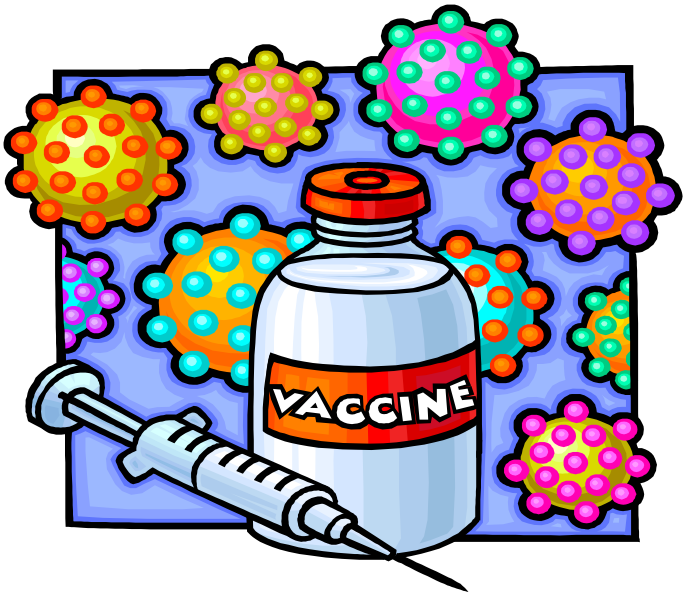
Hepatitis B Immunization in a STD Clinic

Lessons Learned in San Diego County

A Practical Guide



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Foreword

The Sexually Transmitted Disease (STD) and Hepatitis Prevention Program has provided hepatitis B vaccination to clients attending the STD clinic in San Diego County for more than three years through support provided by the Centers for Disease Control and Prevention (CDC). Members of the program staff developed this practical guide based on the lessons learned and expect that it will serve as an aid to STD program and clinic managers who want to incorporate hepatitis B vaccination into the existing services they provide. In many communities, STD incidence has declined and STD clinics have gained capacity to offer expanded services. This is the right time to integrate hepatitis B vaccination into STD clinic services. Providing hepatitis B vaccination services will also lay the groundwork for delivering vaccines that may become available in the future against other sexually transmitted infections .

We hope that many of you will read this guide from beginning to end, although it is designed for quick access to specific topics. The format allows for addition and deletion of materials so they can be tailored to each organization's particular needs. Protocols, forms, and educational handouts can be added as desired. We will strive to keep this guide current and thus welcome your comments and suggestions.

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September, 2001

Acknowledgements

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We also thank the staff of the STD and Hepatitis Prevention Program in San Diego for their efforts in delivering hepatitis vaccination to our STD clinic clients. Members of the Hepatitis Prevention Program, STD clinic team, and field investigative staff are too numerous to mention, but we thank all of them for their efforts in the integration of hepatitis activities into our program. In addition, Sandy Ross, RN, Immunization Program Manager in San Diego County provided valuable advice and assistance during the start-up and early phases of the project.

Lastly, we are very grateful for an unrestricted educational grant provided by the Adult Vaccine Division, Merck and Company, for the reproduction and distribution of this guide.

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Section I-A

SETTING THE STAGE

INTRODUCTION

The Centers for Disease Control and Prevention (CDC) has developed a strategy to eliminate hepatitis B virus (HBV) infection in the United States which focuses on routine hepatitis B vaccination beginning in infancy through adolescence.[1] Added to this population-level approach is the vaccination of adolescents and adults who are at increased risk of acquiring HBV infection through risky lifestyle behaviors such as:

- men having sex with men (MSM)
- injecting drug use (IDU)
- history of STD
- multiple sex partners

A strategy to vaccinate high-risk persons has not been widely implemented because of perceived difficulties in identifying, educating, and motivating high-risk persons to seek HBV vaccination and in providing vaccination services that such persons will utilize. One potential site for delivering hepatitis B vaccination is the public Sexually Transmitted Disease (STD) clinic.

Since a considerable proportion of acute HBV infections are acquired through sexual transmission, it follows that services for this vaccine preventable sexually transmitted infection should be provided at sites where persons at risk for STDs seek care. A recent study showed that 36% of persons with acute hepatitis B had been treated for a STD sometime before they became infected – a missed opportunity for vaccination. [2]

Hepatitis B vaccination in STD clinics is not currently routine. A national survey done in 1997 showed that only 6% of STD Program Managers considered all patients eligible for vaccination, while 22% considered all adolescents (age <19) eligible. Only 48% of STD Program Managers considered HBV infection a STD program responsibility, even though nearly all considered it an important STD.[3] In many communities, STD incidence has declined and STD clinics have gained some capacity to offer additional services. Considering these events, **this is the opportune time to integrate hepatitis B vaccination into STD services**. Providing HBV vaccination services also lays the ground work for future delivery of other vaccines that may become available in the future for sexually transmitted infections.

WHO SHOULD READ THIS MANUAL?

San Diego County has been providing hepatitis B vaccine to STD clinic clients since February 1998 as a demonstration project funded by the CDC. Having learned by trial and error, project personnel documented procedures and produced this manual to share their findings with others. This manual provides guidance for STD program managers who are planning to incorporate hepatitis B vaccination into their clinic protocol. However, many of the guidelines and suggestions can be utilized in any clinic setting trying to establish a routine hepatitis B adult vaccination program.

HOW TO USE THIS MANUAL

While it is hoped that some individuals will read this manual from beginning to end, the manual was designed for quick access to particular topics. The format allows each user to add or delete materials, converting it to a **working document** – protocols, forms, and educational handouts can be integrated as needed.

WHY VACCINATE ADULTS?

Recommendations for universal infant and early adolescent immunization have resulted in school entry and 7th grade vaccination requirements in most states. While this approach will eventually provide a high population coverage level, there is the need to vaccinate unprotected adolescents and adults who currently engage in high-risk activities. Rates of HBV infection are highest in these age groups and have not seen a decline, while rates in children and adolescents have shown the greatest decline. Efforts to vaccinate these high-risk individuals are under way with targeted education and vaccine delivery approaches being evaluated in settings such as:

- STD clinics
- adolescent service sites
- drug treatment centers
- correctional facilities
- family planning programs
- HIV/AIDS services

Hepatitis B vaccine should be offered to all persons who may be engaging in high-risk activities.

In 1989, the Advisory Committee on Immunization Practices (ACIP) recommended that persons at risk for sexually acquired infections be vaccinated against hepatitis B and that hepatitis B vaccination be incorporated into STD treatment guidelines. In 1998, CDC Guidelines for Treatment of Sexually Transmitted Diseases recommended that all persons attending STD clinics and persons known to be at high risk for HBV infection be offered hepatitis B vaccine. Similarly, Healthy People 2010 objectives include the recommendation that persons accessing STD services should be considered at high risk for HBV infection and are candidates for vaccination and prevention counseling. **Objective (#25-13) sets the goal for 90% of STD clinics to be offering HBV vaccination to all clients**.[4] Currently, this recommendation is not the standard of care in STD programs.

It is hoped that all who read this manual will be convinced that they **should offer HBV vaccination to clients in their STD clinic**. However, if unable to provide vaccination, STD clinics should provide education and counseling about hepatitis B and referral to outside vaccination services.

Section I-B

HEPATITIS B: THE FACTS

WHAT IS HEPATITIS B?

- Hepatitis means inflammation of the liver. The liver may become inflamed from a variety of infectious and noninfectious causes. The most common cause is infection with a hepatitis virus - A, B, or C.
- Hepatitis B is a blood-borne virus that can cause acute disease. It may also cause chronic infection that can lead to serious, permanent liver damage.
- Chronic hepatitis B virus (HBV) infection is more prevalent than human immunodeficiency virus (HIV) infection and the hepatitis virus is 100 times more contagious than HIV.

WHAT ARE THE SYMPTOMS OF HEPATITIS B?

- Approximately 40% of people infected with hepatitis B virus have no signs or symptoms.
- Those who experience symptoms typically have a flu-like illness or some of the following symptoms:
  - loss of appetite
  - nausea and vomiting
  - fever
  - abdominal pain in the upper right quadrant (liver area)
  - dark urine
  - yellowing of skin and eyes (jaundice)
- Approximately 6% of adults infected do not become immune and have a persistent chronic infection with ongoing or lifelong viral replication which may cause chronic liver disease. They also are infectious to other individuals.

- Long term complications of chronic HBV infection include:
  - cirrhosis
  - cancer of the liver
  - chronic liver disease
  - liver transplant

HOW IS HBV TRANSMITTED FROM PERSON TO PERSON?

- HBV, like HIV, is a blood-borne virus that is most often **sexually transmitted**.

- HBV is transmitted from an infected person to a noninfected person through infected body fluids, primarily
  - blood
  - semen
  - vaginal secretions

  passing through mucous membranes and broken skin.

- Sexual contact accounts for >60% of acute HBV infections in adults in the U.S.

- Most individuals who acquire hepatitis B virus through **sexual activity** meet one of the following criteria:
  - multiple sex partners (>1 in 6 months)
  - history of STD
  - men who have sex with men
  - sex partner of an injection drug user
  - sex partner of a person with chronic HBV infection

- Other risk factors include:
  - **current or prior injection drug use**
  - exposure to the blood of an infected person through sharing razors, toothbrushes, or washcloths
  - day-to-day contact with a household member who has chronic HBV
  - occupational exposure (e.g. needlesticks) such as occurring among healthcare workers, laboratory workers, emergency response persons, etc.
  - perinatal — mother to infant at childbirth or during infancy

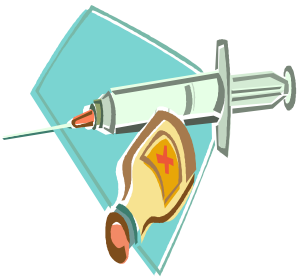
WHO IS INFECTED WITH HBV?

- Currently, 1.2 million Americans are chronically infected with HBV.
- Persons emigrating from countries with high levels of hepatitis B (e.g., Southeast Asia, Africa, Eastern Europe) have an elevated prevalence of chronic infection, and serve as a constant source of HBV that can be transmitted to others.
- An estimated 80,000 people were newly infected in 1999
- Each year 4,000 to 5,000 people in the U.S. will die from HBV-related liver disease.
- Almost 85% of reported acute hepatitis B cases in the United States occur among persons between the ages of 20 and 49 years.
- Approximately 15-25% of persons who attend STD clinics have serologic evidence of HBV infection.
- In a study conducted in San Francisco among men who have sex with men (17 - 22 years of age), only 3% had been vaccinated and 20% had already been infected with HBV[6].

Section I-C

THE VACCINE

HISTORY



♦ The first hepatitis B vaccine was licensed in the United States in 1981. Since 1986, hepatitis B vaccine has been manufactured with recombinant DNA technology and **has no potential for being infectious**.

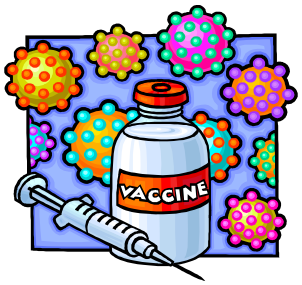
♦ No substances of human origin are used in the manufacture of hepatitis B vaccine, however it does contain yeast.

VACCINE MANUFACTURERS

Currently HBV vaccine is available through two manufacturers:

- Recombivax HB™ – Merck and Co., Inc.
- Engerix-B ™ – Glaxo SmithKline

These vaccines contain noninfectious subunits derived from core and recombinant hepatitis B surface antigen. **These vaccines are considered very safe**. Local site of injection and systemic complaints (nonspecific) have been observed in about 15% of vaccine recipients in clinical trials. During post-market experience, hypersensitivity, both acute and delayed, has been reported. Concerns about long-term delayed-onset syndromes have been raised, but data does not support a causal relationship.



