NATIONAL OPEN UNIVERSITY OF NIGERIA

FACULTY OF HEALTH SCIENCES

COURSE CODE: EHS316

COURSE TITLE: IMMUNOLOGY AND IMMUNISATION


COURSE
GUIDE

EHS 316

IMMUNOLOGY AND IMMUNISATION

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Printed 2019

ISBN:

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INTRODUCTION

EHS 316 titled "Immunology and Immunisation" is a two (2) Units course with four (4) Modules and thirteen (13) Units. The immune system, is made up of innate and acquired immunity, which allows an organism to fight off foreign pathogens.

Immunology is a science that dates back to 1796 when Edward Jenner discovered that cow pox or vaccinia induced protection against human small pox is a fatal disease. This breakthrough led the World Health Organisation (WHO) to announce that small pox had been eradicated in 1979 and is regarded as one of the greatest achievements in modern medicine. The protection conferred against infectious diseases after an initial encounter with a pathogen, or through immunisation or other non-immunologic factors is termed *immunity*. The immune system first tries to deny access to invading microbes by using physical barriers such as skin and mucous membranes lining the respiratory, gastrointestinal and reproductive tracts. However, once the pathogen enters the body, the immune system goes straight into action by alerting the cells responsible for defending the body so as to offer protection against such intruders.

WHAT YOU WILL LEARN IN THIS COURSE

In this course, you have the course units and a course guide. The course guide will tell you what the course is all about. It is general overview of the course materials you will be using and how to use those materials. It also helps you to allocate the appropriate time to each unit so that you can successfully complete the course within the stipulated time limit.

The course guide also helps you to know how to go about your Tutor-Marked Assignment which will form part of your overall assessment at the end of the course. Also, there will be regular tutorial classes that are related to this course, where you can interact with your facilitator and other students. Please, I encourage you to attend these tutorial classes.

COURSE AIMS

The course aims to give you an understanding on Immunology and Immunisation.

COURSE OBJECTIVE

To achieve the aim set above, there are objectives. Each unit has a set of objectives presented at the beginning of the unit. These objectives will guide you on what to concentrate / focus on while studying the unit. Please read the objective before studying the unit and during your study to check your progress.

The Comprehensive Objective of the Course is given below. By the end of the course, you will be able to:

- discuss the scope of Immunology and Immunisation.

WORKING THROUGH THIS COURSE

To successfully complete this course, you are required to read each study unit, read the textbooks materials provided by the National Open University.

Reading the referenced materials can also be of great assistance.
Each unit has self-assessment exercises which you are advised to do and at certain periods during the course you will be required to submit your assignment for the purpose of assessment.

There will be a final examination at the end of the course. The course should take you about 17 weeks to complete.

This course guide will provide you with all the components of the course how to go about studying and hour you should allocate your time to each unit so as to finish on time and successfully.

THE COURSE MATERIALS

The main components of the course are:

- The Study Guide
- Study Units
- Reference / Further Reading
- Assignments
- Presentation Schedule

STUDY UNIT

The study units in this course are given below:

Module 1 Fundamental Principles of Immunology

Unit 1 Nature of Antibodies and Antigens
Unit 2 Blood Groups
Unit 3 Antigen-Antibody Reactions

Module 2 Hypersensitivity

Unit 1 Hypersensitivity
Unit 2 Types of Immunity and Factors Affecting Immunity
Unit 3 Vaccine and Vaccination
Unit 4 Serological Vaccine Efficacy and Coverage Survey

Module 3 principles of Immunisation

Unit 1 Principles of Immunisation and Immunisable Diseases
Unit 2 Immunisation Techniques and Schedules
Unit 3 Cold-chain Management

Module 4 Vaccine Development Technologies

Unit 1 Concept of Vaccine Development Technologies
Unit 2 Immunological Techniques
Unit 3 Adverse Reactions

There are activities related to the lecture in each unit which will help your progress and comprehension of the unit. You are required to work on these exercises which together with the TMAs will enable you to achieve the objectives of each unit.

PRESENTATION SCHEDULE

There is a time-table prepared for the early and timely completion and submissions of your TMAs as well as attending the tutorial classes. You are required to submit all your assignments by the stipulated time and date. Avoid falling behind the schedule time.

ASSESSMENT

There are three aspects to the assessment of this course.

The first one is the self-assessment exercises. The second is tutor -marked assignments and the third is the written examination or the examination to be taken at the end of the course.

Do the exercises or activities in the unit by applying the information and knowledge you acquired during the course. The tutor-marked assignments must be submitted to your facilitator for formal assessment in accordance with the deadlines stated in the presentation schedule and the assignment file.

The work submitted to your tutor for assessment will account for 30% of your total course work.

At the end of this course, you have to sit for a final or end of course examination of about a three hour duration which will account for 70% of your total course mark.

TUTOR-MARKED ASSIGNMENT

This is the continuous assessment component of this course and it accounts for 30% of the total score. You will be given four (3) TMAs by your facilitator to answer. Three of which must be answered before you are allowed to sit for the end of course examination.

These answered assignments are to be returned to your facilitator.
You're expected to complete the assignments by using the information and material in your readings references and study units.

Reading and researching into you references will give you a wider via point and give you a deeper understanding of the subject.

1. Make sure that each assignment reaches your facilitator on or before the deadline given in the presentation schedule and assignment file. If for any reason you are not able to complete your assignment, make sure you contact your facilitator before the assignment is due to discuss the possibility of an extension. Request for extension will not be granted after the due date unless there in exceptional circumstances.

2. Make sure you revise the whole course content before sitting or the examination. The self-assessment activities and TMAs will be useful for

this purposes and if you have any comment please do before the examination. The end of course examination covers information from all parts of the course.

COURSE MARKING SCHEME

Assignment	Marks
Assignments 1 – 3	Three assignments, each will count for 10% making a total of 30% of course marks.
End of course examination	70% of overall course marks
Total	100% of course materials.

FACILITATORS/TUTORS AND TUTORIALS

Sixteen (16) hours are provided for tutorials for this course. You will be notified of the dates, times and location for these tutorial classes.

As soon as you are allocated a tutorial group, the name and phone number of your facilitator will be given to you.

These are the duties of your facilitator: He or she will mark and comment on your assignment. He will monitor your progress and provide any necessary assistance you need. He or she will mark your TMAs and return to you as soon as possible.

(You are expected to mail your tutored assignment to your facilitator at least two days before the schedule date).

Do not delay to contact your facilitator by telephone or e-mail for necessary assistance if: you do not understand any part of the study in the course material; you have difficulty with the self-assessment activities; or you have a problem or question with an assignment or with the grading of the assignment.

It is important and necessary you acted the tutorial classes because this is the only chance to have face to face content with your facilitator and to ask questions which will be answered instantly. It is also period where you can say any problem encountered in the course of your study.

SUMMARY

Immunology therefore, is a branch of biology that covers the study of immune systems in all organisms. Immunology charts, measures, and contextualises the physiological functioning of the immune system in states of both health and diseases; malfunctions of the immune system in immunological disorders (such as autoimmune diseases,[4]hypersensitivities, immune deficiency, and transplant

rejection ; and the physical, chemical, and physiological characteristics of the components of the immune system *in vitro*, *in situ*, and *in vivo*. Immunology has applications in numerous disciplines of medicine, particularly in the fields of organ transplantation, oncology, rheumatology, virology, bacteriology, parasitology, psychiatry, and dermatology.

I wish you success in this course.

MAIN COURSE

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MODULE 1 FUNDAMENTAL PRINCIPLES OF IMMUNOLOGY

UNIT 1 NATURE OF ANTIBODIES AND ANTIGENS

CONTENTS

1.0 INTRODUCTION

Principles of immunology

The immune system is composed of innate and acquired immunity, which allows an organism to fight off foreign pathogens.

Immunology is a science that dates back to 1796 when Edward Jenner discovered that cow pox or vaccinia induced protection against human small pox is a fatal disease. This breakthrough led the World Health Organisation (WHO) to announce that small pox had been eradicated in 1979 and is regarded as one of the greatest achievements in modern medicine. The protection conferred against infectious diseases after an initial encounter with a pathogen, or through immunisation or other non-immunologic factors is termed *immunity*. The immune system first tries to deny access to invading microbes by using physical barriers such as skin and mucous membranes lining the respiratory, gastrointestinal and reproductive tracts. However, once the pathogen enters the body, the immune system goes straight into action by alerting the cells responsible for defending the body so as to offer protection against such intruders.

2.0 OBJECTIVES

By the end of this unit, you will be able to:

- state the fundamental principles of immunology
- explain the nature of antibodies and antigens.

3.0 MAIN CONTENT

3.1 Definition of Terms

Immunology is a branch of biology that covers the study of immune systems in all organisms. Immunology charts, measures, and contextualizes the physiological functioning of the immune system in states of both health and diseases; malfunctions of the immune system in immunological disorders (such as autoimmune diseases,[4] hypersensitivities, immune deficiency, and transplant rejection ; and the physical, chemical, and physiological characteristics of the components of the immune system *in vitro*, *in situ*, and *in vivo*. Immunology has applications in numerous disciplines of medicine, particularly in the fields of organ transplantation, oncology, rheumatology, virology, bacteriology, parasitology, psychiatry, and dermatology.

The term was coined by Russian biologist Ilya Ilyich Mechnikov, who advanced studies on immunology and received the Nobel Prize for his work in 1908. He pinned small thorns into starfish larvae and noticed unusual cells surrounding the thorns. This was the active response of the body trying to maintain its integrity. It was Mechnikov who first observed the phenomenon of phagocytosis, in which the body defends itself against a foreign body.

