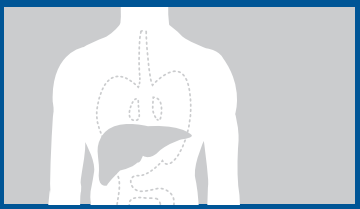
Health Reporting Handbook



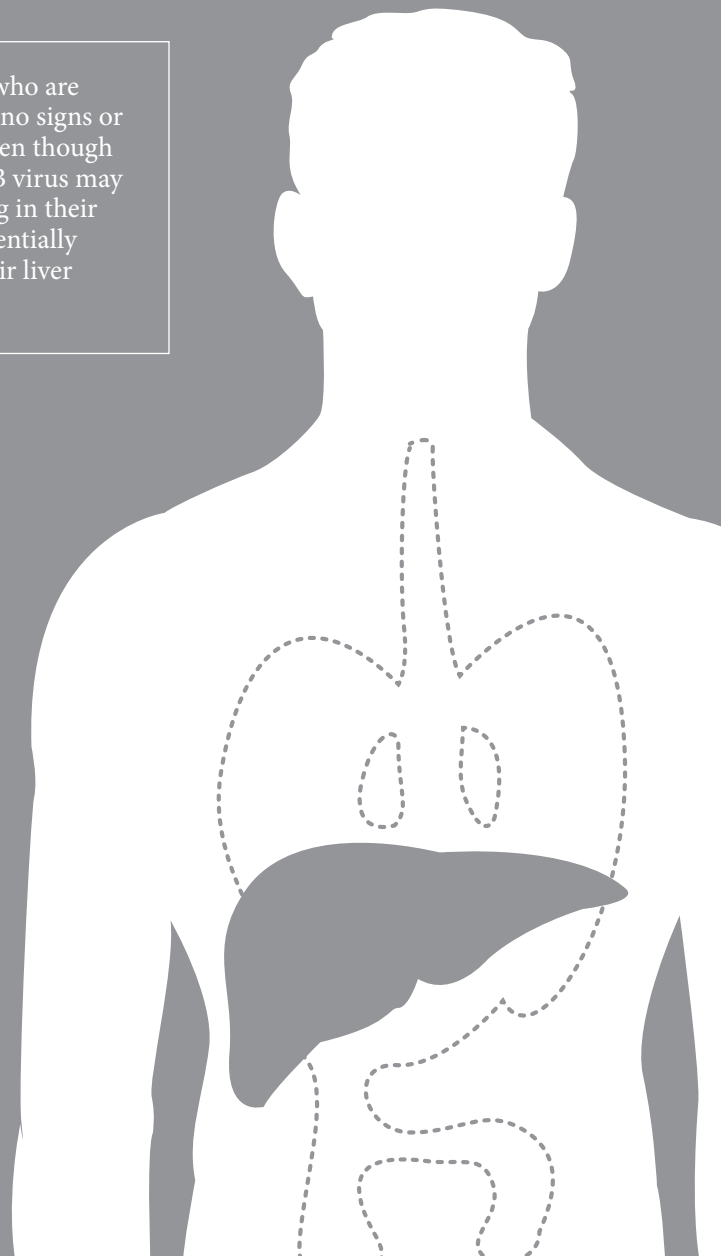
Special focus on chronic hepatitis B

Provided by

Bristol-Myers Squibb

Chronic hepatitis B is known as a "silent" disease.

Most people who are infected have no signs or symptoms, even though the hepatitis B virus may be multiplying in their body and potentially damaging their liver for years.



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Covering Medical News: The Basics

There is no shortage of news driven by medical research. In fact, countless numbers of journal articles are published every year.[1]

As a gateway to making health information accessible to the community, reporters frequently need to translate complex and unfamiliar concepts into news that their audiences can use. This handbook covers some of the essential tools to identify, analyze and interpret findings from medical research and also explains common medical and statistical terms related to clinical trials.