The vaccines are interchangeable in that the total of 3 doses can be in any combination of the 2 vaccines. However, the *vaccines from different manufacturers cannot be mixed in the same syringe*. The current dosage schedule is:

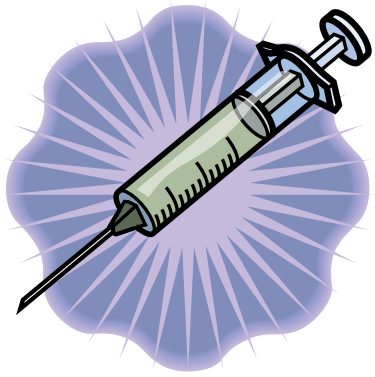
MERCK & CO. **RECOMBIVAX HB ™**

	Initial	1-2 Months	4-6 Months
≥ 20 years - Adult Formulation	10 mcg/1.0 mL	10 mcg/1.0 mL	10 mcg/1.0 mL
0-19 years Pediatric/Adolescent Formulation	5 mcg/0.5 mL	5 mcg/0.5 mL	5 mcg/0.5 mL
Adolescents 11-15 years	10 mcg/1.0 mL	None	10 mcg/1.0 mL

GLAXO SMITHKLINE **ENGERIX-B ™**

	Initial	1-2 Months	4-6 Months
≥ 20 years - Adult Formulation	20 mcg/1.0 mL	20 mcg/1.0 mL	20 mcg/1.0 mL
0-19 years Pediatric/Adolescent Formulation	10 mcg/0.5 mL	10 mcg/0.5 mL	10 mcg/0.5 mL

Review of procedures with immunization program staff in your local or state health department is highly recommended.



DOSAGE SCHEDULE

The vaccination schedule most often used for adults and children has been three intramuscular injections, the second and third administered 1 and 6 months, respectively, after the first(ACIP). The first and second doses of vaccine must be administered at least 1 month apart, and the first and third doses at least 4 months apart. There are other flexible schedules for special populations. The deltoid muscle is the preferred site for intramuscular injection in adults. Please consult the ACIP statement of hepatitis B (11/91), AAP's 2000 *Red Book,* or the package insert for details. Read the package insert carefully for more information on vaccine administration (dosage, storage, etc.).

Variations of this schedule consist of:

- 0-1-4 months
- 0-1-6 months
- 0-2-4 months

There is a minimum amount of time needed between doses, but there is no maximum. The patient never needs to restart the series.

It's Never Too Late To Get The Next Dose Of Vaccine

With three intramuscular doses of vaccine, the vast majority of patients (birth to 19 years) develop an antibody response to protect them from infection if they are exposed. However, even one dose will provide some protection.

Vaccine seroconversion in young, healthy adults is[5]:

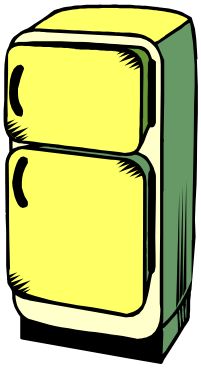
- **50%** after one dose,
- **85%** after two doses and
- greater than **95%** after all three doses.

For most vaccinees, postvaccination titers are not recommended. For specialized employee situations and medical conditions (e.g., immune-compromised persons, HIV positive), postvaccination testing may be indicated (see MMWR November 22, 1991 / 40(RR-13);1-19).

Booster doses of vaccine are not recommended

STORAGE AND HANDLING

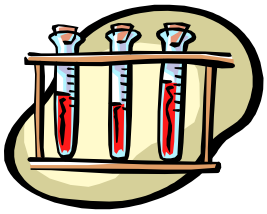
- The vaccine should be stored in the refrigerator at 36°-46° F (2°-8° C).
- **Do not freeze. Discard if vaccine has been frozen**.
- Do not dilute to administer.



Section I-D

PRE-SCREENING

DO CLIENTS NEED TO BE TESTED BEFORE THEY ARE OFFERED THE VACCINE?



The question of whether clients need to be pre-screened for immunity before starting vaccination is an important issue which each site will need to evaluate based on the demographics and risk factors of their patient population and on resource allocation decisions. The question of pre-vaccination screening is primarily related to the high cost of three doses of vaccine ($75 at the federal contract rate to $120+ at commercial prices for the three doses) versus the relatively low cost of screening for infection status ($10-12 core antibody (anti-HBc) test cost).

It is commonly accepted that a patient population would need to have hepatitis B immunity seroprevalence >30% before it becomes more cost-effective to do pre-vaccination testing. An example of populations with such a high immunity seroprevalence would include past or current injection drug users (IDUs) or men who have sex with men (MSM).

If the seroprevalence of your clinic population is unknown, it would be recommended that at least 100-200 clients be tested for hepatitis B core antibody. In almost all STD clinic client populations, HBV immunity should be less than 30% - more likely 15% overall. However, IDUs and MSM groups may be 30-50% immune, and thus, pre-screening could be considered for clients with that profile. Screening a sample of MSM and IDUs may help determine whether pre-screening should be considered for all of these high-risk clients. **(See Screening Protocol, Section VI - Attachments)**

Another consideration is that patients who are at high-risk for HBV infection and are also candidates for pre-screening may not return to the clinic. For this reason, current recommendations for high-risk groups are to **obtain a screening test and administer vaccine dose #1 at first visit and then discontinue further doses if the client is already immune**.

If the decision is made to not screen, clinic staff should understand that persons who are already immune and others who are chronically infected will be receiving vaccine. The vaccine will not harm these patients in any way, but a few chronically infected clients will not learn of their HBsAg+ status nor the prevention measures they and their partner should follow (i.e., vaccination of sex partners and household contacts). Therefore, if financially possible, high-risk clients (MSM and IDU) should be screened to determine immunity status as described and if core-antibody positive, a hepatitis B surface antigen test (HBsAg) should be obtained to determine chronic infection status.

Pre-Screening Guidelines

- Cost effective if overall population has a immunity level >30%
- Screen MSM and IDU clients to determine immunity and chronic infection status
- Give 1st dose of vaccine at time of screening. It may be the only time you see the patient.

GUIDELINES FOR THE ELIMINATION OF HBV INFECTION

In 1991 the CDC Advisory Council on Immunization Practices (ACIP) developed recommendations addressing HBV transmission in all ages. The recommendations included the following:

- Prevention of perinatal HBV infection;
- Routine vaccination of all infants in successive birth cohorts to prevent early childhood, and eventually, adolescent and adult infections;
- Vaccination of high-risk adolescents and adults to prevent infections in persons not vaccinated as infants.

ACIP Vaccination Guidelines for Adolescents and Adults

- History of STD
- Sex partners of chronically infected
- Household contacts of chronically infected
- Hemodialysis
- Clients & staff of institutions for developmentally disabled
- Occupational risk
- All adolescents (11-18 yrs. of age)

www.cdc.gov/nip/publications/ACIP-list.htm

Until now, the primary focus of hepatitis B prevention has been on perinatal HBV infection with routine infant hepatitis B vaccination, the vaccination of health care workers, and subsequently all children 0-18 years of age. Programs focusing on perinatal transmission, infant vaccination and the vaccination of children prior to school admission, have been widely implemented and accepted as standard practice. In most states, "catch-up" vaccination laws have been enacted requiring proof of hepatitis B vaccination prior to admission to seventh grade. In 1991, OSHA passed requirements for HBV vaccination in the occupational setting which has resulted in the near elimination of incident HBV infection in this setting.

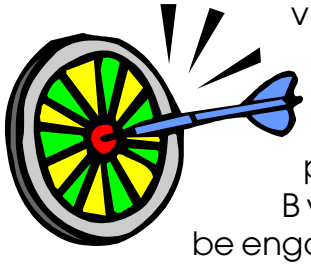
School Entry Requirements

- Kindergarten &/or 1st Grade
  - 42 States
- Middle School
  - 27 States

www.immunize.org
(data from 2001)

TARGET POPULATIONS

New interest in the use of hepatitis B vaccine for adolescents and adults who engage in **high-risk activities** exists today. Efforts to vaccinate these individuals are underway with targeted education and vaccine delivery in settings such as STD clinics, adolescent service sites, drug treatment centers, correctional facilities, family planning programs and HIV/AIDS services. Hepatitis B vaccine should be offered to all individuals who may be engaging in high-risk activities.



High Risk

- Persons who have multiple sexual partners (>1 in 6 months)
- Persons being treated for sexually transmitted diseases or with a history of an STD
- Men who have sex with men
- Persons who inject drugs, and especially those who share needles or other drug "works"
- Sex partners of those with chronic HBV infection
- Household contacts of chronically infected persons

Special At-Risk Populations

- Health care workers and other persons in occupations exposed to blood or blood products
- Clients and staff in institutions for developmentally disabled
- Hemodialysis patients

If you are unable to vaccinate, at least educate

PROGRAM COMPONENTS

THE MOVERS, SHAKERS & DOERS: GETTING BUY-IN

Our STD program wants to offer hepatitis B vaccine. Whom do we need to convince that this is a worthwhile activity?

OUR PATIENTS ARE AT RISK. HOW DO WE GET THIS UP AND RUNNING?

While every public health agency, STD clinic or community clinic is different, there are usually some common organizational features. For example, most health delivery systems have medical and administrative directors. Your particular organization may have an elected board of supervisors or an appointed health officer. Your community may have a very active healthcare coalition comprised of political leaders, healthcare professionals, and consumers.

Whatever the situation, you will need to be familiar with the rules and regulations of your particular organization (or find someone who knows the ropes and is willing to guide you) to assure that you get required approvals and keep everyone appropriately informed. While this may sound removed from the actual task of administering a dose of hepatitis B vaccine, it is absolutely necessary if you hope to add this service and make it part of the standard of care in your organization.

Possible Key Players

- Medical Director
- Administrative Director
- Health Officer
- Board of Supervisors
- Community Healthcare Coalition

WHO SHOULD TAKE THE LEAD?

This will vary from site to site. It may be a collaborative effort between the Chief of the STD Program and the Chief of Immunizations, or it may be a community coalition that initiates the idea of delivering vaccine in the STD clinic and the pursuit of funding for that activity. But there needs to be one individual identified as the lead person to coordinate efforts and keep track of all activities.

Individuals up and down the chain of command need to be kept informed of plans to initiate a new service in the clinic. Whether that requires a face-to-face meeting or merely a memo describing the planned activity will depend on the local organizational and procedural policies. If your activity will involve any collaborations with outside agencies, you need to include representatives from those agencies at every stage and keep lines of communication open.

There are many resources available to assist in all stages of the planning and implementation process. One of the first agencies to approach is the CDC's Division of Viral Hepatitis, Division of STD Prevention, or National Immunization Program. They can provide valuable technical consultation and put you in contact with sites that have successfully implemented hepatitis B vaccination in their STD Clinic or other clinical site. Additionally, your State Department of Health is an essential resource with which you

want to forge a strong alliance. Also, check out the Immunization Action Coalition's new website **to find a list of programs that are up and running**.

www.hepprograms.org

Possible Leaders:

- STD Chief
- Immunization Chief
- Community Leader
- Medical Director

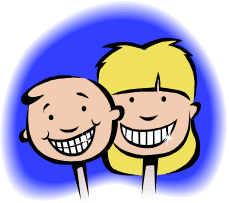
WHO WILL PAY FOR THIS ACTIVITY?

It is unfortunate that the issue of funding raises its ugly head so early in the implementation plan. But anyone with experience in public health knows that until this question can be answered, an organization cannot move forward in pursuing the initiation of vaccine delivery in the STD clinic. Also, the answer to this question may determine who the organization's collaborators will be and how much input they will want into the actual implementation.

The following information addresses only the actual cost of vaccine. It is assumed that you will be using your existing staff. If you plan to hire staff specifically for the delivery and tracking of hepatitis B immunization, additional funding and "approvals" within your organization (including such detail as where the staff will sit and who pays for their paper clips) will be necessary. We have found that existing staff can integrate this service into the clinic routine shortly after gaining familiarity with the procedures.

It's time for a quick course called "Publicly Funded Immunizations 101." There are several public sector sources of funding for vaccines, federal and state, as well as local (city or county).