3.2 Nature of Antibodies and Antigens

An antibody (Ab), also known as an immunoglobulin (Ig), is a large, Y-shaped protein produced mainly by plasma cells that is used by the immune system to neutralise pathogens such as pathogenic bacteria and viruses. The antibody recognises a unique molecule of the pathogen, called an antigen, via the fragment antigen-binding (Fab) variable region. Each tip of the "Y" of an antibody contains a paratope (analogous to a lock) that is specific for one particular epitope (similarly, analogous to a key) on an antigen, allowing these two structures to bind together with precision. Using this binding mechanism, an antibody can *tag* a microbe or an infected cell for attack by other parts of the immune system, or can neutralise its target directly (for example, by inhibiting a part of a microbe that is essential for its invasion and survival). Depending on the antigen, the binding may impede the biological process causing the disease or may activate macrophages to destroy the foreign substance. The ability of an antibody to communicate with the other components of the immune system is mediated via its Fc region (located at the base of the "Y"), which contains a conserved glycosylation site involved in these interactions. The production of antibodies is the main function of the humoral immune system.

Antibodies are glycoproteins belonging to the immunoglobulin superfamily. They constitute most of the gamma globulin fraction of the blood proteins. They are typically made of basic structural units—each with two large heavy chains and two small light chains. There are several different types of antibody heavy chains that define the five different types of crystallisable fragments (Fc) that may be attached to the antigen-binding fragments. The five different types of Fc regions allow antibodies to be grouped into five *isotypes*. Each Fc region of a particular antibody isotype is able to bind to its specific Fc Receptor (except for IgD, which is essentially the BCR), thus allowing the antigen-antibody complex to mediate different roles depending on which FcR it binds. The ability of an antibody to bind to its corresponding FcR is further modulated by the structure of the glycan(s) present at conserved sites within its Fc region. **Natural antibodies**

Humans and higher primates also produce "natural antibodies" that are present in serum before viral infection. Natural antibodies have been defined as antibodies that are produced without any previous infection, vaccination, other foreign antigen exposure or passive immunisation. These antibodies can activate the classical complement pathway leading to lysis of enveloped virus particles long before the adaptive immune response is activated. Many natural antibodies are directed against the disaccharide galactose α(1,3)-galactose (α-Gal), which is found as a terminal sugar on glycosylated cell surface proteins, and generated in response to production of this sugar by bacteria contained in the human gut.

3.3 Disease Diagnosis

Detection of particular antibodies is a very common form of medical diagnostics, and applications such as serology depend on these methods. For example, in biochemical assays for disease diagnosis, a titer of antibodies directed against Epstein-Barr virus or Lyme disease is estimated from the blood. If those antibodies are not present, either the person is not infected or the infection occurred a *very* long time ago, and the B cells generating these specific antibodies have naturally decayed.

In clinical immunology, levels of individual classes of immunoglobulins are measured by nephelometry (or turbidimetry) to characterise the antibody profile of patient. Elevations in different classes of immunoglobulins are sometimes useful in determining the cause of liver damage in patients for whom the diagnosis is unclear. For example, elevated IgA indicates alcoholic cirrhosis, elevated IgM indicates viral hepatitis and primary biliary cirrhosis, while IgG is elevated in viral hepatitis, autoimmune hepatitis and cirrhosis.

3.4 Disease Therapy

Targeted monoclonal antibody therapy is employed to treat diseases such as rheumatoid arthritis, multiple sclerosis, psoriasis, and many forms of cancer including non-Hodgkin's lymphoma, colorectal cancer, head and neck cancer and breast cancer.

3.5 Neo-Antigens

Neo-antigens are those that are entirely absent from the normal human genome. As compared with non-mutated self-antigens, neo-antigens are of relevance to tumor control, as the quality of the T cell pool that is available for these antigens is not affected by central T cell tolerance. Technology to systematically analyse T cell reactivity against neoantigens became available only recently.

3.6 Viral Antigens

For virus-associated tumors, such as cervical cancer and a subset of head and neck cancers, epitopes derived from viral open reading frames contribute to the pool of neoantigens.

3.7 Tumor Antigens

Tumor antigens are those antigens that are presented by MHC class I or MHC class II molecules on the surface of tumor cells. Antigens found only on such cells are called tumor-specific antigens (TSAs) and generally result from a tumor-specific mutation. More common are antigens that are presented by tumor cells and normal cells, called tumor-associated antigens (TAAs). Cytotoxic T lymphocytes that recognize these antigens may be able to destroy tumor cells.

4.0 CONCLUSION

Prior to the designation of immunity, from the etymological root *immunis*, which is Latin for "exempt", early physicians characterised organs that would later be proven as essential components of the immune system. The important lymphoid organs of the immune system are the thymus, bone marrow, and chief lymphatic tissues such as spleen, tonsils, lymph vessels, lymph nodes, adenoids, and liver.

5.0 SUMMARY

The immune system is composed of innate and acquired immunity, which allows an organism to fight off foreign pathogens.

Immunology is a science that dates back to 1796 when Edward Jenner discovered that cow pox or vaccinia induced protection against human small pox is a fatal disease. This breakthrough led the World Health Organisation (WHO) to announce that small pox had been eradicated in 1979 and is regarded as one of the greatest achievements in modern medicine.

6.0 TUTOR-MARKED ASSIGNMENT

1. Briefly define the term Immunology.

2. Write briefly on Antibodies and Antigens.

7.0 REFERENCES/FURTHER READING

World Health Organisation. Immunisation, Vaccines and Biologics (WHO/IVB) database.

Plotkin S.L., Plotkin S.A. "A Short History of Vaccination," In: *Plotkin S, Orenstein W, Offit. P.A. Vaccines*. (5th ed.), Philadelphia: Saunders, 2008.

UNIT 2 BLOOD GROUPS

CONTENTS

1.0 INTRODUCTION

Blood group is a classification of blood, based on the presence and absence of antibodies and inheritedantigenic substances on the surface of red blood cells (RBCs). These antigens may be proteins, carbohydrates, glycoproteins, or glycolipids, depending on the blood group system. Some of these antigens are also present on the surface of other types of cells of various tissues. Several of these red blood cell surface antigens can stem from one allele (or an alternative version of a gene) and collectively form a blood group system. Blood types are inherited and represent contributions from both parents. A total of 36 human blood group systems and 346 antigens are now recognised by the International Society of Blood Transfusion (ISBT). The two most important blood group systems are ABO and Rh; they determine someone's blood type (A, B, AB and O, with +, − or null denoting RhD status) for suitability in blood transfusion.

2.0 OBJECTIVE

By the end of this unit, you will be able to:

- discuss the classification of blood.

3.0 MAIN CONTENT

3.1 Definition of Terms

Blood group is a classification of blood, based on the presence and absence of antibodies and inheritedantigenic substances on the surface of red blood cells (RBCs). These antigens may be proteins, carbohydrates, glycoproteins, or glycolipids, depending on the blood group system. Some of these antigens are also present on the surface of other types of cells of various tissues.
Blood types are inherited and represent contributions from both parents. A total of 36 human blood group systems and 346 antigens are now recognized by the International Society of Blood Transfusion (ISBT). The two most important blood group systems are ABO and Rh; they determine someone's blood type (A, B, AB and O, with +, − or null denoting RhD status) for suitability in blood transfusion.

3.2 ABO Blood group

The ABO blood group system involves two antigens and two antibodies found in human blood. The two antigens are antigen A and antigen B. The two antibodies are antibody A and antibody B. The antigens are present on the red blood cells and the antibodies in the serum. Regarding the antigen property of the blood all human beings can be classified into 4 groups, those with antigen A (group A), those with antigen B (group B), those with both antigen A and B (group AB) and those with neither antigen (group O). The antibodies present together with the antigens are found as follows:

1. Antigen A with antibody B
2. Antigen B with antibody A
3. Antigen AB has no antibodies
4. Antigen nil (group O) with antibody A and B.

There is an agglutination reaction between similar antigen and antibody (for example, antigen A agglutinates the antibody A and antigen B agglutinates the antibody B). Thus, transfusion can be considered safe as long as the serum of the recipient does not contain antibodies for the blood cell antigens of the donor.

The *ABO system* is the most important blood-group system in human-blood transfusion. The associated anti-A and anti-B antibodies are usually *immunoglobulin M*, abbreviated IgM, antibodies. ABO IgM antibodies are produced in the first years of life by sensitisation to environmental substances such as food, bacteria, and viruses. The original terminology used by Karl Landsteiner in 1901 for the classification was A/B/C; in later publications "C" became "O". Type O is often called *0* (*zero*, or *null*) in other languages.

