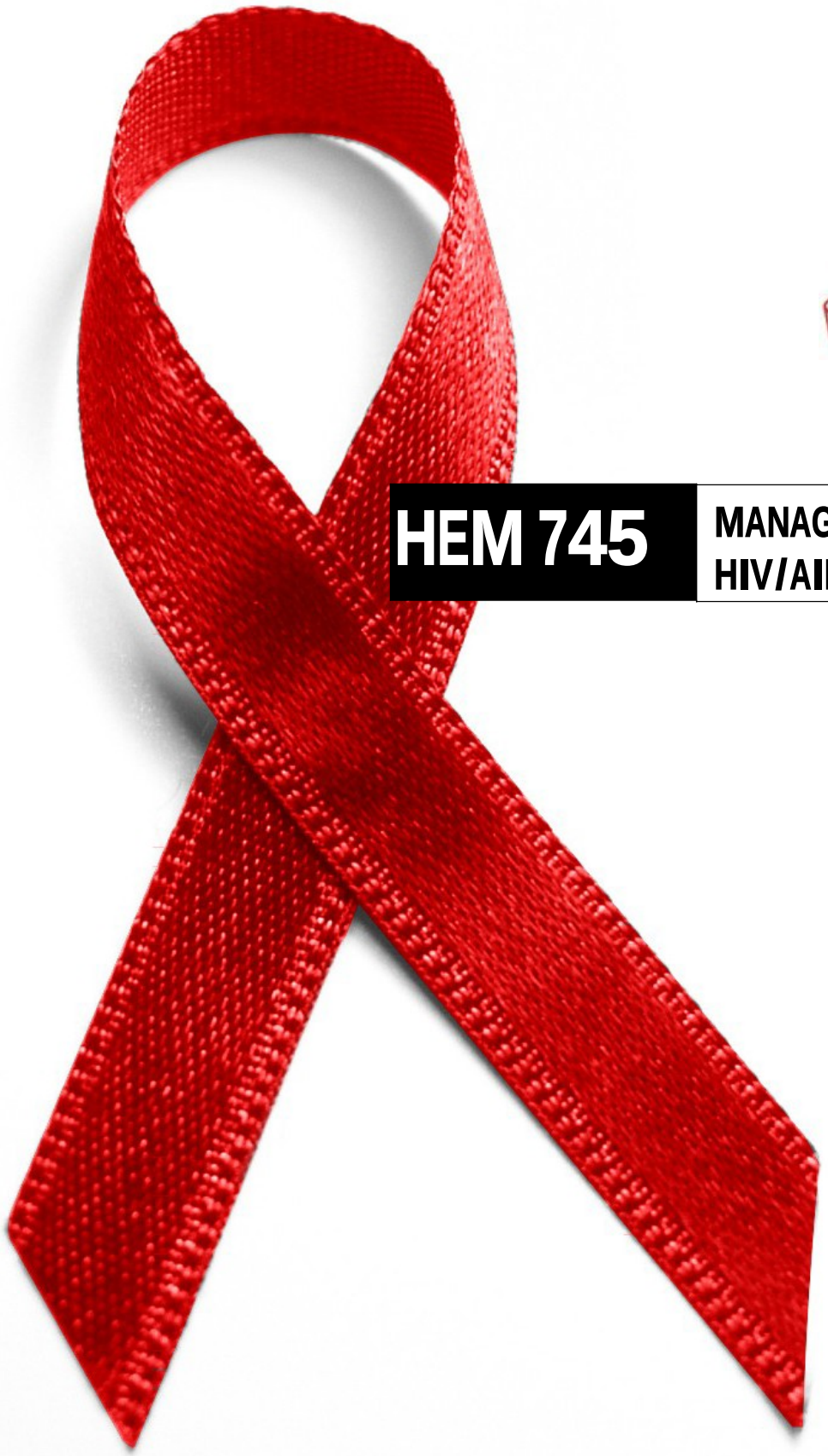

HEM 745 MANAGEMENT AND CARE OF HIV/AIDS

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MODULE 1 DEFINING AND UNDERSTANDING HIV/ AIDS CONCEPTS

UNIT 1 HIV/AIDS: DEFINITIONS/CLASSIFICATIONS AND SYMPTOMS

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1.0INTRODUCTION

The treatment and care of HIV-infected persons includes provision of clinical care, nursing care, emotional support, nutritional care and support. Clinical care includes early diagnosis, antiretroviral therapy, prevention and treatment against opportunist infections. The treatment and care of HIV-infected people requires comprehensive integration of patient-centered medical and social services. Essential elements of this approach include the provision of clinical care, nursing care, nutritional care and support, psychological support, health information and counseling, legal protection, and economic sufficiency. Notable components of successful clinical care include early diagnosis, access to care, antiretroviral therapy, symptom control, prophylaxis against opportunistic infections, treatment of opportunistic infections, malignancies and end of-life care.

