NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

PUBLIC HEALTH GUIDANCE

SCOPE

1 Guidance title

Hepatitis B and C: ways to promote and offer testing to people at greatest risk of infection

1.1 Short title

Hepatitis B and C: ways to promote and offer testing

2 Background

a) The National Institute for Health and Clinical Excellence (NICE) has been asked by the Department of Health (DH) to develop public health guidance on the most cost-effective ways of offering tests to those at risk of infection from hepatitis B and C.

b) NICE public health guidance supports the preventive aspects of relevant national service frameworks (NSFs), where they exist. If it is published after an NSF has been issued, the guidance effectively updates it.

c) This guidance will support a number of related policy documents and guidelines including:

- 'Cancer reform strategy' (DH 2007)
- ‘Drug misuse and dependence: guidelines on clinical management’ (DH 1999)
- 'Getting ahead of the curve' (DH 2002a)
- ‘Guidance for the prevention, testing, treatment and management of hepatitis C in primary care’ (Royal College of General Practitioners 2007)

- 'Hepatitis B screening in pregnancy' (National Screening Committee 2006)
- 'Hepatitis C action plan for England' (DH 2004)
- 'Hepatitis C strategy for England' (DH 2002b)
- 'Immunisation against infectious diseases – the green book' (DH 2006)
- 'Models of care for treatment of adult drug misusers' (National Treatment Agency 2006).

d) This guidance will provide recommendations for good practice, based on the best available evidence of effectiveness, including cost effectiveness. It is aimed at commissioners, managers and practitioners with public health as part of their remit working within the NHS, local authorities and the wider public, private, voluntary and community sectors. It may also be of interest to members of the public, particularly people who have contracted, or who are at greatest risk of contracting, hepatitis B or C.

e) The guidance will support other NICE guidance on: hepatitis treatment, immunisation, antenatal care and needle and syringe programmes. For further details, see section 6.

This guidance will be developed using the NICE public health programme process.

3 The need for guidance

a) In England and Wales between 1995 and 2000, an estimated 3780 people a year were infected with acute hepatitis B. As a result, an estimated 269 people then went on to develop chronic hepatitis B (CHB) each year (Hahné et al. 2004). According to the Chief Medical Officer, an estimated 180,000 people in the UK are chronically infected with the hepatitis B virus (DH 2002a). Other organisations believe that figure may be closer to 360,000, due to migration from areas where the infection is more prevalent

(Pendleton and Wilson-Webb 2007). (An estimated 6500-plus people with chronic hepatitis B migrate to the UK each year.) Chronic infection among permanent residents in England and Wales is estimated to account for only 3.9% of the total annual incidence (Hahné et al. 2004).

b) An estimated 200,000 people in England (0.4%) are chronically infected with the hepatitis C virus (DH 2004). However, only around 70,000 diagnoses have been reported (Health Protection Agency 2009). Further action has been called for to develop a better understanding of the true incidence, prevalence and epidemiology (DH 2002a).

c) For both hepatitis B and C, chronic infection is said to occur when the virus persists for more than 6 months (Tibbs and Smith 2001). However, the proportion of people who may develop a chronic infection differs between the two viruses. Only 10% of non-immunised children aged under 12 months who are infected with hepatitis B will clear the infection naturally (Mast et al. 2008). However, most adults who are acutely infected with it (95%) will recover naturally. The pattern is very different for hepatitis C, where 80% of those infected go on to become chronic carriers (DH 2002b). Chronic infection with either hepatitis B or C increases the risk of chronic liver damage, cirrhosis or primary liver cancer.

d) Between 1995 and 2000, in England and Wales, it was estimated that the following risk factors were linked to a number of chronic hepatitis B cases: injecting drug use (456), heterosexual contact with someone who is infected (191), travel to countries of intermediate (2–8%) or high (greater than 8%) endemicity (155), mother to child transmission (97), homosexual contact (90) and contact with someone in the same household who is a carrier (52) (Hahné et al. 2004). People from various minority ethnic groups in the UK may also be at higher risk (Boxall et al. 1994; Hahné et al.