THE VACCINES FOR CHILDREN (VFC) PROGRAM



The VFC program provides funding for hepatitis B vaccines and other vaccines to a wide range of providers for eligible children/adolescents who are 18 years of age or younger and:

- Medicaid eligible (Medi-Cal and Child Health and Disability Prevention Program (CHDP) eligible in California); or
- Uninsured (do not have health insurance); or
- Are American Indian or Alaska Native

VFC-provided vaccine can also be administered at nonprofit community health centers to children who have health insurance which does not cover vaccines. To become a VFC provider, contact your local immunization program.

AT A MINIMUM:

Under VFC, every STD clinic can offer hepatitis B vaccine to all clients under 19 years of age

http://www.cdc.gov/nip/vfc.htm

FEDERAL 317 GRANT FUNDS

This is the traditional federal funding for public health vaccines, other than VFC; some states may also allocate certain general funds for vaccine purchase. Public health department clinics use this source of funding to vaccinate children who do not qualify for VFC vaccine. In general, these public sector funds are not used for purchase and support of adult vaccination in settings such as an STD Clinic. Childhood immunizations are clearly the priority for these funds.

If you do receive HBV vaccine through VFC or 317, you will need to comply with the accounting and administration rules and regulations of those funds. One important rule is that you cannot charge for the actual dose of vaccine in your clinic, although it is permissible to charge a dose administration fee.

It is worthwhile to contact the state or local health department Immunization Program to pursue the allocation of 317 vaccine funds for adult hepatitis B vaccine. Some limited funds may be designated for a pilot or demonstration project. Even if they are not, it is important to keep in contact with the Immunization Program which can provide excellent technical/legal information and guidance in starting up a new program.

Local public sector agencies, such as a county or city health department may be eligible to obtain vaccines at a reduced cost by accessing the existing federal purchase contract. This is the best vaccine purchase price.

OTHER POTENTIAL FUNDING SOURCES

Local civic organizations or **foundations** may want to support HBV immunizations. Knowing they will receive reports with clearly understood accomplishments, such as number of doses dispensed and number of individuals who completed the vaccine series, may make such a proposal attractive to them. National foundations may also be approached, but you will be competing with significantly higher numbers of proposals. Also, a local funding source allows an inside track and ample opportunities to foster an ongoing relationship.

Possible (Local) Funding Sources:

- Civic Organization
- Foundation
- City or County Government
- HIV Prevention Programs

Your local government entity, whether county or city, may view the cost of hepatitis B vaccine as a necessary expense of running a STD service. If the medical experts and providers in your community view this as a "standard of practice" for high-risk populations, it may be included in the general budget just as is the cost of treating syphilis and gonorrhea.

There may be bulk purchase options available as a governmental agency. If you join or form a coalition of agencies in your state or region, your agency may be eligible for purchase under the federal contract pricing. A portion of the cost of vaccine purchase could be offset by charging a nominal per dose fee within your clinic — a charge of five dollars per dose may not be out of line for most patients, and would certainly help defray costs.

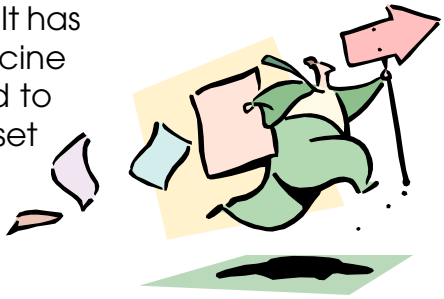
Top Level Buy-in

Vaccine Supply Secured

Creative approaches to supporting adult vaccines are needed. Ultimately, if enough demand is put on federal, state and local funding sources there may be a shift in policy toward public sector support of adult hepatitis B immunization for high-risk individuals. However, this is a long-term goal and until it is achieved, every conceivable funding strategy should be explored.

WHAT'S NEXT?

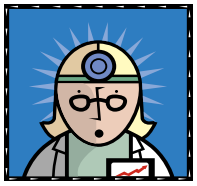
So far, so good. All the Movers and Shakers in the organizational chain think hepatitis B vaccine should be offered in the STD Clinic. Vaccine has been secured for twelve months. It has even been approved that a five dollar vaccine charge (which can be waived) will be added to the fee ordinance and any revenue will be set aside for future vaccine purchase.



While it may seem that most of the challenges have been met, some of the biggest hurdles are just to be overcome, by the Doers!

WHO ARE THE DOERS?

Every site will have its own list but most include:



Clinical Staff
- Doctors
- Nurse Practitioners
- Nurses
- Counselors

Clerical Staff
- Receptionist
- Back Office Support
- Data Entry

Management
- Program Manager
- STD Clinic Manager
- Immunization Manager

Other Departments
- Supply Center
- Immunization Program
- Health Education
- Information Technology

The support and cooperation of these staff members (and maybe some that will be unique to your facility) is necessary to institute hepatitis B vaccination in an existing clinic.

Of course, how these individuals are initially informed of the impending activity will differ by location. Certainly, by the time upper level approval has been gained and a supply of vaccine secured, many of the Doers will have heard about the plan — news travels fast and not always accurately in any large organization.

ONE MORE ACTIVITY

Ideally, mid-level managers and supervisors will have been kept informed of the plan to offer vaccination and will be able to answer the questions and concerns that their staff members raise. A combination of meetings and follow-up written communications is usually an effective way to assure that everyone gets the same information. The follow-up written communication (memos, posters, etc.) is essential to guarantee that everyone is on the same course — it will also be useful documentation in the development of policies and procedures.

Unfortunately, in today's workplace reality of staff reductions and expanding job duties, new activities are often seen as a burden rather than a new opportunity. The frontline clinic staff, both medical and clerical, will be most heavily impacted by this activity and will need to receive a lot of positive reinforcement that this is a worthwhile and important service. As soon as possible, representatives from each group (management, clinical, nursing, clerical etc.) should become involved in working meetings to discuss issues such as:

- Will all patients be offered vaccine, or only a select group?
- Will vaccine be offered every day or only during designated times?
- What paperwork is necessary for this activity? (The answer may depend on who supplies the vaccine, but at least the clinic will need to get some type of informed consent signature).
- Who is responsible for tracking vaccine usage?
- How will tracking be done?
- Can patients just come in for vaccine or does it need to accompany a STD related examination?

The more the staff believes that their input is valued, the easier it will be to implement the program. While not every decision can or should be open to discussion, clinic staff members are very knowledgeable about the problems and barriers that will need to be addressed. Achieving their buy-in (which often begins with the support of one or two key staffers) is essential to successful implementation.

All of these factors lead to the next major topic: identifying and meeting training needs.

Section II-B

THE 4 W'S OF TRAINING: WHO, WHAT, WHY, AND WHEN

All staff – clinicians, nurses, and clerical need training!
And don't forget the patients!
Where do we begin? Who should conduct the trainings?

WHO SHOULD BE TRAINED?

As mentioned in the previous section, key staff should have been kept informed of the intent to offer hepatitis B vaccine in the clinic throughout the initial planning and approval stages. By the time the clinic is ready to focus on training needs, all staff should have attended meetings where information about the importance and relevance of hepatitis B has been presented.

At least two months prior to start-up, communications should be sent to all staff informing them of the implementation date and providing a schedule of training sessions. If the training sessions involve staff from other programs (such as Immunizations, HIV or an outside agency), more lead time may be needed to coordinate everything. Supervisors will need to be involved in determining which staff members attend various training sessions.

If your clinic staff have not administered immunizations for many years, or ever, you may want to include a practicum during which staff members give immunizations under observation to become "certified." It is suggested that the vaccine series be offered to any staff not already immunized (especially the clinic office support staff). This is a way to reinforce staff buy-in, as well as providing them with a tangible personal benefit. It also educates the staff about the vaccination procedures and process; they can now speak to clients with firsthand experience. It provides ready subjects for your physicians and nurses to practice their technique. And, perhaps most importantly, it protects staff who may be engaging in high-risk behaviors but are reluctant to self-identify.

Examples of staff that need to be trained:

- Administrative
- Clinicians (includes part-time physicians)
- Nurses
- Counselors (e.g., HIV)
- Communicable Disease Investigators
- Clerical
- Case Managers
- Outreach Workers

WHAT SHOULD THE TRAINING CONSIST OF?

Materials from training courses offered in San Diego are included in **Section VI, Attachments: Training Materials**. Additionally, sample training materials from CDC can be found on their website.

www.cdc.gov/hepatitis

Not all staff members will need every training component. However, some staff members do need every component, and to have it reviewed many times!

At a minimum, all staff should receive a "Hepatitis A-E 101" training, which covers the basics of symptoms, transmission, risk activities, and disease consequences.

The following are the broad areas which should be covered:

- Hepatitis A, B, C, D & E
- Serology and testing for hepatitis B
- Vaccine issues
- Communicating with patients
- Clinic policies related to HBV vaccination
- Procedures / Forms

WHY IS TRAINING SO IMPORTANT?

The front line staff is instrumental in the success of any vaccination program, and therefore it is critical to ensure that they are properly trained on the subject of hepatitis B.

Many people find it difficult to keep straight the differences between hepatitis A, B, C, D, and E. Providing staff members with a base knowledge of hepatitis will more effectively enable them to answer patient questions on hepatitis. Countless times, patients have stated that they already had hepatitis B but when questioned how they got it the reply is, "I got it from eating bad food". Clearly the patient is confusing hepatitis A with B and the staff needs to be aware of this and be able to communicate to the patient the differences in transmission and possible outcomes.

Providing training on the serology and diagnosis of viral hepatitis is essential for all clinical staff. Clear understanding of the differences among hepatitis A, B and C is imperative. For HBV, it is even more important that medical staff be fluent with explaining acute versus chronic infection to their patients. Administrative and clerical staff do not need to be trained as thoroughly on these issues since a policy should be in place ensuring that patients with these questions will be referred to a medical professional.

Hepatitis is confusing!

Staff members must be able to explain to patients the differences between hepatitis A, B, C, D & E

FORMS, FORMS, FORMS...

The paperwork associated with any new activity always seems to be one of the greatest burdens, but whether a clinic receives federally funded vaccine or buys it directly, accounting for every dose will be required by whomever pays the bills. Informed consents, notations in medical records about administration of vaccine, reasons for a patient declining the vaccine, and appointment reminder slips for the next dose are just a few of the paper trail details involved in delivering one dose of vaccine. Multiply this by 50 or more

patient visits per day and it becomes clear that procedural guidelines, and training about following the guidelines, must be in place prior to commencement of the program.

See Section IV-A, pp. 53 for more detail on forms development. Sample forms from the San Diego Project are also located in **Section VI-Attachments:Forms**.

Paper, paper & more paper

- Informed consent
- Vaccine Information Statement (VIS)
- Notations in medical chart
- Reasons for vaccine decline
- Appointment reminder card
- Immunization record

WHEN SHOULD THE TRAINING TAKE PLACE?

Training schedules will be different for various levels of staff and also depend on the type of training required. The bulk of training should occur in the month just prior to initiation of vaccine delivery. If hands-on training (such as vaccine administration) is involved, this will necessitate longer lead-time.

It is suggested that a training schedule be made available to staff (and supervisors) as early as possible, since lead-time is crucial to pulling staff away from essential duties. Invariably, trainings should be repeated to ensure that all staff members are given an opportunity to attend.

Within the first month of vaccine delivery, discussions on these issues should be held at regular staff meetings, thereby determining if any additional training sessions are needed. Again, this will vary at each site and is dependent on factors such as staff turnover, changes in policies and procedures, and other clinical priorities.

A final word on training…

It never stops!

REFRESHER CLASSES

Day-to-day procedures, seemingly well entrenched in the minds and hearts of all staff, fall by the wayside. It is human nature that familiar activities are often performed on "automatic pilot". Small slips in procedure one day are carried forward to the next day; new staff is trained in less than perfect fashion; and information is miscommunicated, misunderstood and perpetuated.