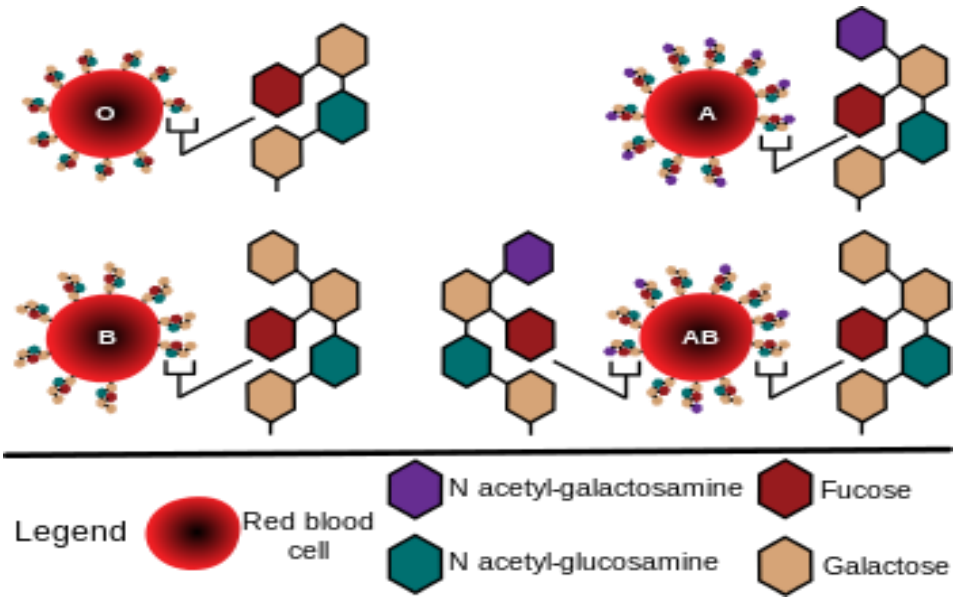

***Fig.2.1:ABO blood group system*: Diagram showing the carbohydrate chains that determine the ABO blood group (Wilson and Marcuse, 2001)**

4.0 CONCLUSION

A complete blood type would describe a full set of 30 substances on the surface of red blood cells, and an individual's blood type is one of many possible combinations of blood-group antigens. Across the 36 blood group systems, 308 different blood-group antigens have been found. Almost always, an individual has the same blood group for life, but very rarely an individual's blood type changes through addition or suppression of an antigen in infection, malignancy, or autoimmune disease

5.0 SUMMARY

Blood group is a classification of blood, based on the presence and absence of antibodies and inheritedantigenic substances on the surface of red blood cells (RBCs). These antigens may be proteins, carbohydrates, glycoproteins, or glycolipids, depending on the blood group system. Some of these antigens are also present on the surface of other types of cells of various tissues. Several of these red blood cell surface antigens can stem from one allele (or an alternative version of a gene) and collectively form a blood group system. Blood types are inherited and represent contributions from both parents. A total of 36 human blood group systems and 346 antigens are now recognised by the International Society of Blood Transfusion (ISBT). The two most important blood group systems are ABO and Rh; they determine someone's blood type (A, B, AB and O, with +, − or null denoting RhD status) for suitability in blood transfusion.

6.0 TUTOR-MARKED ASSIGNMENT

1. Write briefly on the term Blood group.

7.0 REFERENCES/FURTHER READING

Chen RT *et al*., "The Vaccine Adverse Event Reporting System (VAERS)," Vaccine, 1994: 12(6):542–550.

Wilson, CB, Marcuse, EK. "Vaccine safety – vaccine benefits: science and the public's perception," Nature Reviews Immunology, 2001: 1:160–165.

UNIT 3 ANTIGEN-ANTIBODY REACTIONS

CONTENTS

1.0 INTRODUCTION

The first correct description of the antigen-antibody reaction was given by Richard J. Goldberg at the University of Wisconsin in 1952. It came to be known as "Goldberg's theory" (of antigen-antibody reaction).

There are several types of antibodies and antigens, and each antibody is capable of binding only to a specific antigen. The specificity of the binding is due to specific chemical constitution of each antibody. The antigenic determinant or epitope is recognised by the paratope of the antibody, situated at the variable region of the polypeptide chain. The variable region in turn has hyper-variable regions which are unique amino acid sequences in each antibody. Antigens are bound to antibodies through weak and noncovalent interactions such as electrostatic interactions, hydrogen bonds, Van der Waals forces, and hydrophobic interactions.

2.0 OBJECTIVE

By the end of this unit, you will be able to:

- explain the concept of antigen-antibody reactions.

3.0 MAIN CONTENT

3.1 Concept of Antigen-Antibody Reaction

Antigen-Antibody Reaction, is a specific chemical interaction between antibodies produced by B cells of the white blood cells and antigens during immune reaction. It is the fundamental reaction in the body by which the body is protected from complex foreign molecules, such as pathogens and their chemical toxins. In the blood, the antigens are specifically and with high affinity bound by antibodies to form an antigen-

antibody complex. The immune complex is then transported to cellular systems where it can be destroyed or deactivated.

3.2 Chemical Basis of Antigen-Antibody Interaction

Antibodies bind antigens through weak chemical interactions, and bonding is essentially non-covalent. Electrostatic interactions, hydrogen bonds, van der Waals forces, and hydrophobic interactions are all known to be involved depending on the interaction sites. Non-covalent bonds between antibody and antigen can also be mediated by interfacial water molecules. Such indirect bonds can contribute to the phenomenon of cross-reactivity, i.e. the recognition of different but related antigens by a single antibody.

3.3 Precipitation Reaction

Soluble antigens combine with soluble antibodies in presence of an electrolyte at suitable temperature and pH to form insoluble visible complex. This is called a precipitation reaction. It is used for qualitative and quantitative determination of both antigen and antibody. A special ring test is useful for diagnosis of anthrax and determination of adulteration in food.

3.4 Agglutination Reaction

It acts on antigen-antibody reaction in which the antibodies cross-link particulate antigens resulting in the visible clumping of the particle. There are two types, namely active and passive agglutination. They are used in blood tests for diagnosis of enteric fever.

4.0 CONCLUSION

In the blood, the antigens are specifically and with high affinity bound by antibodies to form an antigen-antibody complex. The immune complex is then transported to cellular systems where it can be destroyed or deactivated.

The first correct description of the antigen-antibody reaction was given by Richard J. Goldberg at the University of Wisconsin in 1952.

5.0 SUMMARY

Antigen-Antibody Reaction, is a specific chemical interaction between antibodies produced by B cells of the white blood cells and antigens during immune reaction. It is the fundamental reaction in the body by which the body is protected from complex foreign molecules, such as pathogens and their chemical toxins.

6.0 TUTOR-MARKED ASSIGNMENT

Define the term Antigen-Antibody reaction.

Solution

Antigen-Antibody reaction, is a specific chemical interaction between antibodies produced by B cells of the white blood cells and antigens during immune reaction. It is the fundamental reaction in the body by which the body is protected from complex foreign molecules, such as pathogens and their chemical toxins.

7.0 REFERENCES/FURTHER READING

United Nations Children Fund (UNICEF). Available at: http://www.unicef.org (Accessed 2 December 2009).

Milstien, JB. "Regulation of vaccines: strengthening the science base,"*Journal Public Health Policy*, 2004: 25(2):173–189.

MODULE 2 HYPERSENSITIVITY

UNIT 1 HYPERSENSITIVITY

CONTENTS

1.0 INTRODUCTION

Hypersensitivity may be defined as a process in which the adaptive immune response becomes over sensitive to a variety of infectious and innocuous antigens thereby inflicting injury to the host tissue. The disorders that result from such reactions are termed hypersensitivity diseases.

2.0 OBJECTIVES

By the end of this unit, you will be able to:

- define hypersensitivity
- state types of Hypersensitivity Reactions
- explain diseases associated with Hypersensitivity reactions.

3.0 MAIN CONTENT

3.1 Overview of the Term Hypersensitivity

Hypersensitivity may be defined as a process in which the adaptive immune response becomes over sensitive to a variety of infectious and innocuous antigens thereby inflicting injury to the host tissue. The disorders that result from such reactions are termed hypersensitivity diseases.

The most important function of adaptive immune response is in host defense against microbes. However, it could also be responsible for tissue injury and disease. This reaction could produce discomfort and sometimes may result in fatality. A common cause of hypersensitivity reaction is inability to tolerate self-antigens, a property of the immune system whose responsibility it is to ensure that no reaction occurs between individuals and their own antigens. Inability to self-tolerance and subsequent immune response against self or autologous antigens results in autoimmune diseases.

3.2 Types of Hypersensitivity Reactions

There are five types referred to as Type I, II, III, IV and V. Once contact is established with antigen a variation in timing exists for each of the hypersensitivity reactions. The Type 1 hypersensitivity reaction, which is allergy affects about 17% of the population and it exists in two phases and mediated by IgE. It is an immediate hypersensitivity reaction because antibodies are involved and starts within minutes of contact with the antigen. The mechanism of action involves mast cells and basophils, both of which have receptors for IgE. After interaction of antibody/antigen some physiological substances such as histamine, serotonin and other mediators of inflammation are released thus inducing spasms of the smooth muscle.

The hypersensitivity Type II reaction also called cytotoxic reaction involves IgE and IgM antibodies. These antibodies interact with the antigen in the blood as well as analogous antigens on the surface of human body cells. This is done by opsonization and phagocytosis of cells. These mechanisms set off the complement system that lyses the cell.

Hypersensitivity type III mobilises not only IgE and IgM but also immune complexes. It can rise from soluble antigens. The immune complexes could vary in size, amount, affinity and the isotype of the responding antibody. Consequently, large immune complexes fix the complements and are disposed by mononuclear phagocytes from circulation, whereas the smaller complexes deposit in blood vessel walls and can ligate Fc receptors on mast cells and other leucocytes which can lead to leucocyte activation and tissue injury.

Type IV hypersensitivity called delayed type hypersensitivity (DTH) reaction occurs within 24-72 hours and it is mediated by CD4, CD8 T cells as well as antigen peptide cells (APCs) e.g. Langerhans' cells. The activated T cells migrate to the site of antigenic entry where pro-inflammatory mediators such as Tumor necrosis factor (TNF) are released. The pro-inflammatory mediators facilitate blood flow and extravasation of plasma contents to the area. CD4 and CD8 cells are released resulting in the interferon gamma (IFN-γ) thus enhancing macrophage activity in the area.

The stimulatory or type V hypersensitivity are mediated by auto-antibodies. It is classified as a distinct type of hypersensitivity where the auto-antibodies bind to hormone receptors that imitate the hormone itself and this leads to stimulation of target cells. Autoimmune response defines the ability of an individual immune system to react

with self-antigens. There are some individuals who have auto-antibodies and will show no symptoms, but autoimmune disease results if the regulatory mechanisms breakdown. It is to be noted that the causes of autoimmune diseases are multi-factorial.