2003; Kawsar and Goh 2002). For example, it has been estimated that the rate of acute infection within the South Asian population in England and Wales is twice the estimated average (Hahné et al. 2004).

e) The national immunisation programme recommends that people in many at-risk groups are immunised against hepatitis B (DH 2006). Due to an increased risk of chronic infection, post-exposure immunisation is also recommended for babies born to chronically infected mothers (DH 2006).

f) Between 1996 and 2008 in England, more than two thirds (68%) of the reported incidence of hepatitis C was among men. Half of the total reported was among people aged between 25 and 39 (Health Protection Agency 2009). Where risk factor information was available (11,657 cases), injecting drug use was associated with 92.5% of confirmed cases (Health Protection Agency 2009). A high proportion of these people may also have been homeless at one time (Health Protection Agency 2007). Other risk factors included: transfusion and the receiving of blood products (2.8%), sexual exposure (1.4%), renal failure (0.7%) and transmission from mother to baby (0.5%) (Health Protection Agency 2009). In addition, between January 2008 and May 2009 105 newly acquired HCV cases were among men who have sex with men (Health Protection Agency 2009). Statistics also suggest a higher than average prevalence among people in prison (Prison Reform Trust and National AIDS Trust 2005) and within the South Asian population (Health Protection Agency 2009).

g) NICE recommends a number of treatments for hepatitis B and hepatitis C (see section 6 for related NICE guidance). If someone who is infected can be identified early enough, their risk of developing long-term complications, such as cirrhosis and liver cancer, can be reduced.

4 The guidance

Public health guidance will be developed according to NICE processes and methods. For details see section 5.

This document defines exactly what this guidance will (and will not) examine, and what the guidance developers will consider. The scope is based on a referral from the DH (see appendix A).

4.1 Who is the focus?

4.1.1 Groups that will be covered

Those most at risk of being chronically infected with hepatitis B or C (with no lower or upper age limit) that is:

- people living in England and Wales who were born in countries with intermediate (2–8%) and high (greater than 8%) endemicity
- injecting drug users, including former users and those receiving treatment to come off drugs.

Where there is evidence, the guidance will also consider other at-risk groups for example: those who have been imprisoned, men who have sex with men, people with multiple sexual partners, those who received blood products before 1990 and those who have received medical treatment outside the UK.

4.1.2 Groups that will not be covered

Those at a low risk of chronic hepatitis B or C infection.

4.2 Activities

4.2.1 Activities/measures that will be covered

The following activities and measures may be considered (separately or combined):

a) Awareness-raising among at-risk groups of the risks and consequences of chronic hepatitis B and C infection – and the potential benefits of testing and treatment.

b) Encouraging people in at-risk groups to make use of services that provide testing facilities and to consent to taking a test.

c) Reducing the barriers to hepatitis B and C testing. This could include increasing access to testing facilities, providing a choice of facilities and addressing any associated stigma, cultural or language issues. It could also include ensuring the type of sample taken is acceptable to the individual.

d) Increasing awareness of hepatitis B and C among professionals. This includes enhancing their understanding of which groups are at greatest risk and which diagnostic tests should be carried out on the initial sample to produce a clinically useful result.

e) Ensuring the 'close contacts' of people who have been diagnosed with hepatitis B or C take a test. Close contacts could include sexual partners, family members and others within the same household, or other people who inject drugs.

f) Communicating test results and encouraging people to take up the offer of help from appropriate services and to continue to use them (for example, by being re-tested or taking up referrals).

g) Using 'case finding' strategies as part of current and standard treatment pathways for chronic hepatitis B and C (to determine how cost effectiveness this approach is).

The Programme Development Group (PDG) may consider the principal and alternative measures or approaches. It will also take reasonable steps to identify ineffective measures and approaches.