The achievement of these objectives requires multi-sectoral and multidisciplinary teams that are cross-linked to provide a continuum of care that involves patients, their families, healthcare providers, governmental, nongovernmental organizations, and society at large. Prevention of new infections should be integrated into HIV/AIDS

treatment and care programs as HIV infection remains incurable despite advances in antiretroviral treatment. Toward this end, “social immunization” such as through community mobilization, widespread education, counseling and testing, sexual abstinence until marriage, monogamy, condom use, and female empowerment must be strengthened, as we await the perfection of vaginal microbicides, HIV vaccines and other currently investigational prevention strategies. Even if HIV transmission were to cease completely in Nigeria and other resource-limited countries, the existing burden of HIV/AIDS would continue to task all stakeholders into the foreseeable future.

This module is meant to introduce students to understand the basic concepts and meaning of HIV/AIDS infection. HIV/AIDS is the newest reproductive health infection with serious economic, social and psychological consequences. It affects all facets or categories of people irrespective of age, ethnic group, gender, education and religion. The accurate understanding of HIV/AIDS, it causes, symptoms, prevention, treatment and management of the disease are very important to everybody as they help for prevention, planning and avoidance of the disease, policy and implementation.

2.0 OBJECTIVES

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

Describe basic HIV/AIDS concepts
Define HIV and AIDS
Identify differences between HIV/AIDS
Illustrate how HIV is spread

3.0 MAIN CONTENT

3.1 Definition of Key Terms

HIV - Human immunodeficiency virus
AIDS - Acquired Immune-deficiency syndrome
HIV Prevention - The various ways HIV transmission is prevented
CD4 Cells - These are group of cells responsible for improving the immune system of an individual
Opportunistic infections - The various diseases that accompanied HIV/AIDS disease
Unsafe sex - These are various sexual behavious that expose people to HIV/AIDS infection.

3.2 What is HIV?

HIV stands for Human Immunodeficiency Virus. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome). HIV attacks the immune system's soldiers - the CD4 cells. When the immune system loses too many CD4 cells, you are less able to fight off infection and can develop serious opportunistic infections. A person is diagnosed with AIDS when he or she has less than 200 CD4 cells or one has AIDS-defining opportunistic infections. There is only one reliable way to find out your HIV status and the most common test is an antibody test called ELISA. A positive result means you have antibodies for HIV and you are infected with the virus.

The HIV antibody test is one of the most reliable medical tests. According to the Centers for Disease Control and Prevention (CDC, 2001), it is more than 99% accurate. In addition, all positive results are confirmed with another test (called the Western Blot) to ensure no mistakes are made. While many viruses can be controlled by the immune system, HIV targets and infects the same immune system cells that are supposed to protect us from illnesses. These are a type of white blood cell called CD4 cells. HIV takes over CD4 cells and turns them into virus factories that produce thousands of viral copies. As the virus grows, it damages or kills CD4 cells, weakening the immune system.

3.3 What is AIDS?

AIDS stands for Acquired Immune Deficiency Syndrome. AIDS is the most advanced stage of HIV infection. HIV causes AIDS by attacking the immune system's soldiers – the CD4 cells. When the immune system loses too many CD4 cells, you are less able to fight off infection and can develop serious, often deadly, infections. These are called opportunistic infections (OIs) because they take advantage of the body's weakened defenses. When someone dies of AIDS, it is usually opportunistic infections or other long-term effects of HIV infection that cause death. AIDS refers to the body's immune-compromised state that can no longer stop OIs from developing and becoming so deadly.