Since patients today are actively seeking information to help guide their healthcare decisions, the value of reporting on health and medical issues is growing. News coverage has the potential to inform, motivate and shape the awareness of a patient audience.

Given the high incidence of chronic hepatitis B in the Asian American community, this handbook contains many examples related to the disease. Also included are background materials on chronic hepatitis B, such as a glossary of terms and sample story ideas.

Chronic Hepatitis B: An Overview

Within the United States, approximately 1.25 million people are chronically infected with the hepatitis B virus, and over half are of Asian descent.[2]

Hepatitis B is a liver infection that causes damage to the liver.[3] There are acute and chronic cases. Acute hepatitis B occurs when a person is first infected with the hepatitis B virus and can last up to six months. During this time, people may be able to clear the virus from their systems successfully on their own.[3] People who test positive for the hepatitis B virus for longer than 6 months are considered to be chronically infected.[3]

Chronic hepatitis B infection may stay with a person for a lifetime[3] and if left untreated, the hepatitis B virus can continue to harm the liver and lead to serious complications.[4]

Chronic hepatitis B is also known as a "silent infection" because many people who are infected have no signs or symptoms and are therefore unaware of their status. Because of this, infected people may unknowingly pass the virus to others.[3] The virus can be contracted from infected individuals through unprotected sex, blood, shared or re-used needles, and from an infected mother to her unborn baby.[3]

Hepatitis B can be prevented by a vaccine. For those already chronically infected, there are medications physicians may prescribe to help treat the disease.[3]

Chronic Hepatitis B: Key Statistics

Chronic hepatitis B is an important health issue for Asian Americans, as it disproportionately affects this population.

World:

- Worldwide, an estimated 350 million people are chronically infected with hepatitis B. Approximately 78 percent (275 million) of these cases are in Asia or the Pacific Islands.[2]
- Chronic hepatitis B is responsible for 60-80 percent of cases of liver cancer worldwide.[2]

US:

- In the United States, approximately 1.25 million people are chronically infected with hepatitis B and over half are of Asian descent.[2]
- An estimated one in ten Asian Americans is chronically infected with hepatitis B.[5]
  - Chinese Americans have a six times higher risk for liver cancer caused by hepatitis B than Caucasian Americans.[6]
  - Korean Americans have an eight times higher risk for liver cancer caused by hepatitis B than Caucasian Americans.[6]
  - Vietnamese Americans have a 13 times higher risk for liver cancer caused by hepatitis B than Caucasian Americans.[6]

POTENTIAL STORY TOPICS:

Statistics on the prevalence of chronic hepatitis B

The burden of chronic hepatitis B among Asian Americans

Sources Of Medical Information

Medical data informs the healthcare community on topics ranging from new information about disease conditions to how medications can be utilized within a population. Researchers share the results of their work with the medical community by presenting and/or publishing their findings. This scientific exchange of new medical data also provides journalists with a steady stream of medical news stories.

- Formats for information shared at medical conferences:
  - **Presentation abstract:** a synopsis of the study that is submitted to a medical association for presentation at a medical conference.[7] Accepted abstracts are published in an abstract book distributed either prior to or during the conference. The sponsoring organization may make the abstract book available to reporters.[8]
  - **Oral presentation:** the researcher is invited to share his or her findings (usually as a slideshow presentation) at a live lecture during the conference.[9]
  - **Poster presentation:** the study is summarized on a large poster board, and then presented in a session at the conference along with other studies. Poster presentations usually have a researcher from each study stand by his or her corresponding poster to answer questions related to the study.[10]

Sources Of Medical Information *(Cont'd)*

- Formats for information shared in medical journals.
  - **Peer-reviewed medical journals**: contain information independently reviewed by a group of experts from a particular medical specialty.[1] Examples include:
    - -- **General medical journals:** encapsulate many different aspects of medicine and appeal to a wide variety of physicians and other health professionals. Examples include the *New England Journal of Medicine (NEJM)*, the *Journal of the American Medical Association (JAMA)*, and *The Lancet*.[1]
    - -- **Specialty medical journals:** focus on a specific area of medicine, such as infectious diseases. Examples include *Hepatology*, *Clinical Gastroenterology and Hepatology,* and *Gastroenterology.*
  - **Non-peer reviewed medical journals:** contain information not independently reviewed by a group of experts prior to publication.[1]

