IN BRIEF A Summary of the Evidence

Screening for Hepatitis C: A Review

Key Messages

- It is unclear if screening the general population for hepatitis C would be more clinically effective and less harmful than not screening because of a lack of clinical trial data.
- Antibody tests are sufficiently able to identify individuals with active hepatitis C infection and may be acceptable as a first step in a screening pathway.
- No conclusions can be made about the clinical validity of any particular hepatitis C test — either the antibody test or the antigen test — because of limited evidence.
- The results of this CADTH review should not be interpreted as a stand-alone document. The criteria for this review were selected by the Canadian Task Force on Preventive Health Care to inform the development of recommendations on hepatitis C screening.

Context

Hepatitis C is a virus that is spread through blood contact; for example, by injection or infusion of blood from an infected person. Some infections (about 15% to 50%) clear on their own, while others go on for many years (called a chronic infection), often without symptoms. People might not know they are infected until they start experiencing symptoms of cirrhosis (a type of liver disease) or liver cancer, which could develop within 20 years of infection. However, most people will live with a chronic hepatitis C infection their entire lives without developing liver disease. It is difficult to predict who will develop disease; and once symptoms show, the disease could already be serious. Early detection of hepatitis C infection may lead to early treatment, preventing complications and transmission to others. On the other hand, screening could cause unnecessary stress or harm to individuals who would otherwise remain healthy.

Issue

In recent years, new medications have become available that can cure hepatitis C infection. The availability of these medications in Canada has spurred interest in screening. The cost of these medications is still high, and large-scale screening programs are also expensive and challenging to implement. While several guidelines recommend screening people in high-risk populations, such as inmates or people who inject drugs, it is not clear if screening the general population is useful or reasonable.

The Canadian Task Force on Preventive Health Care requested that CADTH perform a systematic review to assess the research evidence on the clinical effectiveness, harms, cost-effectiveness, and patient preferences and values of screening for hepatitis C in adults. This review will be used, among other resources, to inform the Task Force recommendations on screening for hepatitis C.

There are a variety of antibody (Ab) tests, which use enzyme immunoassays to detect antibodies in the blood formed in response to the hepatitis C virus. However, the presence of these antibodies in the blood does not necessarily mean a person has an active hepatitis C infection — it may indicate past infection in people who have cleared the virus, either spontaneously or with treatment. Furthermore, people with new infections might not start making antibodies until 12 weeks following exposure, so this type of test might not be effective for those recently infected or for the immunocompromised (those who can't make antibodies adequately). Therefore, a confirmatory test is needed, such as a polymerase chain reaction (PCR) test for the presence of hepatitis C ribonucleic acid (RNA) in the blood.

Antigen (Ag) tests detect components of the virus itself, so they have the potential to be used instead of Ab tests, or in combination with Ab tests, as part of a screening pathway — that is, a screening process with multiple steps. However, Ag tests might not be sensitive enough, so they also require a confirmatory test using PCR. Testing for hepatitis C RNA using PCR has high sensitivity, but it is expensive. Testing with PCR also runs the risk of showing false-positive results if cross-contamination of samples occurs, which is possible in a large-scale screening program. Therefore, PCR is not currently used as a screening test but only as the confirmatory test.

Technology

Screening for hepatitis C infection can be done using two main types of blood tests: a test for antibodies to the hepatitis C virus, and a test for hepatitis C antigens (parts of the actual virus particle).
Methods

CADTH conducted a systematic review of existing research. A literature search was performed, and studies were considered for inclusion if results were reported for adults (at least 18-years-old) who were not pregnant, did not have symptoms of hepatitis C infection, had unknown liver enzyme values, and had not previously received treatment for hepatitis C.

Results

The review did not find any studies on the clinical effectiveness of screening that met the inclusion criteria of the review. One study was found related to harms, and one study was found related to cost-effectiveness. However, this lack of research evidence does not necessarily mean that screening would be ineffective in clinical practice.

Twenty-six studies evaluated the clinical validity of Ab and Ag screening tests. Results from studies with large sample sizes showed that Ab tests are sufficiently able to identify individuals with active hepatitis C infection (71% to 87.5% of people who tested positive using an Ab test were confirmed using PCR to have an active infection). Therefore, Ab tests may be acceptable as a first step in a screening pathway. There were inconsistent results observed among the Ab tests and Ag tests, and no conclusions can be made about the clinical validity of a particular test in a screening pathway.

Twelve studies were included about patient preferences and values. They showed that individuals make decisions about screening that appear reasonable and feasible within their own life situations, psychological contexts, and unique knowledge about screening and hepatitis C in general. People who were interested in screening generally want it to be convenient, initiated by the provider (e.g., offered routinely), and in a setting that offers a sense of anonymity because of the associated stigma of having hepatitis C. It is also important for them that the conversation around testing and results is of appropriate quality and depth.

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