3.3 Diseases Associated With Hypersensitivity Reactions

Hypersensitivity diseases are clinically heterogeneous group of disorders whose manifestations are defined by the type of immune response that leads to cell and tissue injury. The mechanisms of immune response that leads to different types of hypersensitivity reactions have been stated above. There are some individuals prone to produce IgE in response to environmental allergens and show strong immediate hypersensitivity are said to be atopic and they suffer from allergy. This form of allergy may present in different forms such as hay fever, asthma, urticaria (hives) or chronic skin irritation. In extreme cases known as anaphylaxis, the mast cell and basophil derived mediators restrict the airways to the point of asphyxiation and produce cardiovascular collapse leading to death.

Myasthenia gravis is an example of type II hypersensitivity reaction in which the antibody inhibits acetylcholine binding as well as down modulating receptors. Type III hypersensitivity reaction is presented in immune complexes mediated reactions such as Arthus reaction. The delayed type hypersensitivity results from tissue injury as a result of the production of reactive oxygen species, hydrolytic enzymes, nitric oxide and some pro-inflammatory mediators such cytokines. Insulin-dependent diabetes which is an organ specific auto immune disease is caused by DTH reactions induced by auto T cells. Diseases caused from Hypersensitivity reactions are caused by disorders of immune response. The reactions are classified into five types based on the type of immune response and the effector mechanisms that are responsible for cell and tissue injury. The immune response could be autoimmune responses against self-antigens or uncontrolled or over reaction to foreign antigens. The immediate hypersensitivity occurs within few minutes of being challenged with an antigen and in extreme cases death may occur due to asphyxiation and circulatory collapse.

4.0 CONCLUSION

The most important function of adaptive immune response is in host defense against microbes. However, it could also be responsible for tissue injury and disease. This reaction could produce discomfort and sometimes may result in fatality. A common cause of hypersensitivity reaction is inability to tolerate self-antigens, a property of the immune system whose responsibility it is to ensure that no reaction occurs between individuals and their own antigens.

5.0 SUMMARY

There are five types hypersensitivity reaction referred to as Type I, II, III, IV and V. Once contact is established with antigen a variation in timing exists for each of the hypersensitivity reactions. The Type 1 hypersensitivity reaction, which is allergy affects about 17% of the population and it exists in two phases and mediated by IgE. It is an

immediate hypersensitivity reaction because antibodies are involved and starts within minutes of contact with the antigen. The mechanism of action involves mast cells and basophils, both of which have receptors for IgE. After interaction of antibody/antigen some physiological substances such as histamine, serotonin and other mediators of inflammation are released thus inducing spasms of the smooth muscle.

6.0 TUTOR-MARKED ASSIGNMENT

1. Define the term hypersensitivity.
2. What are the mechanisms involved in hypersensitive reactions.

7.0 REFERENCES/FURTHER READING

Baylor N.W., Midthun K. "Regulation and testing of vaccines," In: Plotkin S, Orenstein W, Offit P.A. Vaccines, 5th edition, Philadelphia: Saunders, 2008.

Duclos P, Bentsi-Enchill A.D., Pfeifer D. "Vaccine safety and adverse events: lessons learnt," In: Kaufmann SHE and Lamert PH. The Grand Challenge for the Future, Basel, Switzerland: 2005: 209–229.

UNIT 2 TYPES OF IMMUNITY AND FACTORS AFFECTING IMMUNITY

CONTENTS

1.0 INTRODUCTION

The immune system is designed to detect and destroy foreign invaders inside the body like bacteria and viruses. When working optimally, the immune system can prevent sickness when we're exposed to germs. Several factors like sleep, diet, stress and hygiene can affect the immune system's performance, and any offsets in these behaviors can cause havoc on immune function. Often times the impact of these factors go unnoticed, but if you tend to get sick after a big project at work or during finals at school, it's likely because your immune system has suffered due to stress, lack of sleep, binge eating or unhygienic behaviors.

2.0 OBJECTIVE

At the end of this unit, you will be able to:

- discuss the types of immunity and factors affecting immunity.

3.0 MAIN CONTENT

3.1 Types of Immunity and Factors Affecting Immunity

Active immunity occurs when our own immune system is responsible for protecting us from a pathogen.

Passive immunity occurs when we are protected from a pathogen by immunity gained from someone else.
Both of these different types of immunity can be acquired in different ways.

Individuals rely on active immunity more so than passive immunity. Active immunity is created by our own immune system when we are exposed to a potential disease-causing agent (i.e., pathogen). Most of the time, we are exposed to these potential pathogens naturally throughout the course of our day — in the air we breathe, the food we eat, and the things we touch. Luckily, most of these exposures are to agents that will not result in

disease, either because they are harmless or because our immune system works to neutralise them.

In addition to "fighting off" these pathogens, active immunity is important because it lasts a long time in the form of immunologic memory. Immunologic memory consists of B and T cells that can recognize a particular pathogen. These cells circulate at low levels in our bodies and if "activated" by recognising that pathogen in their travels, they quickly start to multiply and signal other elements of the immune system to activate as well. Memory cells are crucial for two reasons. First, they allow our immune systems to respond quickly. Second, they are specific for the pathogen, so the immune response is ready the moment the pathogen is encountered.

Because we don't know about most of the work our immune system does, we often do not think about how busy it is. But, the reality is that like our hearts and lungs, our immune system is constantly working to keep us healthy. This effort is evidenced by the fact that our immune system generates grams of antibodies every single day!

Vaccines contribute to active immunity by providing us with a controlled way to create an immune response. When a vaccine is introduced, our immune system treats it like any other exposure. It works to stop the "assault" and, in the process, immunologic memory develops. Because vaccines are designed such that they do not cause illness, we gain the benefits of the exposure without the risks associated with fighting off a natural infection. In this way, vaccines offer our immune systems a chance to "train" for a future encounter and provide us with a "shortcut" to protection. We gain the immunity that follows surviving a natural infection without having to pay the price of natural infection.

The immune system is designed to detect and destroy foreign invaders inside the body like bacteria and viruses. When working optimally, the immune system can prevent sickness when we're exposed to germs. Several factors like sleep, diet, stress and hygiene can affect the immune system's performance, and any offsets in these behaviors can cause havoc on immune function. Often times the impact of these factors go unnoticed, but if you tend to get sick after a big project at work or during finals at school, it's likely because your immune system has suffered due to stress, lack of sleep, binge eating or unhygienic behaviors.

Factors Affecting Immunity

- **Hand Washing**

People tend to overestimate their hygiene. Studies show that only 67% of people wash their hands after using a public restroom, vs. 85% who report washing their hands after public restroom use. And even if you do wash your hands, you may not be doing it *correctly*: Centers for Disease Control recommends 15 seconds of scrubbing your hands with soap, or humming the "Happy Birthday" song TWO TIMES! You should try it - it feels like an eternity when you're standing in front of a mirror in a public restroom, next to a stranger that you might be trying to avoid talking to.

As you probably know, the restroom isn't the only place you should be washing your hands. But studies show we do a better job in the restroom, likely due to social pressure and the convenient location of soap and a sink. An even smaller percentage of people report washing their hands after participating in other activities that significantly increase risk of exposure to microbes like petting a dog or cat (42% of people), handling money (27% of people), and coughing or sneezing (39% of people).

- **Sleep Cycles**

The immune system is influenced by the sleep-wake cycles of our circadian rhythms. Studies suggest that while we're sleeping we have decreased levels of the stress hormone cortisol, which can suppress immune function, and increased signals that activate the immune system. Even though we know that sleep is important, it can be difficult to get enough, especially during busy times of the year. According to a Gallup survey, 56% of adults say they get enough sleep. However, 7 hours is the minimum recommended amount of sleep for adults and only 40% of us are averaging 6.8 hours of sleep per night.

- **Nutrients From Food**

Everywhere we turn, we see PSAs, news stories and blogs boasting the importance of fruits and vegetables for a plethora of health reasons, and the same applies to immune health. Studies show vitamins C, A, E, B6 and B12 and minerals like iron and zinc are important for the maintenance of immune function, all of which can be found in fruits and veggies. If you're a clean-eating enthusiast, you're probably getting enough of these vitamins and minerals, but many of us aren't. The Dietary Guidelines for Americans recommends 4.5 cups of fruit and vegetables per day.

- **Cortisol Levels**

Another challenge that plagues our immune system is a familiar foe to many of us. STRESS. Hectic work schedules and abundant daily responsibilities can leave us frazzled. Increased levels of the stress hormone, cortisol, makes it difficult for the immune system to function properly. The *American Psychological Association* reports that 75% of Americans experience moderate to high levels of stress. In addition to the direct impact of stress on immune function, unmanaged stress can influence our sleep patterns, our mood, our dietary intake and our physical activity levels. All of these factors are associated with immune system function.

- **Supplement Intake**

To promote and support healthy behaviors, supplements and fortified foods have been widely used to support immune health. According to *Nutraingredients*, 29% of supplement users take an immune health product.

Beta-glucan is an emerging ingredient in immune health supplements. Beta-glucan is a naturally occurring glucose polymer or insoluble fiber found in cereal grains like oat and

barley, certain types of mushrooms, yeast, seaweed, and algae. Although all types of beta-glucan have some health benefit, the beta-glucan found in yeast, mushrooms and algae can provide benefits that support immune health.

4.0 CONCLUSION

The immune system is designed to detect and destroy foreign invaders inside the body like bacteria and viruses. When working optimally, the immune system can prevent sickness when we're exposed to germs. Several factors like sleep, diet, stress and hygiene can affect the immune system's performance, and any offsets in these behaviors can cause havoc on immune function. Often times the impact of these factors go unnoticed, but if you tend to get sick after a big project at work or during finals at school, it's likely because your immune system has suffered due to stress, lack of sleep, binge eating or unhygienic behaviors.