Tip: *Sign up to receive an advance copy and/or e-mail alerts of relevant medical journals to give yourself extra time to research articles and develop your own story.*

Tip: *Be sure to note the embargo policies of the journal or medical association that is issuing the research report. Generally, a news story cannot appear before the study publication in a journal or presentation date at a medical conference.*[1]

Navigating Your Way Around a Medical Study

Finding Key Information From A Study

Medical research findings are usually presented in a standard format that contains information about the trial's objective, how it was conducted (methodology), key results and conclusions. This information is first summarized in an abstract and then detailed in the full article. A published study also features introduction and discussion sections where the authors provide their perspectives on the study and results and put them in context.

Tip: *It is helpful to read a study published in a medical journal in the following order:*[1]

1. *Abstract – to obtain a general overview of the paper.*
2. *Introduction – to find the necessary background information and context for why the researchers conducted the current study.*
3. *The body of the paper (methodology, results, tables, etc.) – to fill in the details of the study, to provide context for the results, and to examine the charts and tables to obtain a visual illustration of the results.*
4. *Conclusion – to understand if the findings may be of value to patients and physicians.*

Navigating Your Way Around a Medical Study *(Cont'd)*

Sample Abstract

"Hepatitis B Awareness, Knowledge, and Screening Among Asian Americans." Nguyen TT, Taylor V, Chen MS, Bastani R, Maxwell AE, McPhee SJ. *J Cancer Educ.* 2007:22(4):266-72.[11]

BACKGROUND:
Due to the high prevalence of hepatitis B, Asian Americans have high rates of liver cancer. Screening for hepatitis B leads to monitoring and treatment and prevent further infection through vaccination of contacts.

This section typically provides scientific context and rationale for why the study was conducted.[7]

METHODS:
We reviewed the published literature up to 2006 on hepatitis B awareness, knowledge, and screening among Asian Americans.

This section typically describes the patient population analyzed, how the study was conducted, and the endpoints (outcome measures) that were evaluated.[7]

RESULTS:
Many Asian Americans lack knowledge about hepatitis B and have not been screened. Socio-demographics, knowledge, beliefs, and health care variables are associated with screening.

This section typically summarizes the data that was collected from each participant and details the most important findings of the study.[7]

CONCLUSIONS:
Further research and health policy changes are needed to address the problem of hepatitis B and liver cancer among Asian Americans.

This section typically describes the significance of the results in relation to the study's purpose and may also place them in larger context within a specific disease field.[7]

POTENTIAL STORY TOPICS:

Latest developments in chronic hepatitis B: updates from medical conference
Consequences of untreated chronic hepatitis B

Commonly Used Terms

The following terms and concepts frequently appear in published research studies:

STATISTICAL TERMS

Confidence interval (CI): describes how precise a particular finding is and suggests how reliable it may be beyond the specific study. It is reported as a range of values above and below the study finding; the more narrow the range, the more precise the result.[12] For example, a health condition that is present in ten percent of a population with a confidence interval of plus or minus two percent means that the actual value lies between eight percent and 12 percent.[13]

Mean: the arithmetic average or the sum of all the values divided by the number of values.[14] There will always be patients in the study who did better or worse than the mean.