Regular refresher courses should be planned for all staff members (at least annually). Staff should be given a role in planning and leading the trainings, and the sessions should be challenging and fun. As hepatitis B vaccination is something positive and proactive that the staff is doing for the patients, so should the training sessions be for the staff.

TRAINING RESOURCES

There are a variety of resources available from health departments, universities and community based professionals. Trainings on hepatitis A-E should be available from the following divisions of local health departments:

- Communicable Disease
- Epidemiology
- Health Education
- Public Health Lab
- Immunizations

In the community, trainers can also be found at:

- American Liver Foundation
- Local hospitals and universities
- Vaccine manufacturers

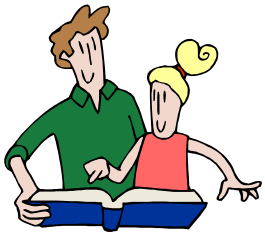
Training Needs

- Annual Trainings
- Involve Staff
- Challenging
- Fun

PATIENT EDUCATION

WHAT THEY NEED TO KNOW:

- What is hepatitis B
- Why they need the vaccine
- The vaccine is safe
- Cost of vaccine



TYPES OF EDUCATIONAL MATERIALS

- Brochures
- Fact Sheets
- Vaccine Information Statement (VIS)
- Videos
- Posters
- Information Counseling

BROCHURES & FACT SHEETS:

There are several free resources for good patient education

- CDC
  - Can be downloaded from website, or
  - Ordered in quantity

- Vaccine Manufacturers
  - Call a local vaccine representative to obtain all the needed materials

- Immunization Action Coalition
  - All materials can be downloaded from their website, modified, and copied in quantity as long as the organization is acknowledged
  - Many materials are in Spanish & other languages
  - Materials for high-risk populations
    - Sexually active adults
    - MSM
    - Asian/Pacific Islander communities

    www.immunize.org

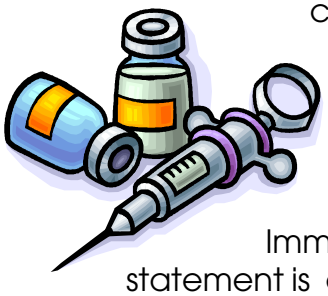
CREATE YOUR OWN

If you are developing your own materials it is a good idea to test the information in a focus group setting. Obtaining feed back from the targeted population is the best way to ensure that the appropriate information is being communicated.

The reading level of your clients and language needs are important considerations when developing educational materials. Health educators are trained to understand these issues and are a great resource.

VACCINE INFORMATION STATEMENT (VIS)

All patients must read a VIS statement when receiving federally purchased vaccine. The statements are mainly designed for childhood vaccination; nevertheless, they provide all pertinent information on the vaccine, including possible side effects.



VIS statements are available through local immunization programs, the CDC, or from the Immunization Action Coalition website. The hepatitis B statement is available in Spanish and many other languages.

VIDEOS

Hepatitis B and C prevention videos that target adults are limited. The majority of available videos are directed towards adolescents and children. The videos are short (<10 min.), upbeat, and catchy. There is a charge (approximately $30) for each video .

- **"The Silent Killer"** (9 min.) Hepatitis prevention for adults. Hepatitis Foundation International www.hepfi.org

- **"Get The Facts, Then Get The Vax!"** For Teens (6 min.) Immunization Action Coalition www.immunize.org

- **"Respect Yourself - Protect Yourself: Teens talk to teens about liver wellness, substance abuse & hepatitis prevention"** (9 min.) Hepatitis Foundation International www.hepfi.org

POSTERS

Vaccine manufacturers have hepatitis B posters, or you can make your own. (**See sample, Section VI-Attachments, Patient Education Materials)** Posters work well in waiting rooms where patients may not read literature that has been handed to them.

INFORMATION COUNSELING

The best type of patient education is one-on-one counseling. Patients respond better to having a service recommended by a health care professional, rather than merely reading about something they "should do." Employing an information counselor specifically for hepatitis B may not be feasible for most clinics, but the counselor can be utilized for other services as well.

- HIV counselors can be cross-trained to discuss hepatitis A and B vaccination

- STD counselors can also discuss vaccination services
  *See **Section IV-D, pp. 63** for more detail on the information counseling done in San Diego.*

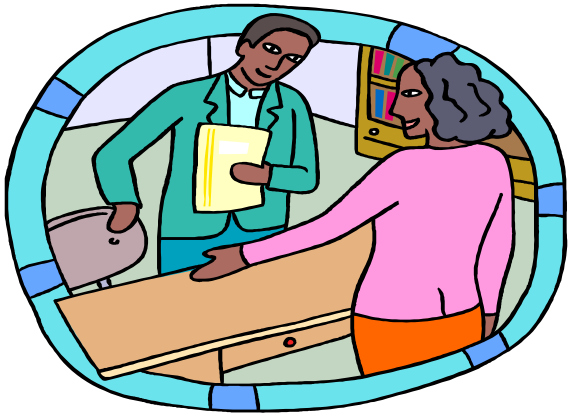
- Family planning counselors should discuss STD prevention, including hepatitis B vaccination, during patient education sessions.

- Clinic nursing staff, clinicians, and others can offer patients vaccination, and if the patients have questions, staff members can give them 20-30 second messages on why they should get vaccinated now.

- Create an atmosphere in which every individual in the clinic who has contact with the clients brings up the issue of HBV vaccine. Many clients will initially think they don't want the vaccine, but will change their minds as they learn more about the benefits and safety of the vaccine.

    - In San Diego, 40% of those who started the vaccination series originally noted on their risk assessment form "no" or "not sure" when first asked if they wanted the vaccine.

- If you are offering the vaccine at no or low fee, mention the actual cost of the vaccine. Placing a dollar value on the service often makes it more appealing to the clients.



The vaccine message:
It's safe and protects against a potentially fatal disease

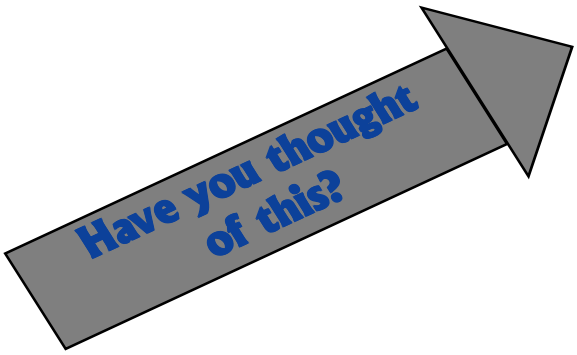
IMPLEMENTATION

POLICIES AND PROCEDURES

The policies and protocols should be written and made available to all staff before administering the first dose of hepatitis B vaccine. Depending on the standard practices of the particular agency, these may need to be reviewed and signed off by administrators within the organization. Or, they may be something that only the clinic medical director needs to review.

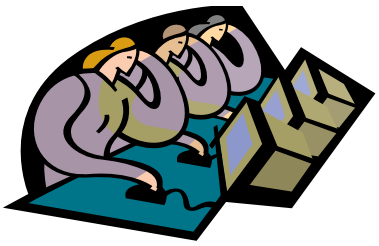
Who is responsible for writing them will also vary with each site — it may be the clinic manager, the Chief of the STD Program, a staff nurse, or it may be a group activity accomplished during working meetings. Depending on the policies and procedures already in place within the clinic, the addition of hepatitis B vaccination may require only simple amendments to certain sections of the document, or it may require a comprehensive component addressing all aspects of immunization practices.

There are a number of issues which will need to be included in your policies and procedures, including:



- Will pre-vaccination testing for prior infection be performed before the first dose is administered?
- Will documentation of prior vaccination (either complete series or doses received to date) be required?
- Will HBV vaccine be offered to all clients, to "high risk" persons, or just adolescents?

TRACKING



How do we keep track of patients? How do we get them to return for their next dose? The answer to these questions is dependent on many factors unique to each site. Issues such as staff resources, level of computerization in the clinic, appointments versus walk-in service, and philosophy toward client responsibility will play into how these issues are resolved. Following are some key considerations.

STAFF RESOURCES:

Ideally, the clinic will have clerical/support staff to mail or telephone reminder messages. If mail reminders are used, have the patients address their own postcards when they receive the previous dose; these could be kept in a "tickler box" by date of return and dropped in the mail at the appropriate time.

With a typical STD clinic patient population, many mailings will be returned for incorrect address. Additionally, phone calls will yield an abundance of "disconnected" or "wrong number" results. How far staff is instructed to go in pursuing more updated information from the patient will be an individual clinic decision.

KEY MESSAGES

- "It's never too late to get your 2nd or 3rd dose of vaccine."
- "Power to the Patient"
- "You need all 3 doses to be fully protected"

An even easier technique is to give patients an appointment reminder card at the time they receive each dose. This method puts the responsibility for remembering on the client — which may be congruent with a "take charge of your health" philosophy espoused at some clinics. The return appointment card should clearly state that if the patients misses their "appointment," they can still get the next dose at a later date. Many patients believe that it is "too late to continue the vaccine series" if they have missed their return appointment.

IT'S NEVER TOO LATE TO GET THE NEXT DOSE!

It is vital that the clinic staff emphasize the importance of receiving all three doses of vaccine to ensure full protection. This message should be stated several times during each clinic visit. Posters on the wall and a similar message on the "next appointment" card will reinforce this fact. However, keep in mind that one dose is better than none and still provides some level of protection.

Client Sensitivity:

- Keep in mind the sensitive nature of the client visit
- Don't use **STD Clinic** for return address or when leaving a phone message

COMPUTERS & OTHER TECHNOLOGICAL ADVANCES:

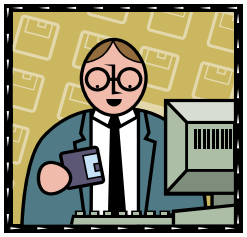
If the clinic has a computerized patient registry and management systems in place, it will be quite easy to generate lists of patients who are due or overdue for doses 2 or 3. The computer program may also be able to generate a personalized reminder letter. Staff resources will again need to be addressed, as state-of-the-art systems require some allocation of staff to extract the list or write the program which will produce letters.

Today, automated telephone call generating systems are available. If the clinic has access to such a system, calls can be made to remind clients of their next dose appointment or that they missed their appointment.

COMPUTERIZED TRACKING SYSTEMS

- **State Immunization Registry**

Many states now have an immunization registry used to keep track of childhood vaccinations. If your county or city uses this system it may be possible to use it for tracking adult vaccinations. Most systems can run reports on doses given and patients that are overdue for the next dose.



- **VacTrac**

This program was designed by Glaxo SmithKline Pharmaceuticals and is free. It is worth a try, particularly in a clinic that does not have another tracking system. The program has report generating capabilities that include:

- Doses given
- Overdue patients
- Letter writing

WE'RE ALL ADULTS:

AKA – Do Nothing

The assumption is made that clients need to be responsible for their own health. Therefore, beyond any reminders (written or verbal) given at the last visit, the clinic staff takes no further action. The experience in pilot projects shows that at least 50% of clients will come back on their own for dose #2 and 25% for dose #3. **Others will be vaccinated for dose 2 or 3 when they return for a new STD event many months or even years later**.

Remember, there is no maximum time period between doses.

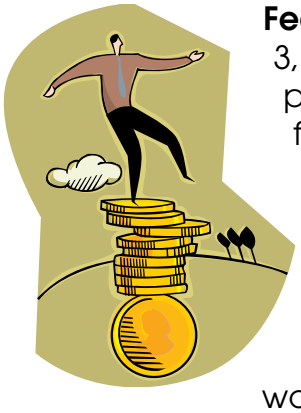
MISSED OPPORTUNITIES:

Whatever strategy is utilized for increasing vaccine series completion, one thing to be avoided is "missed opportunities." This is a term used frequently in childhood immunization coverage studies: the patient was in the office/clinic, was due or overdue for a vaccination and walked out without it! This is really a staff training issue — all clinical staff should receive constant reinforcement to review and note every patient's vaccination status.