5.0 SUMMARY

There basically two types of immunity which are:

- Active immunity occurs when our own immune system is responsible for protecting us from a pathogen.
- Passive immunity occurs when we are protected from a pathogen by immunity gained from someone else.
- Both of these different types of immunity can be acquired in different ways.

6.0 TUTOR-MARKED ASSIGNMENT

1. List the types of immunity.
2. List the factors that affect immunity.

7.0 REFERENCES/FURTHER READING

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UNIT 3 VACCINE AND VACCINATION

CONTENTS

1.0 INTRODUCTION

A vaccine is a biological preparation that improves immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism, and is often made from weakened or killed forms of the microbe, its toxins or one of its surface proteins. The agent stimulates the body's immune system to recognise the agent as foreign, destroy it, and "remember" it, so that the immune system can more easily recognise and destroy any of these microorganisms that it later encounters vaccination is an injection of a killed microbe in order to stimulate the immune system against the microbe, thereby preventing disease. Vaccinations, or immunisations, work by stimulating the immune system, the natural disease-fighting system of the body.

2.0 OBJECTIVE

By the end of this unit, you will be able to:

- explain the terms vaccine and vaccination.

3.0 MAIN CONTENT

3.1 Overview of terms

A vaccine is a biological preparation that improves immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism, and is often made from weakened or killed forms of the microbe, its toxins or one of its surface proteins. The agent stimulates the body's immune system to recognise the agent as foreign, destroy it, and "remember" it, so that the immune system can more easily recognise and destroy any of these microorganisms that it later encounters vaccination is an injection of a killed microbe in order to stimulate the immune system against the microbe, thereby preventing disease. Vaccinations, or immunisations, work by stimulating the immune system, the natural disease-fighting system of the body.

Similar to other drugs, vaccines have the potential to cause allergic reactions. Vaccines, specifically individual components of the vaccine, are known to, although rarely, cause serious complications. Even after an allergic reaction after vaccination, it is difficult to ascertain whether the allergic reaction was caused by the vaccine itself or other factors. Recently, mild allergic reactions caused by vaccinations have become common in practice due to an increased amount of vaccinations, however, these mild allergic reactions can still lead to serious complications and therefore require attention.

The vaccine components include active immunising antigens, conjugating agents, preservatives, stabilizers, antimicrobial agents, adjuvants and culture media used in the preparation of the vaccine, as well as inadvertent contaminants that are introduced during vaccine handling almost all the vaccine components can be considered as potential triggers of an allergic reaction. Of particular importance are culture derived proteins from egg, gelatin and yeast. Other sources of allergic reaction are antibiotics and vaccination antigens.

The most immediate reactions are Type I hypersensitivity reactions that are mediated by the interaction of IgE antibodies against a particular vaccine component. These reactions typically occur within minutes of exposure to the relevant allergen and almost always occur within 4 hours of exposure to the relevant allergen, however, possible exceptions for delayed-onset reactions do occur. The most common symptoms of IgE-mediated allergic reactions are urticaria and angioedema, with less common symptoms including nasal congestion, cough, stridor, wheezing, shortness of breath, vomiting, abdominal pain, diarrhea and hypotension. Anaphylaxis, an acute hypersensitivity reaction with multi-organ system involvement can present as a severe life-threatening reaction, or can occur after vaccination.

It has been reported that the average rate for immediate type reactions in children and adolescents is 0.22 per 100,000 doses of vaccinations. A total of 31% of these patients reported immediate type reactions after the first vaccination. This observation suggests either a pre-sensitisation to a component of the vaccine or a non-immunologically mediated reaction. In contrast, the reported cases of potential anaphylaxis after vaccination amount to 0.065 per 100,000 given doses of vaccines.

Type IV hypersensitivity delayed reactions have also been reported, however, these reactions are generally considered to be harmless. Type IV hypersensitivity reactions generally begin 48 hours after vaccination and peak between 72 and 96 hours. These reactions are typically observed following vaccines containing thimerosal, aluminum and anti-microbial agents. The occurrence of such an event is not a contraindication for further vaccinations. Type IV reactions are becoming less frequent as mercury is being removed from modern vaccines. Another reported hypersensitivity reaction includes erythema multiforme. This reaction can be quite severe in children and is triggered by a number of allergens, including vaccine components.

The majorities of delayed reactions are classified as Type III hypersensitivity and are attributed primarily to the formation of immune complexes, however, less well-defined mechanisms, including T cell-mediated processes, may also play a role. The most common signs of delayed-type reactions include rashes, which may include as urticaria, erythema multiforme, and/or maculopapular eruptions. Angioedema may also occur, particularly in association with urticaria or erythema multiforme eruptions. Although uncommon, arthralgia, arthritis, joint swelling, serum sickness, and Henoch-Schönlein purpura may occur, in conjunction with a variety of other hematologic, renal and gastrointestinal manifestations. Some delayed reactions, however, may not be immunologically mediated. Persistent hard nodules at the injection site may involve irritant reactions, usually induced by adjuvants such as aluminum and do not necessarily reflect immunologic hypersensitivity to vaccine constituents.

Rarely, hyper-immunised patients by previous injections of a vaccine (e.g., tetanus vaccination) developed a local immune complex mediated by a Arthus-type reaction at the site of vaccine injection. T-cell mediated reactions usually manifest in the form of local eczema, starting from 2-8 hours up to 2 days after vaccination. Sometimes the reaction may extend beyond the injection area and may even become generalised.

Idiopathic and autoimmune responses are other immune related reactions. Self-reactive antibodies, created by molecular mimicry between the vaccine antigen and endogenous epitope, may be induced by vaccination. For example, idiopathic thrombocytopenic purpura may be produced by several viral infections that may induce auto antibodies to platelet surface glycoprotein. Such reported cases are 1 in 3,000 for rubella virus, 1 in 30,000 for measles, mumps, and rubella (MMR) vaccine and 1 in 6,000 for the measles virus. The Guillain-Barré syndrome (GBS) outbreak in 1976-1977, as a result of a swine influenza vaccine campaign, is the most well documented example of an autoimmune reaction to vaccinations. Briefly, in fear of an influenza pandemic, an 'immunisation campaign' took place throughout 1976-1977. Many people immunised with the swine influenza vaccine during the campaign period (approximately 0.04 per 100,000 vaccinations) developed GBS within 6 weeks following immunization. At the end of the 'immunization campaign', however, there were no further reported cases of GBS. Recently the estimated rate of influenza vaccination-related GBS in Korea was reported to be 0-0.025 per 100,000 distributed doses which is considerably lower than 0.04 to less than one case per 100,000 vaccinations reported in previous studies.

4.0 CONCLUSION

Similar to other drugs, vaccines have the potential to cause allergic reactions. Vaccines, specifically individual components of the vaccine, are known to, although rarely, cause serious complications. Even after an allergic reaction after vaccination, it is difficult to ascertain whether the allergic reaction was caused by the vaccine itself or other factors. Recently, mild allergic reactions caused by vaccinations have become common in practice due to an increased amount of vaccinations, however, these mild allergic reactions can still lead to serious complications and therefore require attention.

The vaccine components include active immunising antigens, conjugating agents, preservatives, stabilizers, antimicrobial agents, adjuvants and culture media used in the preparation of the vaccine, as well as inadvertent contaminants that are introduced during vaccine handling almost all the vaccine components can be considered as potential triggers of an allergic reaction.

5.0 SUMMARY

A vaccine is a biological preparation that improves immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism, and is often made from weakened or killed forms of the microbe, its toxins or one of its surface proteins. The agent stimulates the body's immune system to recognise the agent as foreign, destroy it, and "remember" it, so that the immune system can more easily recognise and destroy any of these microorganisms that it later encounters vaccination is an injection of a killed microbe in order to stimulate the immune system against the microbe, thereby preventing disease. Vaccinations, or immunisations, work by stimulating the immune system, the natural disease-fighting system of the body.

6.0 TUTOR-MARKED ASSIGNMENT

1. Write briefly on vaccine and vaccination.

7.0 REFERENCES/FURTHER READING

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UNIT 4 SEROLOGICAL VACCINE EFFICACY AND COVERAGE SURVEY

CONTENTS

1.0 INTRODUCTION

Response to a vaccine is usually determined by measuring the appearance and/or concentration of specific antibodies in serum. Measles, mumps, rubella hepatitis B, varicella – circulating antibodies correlate with clinical protection, but only measures the humoral arm of immune response.

Percent of the target population that has received the last recommended dose for each vaccine recommended in the national schedule by vaccine.

2.0 OBJECTIVES

By the end of this unit, you will be able to:

- explain Serological vaccine efficacy and coverage survey.

3.0 MAIN CONTENT

3.1 Definition of Terms

Response to a vaccine is usually determined by measuring the appearance and/or concentration of specific antibodies in serum. Measles, mumps, rubella hepatitis B, varicella – circulating antibodies correlate with clinical protection, but only measures the humoral arm of immune response.

Percent of the target population that has received the last recommended dose for each vaccine recommended in the national schedule by vaccine: This should include all vaccines within a country's routine immunisation schedule (e.g., Bacillus Calmette–Guérin (BCG); polio; pneumococcal conjugate vaccine (PCV); rotavirus; diphtheria, tetanus, pertussis-Hepatitis B-Haemophilus influenzae type B vaccine (DTP-HepBHib); measles (MCV); rubella; human papilloma virus (HPV); tetanus toxoid (TT); influenza; and others as determined by the national schedule.

Numerator

The number of individuals in the target group for each vaccine that has received the last recommended dose in the series. For vaccines in the infant immunisation schedule, this would be the number of children aged 12–23 months who have received the specified vaccinations before their first birthday.

Denominator

The total number of individuals in the target group for each vaccine. For vaccines in the infant immunisation schedule, this would be the total number of infants surviving to age one.

