in such situations.[24]

Weight reduction should be recommended in obese patients as obesity is associated with faster disease progression[4"] and a poorer response to treatment.[4']

Patients should be counselled on how to avoid transmitting the virus to others.-[4] People infected with HCV should not donate organs, tissues, blood or semen.[IS] They should not share toothbrushes, razor blades or other domestic items that may have blood on them. Cuts or abrasions on the skin should be covered.[24]

People with one long-term sexual partner do not need to change their sexual practices,[17.IM] but should be encouraged to discuss the issue with their partner.[24]

In women, the risk of mother to infant transmission is 0-6%.[20,~*] HCV infection is not a factor in determining the mode of delivery, except where the patient is also HIV positive.[14] There is no risk of transmission during breastfeeding."[1]

HCV is not spread by contact such as coughing, sneezing, hugging, food or water, shared eating utensils or drinking glasses. Patients should not be excluded from work, school, play, childcare or other settings on the basis of HCV status.[24]

Support and follow up

GPs should identify the psychosocial supports available to patients and their families at the time of diagnosis.'" At the initial consultation, a follow up appointment should be given at which any questions or concerns the patient or the patient's family may have can be dealt with.

Subsequent management of patients with hepatitis C

Having determined that a patient is HCV positive by both ELISA and RIBA testing, consideration should be given to antiviral treatment. HCV-PCR testing should be performed, and where-positive, liver biopsy is recommended. The decision on antiviral therapy can only be made after a liver biopsy has confirmed chronic active liver disease.[24]

The following criteria help clinicians predict which patients benefit from therapy. However, if a clinician feels that the patient would benefit from referral or indeed if the patient expresses a strong preference to see a hepatologist despite not fulfilling these criteria, then referral is appropriate.

- The individual should be HCV-PCR positive, or be strongly RIBA positive. (To minimise false negative PCR, serum should be separated within 2-4 hours of collection and stored at -20°C.)[w]
- The individual should be free from non-prescribed opiate use for at least six months
- The individual should be free from unstable cocaine use for at least six months
- The individual should not be using benzodiazepines or tricyclic antidepressants except in prescribed therapeutic doses
- Alcohol intake should be less than the recommended 21 units per week in men and 14 units per week in women[4']
- If the individual has concurrent, significant psychiatric morbidity, evaluation by a psychiatrist may be necessary prior to initiating antiviral therapy
- Major concurrent social problems with lack of support structures, in some instances, may be an indication for delaying initiation of therapy.

The decision on whether the patient would benefit from diagnostic and therapeutic interventions at a specialist clinic should be the product of a shared decision-making process between doctor and patient. To facilitate a rapid assessment of patients at the hepatology clinic, it is essential to provide the following information (where available) upon referral:

- Results of HCV screening test and, if available, subsequent PCR/genotype testing (and a copy of the results)
- Clinical evaluation of liver status
- Results of LFT/FBC
- Contact address or telephone number for correspondence with patient
- Is the patient free from unstable drug use?

It is also useful to provide the following information, if available, upon referral:

- Results of tests for other bloodborne viruses (including HIV and HBV)
- Details of vaccinations against hepatitis B and A
- Duration of methadone therapy and dose
- Whether or not the potential risks and benefits of treatment have been discussed with the patient.

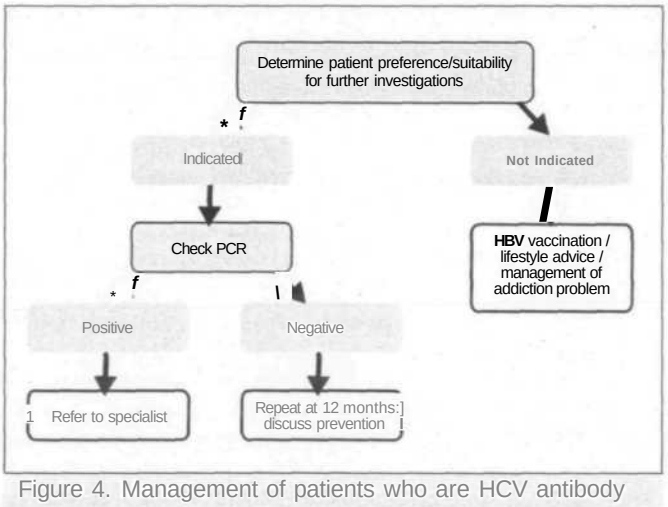

Figure 4. Management of patients who are HCV antibody positive.

Conclusions

HCV is a common infection among patients who attend GPs for methadone maintenance treatment. The morbidity associated with chronic HCV infection is significant.

This paper outlines the role GPs can play in caring for people at risk of HCV based on our understanding of the epidemiology, diagnosis and treatment of HCV infection at the time of development of these guidelines, particularly with regard to: reducing the number of incident cases; determining the prevalence; appropriately managing other risk factors for chronic liver disease; and facilitating assessment for antiviral therapy.

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