4.2.2 Activities/measures that will not be covered

a) Evaluation of the validity or comparative diagnostic effectiveness of different types of hepatitis B or C test.

b) Alternative treatment pathways and treatments for chronic hepatitis B and C (drugs used, dosage, frequency and duration).

c) Screening programmes for hepatitis B and C.

d) Immunisation of at-risk groups for hepatitis B.

e) Post-vaccination testing for hepatitis B.

4.3 Key questions and outcomes

Below are the overarching questions that will be addressed, along with some of the outcomes that would be considered as evidence of effectiveness:

Question 1: Which interventions are effective and cost effective in encouraging people from high-risk groups to use services that currently (or potentially could) offer hepatitis B or C testing?

Question 2: What prevents people in high-risk groups from seeking and accepting a hepatitis B or hepatitis C test? How do these factors differ for each group – and what factors increase the likelihood that they will seek and accept a test?

Question 3: Which interventions are effective and cost effective at overcoming the barriers to hepatitis B or C testing faced by high-risk groups and professionals?

Question 4: What type of services and activities need to be commissioned to encourage people who have tested positive to continue to seek support?

Expected outcomes:

These may include a change in:

- attitudes and knowledge about hepatitis B and C among people at increased risk and among professionals
- awareness of hepatitis B and C testing facilities
- the number and type of venues offering tests
- the number of at-risk people seeking or accepting a test
- the number of tests carried out
- the number of positive test results and referrals to appropriate services.

4.4 Status of this document

This is the final scope, incorporating comments from a 4-week consultation which included a stakeholder meeting on 29 September 2010.

5 Further information

The public health guidance development process and methods are described in 'The NICE public health guidance development process: An overview for stakeholders including public health practitioners, policy makers and the public (second edition, 2009)' available at www.nice.org.uk/phprocess and 'Methods for development of NICE public health guidance (second edition, 2009)' available at www.nice.org.uk/phmethods

6 Related NICE guidance

Published

Hepatitis C – peginterferon alfa and ribavirin. NICE technology appraisal 200 (2010). Available from www.nice.org.uk/guidance/TA200

Hepatitis B – tenofovir disoproxil fumarate. NICE technology appraisal 173 (2009). Available from www.nice.org.uk/guidance/TA173

Reducing differences in the uptake of immunisations. NICE public health guidance 21 (2009). Available from www.nice.org.uk/guidance/PH21

Needle and syringe programmes. NICE public health guidance 18 (2009). Available from www.nice.org.uk/guidance/PH18

Antenatal care. NICE clinical guideline 62 (2008). Available from: www.nice.org.uk/guidance/CG62

Hepatitis B – telbivudine. NICE technology appraisal 154 (2008). Available from www.nice.org.uk/guidance/TA154

Hepatitis B – entecavir. NICE technology appraisal 153 (2008). Available from www.nice.org.uk/guidance/TA153

Prevention of sexually transmitted infections and under 18 conceptions. NICE public health guidance 3 (2007). Available from www.nice.org.uk/guidance/PH3

Hepatitis C – peginterferon alfa and ribavirin. NICE technology appraisal 106 (2006). Available from www.nice.org.uk/guidance/TA106

Hepatitis B (chronic) – adefovir dipivoxil and peginterferon alfa-2a. NICE technology appraisal 96 (2006). Available from www.nice.org.uk/guidance/TA96

Hepatitis C – pegylated interferons, ribavirin and alfa interferon. NICE technology appraisal 75 (2004). Available from www.nice.org.uk/guidance/TA75

Under development

Increasing the uptake of HIV testing among black Africans in England. NICE public health guidance (publication expected March 2011)

Increasing the uptake of HIV testing among men who have sex with men. NICE public health guidance (publication expected March 2011)

Hepatitis B (adults) – entecavir and tenofovir disoproxil fumarate. NICE technology appraisal (publication expected March 2012)

OraQuick® HCV Rapid Antibody Test. NICE medical technologies (publication expected September 2011)

Tuberculosis – hard to reach groups. NICE public health guidance (publication expected March 2012)

The diagnosis and management of hepatitis B in children, adolescents and adults. NICE clinical guideline (publication tbc)

Appendix A Referral from the Department of Health

The Department of Health asked NICE:

'To produce programme guidance for commissioners and clinicians working in various settings on the most cost-effective methods for offering testing for hepatitis B and C to those at risk of infection.'