Median: the mid-way point or middle value, e.g. half of the values were higher and half were lower.[14]

***P* value (probability value):** A *P* value (as determined by a statistical formula) of 0.05 or less generally means the result is statistically significant (depending upon study methodology). Results that are statistically significant are unlikely to be due to chance. A *P* value of 0.05 means there is no more than a five percent chance (5 out of 100) that the result is due to chance.[1]

Statistical significance: the probability that an event or difference occurred by chance alone. In clinical trials, the level of statistical significance depends on the number of participants studied and the observations made, as well as the magnitude of differences observed.[15]

POTENTIAL STORY TOPICS:

The basics of chronic hepatitis B: transmission, symptoms, treatment

Commonly Used Terms *(Cont'd)*

CLINICAL TRIAL TERMS

Clinical investigator: A medical researcher in charge of carrying out a clinical trial's protocol.[15]

Clinical trial: a research study that tests the effectiveness and safety of medications, devices, and treatment paradigms in humans.[16]

> **Phase I trial:** initial studies conducted with a small number of volunteers with or without the disease (can be fewer than 80) to assess safety and various dose ranges for an experimental treatment.[16,17]
>
> **Phase II trial:** mid-stage studies (which occur after Phase I) typically involving a larger number of individuals (can be 100–300 patient volunteers) to further assess safety and effectiveness of an experimental treatment.[16,17]
>
> **Phase III trial:** large trials (which occur after Phase II and can involve 1,000-3,000 patient volunteers) carried out to confirm effectiveness of an experimental treatment, identify adverse events, often compare it to commonly used treatments, and collect information to evaluate the overall risk/benefit ratio and provide the basis for full prescribing information.[16,17]

CLINICAL TRIAL TYPES

Blinded study: a study in which the participants, the investigators and/or anyone assessing the data are unaware of the treatment assignment(s). Blinding prevents individual biases from affecting study results.[15]

> **Double-blind study:** neither the research team nor the participants are aware of the treatment assignment.[15]
>
> **Single-blind study:** either the investigator or participant is unaware of what medication the participant is taking.[15]

Commonly Used Terms *(Cont'd)*

Endpoint: an overall measurable outcome that the study is designed to evaluate.[15]

> **Primary endpoint(s):** the outcome measure used to answer the main objective of the study.[18]
> **Secondary endpoint(s):** the outcome measures for other related questions in the study.

Non-inferiority study: a type of research study intended to show that the effect of a treatment is not worse than that of an active control, by no more than a specified range.[19]

Open-label trial: both the researchers and participants know which treatment the participants are taking; opposite of a blinded study.[15]

Post-hoc analysis: an examination of data after the experiment has concluded, for analyses that were not specified previously.[14]

Prospective study: a type of research study that looks ahead by following a group of people over a specific amount of time based on the same medical and statistical techniques. Prospective studies are typically the preferred method of conducting studies because they are planned before the data is collected. This practice helps reduce bias.[20]

Randomized clinical trial: a study in which the participants are assigned by chance to separate groups that compare different treatments.[15] Randomization ensures similarity between the groups and supports an objective comparison of the treatments being studied. A randomized study contributes to the strength of scientific evidence in support of its conclusion.[1]

Tip: **Large, randomized, double-blind, controlled prospective clinical trials** *provide the highest quality of scientific evidence.*[1]

Commonly Used Terms *(Cont'd)*

Retrospective study: a type of research study that measures outcomes by looking back in time on pre-existing data, including laboratory samples, records, statistics or people's memories. The outcomes may be inaccurate because memories may fade and records may not contain the information of interest.[1]

Subanalysis study: a type of research study that examines data from a subset of participants from a larger study.

Fact Finding

The following selected resources are key starting points for gathering information on most medical topics:

Medical Literature Databases

- PubMed – www.pubmed.com: includes links to full text articles and other related resources.
- Medline Plus – www.medlineplus.gov: includes extensive information about drugs, a medical dictionary, an illustrated medical encyclopedia, interactive patient tutorials and latest health news.

Government Agencies and Resources

- National Institutes of Health (NIH) – www.nih.gov: primary federal government agency for conducting and supporting medical research.
- U.S. Food and Drug Administration (FDA) – www.fda.gov
- Centers for Disease Control and Prevention (CDC) – www.cdc.gov
- National Center for Health Statistics (NCHS) – www.cdc.gov/nchs: part of the CDC that provides U.S. public health statistics on diseases, pregnancies, births, aging and mortality.