Disaggregation

Age, place of residence, sex, socio-economic status.
DTP1-DTP3 dropout rate, MCV1-MCV2 dropout, full immunisation coverage where possible.

Data Requirement(s):

Example of a national schedule is:

- At birth: BCG, HepB, oral polio vaccine
- At 6, 10 and 14 weeks: DTP-HepB-Hib, PCV, rotavirus, oral polio vaccine (with one dose of inactivated polio vaccine)
- At 9 months: measles
- At 18 months measles
- For adolescents: HPV
- TT: multiple
- For persons aged over 60 years: influenza.

For survey data, the vaccination status of children aged 12–23 months is used for vaccines included in the infant immunization schedule, collected from child health cards or, if there is no card, from recall by the care-taker.

4.0 CONCLUSION

Response to a vaccine is usually determined by measuring the appearance and/or concentration of specific antibodies in serum. Measles, mumps, rubella hepatitis B, varicella – circulating antibodies correlate with clinical protection, but only measures the humoral arm of immune response.

5.0 SUMMARY

Percent of the target population that has received the last recommended dose for each vaccine recommended in the national schedule by vaccine: This should include all vaccines within a country's routine immunization schedule (e.g., Bacillus Calmette–Guérin (BCG); polio; pneumococcal conjugate vaccine (PCV); rotavirus; diphtheria, tetanus, pertussis-Hepatitis B-Haemophilus influenzae type B vaccine (DTP-HepBHib); measles (MCV); rubella; human papilloma virus (HPV); tetanus toxoid (TT); influenza; and others as determined by the national schedule.

6.0 TUTOR-MARKED ASSIGNMENT

1. Write short note on the following:
   Numerator
   Denominator
   Disaggregation

7.0 REFERENCES/FURTHER READING

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MODULE 3 PRINCIPLES OF IMMUNISATION

Unit 1 Principles of Immunisation and Immunisable diseases
Unit 2 Immunisation Techniques and Schedules
Unit 3 Cold-Chain Management

UNIT 1 PRINCIPLES OF IMMUNISATION AND IMMUNISABLE DISEASES

CONTENTS

1.0 INTRODUCTION

Immunisation is the process of introducing weakened or killed germs (vaccines) into the body, which increase body immunity to protect one from a particular disease. These weakened or killed germs stimulate the body to produce antibodies that will fight or weaken any disease organism that attempts to enter the body.

Few medical interventions of the past century can rival the effect that immunisation has had on longevity, economic savings, and quality of life.

2.0 OBJECTIVES

By the end of this unit, you will be able to:

- explain what is meant by immunisation and its types.

3.0 MAIN CONTENT

3.1 Definition of Terms

Immunisation is the process of introducing weakened or killed germs (vaccines) into the body, which increase body immunity to protect one from a particular disease. These weakened or killed germs stimulate the body to produce antibodies that will fight or weaken any disease organism that attempts to enter the body.

Few medical interventions of the past century can rival the effect that immunisation has had on longevity, economic savings, and quality of life. Seventeen diseases are now preventable through vaccines routinely administered to children and adults in the United States and most vaccine-preventable diseases of childhood are at historically low levels Health care providers deliver the vast majority of vaccines in the United States in the course of providing routine health services and therefore play an integral role in the nation's public health system.

IMMUNISABLE DISEASES

Infectious diseases cause much illness, death and may result in disabilities to a child. It is therefore important to protect the child against the common infections which affect young children.

The most common and serious vaccine-preventable diseases tracked by the World Health Organisation (WHO) are: diphtheria, Haemophilus influenzae serotype b infection, hepatitis B, measles, meningitis, mumps, pertussis, poliomyelitis, rubella, tetanus, tuberculosis, and yellow fever.

DIPHTHERIA

Diphtheria is an infection caused by the bacterium Corynebacterium diphtheriae. Diphtheria causes a thick covering in the back of the throat. It can lead to difficulty breathing, heart failure, paralysis, and even death. CDC recommends vaccines for infants, children, teens and adults to prevent diphtheria.

HAEMOPHILUS INFLUENZAE SEROTYPE B INFECTION

Haemophilus influenzae (formerly called Pfeiffer's bacillus or *Bacillus influenzae*) is a Gram-negative, coccobacillary, facultatively anaerobic pathogenic bacterium belonging to the Pasteurellaceae family. *H. influenzae* was first described in 1892 by Richard Pfeiffer during an influenza pandemic.

MEASLES,

Measles is a highly contagious infectious disease caused by the measles virus. Symptoms usually develop 10–12 days after exposure to an infected person and last 7–10 days. Initial symptoms typically include fever, often greater than 40 °C (104 °F), cough, runny nose, and inflamed eyes.

HEPATITIS B,

Hepatitis B (HBV) is a liver disease caused by the hepatitis B virus. Most hepatitis B infections clear up within one to two months without treatment. When the infection lasts more than six months, it can develop into chronic hepatitis B, which can lead to chronic

inflammation of the liver, cirrhosis (scarring of the liver), liver cancer, and/or liver failure.

MENINGITIS

Meningitis is an inflammation (swelling) of the protective membranes covering the brain and spinal cord. A bacterial or viral infection of the fluid surrounding the brain and spinal cord usually causes the swelling. However, injuries, cancer, certain drugs, and other types of infections also can cause meningitis.

YELLOW FEVER

Yellow fever is an acute viral haemorrhagic disease transmitted by infected mosquitoes. The "yellow" in the name refers to the jaundice that affects some patients. Symptoms of yellow fever include fever, headache, jaundice, muscle pain, nausea, vomiting and fatigue.

TUBERCULOSIS

Tuberculosis (TB) is a potentially serious infectious disease that mainly affects your lungs. The bacteria that cause tuberculosis are spread from one person to another through tiny droplets released into the air via coughs and sneezes.

POLIOMYELITIS

Polio, also called poliomyelitis or infantile paralysis, is an infectious disease caused by the poliovirus. In about 0.5 percent of cases there is muscle weakness resulting in an inability to move.

3.2 Types of Immunisation

Active immunisation

Active immunisation can occur naturally when a person comes in contact with, for example, a microbe. The immune system will eventually create antibodies and other defenses against the microbe. The next time, the immune response against this microbe can be very efficient; this is the case in many of the childhood infections that a person only contracts once, but then is immune.

Artificial active immunisation is where the microbe, or parts of it, are injected into the person before they are able to take it in naturally. If whole microbes are used, they are pre-treated.

The importance of immunisation is so great that the American Centers for Disease Control and Prevention has named it one of the "Ten Great Public Health Achievements in the 20th Century". Live attenuated vaccines have decreased pathogenicity. Their

effectiveness depends on the immune systems ability to replicate and elicits a response similar to natural infection. It is usually effective with a single dose. Examples of live, attenuated vaccines include measles, mumps, rubella, MMR, yellow fever, varicella, rotavirus, and influenza

Passive immunisation

Passive immunisation is where pre-synthesised elements of the immune system are transferred to a person so that the body does not need to produce these elements itself. Currently, antibodies can be used for passive immunisation. This method of immunisation begins to work very quickly, but it is short lasting, because the antibodies are naturally broken down, and if there are no B cells to produce more antibodies, they will disappear.

Passive immunisation occurs physiologically, when antibodies are transferred from mother to fetus during pregnancy, to protect the fetus before and shortly after birth.

Artificial passive immunisation is normally administered by injection and is used if there has been a recent outbreak of a particular disease or as an emergency treatment for toxicity, as in for tetanus. The antibodies can be produced in animals, called "serum therapy," although there is a high chance of anaphylactic shock because of immunity against animal serum itself. Thus, humanised antibodies produced *in vitro* by cell culture are used instead if available.

3.3 Vaccine Impact

Direct and Indirect Effects

Immunisations against specific infectious diseases protect individuals against infection and thereby prevent symptomatic illnesses. Specific vaccines may blunt the severity of clinical illness (e.g., rotavirus vaccines and severe gastroenteritis) or reduce complications (e.g., zoster vaccines and postherpetic neuralgia). Some immunisations also reduce transmission of infectious disease agents from immunised people to others, thereby reducing the impact of infection spread. This indirect impact is known as *herd immunity*. The level of immunisation in a population that is required to achieve indirect protection of unimmunised people varies substantially with the specific vaccine.

Since childhood vaccines have become widely available in the United States, major declines in rates of vaccine-preventable diseases among both children and adults have become evident For example, vaccination of children <5 years of age against seven types of *Streptococcus pneumoniae* led to a >90% overall reduction in invasive disease caused by those types. A series of childhood vaccines targeting 13 vaccine-preventable diseases in a single birth cohort leads to prevention of 42,000 premature deaths and 20 million illnesses and saves nearly $70 billion (U.S.).

4.0 CONCLUSION

Few medical interventions of the past century can rival the effect that immunisation has had on longevity, economic savings, and quality of life. Seventeen diseases are now preventable through vaccines routinely administered to children and adults in the United States and most vaccine-preventable diseases of childhood are at historically low levels Health care providers deliver the vast majority of vaccines in the United States in the course of providing routine health services and therefore play an integral role in the nation's public health system.

5.0 SUMMARY

Immunisation is the process of introducing weakened or killed germs (vaccines) into the body, which increase body immunity to protect one from a particular disease. These weakened or killed germs stimulate the body to produce antibodies that will fight or weaken any disease organism that attempts to enter the body.

6.0 TUTOR-MARKED ASSIGNMENT

1. Define the term immunisation.

7.0 REFERENCES/FURTHER READING

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UNIT 2 IMMUNISATION TECHNIQUES AND SCHEDULES

CONTENTS

1.0 INTRODUCTION

Immunisation, or immunisation, is the process by which an individual's immune system becomes fortified against an agent (known as the immunogen).