Appendix B Potential considerations

It is anticipated that the Programme Development Group (PDG) will consider the following issues in relation to the activities under consideration:

- Whether they are based on an underlying theory or conceptual model.
- Whether the intervention targets specific individuals or populations.
- Whether it is effective and cost effective.
- Critical elements. For example, whether effectiveness and cost effectiveness varies according to:
    - the diversity of the population (for example, in terms of age, gender or ethnicity)
    - the status of the person delivering it and the way it is delivered (one-to-one or group-based)
    - the content and intensity of the intervention
    - its frequency, length and duration
    - where the intervention is delivered and whether it is transferable to other settings.
- Any trade-offs between equity and efficiency.
- Any social or cultural factors that prevent – or support – effective implementation.
- Any adverse or unintended effects.
- Current practice.
- Availability and accessibility for different groups.

Appendix C References

Boxall E, Skidmore S, Evans C et al. (1994) The prevalence of hepatitis B and C in an antenatal population of various ethnic origins. Epidemiology and Infection 113: 523–8

Department of Health (1999) Drug misuse and dependence: guidelines on clinical management. London: Department of Health

Department of Health (2002a) Getting ahead of the curve: a strategy for combating infectious diseases (including other aspects of health protection). London: Department of Health

Department of Health (2002b) Hepatitis C strategy for England. London: Department of Health

Department of Health (2004) Hepatitis C action plan for England. London: Department of Health

Department of Health (2006) Immunisation against infectious disease – the green book. London: Department of Health

Department of Health (2007) Cancer reform strategy. London: Department of Health

Hahné S, Ramsay M, Soldan K et al. (2003) Hepatitis B incidence among South Asian children in England and Wales: implications for immunisation policy. Archives of Disease in Childhood 88: 1082–3

Hahné S, Ramsay M, Balogun K et al. (2004) Incidence and routes of transmission of hepatitis B virus in England and Wales, 1995–2000: implications for immunization policy. Journal of Clinical Virology 29: 211–20

Health Protection Agency (2007) Shooting up. Infections among injecting drug users in the United Kingdom 2006. An update. London: Health Protection Agency

Health Protection Agency (2009) Hepatitis C in the UK 2009. London: Health Protection Agency Centre for Infections

Kawsar M, Goh BT (2002) Hepatitis B virus infection among Chinese residents in the United Kingdom. Sexually Transmitted Infections 78: 166–8

Mast EE, Goldstein S, Ward JW (2008) Hepatitis B vaccines. In: Plotkin SA, Orenstein WA, Offit PA, editors. Vaccines. London: Saunders

National Screening Committee (2006) The UK NSC policy on hepatitis B screening in pregnancy [online]. Available from www.screening.nhs.uk/hepatitisb [accessed 17 June 2010]

National Treatment Agency (2006) Models of care for treatment of adult drug misusers. London: National Treatment Agency

Pendleton S, Wilson-Webb P (2007) Rising curve: chronic hepatitis B infection in the UK. Canterbury: Hepatitis B Foundation

Prison Reform Trust, National AIDS Trust (2005) HIV and hepatitis in UK prisons: addressing prisoners' healthcare needs. London: Prison Reform Trust

Royal College of General Practitioners (2007) Guidance for the prevention, testing, treatment and management of hepatitis C in primary care. London: Royal College of General Practitioners

Tibbs CJ, Smith HM (2001) Clinicians' guide to hepatitis. London: Hodder Arnold