

Internal Medicine Specialists, P.C.

PATIENT INFORMED CONSENT FORM FOR PNEUMOCOCCAL VACCINATION

PNEUMONIA

Pneumococcal pneumonia is a respiratory infection caused by a bacterium. People who get pneumonia may have fevers, chills, headache, cough, muscle aches, shortness of breath, and/or chest pain. Complications may lead to worsening respiratory status and the need for hospitalization, respiratory failure, and possibly death. It is not possible to estimate the risk of an individual contracting Pneumococcal pneumonia in any particular year, but for patients who are elderly and people who have diabetes, heart, lung or kidney diseases, as well as other immune-compromising conditions or absence of their spleen, it may lead to especially serious infections. Pneumococcal pneumonia may be fatal in up to 5-10% of people who develop it. The emergence of strains of Pneumococci with increased resistance to one or more of the common antibiotics emphasizes the importance of vaccine prophylaxis against Pneumococcal disease. It is estimated that between 400,000-500,000 cases of Pneumococcal pneumonia may occur annually. Approximately 25% of all patients with Pneumococcal pneumonia develop the presence of bacteria in their bloodstream and, when this occurs, the fatality rate may increase to approximately 30%. Streptococcus pneumoniae may also cause meningitis and ear infections.

THE VACCINE

The injection of the Pneumococcal vaccine will not give you pneumonia because the vaccine is made from highly purified capsular polysaccharides from the 23 most prevalent or invasive Pneumococcal types, which account for approximately 85-90% of all Pneumococcal infections. These polysaccharides are part of the bacteria and no actual live bacteria are in the vaccine. The purpose of receiving the Pneumococcal vaccine is to try and prevent you from becoming ill with Pneumococcal infections and to possibly reduce the severity of an infection should you get one. The Pneumococcal vaccine will not prevent you from getting pneumonia from either a bacteria or virus which is not contained within the vaccine. The efficacy of the vaccine varies depending upon the patient population studied, but it is usually effective in approximately 75% or more of patients.

RISKS AND POSSIBLE SIDE EFFECTS

Side effects of the Pneumococcal vaccine are generally mild in adults and occur at a low frequency. These reactions usually consist of tenderness at the injection site, fever, malaise and/or muscle aches. These symptoms may last up to 48 hours. Severe allergic reactions may occur, but they are rare.

Neurological disorders such as paresthesias and acute radiculoneuropathy including Guillain-Barré syndrome have been rarely reported in temporal association with administration of the Pneumococcal vaccine; however, no cause and effect relationship has been established. Very rarely, anaphylactoid reactions have been reported.

SPECIAL PRECAUTIONS

It is not known whether the Pneumococcal vaccine can cause fetal harm and, therefore, should not be given to pregnant women unless the risk of pneumonia clearly outweighs the potential risk to the fetus. It is not known whether this drug is excreted in human milk and, therefore, nursing mothers should also avoid receiving the vaccine until they have completed nursing. Patients who are allergic to any component of the vaccine should not receive this vaccine until they have contacted and discussed the issue their personal physician. Persons with fever should not receive the vaccine. People who have received any other type of vaccine within 14 days prior to receiving the Pneumococcal vaccine should contact their personal physician before receiving the vaccine. If you have a reaction, contact your personal physician immediately. If you have any questions, also feel free to call and speak with us.

The protective duration of the Pneumococcal vaccine is unknown. Certain populations should receive revaccination at least 6 years after their initial vaccination. To find out if you fall within one of these risk categories, please discuss this issue with your physician.

WHAT TO DO IF THERE IS A SERIOUS REACTION

1. Call your doctor or get the person to a physician immediately.
2. Write down what happened, including the date, time, and the events that occurred.
3. Ask you doctor, nurse or Health Department to file a vaccine adverse event report form or call 1-800-822-7967.

The National Vaccine Injury Compensation program gives compensation (payment) for some persons thought to be injured by vaccines. For details, call 1-800-338-2382.

If you want to learn more, ask your doctor or nurse. They can give you the vaccine package insert or suggest other sources of information. The above information was obtained from the U.S. Department of Health and Human Services, Public Health Services, Center for Disease Control and Prevention.

CONSENT

I have read the above information and have had an opportunity to ask questions. I understand the benefits and risks of the Pneumococcal vaccine as described. I request that the vaccine be given to me or to the person named below for whom I am authorized to sign. I further understand that the Pneumococcal vaccination is considered a preventative healthcare measure and, as such, may not be covered by my insurance company. I agree to pay any costs associated with the vaccine not covered by my insurance company.

Name

Date

Signature

Relationship (if not patient)