Tips on AVOIDING Missed Opportunities:

- Put "consent form" in easily viewed location of chart to remind clinician to check vaccination status
- Add a hepatitis B check off box to your list of services available to patient
- Flag charts with a specific color for patients who have started the vaccine series

HANDLING PATIENT FLOW



Feast or famine — one day no patients are returning for doses 2 and 3, while the next day the line is out the door with "vaccine only" patients and two of your nurses are out with the flu. If there was a foolproof solution to this problem, the world would be beating a path to our door. Here are some less than foolproof suggestions.

Hours/Days: If the available nursing staff is adequate, the clinic might establish "immunization days or hours" — that is, certain times that a nurse is dedicated to giving doses 2 and 3 only; clients would be instructed to return at those times if they only need vaccine (no other STD services would be available at that time.) Each clinic knows its usual patient load and can best direct dose 2 and 3 patients to the clinic's less busy times. Giving dose 2 or 3 usually only takes five minutes once the client arrives at the nursing station.

Extended hours: Clinic hours can be extended to evenings or Saturdays, and strictly for vaccinations. This will relieve the burden during regular clinic hours.

Nursing staff: If there is additional funding to enhance staffing for this activity, the ideal use would be for an immunization nurse or licensed vocational nurse (the least costly staff permitted to give immunizations). This individual may also be able to assist with callback activities and paperwork related to hepatitis B vaccination.

FREQUENTLY ASKED QUESTIONS:

- **My patient said he received two doses of vaccine three years ago, do they still count?**

The series never has to be started over!

If the patient truly received two doses of hepatitis B vaccine three years ago, it would be appropriate to give him/her the third dose and consider the series complete.

According to medical guidelines there is no need to start the vaccine series again, regardless of how much time has elapsed between doses.

- **Do we need documentation?**

The real issue here is your clinic's policy on accepting the patient's statement if they have no documentation. It may be that the patient's verbal history would be accepted if they could give a reasonable history such as why they had the shots and approximately how long ago. From this history, it should be clear whether or not the patient is confusing hepatitis A vaccine and hepatitis B vaccine. Some clinics may decide that they would want more substantial evidence of previous doses (e.g., a vaccine record) and err on the side of giving an extra dose.

Hepatitis B vaccine is given to some members of the military but it is not a routine vaccination.

- **People who don't want a STD exam have heard they can get hepatitis B vaccine at the STD clinic; how do we handle that situation?**

  Word will soon get out in the community that hepatitis B vaccine is available at no cost (or low cost) at the STD clinic. Clinic policy should be clearly in place from day one as to how to handle this situation. It may be necessary to institute an inflexible rule that only clients receiving an STD examination are eligible for the vaccine. To avoid public relations problems and irate clientele, *all* staff must adhere to this policy and state the rule to every walk-in or telephone inquiry. It would be advisable to post this policy in the STD waiting room where all existing and future clients can read it.

  It also needs to be clarified as to what comprises a "STD exam" at the clinic. At the minimum, the clinic may require completion of a sexual history questionnaire and a urine specimen for chlamydia and gonorrhea screening.

- **OH NO! We gave dose #2 only 14 days after dose #1. What do we do now?**

  This can happen in any clinic. The clinic's medical director should establish procedures to be followed in such instances.

  Since the vaccine has not been tested and proven effective for such a short interval, it is recommended that the dose given too early be ignored. Act as if it never happened and put the patient back on the correct schedule. The patient must be informed of the error and instructed to return for the remaining doses on the original schedule.

If the dose has been given too early…

Is it a training issue?

What will the clinic do to ensure this doesn't happen again?

It is trickier when the case is that the early dose is #3 and it was only 14 days early. While some medical providers believe that the dose's effectiveness will not be impacted by being administered two weeks early, the efficacy of the dose is as yet unknown. The safest route is to inform the patient and offer him or her another dose #3 at the correct interval.

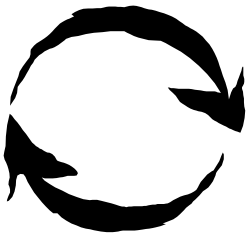
- **Do we need parental consent for patients under 18 years old?**

Most states have a law that allows minors to consent for STD services. However, whether hepatitis B vaccine is considered a "STD service" is interpreted differently by everyone. Most jurisdictions consider hepatitis B vaccine as STD treatment, but to determine if minors require parental consent, check with the local authority.

Remember:

Every dose of hepatitis B vaccine given to an adult or child requires a signed informed consent that they were given the VIS statment.

ONCE THE PROTOCOL IS WRITTEN, IS THAT THE END OF IT?



The clinic protocol should be an ever-evolving document. New situations arise that need to be addressed, policies change and staff members leave. Even if none of these changes occur, the protocol should be reviewed at least once per year. Also, staff should be required to attend training or reacquaint themselves with the protocol annually, to ensure that staff members are actually following protocols correctly. Often, policies are not followed as written, so it is important to monitor practice versus policy regularly. Frequently, practices that deviate from policy prove to be a better way to do things; when this happens, the policy should be updated accordingly.

While it is hoped that no adverse event ever occurs in a clinic, the reality is that clinic protocol is a document which should accurately reflect procedures and staff responsibilities. Should an adverse event occur the protocols become important legal documents. Staff members should be encouraged to refer to the protocol in unusual situations or whenever an issue arises.

The following section, "The San Diego Experience", will illustrate how hepatitis B immunization was successfully integrated into a well-established STD Clinical Service. Examples of data collection tools, health education materials, and training materials are included for your reference and use.

CASE STUDY

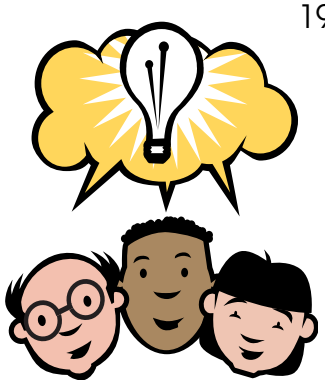
HEPATITIS B IMMUNIZATION IN A STD CLINIC

THE SAN DIEGO EXPERIENCE

Section III-A

SETTING THE STAGE

INTRODUCTION



The San Diego High-Risk Hepatitis B Demonstration Project began in October 1997 when a Project Coordinator was hired. Over the next 3-4 months, an Assistant Coordinator/Health Educator joined the project. The project was organizationally located in the STD Control Program, Office of Public Health, Health and Human Services Agency, County of San Diego, under the overall direction of the STD Control Officer. Health education materials and protocols were developed, a vaccine supply was secured, and staff education meetings were conducted. Community sites, both clinical and non-clinical, were approached and offered an opportunity to participate. Considerable effort was expended to document procedures, cost, and human activities focusing on how this program was implemented and would function as a routine, integrated service in a clinic providing STD services. On February 11, 1998, vaccination began in the Health Department's main STD clinic.

This next section will provide a detailed account of how a hepatitis B vaccination program was integrated into a busy STD clinic.

Section III-B

SAN DIEGO: THE FACTS

SAN DIEGO DEMOGRAPHICS

San Diego County is a large metropolitan county with a population of 2.9 million.

- 62% White
- 22% Hispanic
- 8% Asian
- 6% African-American
- 2% other races/ethnicities

San Diego County encompasses a variety of communities: inner-city, large areas of suburban housing, and many rural communities. An area in central and southeast San Diego has been identified as a high-risk STD area (a 10 contiguous zip code area) with approximately 485,000 persons. The population residing in this area is

- 39% White
- 29% Hispanic
- 18% African-American
- 14% other races/ethnicities

Many of the high-risk persons who would be candidates for hepatitis B vaccination live in this geographical area.

HEPATITIS B INFECTION IN SAN DIEGO

In San Diego County, viral hepatitis is a common infection. Every year approximately 1,000 newly identified persons with chronic hepatitis B are reported (1,071 in 2000). To estimate the characteristics of those persons, the San Diego Hepatitis Project did a survey of providers who reported

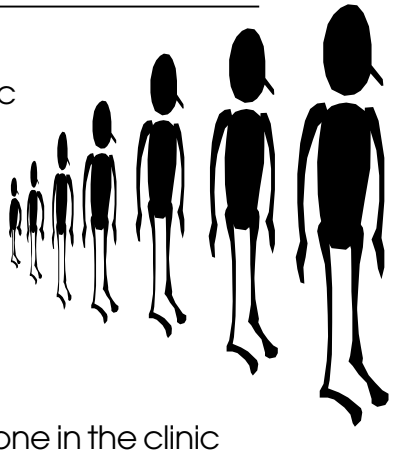
chronic hepatitis B during a two-month period (Aug. – Sept. 1997, N=114); 46% of cases were Asian or Pacific Islanders and among all persons reported in the survey, 25% were MSM and 7% were IDUs.

Acute hepatitis B has been declining from the 150-180 range since the early 1990's (151 cases/year; 5.8 per 100,000/yr., 1990-93) to <50 cases per year (42 cases/year; 1.5 per 100,000/yr., 1994-2000). In 1999-2000, the San Diego Hepatitis Project interviewed 64 (85%) of 75 reported acute cases of hepatitis B.

- 33% were MSM,
- 9% were IDUs, and
- 34% had >1 sex partners in the past 6 months.

A limited serologic survey was also conducted with 300 consecutive clients in the STD clinic. This was done at the initiation of the hepatitis B vaccine service, and showed an overall past infection prevalence of 15% (anti-HBc) and a chronic infection rate of 1% (HBsAg). Past infection was more common in IDUs (50%) and MSM (37%). However, these estimates were based on small numbers of clients.

STD CLINIC POPULATION



In order to obtain an accurate picture of the clinic population, a risk assessment form was developed to capture demographics, STD history, risk behavior, and specific hepatitis B and C risk factors. This data was compiled for an in depth project evaluation, but the data is also important for routine program monitoring and identification of high-risk clients needing special services.

This risk assessment information collection was done in the clinic as a routine part of clinic registration but it could be a designated special activity during selected periods (e.g., one month per year or two weeks each quarter, etc.). However, vaccination services could be successfully delivered without collecting or computerizing any additional hepatitis information.

The following STD patient profile was derived from a patient questionnaire completed by every patient at time of clinic registration in San Diego. A copy of the most recent patient risk assessment form is included in **Section VI-Attachments: Forms**.

CLINIC DEMOGRAPHICS:

SEX:	MALE	67%	FEMALE	33%
RACE/ETH:	WHITE	44%	ASIAN	4%
	BLACK	20%	OTHER	6%
	HISPANIC	26%		
AGE GROUPS:	12-18 YRS.	6%	30-44 YRS.	37%
	19-24 YRS.	23%	45+ YRS.	11%
	25-29 YRS.	23%		

SELF-REPORTED RISK BEHAVIORS:

IDU:	MALES	6%	MSM:	13%
	FEMALES	6%		
>25 LIFETIME SEX PARTNERS:	MALES	37%	FEMALES	16%
HEPATITIS B PREVALENCE:	Overall		15% resolved/immune 1% (chronic HBV)	
	IDU		50% resolved/immune	
	MSM		37% resolved/immune	

A profile of the clinic population is very helpful for program planning and resource allocation, as these are both important elements for implementing hepatitis B vaccine delivery in a STD Clinic.

The first risk assessment form consisted of a list of questions asked by the nurse. However, because the questions asked more than the clinician actually needed to know for treatment purposes, the form was changed to a self-administered format. If the questions are just basic risk questions that relate to the patient visit, it would be reasonable to have the clinician asking the questions.

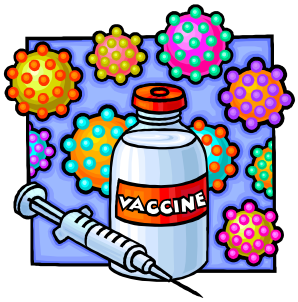
STD Clinical Services operates clinics at four physical sites (a main clinic with 3 satellite clinics). The centrally located main clinic site is open 5 days per week and provides 73% of the total annual STD clinic visits. Overall, about 15,000 patient visits are recorded each year; 60% of these visits are for a new STD problem and the remainder are for ongoing treatment, follow-up and vaccination.