Professional Medical Organizations

- American Medical Association (AMA)
- American College of Physicians (ACP)
- Association of Asian Pacific Community Health Organizations (AAPCHO)

Examples of Peer-reviewed Medical Journals

- *New England Journal of Medicine (NEJM)*
- *Journal of the American Medical Association (JAMA)*
- *The Lancet*

Pharmaceutical and Biotech Industry Trade Groups

- Pharmaceutical Researchers and Manufacturers of America (PhRMA) – www.phrma.org
- Biotechnology Industry Organization (BIO) – www.bio.org

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Chronic Hepatitis B Story Topics

As seen in the examples throughout, consider these topics for developing stories about chronic hepatitis B:

- The basics of chronic hepatitis B: transmission, symptoms, treatment
- Burden of chronic hepatitis B among Asian Americans
- Perceptions about chronic hepatitis B among Asian Americans
- Barriers to seeking treatment
- Consequences of untreated chronic hepatitis B
- Pregnancy and chronic hepatitis B
- Latest developments in chronic hepatitis B: updates from a medical conference or journal
- Recent literature on chronic hepatitis B

Additional Resources

Patient and Disease-related Organizations

- American Liver Foundation (ALF) – www.liverfoundation.org
- National Viral Hepatitis Roundtable (NVHR) – www.nvhr.org
- Hepatitis B Foundation (HBF) – www.hepb.org
- Hepatitis Foundation International (HFI) – www.hepfi.org

Asian American Health Organizations

- National Task Force on Hepatitis B: Focus on Asians and Pacific Islanders – www.hepbtaskforce.org
- Association of Asian Pacific Community Health Organizations (AAPCHO) – www.aapcho.org
- The Asian and Pacific Islander American Health Forum (APIAHF) – www.apiahf.org
- The Hepatitis B Initiative (AAPI [Asian American Pacific Islander] hepatitis B organization) – www.hepbinitiative.org

Professional Medical Organizations

- Asian Pacific Association for the Study of the Liver (APASL) – www.apasl.info
- American Association for the Study of Liver Diseases (AASLD) – www.aasld.org
- European Association for the Study of the Liver (EASL) – www.easl.ch
- American Gastroenterological Association (AGA) – www.gastro.org

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Chronic Hepatitis B Glossary

The following list are key terms for your use in interpreting information and developing stories on chronic hepatitis B.

Acute hepatitis infection: occurs when a person is first infected with the hepatitis B virus and can last up to six months. During this time, people are contagious and can spread the hepatitis B virus to others. However, they may be able to clear the virus successfully from their systems on their own.[3]

Adherence: refers generally to following a prescribed treatment regimen, as prescribed by a healthcare professional.[22]

Adverse events (side effects): any undesired or unexpected actions or effects of a drug or treatment.[15]

ALT (alanine aminotransferase): an enzyme that is produced in the liver and other organs. An increase in ALT levels is often associated with inflammation of the liver or liver damage.[21]

Antibody (Ab): a protein produced by the body's immune system to identify and fight a foreign body such as a virus.[21]

Antigen (Ag): a protein on the surface of a virus, bacteria, or cell that is recognized and attacked by the body's immune system. Antigens stimulate the production of antibodies to fight foreign bodies.[21]

AST (aspartate aminotransferase): an enzyme that is produced in the liver and other organs. Elevated levels may indicate inflammation of the liver or liver damage.[21]

Biopsy of the liver: examination of a sample of liver cells under a microscope to determine the extent of liver damage or inflammation.[21]

Chronic hepatitis B infection: people who test positive for the hepatitis B virus for longer than 6 months are considered to be chronically infected.[3]

Cirrhosis: a serious liver condition in which there is irreversible scarring of the liver due to ongoing damage from multiple causes, including liver-specific viruses, such as hepatitis B.[21]