When this system is exposed to molecules that are foreign to the body, called *non-self*, it will orchestrate an immune response, and it will also develop the ability to quickly respond to a subsequent encounter because of immunological memory. This is a function of the adaptive immune system.

2.0 OBJECTIVE

By the end of this unit, you will be able to:

- discuss immunisation techniques and schedules.

3.0 MAIN CONTENT

3.1 Overview of the Term

Immunisation, or immunisation, is the process by which an individual's immune system becomes fortified against an agent (known as the immunogen).

When this system is exposed to molecules that are foreign to the body, called *non-self*, it will orchestrate an immune response, and it will also develop the ability to quickly respond to a subsequent encounter because of immunological memory. This is a function of the adaptive immune system. Therefore, by exposing an animal to an immunogen in a controlled way, its body can learn to protect itself: this is called active immunisation.
The most important elements of the immune system that are improved by immunisation are the T cells, B cells, and the antibodies B cells produce. Memory B cells and memory T cells are responsible for a swift response to a second encounter with a foreign molecule. Passive immunisation is direct introduction of these elements into the body, instead of production of these elements by the body itself.

Immunisation is done through various techniques, most commonly vaccination. Vaccines against microorganisms that cause diseases can prepare the body's immune system, thus helping to fight or prevent an infection. The fact that mutations can cause cancercells to produce proteins or other molecules that are known to the body forms the theoretical basis for therapeutic cancer vaccines. Other molecules can be used for immunisation as well, for example in experimental vaccines against nicotine or the hormone ghrelin in experiments to create an obesity vaccine.

Immunisations are often widely stated as less risky and an easier way to become immune to a particular disease than risking a milder form of the disease itself. They are important for both adults and children in that they can protect us from the many diseases out there. Immunisation not only protects children against deadly diseases but also helps in developing children's immune systems. Through the use of immunisations, some infections and diseases have almost completely been eradicated throughout the United States and the World.

One example is polio. Thanks to dedicated health care professionals and the parents of children who vaccinated on schedule, polio has been eliminated in the U.S. since 1979. Polio is still found in other parts of the world so certain people could still be at risk of getting it. This includes those people who have never had the vaccine, those who didn't receive all doses of the vaccine, or those traveling to areas of the world where polio is still prevalent.

4.0 CONCLUSION

The most important elements of the immune system that are improved by immunisation are the T cells, B cells, and the antibodies B cells produce. Memory B cells and memory T cells are responsible for a swift response to a second encounter with a foreign molecule. Passive immunisation is direct introduction of these elements into the body, instead of production of these elements by the body itself.

5.0 SUMMARY

Immunisations are often widely stated as less risky and an easier way to become immune to a particular disease than risking a milder form of the disease itself. They are important for both adults and children in that they can protect us from the many diseases out there. Immunisation not only protects children against deadly diseases but also helps in developing children's immune systems.

6.0 TUTOR-MARKED ASSIGNMENT

1. Define the term immunisation.

7.0 REFERENCES/FURTHER READING

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UNIT 3 COLD-CHAIN MANAGEMENT

CONTENTS

1.0 INTRODUCTION

A cold chain or cool chain is a temperature-controlled supply chain. An unbroken cold chain is an uninterrupted series of refrigerated production, storage and distribution activities, along with associated equipment and logistics, which maintain a desired low-temperature range. It is used to preserve and to extend and ensure the shelf life of products, such as fresh agricultural produce, seafood, frozen food, photographic film, chemicals, and pharmaceutical drugs. Such products, during transport and when in transient storage, are sometimes called cool cargo. Unlike other goods or merchandise, cold chain goods are perishable and always en route towards end use or destination, even when held temporarily in cold stores and hence commonly referred to as cargo during its entire logistics cycle.

Cold chain logistics includes all of the means used to ensure a constant temperature for a product that is not heat stable, from the time it is manufactured until the time it is used.

2.0 OBJECTIVES

By the end of this unit, you will be able to:

- explain cold-chain management.

3.0 MAIN CONTENT

3.1 Definition of Term

A cold chain or cool chain is a temperature-controlled supply chain. An unbroken cold chain is an uninterrupted series of refrigerated production, storage and distribution activities, along with associated equipment and logistics, which maintain a desired low-temperature range. It is used to preserve and to extend and ensure the shelf life of products, such as fresh agricultural produce,seafood, frozen food, photographic film, chemicals, and pharmaceutical drugs. Such products, during transport and when in transient storage, are sometimes called cool cargo. Unlike other goods or merchandise,

cold chain goods are perishable and always en route towards end use or destination, even when held temporarily in cold stores and hence commonly referred to as cargo during its entire logistics cycle.

Cold chain logistics includes all of the means used to ensure a constant temperature for a product that is not heat stable, from the time it is manufactured until the time it is used. Moreover, cold chain is considered as a science, a technology and a process. It is a science as it requires the understanding of the chemical and biological processes associated with product perishability. It is a technology as it relies on physical means to ensure desirable temperature conditions along the supply chain. It is a process as a series of tasks must be performed to manufacture, store, transport and monitor temperature sensitive products.

Cold chains are common in the food and pharmaceutical industries and also in some chemical shipments. One common temperature range for a cold chain in pharmaceutical industries is 2 to 8 °C (36 to 46 °F), but the specific temperature (and time at temperature) tolerances depend on the actual product being shipped. Unique to fresh produce cargoes, the cold chain requires to additionally maintain product specific environment parameters[1] which include air quality levels (carbon dioxide, oxygen, humidity and others), which makes this the most complicated cold chain to operate.

This is important in the supply of vaccines to distant clinics in hot climates served by poorly developed transport networks. Disruption of a cold chain due to war may produce consequences similar to the smallpox outbreaks in the Philippines during the Spanish–American War.

There have been numerous events where vaccines have been shipped to third world countries with little to no cold chain infrastructure (Sub-Sahara Africa) where the vaccines were inactivated due to excess exposure to heat. Patients that thought they were being immunized, in reality were put at greater risk due to the inactivated vaccines they received. Thus great attention is now being paid to the entire cold chain distribution process to ensure that simple diseases can eventually be eradicated from society.

Traditionally all historical stability data developed for vaccines was based on the temperature range of 2–8 °C (36–46 °F). With recent development of biological products by former vaccine developers, biologics has fallen into the same category of storage at 2–8 °C (36–46 °F) due to the nature of the products and the lack of testing these products at wider storage conditions.

The cold chain distribution process is an extension of the good manufacturing practice (GMP) environment that all drugs and biological products are required to adhere to, enforced by the various health regulatory bodies. As such, the distribution process must be validated to ensure that there is no negative impact to the safety, efficacy or quality of the drug substance. The GMP environment requires that all processes that might impact the safety, efficacy or quality of the drug substance must be validated, including storage and distribution of the drug substance.

4.0 CONCLUSION

Cold chain logistics includes all of the means used to ensure a constant temperature for a product that is not heat stable, from the time it is manufactured until the time it is used. Moreover, cold chain is considered as a science, a technology and a process. It is a science as it requires the understanding of the chemical and biological processes associated with product perishability. It is a technology as it relies on physical means to ensure desirable temperature conditions along the supply chain. It is a process as a series of tasks must be performed to manufacture, store, transport and monitor temperature sensitive products.

Cold chains are common in the food and pharmaceutical industries and also in some chemical shipments.

5.0 SUMMARY

The cold chain distribution process is an extension of the good manufacturing practice (GMP) environment that all drugs and biological products are required to adhere to, enforced by the various health regulatory bodies. As such, the distribution process must be validated to ensure that there is no negative impact to the safety, efficacy or quality of the drug substance. The GMP environment requires that all processes that might impact the safety, efficacy or quality of the drug substance must be validated, including storage and distribution of the drug substance.

6.0 TUTOR-MARKED ASSIGNMENT

1. Define the term cold-chain management.

7.0 REFERENCES/FURTHER READING

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MODULE 4 VACCINE DEVELOPMENT TECHNOLOGIES

Unit 1 Concept of Vaccine Development Technologies
Unit 2 Immunological Techniques
Unit 3 Adverse Reactions

UNIT 1 CONCEPT OF VACCINE DEVELOPMENT TECHNOLOGIES

CONTENTS

1.0 INTRODUCTION

A vaccine is a biological preparation that provides active acquired immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism and is often made from weakened or killed forms of the microbe, its toxins, or one of its surface proteins. The agent stimulates the body's immune system to recognise the agent as a threat, destroy it, and to further recognise and destroy any of the microorganisms associated with that agent that it may encounter in the future. Vaccines can be prophylactic (example: to prevent or ameliorate the effects of a future infection by a natural or "wild"pathogen), or therapeutic (e.g., vaccines against cancer are being investigated).

2.0 OBJECTIVE

By the end of this unit, you will be able to:

- explain vaccine development technologies.

3.0 MAIN CONTENT

3.1 Definition of Term

A vaccine is a biological preparation that provides active acquired immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism and is often made from weakened or killed forms of the microbe, its toxins, or one of its surface proteins. The agent stimulates the body's immune system to recognise the agent as a threat, destroy it, and to further recognise and destroy any of the microorganisms associated with that agent that it may encounter in the future. Vaccines can be prophylactic (example: to prevent or ameliorate the effects of a future infection by a natural or "wild"pathogen), or therapeutic (e.g., vaccines against cancer are being investigated).

The administration of vaccines is called vaccination. Vaccination is the most effective method of preventing infectious diseases; widespread immunity due to vaccination is largely responsible for the worldwide eradication of smallpox and the restriction of diseases such as polio, measles, and tetanus from much of the world. The effectiveness of vaccination has been widely studied and verified; for example, vaccines that have proven effective include the influenza vaccine, the HPV vaccine, and the chicken pox vaccine. The World Health Organisation (WHO) reports that licensed vaccines are currently available for twenty-five different preventable infections.