Section III-C

THE VACCINE

SAN DIEGO'S POLICY

For this project, adult and pediatric Merck & Co. as well as Glaxo SmithKline vaccine were available through the State Immunization Program supplies (provided by the CDC National Immunization Program). When adult formula vaccine supplies were not readily available, the San Diego Hepatitis Project sometimes used 2 Merck pediatric doses (if vaccine were being purchased, this approach could save approximately $8 per dose). Immunization program staff members stored the vaccine in clinic refrigerators and distributed as needed to participating sites. The STD clinic completed the standard vaccine usage-by-dose aggregate quarterly reports. These reports provide a satisfactory estimate of vaccine acceptance and completion rates for doses two and three. Vaccine software would be more accurate, but requires data entry. The advantage of such software is that it can produce overdue lists, reminder letters, etc. Some of these software products are listed below, although the project has not evaluated them in depth.



- VacTrac by Glaxo SmithKline
- AKC (All Kids Count) Immunization Registry - County of San Diego Immunization Registry

Dosage Schedule

The San Diego STD Clinics follow the minimum time schedule of 0,1, and 4 months for vaccine delivery.

- Dose 1 = 0 days
- Dose 2 = 28 days (1 month or 4 weeks) after dose 1
- Dose 3 = 112 days (4 months or 16 weeks) after dose 1 and at least 56 days (2 months or 8 weeks) after dose 2

Return Doses

Return vaccine patients are fast-tracked through the clinic so that they do not have a long wait and are thus not discouraged from returning again. This can be used as a selling point, advising patients on their first visit that they will not be required to wait long to receive their next dose.

Section III-D

PRE-SCREENING

BASELINE TESTING

HEPATITIS B CORE ANTIBODY TESTING

- **Why test all the patients coming to the clinic?**

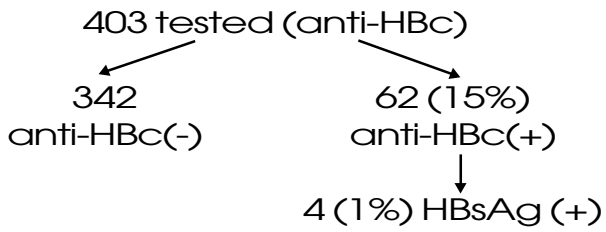
For a limited time period, all patients were tested in order to establish baseline hepatitis B seroprevalence in the STD Clinic patient population.

A baseline sample of serologic testing was conducted for one month prior to the initiation of vaccine delivery. All STD clinic patients having a routine blood draw were offered testing for hepatitis B core antibody (anti-HBc). All specimens testing positive for core antibody were subsequently tested for surface antigen (HBsAg).

Each individual testing positive was notified of his or her test results, in one or more of the following manners:

- Revisited the STD clinic for results or follow-up treatment
- A letter was mailed to patient's last known address.
  - Of 58 letters mailed, 15 (25%) were returned as undeliverable.

Results of baseline testing:

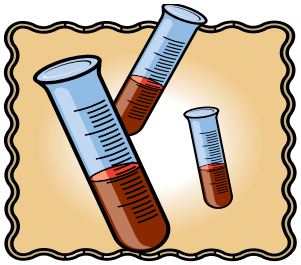


After the baseline testing was completed, testing was offered only to high-risk groups:

- MSM
- IDU
- Sex partner of an IDU
- Sex partner of chronic HBV-infected person (carrier)

All high-risk persons were offered the first dose of the vaccine at the initial visit.

The detailed Clinic Protocol for this baseline testing can be found in **Section VI-Attachments: Forms.**



Section IV-A

PROGRAM COMPONENTS

GETTING BUY-IN

How it Actually Came About

The STD Program and Immunization Program Chiefs discovered, through a series of informal hallway conversations and at Program Manager meetings, that they shared a common vision to expand the scope of their prospective programs. For the STD Program, this meant offering a new prevention service (vaccination) to enhance the standard prevention techniques of education and counseling; for the Immunization Program, it meant expanding the concept of immunization from the traditional infant/child focus to immunization throughout the life span.

In a collaborative effort the STD and Immunization Program Chiefs wrote a proposal describing the service and submitted it to funding sources. Through several months of telephone conversations, e-mails, and written communications, the various agencies involved in supporting this innovative endeavor (Hepatitis Division, NIP, CDC; California State Department of Health Immunization Branch; and County of San Diego Office of Public Health) set in motion the funding and vaccine supply mechanisms.

Then commenced the real challenges: how to establish the frontline staff, specifically who would actually implement the service, and how to support the offering of hepatitis B vaccination as part of standard STD Clinic service. Major concerns and misconceptions included:

1. Nurse and clinician staff concerns that this new service would detract from the primary mission of diagnosing and treating STDs
2. Hepatitis B is not really a STD
3. Patients with STD symptoms would be turned away unless an "immunization nurse" was hired to handle this additional work load

4. The clinic would be reduced to an immunization clinic
5. Clerical staff concerns that additional paperwork would overburden them along with the increased patient load

How were these concerns addressed?

1. Involving staff in meetings/discussions about the addition of hepatitis B vaccination to the STD Clinic service
2. Staff training
3. Development and pilot testing of paperwork and procedures
4. Listening to the ideas and concerns of the clinic staff and responding to them
5. Review and redesign of paperwork and procedures to incorporate the suggestions of staff

Implementation activities included:

1. Designated a Project Coordinator to assume the lead
2. Held meetings with frontline staff to introduce the proposal and invite input from the clinic staff
3. Provided formal staff training about hepatitis B
4. Introduced forms and protocols to be used
5. Pilot tested the forms and protocols
6. Reviewed effectiveness of forms and protocols with staff to address problems and deficiencies
7. Incorporated changes into forms and protocols
8. Identified/designed patient education materials

Outcome

Once staff members realized that a vaccination service could be incorporated into the routine without a substantial increase in work and that the clients wanted and needed the service, hepatitis B vaccination became routine. The staff knew that patients had no place else to get vaccinated and they rose to the occasion. The staff realized that hepatitis B vaccination and other hepatitis services offered to STD clinic clients is GOOD PUBLIC HEALTH.

FORMS DEVELOPMENT

This is a crucial component in getting the vaccination program up and running. Forms will be used as a data collection tool and, eventually will end up in a database for program analysis. Involving key staff from the beginning of the forms development process will save a great deal of time in the future, with less need for time and resource consuming revisions.

The main forms used in the San Diego Hepatitis Project:

- **Consent Form**

- All patients receiving hepatitis B vaccine must sign a separate consent form documenting that they have read the Vaccine Information Statement (VIS).
- Based on a modified version of the childhood vaccination consent form (**Section VI - Attachments: Forms**)
- The clinic may already have a general consent form that will cover the vaccine

- **Risk Assessment**

- This form was designed to learn more about the risk factors of both patients who accepted and those who declined the vaccine. (**Section VI - Attachments: Forms**)
- The clinician could easily look over the form as a tool for learning about the high-risk activities of the patient.
- Another option, which has not been evaluated, is to design the risk assessment as an educational tool for the patient, (e.g., if the patient answered "Yes" to any of the above questions, that patient should receive the hepatitis B vaccine).

- **Tracking Form**

  - The risk assessment form was entered into a database for later analysis, thus enabling identification of those who were due for their next dose and those who were overdue.

  - If the clinic is not collecting risk behavior information, there should be a simple form to keep track of patients who are due for their next dose.

  - At the minimum, a manual tickler system could be set up, which holds patients' next dose cards filed in order of due date.

  - Lastly, all tracking systems could be omitted, and simply wait for the patient to return. Many patients will return on their own for STD reasons, as well as for the vaccine.

All forms and instuctions used in the San Diego Project are found in Section VI - Attachments, behind the Forms tab.

DATA BASE DESIGN

As discussed in Section II-D, collection of specific vaccination delivery data will vary from program to program. In San Diego, a self-administered risk assessment form was developed for the collection of information to answer the following questions:

1. Who is accepting the vaccine?
2. What are the characteristics (demographics and risk behaviors) of those who accept vaccination?
3. What are the characteristics (as above) of those who decline the vaccine?
4. Why are those who decline doing so?
5. How many patients have returned for doses 2 and 3?

Once the risk assessment questionnaire was developed and field tested, an Epi Info (version 6) database was designed. The database mirrored

the risk assessment form, for ease of data entry. **Epi Info is a database program designed by the CDC**. It is free of charge and can be downloaded from the following website: **www.cdc.gov/epiinfo**.

In San Diego, the risk assessment form has been revised several times as the program evolved (most recent version found in **Section VI - Attachments: Forms**). Questions were added to address newly identified issues and those that were not providing useful information were deleted. After 3 years, the form is still being revised to answer additional questions. Each revision of the risk assessment questionnaire necessitates a data base revision as well. Following are the key points learned from three years of revisions.

Key Points

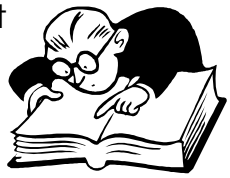
Pilot Test

It is critical to pilot the questionnaire with the individuals who are going to fill it out. Be sure that the target population understands what each question means and that they are answering it appropriately.

After any questionnaire modification, the data collected should be **reviewed within 30 days to determine its usefulness**. If the questions are not being answered or there are inconsistencies in how they are being answered, it is important to correct these problems at the start.

Data Dictionary

A data dictionary (data key) is a guide to the definitions of every variable in a database and to the characteristics of the variable, e.g., numerical, text, or date. Do this at the time of creating the database. Inevitably, there will be several different people working with the database, so a good data key will ensure that each individual understands the different variables.



Record Changes

Each time a change is made, be sure to keep a record of when and why the change was made. This is especially important when deleting or adding a variable or question. If this issue is not considered during analysis, it may appear that a number of questions were not answered (when in fact the question was not even asked). The best place to record these changes is in the data key.

Keep It Simple

Be sure all the needed information is being collected, but by keeping the database and questionnaire simple, later problems can be avoided.

Unique Identifier

Every person who fills out the patient questionnaire should have a unique identifier (i.e., clinic ID number). Once the patients are in the database, this will be the easiest way to look them up again rather than using name and date of birth.

Common Variables

If the database will be linked with another in the future (e.g., lab, clinic), be sure to use the same variable names, or the database will be incomplete. For instance, if one database uses "date of birth" and the other uses "age," the information cannot be merged. Of course, the same unique identifier must be used for each patient in any databases the clinic joins.

Dates

Examining data for various time periods is always important. For example, in the month following a clinic's new evening hours of operation were fewer or more clients served? Were more dose 2 and 3 vaccinations delivered?

Each time a risk assessment form is completed, **a date of visit should be recorded**. Dates of testing and vaccination are also important data entries.

Missing Data

If the patient did not answer a question, is that a blank because they accidentally skipped the question or because it doesn't apply to them? It can be left blank, but another option is to assign all missing data a certain number, such as 9, so that it can be determined to be a blank and not a data entry error. Whatever the clinic decides to do, it should be consistent.

Back Up Data

Be sure to back up the data daily, to prevent loss.

Repeat Patients

What should be done about a patient who fills out the questionnaire several times? Should the database be updated with each new form? Using the initial data may be the best option. However, if a patient originally declined the vaccine and subsequently decides to accept, then risk assessment data from the vaccine acceptance visit should be entered.

Data Cleaning

This is a time consuming and never-ending job, but a crucial one. Establish a schedule to clean data (i.e., monthly, quarterly, etc.). One person should be assigned responsibility for this, because using a different person each time will create inconsistencies.

Anticipate Problems

Anticipating problems will streamline the data cleaning. Try to foresee what the issues will be for the data entry staff and create an algorithm of how to handle them. For example, if certain key variables are missing, data entry might set the form aside until this information is added.