Chronic Hepatitis B Glossary *(Cont'd)*

Clotting factors: proteins created in the liver to maintain normal blood clotting. An interruption in the blood's ability to clot may indicate not enough clotting factors are being made by the liver.[21]

Complete blood count (CBC): a test measuring the amount of white blood cells, red blood cells, hemoglobin and platelets in the body.[21]

DNA (deoxyribonucleic acid): the molecule inside the nucleus of a cell that carries the genetic instructions for making the living organism.[23]

DNA polymerase: an enzyme necessary for the hepatitis B virus DNA to make copies of itself.[21]

Decompensated cirrhosis: a late stage of cirrhosis that can be detected by irregular blood tests and other complications[21].

e-Antibody (HBeAb or anti-HBe): a protein produced by the immune system during or after an increase in the replication of the hepatitis B virus.[21]

e-Antigen (HBeAg): a protein that is used as a marker to help determine the presence of hepatitis B infection. This marker may indicate that the hepatitis B virus (HBV) DNA is actively replicating. Presence or absence of the E-antigen is used to help determine the clinical management of patients with chronic HBV infection.[21]

Fibrosis: growth of fibrous (scar) tissue.[21]

Hepatitis B: caused by the hepatitis B virus (HBV), possibly resulting in damage to the liver.[3]

Hepatitis B Panel: There are three hepatitis B blood tests that make up the Hepatitis B Panel:

> **Hepatitis B surface antigen (HBsAg):** the protein on the surface of the hepatitis B virus that is used to determine if the virus is present in the body.[21]

Chronic Hepatitis B Glossary *(Cont'd)*

Hepatitis B surface antibody (HBsAb or anti-HBs): the antibody formed in response to the hepatitis B surface antigen. A positive test indicates the immune system has developed a defensive antibody against the hepatitis B virus and has long-term immunity.[21]

Hepatitis B core antibody (HBcAb or anti-HBc): this blood test is used in conjunction with the above two tests to determine if a person has been exposed to the hepatitis B virus.[21]

HBV DNA (deoxyribonucleic acid): a marker that indicates a virus is replicating actively. HBV DNA levels are used, along with other markers like HBeAg and ALT, to assess and monitor patients with chronic hepatitis B.[21]

Hepatocellular carcinoma (HCC): a malignant (harmful) tumor in the liver, a type of liver cancer.[21]

Histology: the study of tissue under a microscope. Histological evaluations may be conducted on samples from a liver biopsy to identify and monitor possible liver damage.[21]

Immune system: The body's system of defense against attack from foreign bodies such as viruses and bacteria.[21]

Liver enzymes: proteins that facilitate and speed up chemical reactions needed for bodily functions. Higher blood levels of certain enzymes, such as ALT and AST, are higher when the liver is injured, as these enzymes flow into the blood when the cell is injured.[21]

Proteins: compounds consisting of a chain of amino acids. Proteins are essential to the human body.[21]

Resistance: describes when the virus is able to mutate to escape treatment effects.[22]

Chronic Hepatitis B Glossary *(Cont'd)*

Reverse transcription (RT): the conversion of RNA (ribonucleic acid) into DNA, the form in which the cell carries its genes. This process is in the reverse order from the usual DNA-to-RNA conversion.[22]

Seroconversion: a change from antigen positive/antibody negative to antigen negative/antibody positive. Seroconversion of surface antigen to surface antibody indicates a clearance of HBV infection from the body.[21]

Viral load: the amount of virus present in the blood.[21]

Virus: a small microorganism (smaller than bacteria), that can enter the body and cause disease. A virus can only reproduce inside a host and can also mutate to make small changes.[21]

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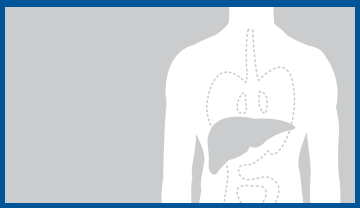

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