The terms *vaccine* and *vaccination* are derived from *Variolae vaccinae* (smallpox of the cow), the term devised by Edward Jenner to denote cowpox. He used it in 1798 in the long title of his *Inquiry into the Variolae vaccinae known as the Cow Pox*, in which he described the protective effect of cowpox against smallpox. In 1881, to honor Jenner, Louis Pasteur proposed that the terms should be extended to cover the new protective inoculations then being developed.

4.0 CONCLUSION

The terms *vaccine* and *vaccination* are derived from *Variolae vaccinae* (smallpox of the cow), the term devised by Edward Jenner to denote cowpox. He used it in 1798 in the long title of his *Inquiry into the Variolae vaccinae known as the Cow Pox*, in which he described the protective effect of cowpox against smallpox. In 1881, to honor Jenner, Louis Pasteur proposed that the terms should be extended to cover the new protective inoculations then being developed.

5.0 SUMMARY

There is overwhelming scientific consensus that vaccines are a very safe and effective way to fight and eradicate infectious diseases. Limitations to their effectiveness, nevertheless, exist. Sometimes, protection fails because the host's immune system simply does not respond adequately or at all. Lack of response commonly results from

clinical factors such as diabetes, steroid use, HIV infection, or age. It also might fail for genetic reasons if the host's immune system includes no strains of B cells that can generate antibodies suited to reacting effectively and binding to the antigens associated with the pathogen.

6.0 TUTOR-MARKED ASSIGNMENT

1. Define the term vaccine.

7.0 REFERENCES/FURTHER READING

Folb, and Bernatowska (2004). "A Global Perspective on Vaccine Safety and Public Health: The Global Advisory Committee on Vaccine Safety", *American Journal of Public Health*, November: 94(11): 1926–1931.

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UNIT 2 IMMUNOLOGICAL TECHNIQUES

CONTENTS

1.0 INTRODUCTION

Immunological techniques are the wide varieties of methods and focused experimental protocols developed by immunologists for inducing, measuring, and characterising immune responses. The most common immunological methods relate to the production and use of antibodies to identify particular proteins in biological samples.

2.0 OBJECTIVE

By the end of this unit, you will be able to:
explain Immunological techniques.

3.0 MAIN CONTENT

3.1 Definition of Term

Immunological techniques are the wide varieties of methods and focused experimental protocols developed by immunologists for inducing, measuring, and characterising immune responses. The most common immunological methods relate to the production and use of antibodies to identify particular proteins in biological samples. They allow the immunologists to alter the immune system through cellular, molecular and genetic manipulation:

- Immunoelectrophoresis
- Immunohistochemistry
- Translational Immunology
- Biochemical Techniques
- Immunoassay
- Detection of Antibodies or Antigens
- Immunologic therapies
- Immunoprofiling

Immunological techniques include both experimental methods to study the immune system and methods to generate or use immunological reagents as experimental tools. The most common immunological methods relate to the production and use of antibodies to detect specific proteins in biological samples.

3.0 CONCLUSION

Immunological techniques are the wide varieties of methods and focused experimental protocols developed by immunologists for inducing, measuring, and characterising immune responses.

5.0 SUMMARY

Immunological techniques include both experimental methods to study the immune system and methods to generate or use immunological reagents as experimental tools. The most common immunological methods relate to the production and use of antibodies to detect specific proteins in biological samples.

6.0 TUTOR-MARKED ASSIGNMENT

1. Define immunological techniques.

7.0 REFERENCES/FURTHER READING

The GTN "Surveillance for Adverse Events Following Immunisations" training course has been held at: University of Cape Town in South Africa; National Pharmacovigilance Centre in Tunisia; Epidemiological Unit, Ministry of Health in Sri Lanka; and, Tarassevich Institute in Russia. For moreinformation,

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UNIT 3 ADVERSE REACTIONS

CONTENTS

1.0 INTRODUCTION

Immunology of adverse drug reactions: Adverse reactions to drugs often include an immunologic response. Immunologic reactions are often classified as Type I, Type II, Type III or Type IV, and these reaction types often correlate with clinical manifestations.

Since the beneficial effects of vaccines are a result of changes in the immune system, it would not be surprising if some of the adverse effects were also. A classification of immunologic reactions that can cause disease has been proposed by Coombs and Gell (1968). Four reactions make up the classification: type I, immediate hypersensitivity, the most serious clinical manifestation of which is anaphylaxis; type II, reaction of antibody with tissue antigens; type III, Arthus-type reaction, caused by deposition of antigen-antibody complexes in tissues, leading to the tissue-damaging effects of complement and leukocytes; and type IV, delayed-type hypersensitivity, which is mediated largely by T lymphocytes and macrophages.

2.0 OBJECTIVE

By the end of this unit, you will be able to:

- discuss adverse reaction.

3.0 MAIN CONTENT

3.1 Definition of Term

Immunology of adverse drug reactions: Adverse reactions to drugs often include an immunologic response. Immunologic reactions are often classified as Type I, Type II, Type III or Type IV, and these reaction types often correlate with clinical manifestations. Since the beneficial effects of vaccines are a result of changes in the immune system, it would not be surprising if some of the adverse effects were also. A classification of immunologic reactions that can cause disease has been proposed by Coombs and Gell (1968).

Four reactions make up the classification: type I, immediate hypersensitivity, the most serious clinical manifestation of which is anaphylaxis; type II, reaction of antibody with tissue antigens; type III, Arthus-type reaction, caused by deposition of antigen-antibody complexes in tissues, leading to the tissue-damaging effects of complement and leukocytes; and type IV, delayed-type hypersensitivity, which is mediated largely by T lymphocytes and macrophages. In clinical reactions to foreign antigens, these categories frequently overlap. These reactions are a by-product of the body's capacity to reject foreign invasion, particularly by microorganisms. If these reactions are responsible for causing adverse events to vaccines, then these reactions would be extensions of the beneficial responses to vaccines, which are mediated by protective immunoglobulin G (IgG) antibodies and T-lymphocyte responses.

3.2 Interaction of Antibody with Normal Tissue Antigens

In type II reactions, antibody combines with an antigen expressed on normal tissue cells, complement is activated, and the resultant inflammation damages the tissue. It is not clear whether this type of reaction is triggered by alteration in the expression of a tissue antigen or by the formation of an antibody to an antigen in food or an invading microorganism that then cross-reacts with a host antigen. Antigens in a vaccine could theoretically mimic a tissue antigen and elicit such a cross-reacting response, but this has not been shown. On first exposure to such an antigen, any resultant tissue reaction would be expected to develop in about 2 or 3 weeks; on re-exposure, a tissue reaction might occur within a few days. (These estimates are hypothetical and are based on what is known about primary and secondary antibody responses to foreign antigens.) The basis for type II reactions is not understood.

Arthus Reaction

The Arthus reaction is mediated differently from either anaphylaxis or type II reactions. Basic to this type III or Arthus reaction is the formation of antigen-antibody complexes, with a moderate excess of antigen, with deposition in the walls of blood vessels, and consequent organ damage. This is not an acute, immediately overwhelming condition. It generally develops over 6 to 12 hours if antibody levels are already high, or it can develop over several days (e.g., in serum sickness) as antibody levels increase and antigen persists. In this reaction, immune complexes in the walls of blood vessels initiate an inflammatory reaction involving complement and leukocytes, particularly neutrophils. Tissue sections show acute inflammation, and profound tissue destruction can occur.
Localised Arthus reactions have been reported to be common at the site of injection of some vaccines and occur when re-immunisation is performed in the presence of high levels of circulating IgG antibody. They are characterised by pain, swelling, induration, and edema.

Bottom of Form beginning several hours after immunisation and usually reaching a peak 12 to 36 hours after immunisation. They are self-limited, resolving over the course of a

few days. Their frequency and severity can be lessened by spacing immunisations more widely, as has been recommended for tetanus-diphtheria toxoid booster injections.

Generalised Arthus reactions of a serum sickness-like character have also been invoked following vaccine administration. Such generalised serum sickness-like reactions were common in the era when horse serum was used to treat or prevent many infectious diseases and when very large quantities of immunogenic foreign protein were infused (sometimes repeatedly). These reactions require both IgG antibody and circulating excess antigen. Considering the small quantity of protein in present-day vaccines that is injected, it is not clear that such reactions could occur as a result of immunisation. In animal models, symptoms and pathology tend to localise in the kidney, skin, joints, lung, and brain. The manifestations after vaccination most commonly ascribed to serum sickness-like mechanisms are arthritis and fever.

4.0 CONCLUSION

Since the beneficial effects of vaccines are a result of changes in the immune system, it would not be surprising if some of the adverse effects were also. A classification of immunologic reactions that can cause disease has been proposed by Coombs and Gell (1968). Four reactions make up the classification: type I, immediate hypersensitivity, the most serious clinical manifestation of which is anaphylaxis; type II, reaction of antibody with tissue antigens; type III, Arthus-type reaction, caused by deposition of antigen-antibody complexes in tissues, leading to the tissue-damaging effects of complement and leukocytes; and type IV, delayed-type hypersensitivity, which is mediated largely by T lymphocytes and macrophages.

5.0 SUMMARY

These reactions are a by-product of the body's capacity to reject foreign invasion, particularly by microorganisms. If these reactions are responsible for causing adverse events to vaccines, then these reactions would be extensions of the beneficial responses to vaccines, which are mediated by protective immunoglobulin G (IgG) antibodies and T-lymphocyte responses.

6.0 TUTOR-MARKED ASSIGNMENT

1. Define Adverse reaction.

7.0 REFERENCES/FURTHER READING

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Plotkin SL, Plotkin SA. (2008)."A short history of vaccination," In: Plotkin S, Orenstein W, Offit PA. Vaccines, 5th edition, Philadelphia: Saunders.