Check File

A check file sets limits or parameters for data entry and will not allow entry of data not meeting those parameters, e.g., age <12 years in an STD clinic. Incorporating a check file into the database will decrease data entry errors.

TRAINING

WHERE TRAINERS WERE FOUND:

- **EIS Officer**
  - The San Diego STD and Hepatitis Services Program employed an EIS (Epidemic Intelligence Service) officer for several years. An EIS officer is usually a physician or other doctoral health professional assigned by the CDC to work at the local or state level for two years. The EIS officers stationed with the San Diego Hepatitis Project have been eager to help with staff training issues.

- **Local Immunization Program Staff**
  - These are the immunization experts. Call on them for guidance and training assistance.

- **American Liver Foundation**
  - The local chapter of the American Liver Foundation has been able to refer numerous experts on the subject of hepatitis.

- **Vaccine Manufacturers**
  - Vaccine manufacturers and other pharmaceutical companies can refer hepatologists and others to lead trainings. Some have health educators on staff who will provide training sessions.

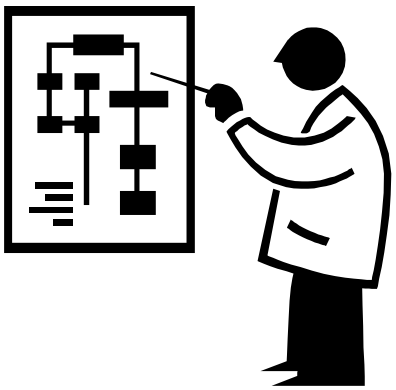
Hepatitis B
Get Vaccinated!!

TRAINING TOPICS

Materials from training offered in San Diego are included in **Section VI - Attachments: Training Materials**. Not all staff members need every component, while some staff members need every component and to have it reviewed many times.

Training for our Clinical Staff

The Project's EIS officer conducted the initial clinical staff training covering the following topics:



Hepatitis A-E

- Transmission
- Prevention
- Complications

Serology and Testing for Hepatitis B

- When to test
- Interpretation of tests
- Case reviews

Information updates are ideally held on a biannual basis to keep current staff up to date and on track with the project goals, in addition to training any new staff members who join the program. Additionally, during monthly clinic staff meetings a hepatitis staff member is present to answer any questions .

Training for Clinic Support Staff and Counselors

Ideally, a physician or nurse should conduct this training, as these providers are most likely to fully understand the serology of hepatitis B. However, if the group only needs the basics of hepatitis, a health educator should be capable of conducting the training.

Topics to be covered include the same as for clinical staff, plus:

- **Communicating with patients**
  - Basic facts of hepatitis A, B and C
  - FAQs (Frequently Asked Questions)

- **Procedures / Forms**
  - Any new forms added

Non-clinical staff need clear guidelines regarding the parameters of their expertise. They should know their own limits in answering patients' questions and know when the patient should be referred to a clinical staff member.

PATIENT EDUCATION

The various options of patient education materials were explained in **Section II-C, pp. 31-34**.

In the San Diego Hepatitis Project, a fact sheet and a poster were used for the main patient education (see samples, **Section VI - Attachments: Patient Education Materials**).

- **Fact Sheet**

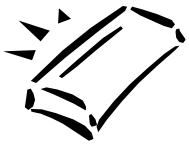
The Fact Sheet has been through several changes based on one-to-one interviews conducted with clients in the STD Clinic. This feedback from the target population was important to ensure that the right message was being conveyed. A few changes were also made based on feedback from the staff, who reported that they were getting the same questions repeatedly from patients. Therefore, more information was added to the fact sheet, thus decreasing the repetition of questions.

- **Poster**

The poster that was developed is a larger version of the fact sheet. However, it was enlarged to a size that is very difficult for patients sitting in the waiting room to ignore.

- **Videos**

The San Diego STD Clinic does not use patient education videos in the waiting room. The main reason for this is that patients seem to be less restless during a long wait if they can watch something entertaining, such as a movie. However, a listing of available educational videos can be found in **Section II-C, pp. 33**.



IMPLEMENTATION

Vaccine was first offered in the central San Diego STD Clinic beginning February 11, 1998. It was offered to all patients who had not been previously vaccinated with hepatitis B vaccine or who had not been previously infected with hepatitis B.

CLINIC & PATIENT FLOW

1. Patients received a fact sheet on HBV infection and were offered hepatitis B vaccine free of charge.

2. Patients were asked to complete a risk assessment questionnaire to determine their eligibility for vaccination and to identify potential risk factors for hepatitis B transmission. This risk assessment form specifically asked the patient if he or she wanted to start the vaccine series today.

   The questionnaire collects information on:
   - demographics
   - sexual behavior history
   - STD history
   - IDU history
   - interest in receiving the vaccine
   - reasons for declining vaccination

   Patients considered eligible for vaccination were those who reported no previous vaccination for hepatitis B or no previous infection with hepatitis B. Vaccine was administered on a 0, 1, and 4 month schedule.

3. Informed consent was obtained from all patients as required for federally funded vaccines; patients were given a copy of the Vaccine Information Statement each time they received a dose.

4. Nurses completed a simple "Dose2/3" form when patients returned for subsequent doses indicating the dose received and the date administered.

5. At the time of the 3rd dose, all clients who were under age 20 or high-risk (commercial sex workers, MSM, IDU, HIV+ and history of bacterial STD in past 5 years) were screened for chlamydia and gonorrhea using urine-based amplification testing.

INFORMATION COUNSELING

Review of patient acceptance of vaccine data after one year of vaccine implementation showed that 70% of eligible patients were accepting the vaccine. While a 70% rate of acceptance was comparable with, or even a bit higher, than that reported from similar experience in other STD clinics, there was strong interest in trying to improve this rate of acceptance, especially among high-risk clients (MSM, IDU, clients with multiple sex partners). Drawing on experience from HIV "information only" counseling instituted during the beginning of HIV testing (1987-1990), a five to seven minute HBV and vaccination message was developed.

The intent of this "preclinical" one-to-one counseling session is to:

1) **Answer** any questions the patient might have (with the added benefit of reducing exam time for the clinician and nursing staff.)

2) **Review** the patient's completed risk assessment and discuss his or her eligibility for hepatitis, STD and HIV counseling and testing, and hepatitis vaccination.

3) **Promote** the vaccine for those individuals who were undecided about whether or not to accept the vaccine (data analysis showed that 40% of those who first responded "No" or "Not Sure" on the risk assessment form about beginning the vaccine series would change their mind when a staff member recommended the vaccine).

Information counseling was implemented June 2000, and preliminary data shows that vaccine acceptance increased about 10% among those who received the one-to-one counseling. It has also lessened the amount of time nurses spend answering questions and has made productive use of the sometimes prolonged wait time that may occur in a walk-in service clinic.

Staffing for this counseling session has been accomplished through a combination of assigned staff and the use of student interns from local colleges. This is an opportunity to be creative and seek volunteers or student interns through affiliations with colleges in the community.

Currently the hepatitis informational counseling has been transferred to HIV advisors who now see all clinic clients before their visit to the clinician. Previously, they only saw the clients who asked for HIV testing and were referred to them after the clinical examination. HIV advisors provide the patients with hepatitis, STD and HIV pretest counseling. Utilizing HIV counseling staff was found to be the most efficient way to provide hepatitis counseling and also to increase acceptance of HIV counseling and testing. This is a win-win situation.

CASE MANAGEMENT

In order to improve the return rate for doses #2 and #3, a case management component was evaluated for a 1-1/2 year period. Patients were categorized by risk based on their answers to the risk assessment questionnaire. Patients in the high and moderate risk categories were followed by a team of 2 full-time case managers.

The risk categories were:

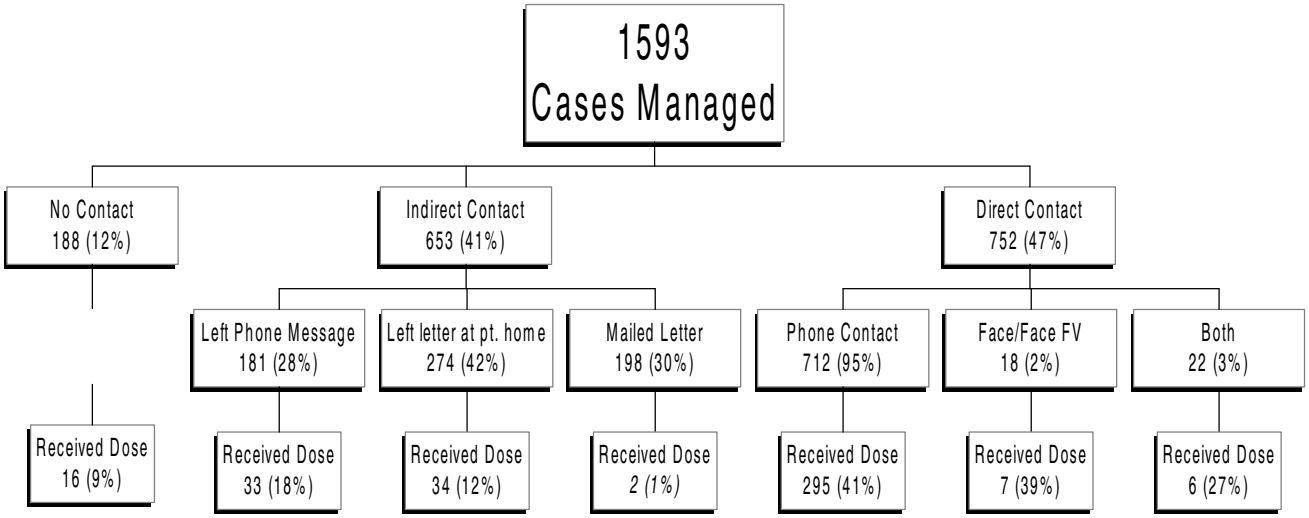
- **High Risk**
  - MSM
  - IDU
  - Persons <30 years old with >10 lifetime sex partners
- **Moderate Risk**
  - Persons with a history of any STD
- **Low Risk**
  - Remaining persons

The case management component was based on the Disease Intervention Specialist (DIS) field investigation model. A list of overdue patients was generated approximately every 3-4 weeks. Patients in the High Risk Category who were 45 days past their scheduled due date were considered overdue and eligible for case management.

A protocol was developed to ensure that each case manager was taking the same measures to convince the patients to return for their second and third doses. The protocol was tested with the first three lists and revisions were made based on feedback from the case managers.

RESULTS OF CASE MANAGEMENT

9/28/1998 - 4/24/2000



Recommendations:

The decision of whether or not to devote staff to case management to improve vaccine completion will vary from site to site. The biggest factor has to do with personnel and monetary resources. Case management does increase the return rate, but is it enough to justify the time and money? This is the question each site will have to answer. The San Diego Hepatitis Project decided it was not cost-efficient.

Using a less time intensive form of case management could consist of mailing letters to patients. The San Diego Hepatitis Project, found, however, that 26% of all letters mailed, were returned. It's a question of the time and effort that is expendable in a particular clinic. Currently the San Diego Hepatitis Project provides only reminders and education at the time a dose is received, about the importance of the next dose, but does not send letters or make phone calls.

HEPATITIS B
THE ONLY STD WITH A VACCINE

WHAT IS HEPATITIS B?

- A disease caused by a virus that affects the liver and can make you very sick
- The virus is spread through
  *blood *semen
  *vaginal fluids
- It is easier to catch than HIV
- Every year more than 5,000 people in the U.S. die

WHY DO I NEED THE VACCINE?

YOU NEED THE VACCINE IF YOU ARE:

- Having sex with more than one person
- Currently have a STD or had one in the past
- Not using a condom during sex
- Sharing needles
- Living in the same house with a person who has Hepatitis B

HOW CAN I PROTECT MYSELF?

- Get the vaccine, it can keep you from getting really sick
- You need all 3 shots to be totally protected
- Use condoms during sex
- Don't share razors or toothbrushes with anyone
- Make sure any needles for drugs, body piercing or tattooing are sterilized (cleaned with bleach)
- Wear gloves when touching or cleaning up blood

IS THE SHOT SAFE?

- **YES**
- There are almost no side effects
- Your arm may get a little sore or red at the point where the shot is given
- Getting the hepatitis B virus will cause more problems than getting

3 SHOTS IS ALL IT TAKES
START THE VACCINE SERIES TODAY!

County of San Diego, Department of Health Services

LA HEPATITIS B
LA ÚNICA ETS CON UNA VACUNA

¿QUÉ ES LA HEPATITIS B?

- Una enfermedad grave
- El virus se transmite a través de sangre contaminada y contacto íntimo con personas infectadas
- Hepatits B **NO** se transmite por agua o alimento
- Es más contagiosa que VIH/SIDA

¿POR QUÉ NECESITO LA VACUNA?

NECESITA LA VACUNA SI:

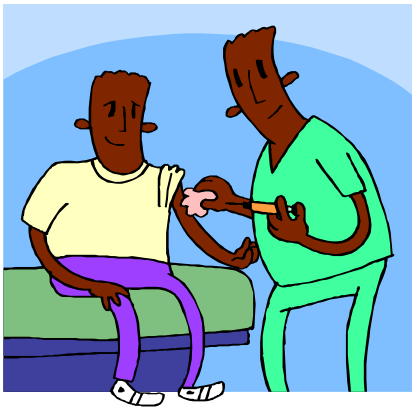
- Tiene sexo con más de una persona
- No usa condones durante el sexo
- Comparte agujas
- Vive en la misma casa que una persona infectada con la Hepatitis B
- Use guantes cada vez que tenga contacto con sangre

¿CÓMO PUEDO PROTEGERME?

- Tome la vacuna
- Necesita 3 dosis de la vacuna para estar totalmente protegido
- Use condones durante el sexo
- No comparta navajas de afeitar o cepillos de dientes
- Limpie con blanqueador (cloro) agujas que usa para drogas, tatuajes y para perforar el cuerpo

¿LA VACUNA ES SEGURA?

- **Sí**, la vacuna para la Hepatitis B es una de las vacunas más seguras
- Puede tener un poco de dolor en su brazo y una leve fiebre despues de tomar la vacuna



Ofrecemos aquí las inyecciones

Pregunta hoy al doctor o a la enfermera por la primera inyeccion de hepatitis B

FREE VACCINE

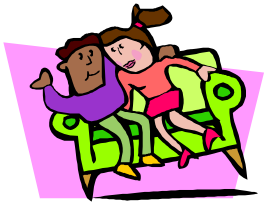
Hepatitis B

Don't risk your life
Start the vaccine series today

THE ONLY STD WITH A VACCINE

Don't think you're at risk? Keep reading…

YOU ARE AT RISK IF YOU HAVE…



- Ever had an STD
- Think you have an STD now
- Sex with more than one person

- Ever injected drugs

PROTECT YOURSELF

- Get the vaccine here today
- Use condoms during sex
- Don't share razors or toothbrushes
- Clean all needles with bleach

COMPLICATIONS

- Liver Cancer
- Cirrhosis
- Liver Transplant

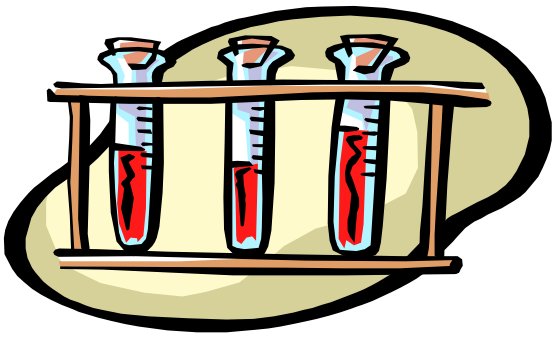
- Death– More than 6,000 people/year die in the U.S.

HEPATITIS B IS A SERIOUS DISEASE

- It damages your liver
- The virus is spread through
  - *blood
  - *semen
  - *vaginal fluids

THE SHOT IS SAFE

- Almost no side effects
- Redness or soreness of the arm



*FREE**
Hepatitis B & C Blood Testing Available Here

WHAT ARE HEPATITIS B and C?

Liver diseases caused by a virus that gets in the blood

You get hepatitis B & C by contact with the blood or body fluids of an infected person, for example:

- ✓ Injecting drugs
- ✓ Having multiple sex partners
- ✓ Sharing intranasal (nose) straws when snorting drugs
- ✓ Getting unsafe tattoos
- ✓ Receiving a blood transfusion or organ donation **before** 1992

WHY SHOULD I GET TESTED TODAY?

Because you may be infected without feeling sick

If you are infected you should make some lifestyle changes to decrease the amount of stress on your liver

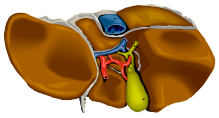
The offer for ***FREE TESTING*** is limited, take advantage today!

Hepatitis B and C

What you need to know

What Are Hepatitis B & C?

- Diseases caused by viruses that infect the blood
- The viruses cause inflammation of the liver
- Can lead to major liver damage and even death



How is the Hepatitis B Virus Spread?

✓ Through contact with blood & body fluids of an infected person

- Multiple sex partners
- Unprotected sex
- Men having sex with men
- Injecting drugs
- Intranasal drug use
- Unsafe Tattooing

How is the Hepatitis C Virus Spread?

✓ Through contact with blood of an infected person

- Injecting drugs / sharing works
- Sex partner of an injection drug user
- Intranasal drug use
- Blood transfusion before 1992
- Unsafe Tattooing

Are Hepatitis B & C Serious?

- YES!
- They are easier to catch than HIV
- Both cause serious liver damage
  - ✓ Cirrhosis
  - ✓ Liver cancer
  - ✓ Liver transplant
  - ✓ Death

What Should I Do?

- Everyone should get the vaccine for hepatitis B
  - ✓ Dose 1, get today
  - ✓ Dose 2, in one month
  - ✓ Dose 3, three months later
- No additional cost

How Do I Keep Myself Safe?

- Don't use drugs
  - If you do, don't share needles, works, or straws

- Practice safer sex
  - Use condoms
  - Limit your number of sex partners

- Make sure needles used for tattooing or piercing have been sterilized (cleaned with bleach)

What Should I Do?

- If you're at "high-risk" for Hep C you should get tested
- No additional cost

What If My Test Is Positive?

- Referral list of doctors
- Treatment may be available through your private physician

EPILOGUE

Integrating hepatitis B vaccination into existing STD clinic services is only one facet of hepatitis services provided in San Diego County over the past three years. The provision of hepatitis B vaccination in a variety of clinical and non-clinical sites serving high-risk clients (See next page; Hepatitis Integration, Slide 2) estimated that sites should have a vaccine acceptance of at least 65% among new client visits. This benchmark percentage allows for clients already vaccinated or claiming prior infection (approximately 15-20%) and a reasonable refusal/failure-to-offer rate. Using this 65%, a target number was calculated (.65 x new client visits)

The estimated vaccine acceptance and completion percentages are shown in Slides 3-6. For example, in slide 3, the Job Corps administered 42 doses per month which was 86% of the target number. An example of sites by client risk level, vaccine acceptance, and volume of clients is shown in Slide 7. We intend to maintain our subsequent efforts on sites serving high-risk clients which present a good opportunity to vaccinate as many high-risk clients as possible.

In addition to integrating hepatitis B vaccine in services targeting high-risk groups, the CDC is promoting, through its Viral Hepatitis Integration Projects (VHIP), a comprehensive package of services for preventing hepatitis A, B, and C. Many high-risk clients have specific risk behaviors that require multiple hepatitis services -- vaccination, serologic screening, and prevention counseling.

In San Diego County, we have integrated comprehensive hepatitis services into the STD clinic and are incrementally adding services at HIV counseling and testing sites and substance abuse rehabilitation sites. Comprehensive services are provided selectively, based on risk behavior. The core clinical services provided in our STD clinic are shown in Slides 8 and 9. We plan to continue this integration effort and encourage others to develop comprehensive hepatitis services in sites serving high-risk clients when opportunities arise.

Hepatitis B Vaccination in High-Risk Sites
San Diego, 1998-2001

Authors:
Robert A. Gunn, Stacey O'Neill, Paula Murray, Carolyn Brennan, Harold Margolis

Centers for Disease Control and Prevention and Health and Human Services Agency, San Diego, CA

Slide 1

HIGH-RISK SITES

- STD Clinic
- Drug Rehabilitation Programs
- Methadone Treatment Sites
- Social Service Centers for MSM Clients
- Mobile Clinic for Homeless Teens
- Job Corps Program - Disadvantaged Youth
- Juvenile Detention
- Adult County Detention
- HIV Testing Sites

Slide 2

VACCINE ACCEPTANCE (> 50% OF TARGET)

		HBV Vaccine Per Month				
Site	(%) of Target	Dose #1	#2 (%)	#3 (%)	Mos.	Total Doses
Job Corps	(86)	42	(67)	(26)	32	2,592
STD	(73)	332	(53)	(34)	36	22,356
Methadone	(58)	15	(53)	(3)	9	261

Slide 3

VACCINE ACCEPTANCE (25 - 50% OF TARGET)

		HBV Vaccine Per Month				
Site	% of Target	Dose #1	#2 (%)	#3 (%)	Mos.	Total Doses
Family Planning	(32)	25	(68)	(36)	17	867
Teen Clinic	(25)	32	(63)	(34)	18	1,134

Slide 4

VACCINE ACCEPTANCE (< 25% of Target)

		HBV Vaccine Per Month				
Site	(%) of Target	Dose #1	#2 (%)	#3 (%)	Mos.	Total Doses
College Health	(24)	63	(68)	(40)	15	1,965
Juvenile Det.	(20)	52	(75)	(33)	18	1,944
Women's Jail	(20)	33	(36)	(6)	23	1,081
University	(13)	150	(77)	(30)	16	4,960
Men's Jail	(6)	45	(51)	(2)	24	1,656
Comm. Clinic	(2)	38	(61)	(21)	27	1,863
TOTAL						40,679

Slide 5

NON-CLINICAL SITES

		HBV Vaccine Per Mo.				
Site	(%) of Target	Dose #1	#2 (%)	#3 (%)	Mos.	Total Doses
Drug Programs	(NA)	20	(40)	(35)	20	700
MSM Center	(NA)	13	(62)	(38)	20	520
						1,220

Slide 6

SITE SUMMARY

Selected Sites	Client's Risk	Offer/Accept Dose #1	Client Volume
STD	High	High	High
Drug Programs MSM Center	High	High	Low
Community Clinics	Low	Low	High
Short-Term Corrections	High	Low	High

Slide 7

CORE CLINICAL SERVICES

- All clients
  - Risk assessment
  - STD (GC & CT) screening
  - HIV C and T
  - HBV vaccination
- Selective Risk-Based
  - HBV screening
  - HCV screening
  - HAV vaccination

Slide 8

SELECTIVE HEPATITIS SERVICES, BASED ON RISK, STD CLINIC
San Diego, CA

Group	Screening B	Screening C	Vaccination A	Vaccination B
IDU	✓	✓	✓	✓
MSM	✓		✓	✓
Sex Worker				✓
All Teens				✓
Clients < 30 yrs and >10 life partners				✓

Slide 9

INTEGRATION ISSUES

- STD/HIV/Hepatitis/Immunization program collaboration - Fed, State, Local
- Explicit objectives in program plans
- Balance - overall objectives vs. program
- WIN-WIN-WIN-WIN
  ↓ Program specific service offset by
  ↑ higher risk possible "core" transmitters receiving prevention services

Slide 10

SUMMARY

- STD clinic successful site
  - High risk, high acceptance, high volume
- One-Stop integrated services should improve hepatitis/HIV/STD service delivery
- HB vaccination and hepatitis screening can be done at other sites for high-risk clients
- Lower risk primary care type services and short-term corrections problematic

Slide 11