3.4 What is the Difference between HIV and AIDS?

You don't have AIDS as soon as you are infected with HIV. You can be HIV+ for many years with no signs of disease, or only mild-to-moderate symptoms. But without treatment, HIV will eventually wear down the immune system in most people to the point that they develop more serious OIs. The Centers for Disease Control and Prevention (CDC, 2001) defines someone as having AIDS if he or she is HIV+ and meets one or both of these conditions:

Has had at least one of 21 AIDS-defining opportunistic infections

Has had a CD4 cell count (T-cell count) of 200 cells or less (a normal CD4 count varies by laboratory, but usually is in the 600 to 1,500 range)

3.5 How can one know if he/she has HIV?

Most people can not tell that they have been exposed or infected. It can take up to 12 weeks for an HIV test to come back positive. However most people respond much faster. Within two to four weeks of exposure to HIV, you might have flu-like symptoms such as fever, swollen glands, muscle aches, or rash. The only way to know for sure if you are infected is take an HIV test. If you are infected, your immune system will make antibodies to fight the virus. The HIV test looks for these antibodies. If you have them in your blood, it means that you have HIV infection.

3.6 How HIV Spreads

There is still misunderstanding about how HIV is transmitted from one person to another. Knowing the basics helps you avoid getting the virus if you are HIV-, and avoid passing it on if you are HIV+.

HIV is spread through the following body fluids:

Blood (including menstrual blood)
Semen and other male sexual fluids ("pre-cum")
Vaginal fluids
Breast milk

HIV is not spread through these body fluids:

Sweat
Tears
Saliva (spit)
Shaking of hands
Eating together in the same plate.

The spread of HIV can be prevented! There are ways to avoid, or at least, reduce contact with the bodily fluids that spread HIV (blood, sexual fluids and breast milk).

SELF ASSESSMENT EXERCISE

The Centers for Disease Control and Prevention (CDC) defines someone as having AIDS if he or she is HIV+ and meets one or both of these conditions, namely

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4.0 CONCLUSION

In this unit, we observed that HIV stands for Human Immunodeficiency Virus. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome). HIV attacks the immune system's soldiers - the CD4 cells. When the immune system loses too many CD4 cells, you are less able to fight off infection and can develop serious opportunistic infections. A person is diagnosed with AIDS when he or she has less than 200 CD4 cells or one has AIDS-defining opportunistic infections. Also, AIDS stands for Acquired Immune Deficiency Syndrome. AIDS is the most advanced stage of HIV infection. HIV causes AIDS by attacking the immune system's soldiers – the CD4 cells. There is thus, still misunderstanding about how HIV is transmitted from one person to another. Knowing the basics helps you avoid getting the virus if you are HIV-, and avoid passing it on if you are HIV+.

5.0 SUMMARY

This unit provided a broad view of concepts of HIV/AIDS, its distinctions and signs of HIV/AIDS infection. We hope you enjoyed this introductory unit. Now let us attempt the questions below.

6.0 TUTOR MARKED ASSIGNMENT

1. Define HIV and AIDS
2. Illustrate the difference between HIV and AIDS.

ANSWER TO SELF ASSESSMENT EXERCISE

The Centers for Disease Control and Prevention (CDC) defines someone as having AIDS if he or she is HIV+ and meets one or both of these conditions:

Has had at least one of 21 AIDS-defining opportunistic infections
Has had a CD4 cell count (T-cell count) of 200 cells or less (a normal CD4 count varies by laboratory, but usually is in the 600 to 1,500 range)

7.0 REFERENCES/FURTHER READINGS

Centers for Disease Control and Prevention. HIV/AIDS—United States, 1981–2000. MMWR Morb Mortal Wkly Rep 2001; 50:430–4.

Centers for Disease Control and Prevention. The Global HIV/AIDS epidemic, 2001. MMWR Morb Mortal Wkly Rep 2001; 50:434–9

UNIT 2 HIV/AIDS: MODES OF TRANSMISSION

CONTENTS

1.0 INTRODUCTION

In the past, HIV was spread in blood products, such as whole blood or the "factor" used by hemophiliacs. Many people were infected this way. The blood supply is now much more strictly tested and controlled. The possibility of being infected from receiving blood in the U.S. and other developed countries is extremely low. You cannot get HIV from donating blood – a new clean needle is used for each donation. Sometimes, primarily healthcare workers are occasionally infected through needle sticks with infected blood, or through other medical accidents. This is a very tiny percentage of overall infections. (CDC, 2001)

2.0 OBJECTIVES

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

Illustrate the role of re-using and sharing of needles on HIV infection
Illustrate the influence of unprotected/unsafe sex on HIV infection
Describe mother-to-child transmission of HIV infection
Define freak transmission
Ascertain true versus false risk of transmission of HIV

3.0 MAIN CONTENT

3.1 HIV/AIDS: Methods of Transmission

Today, the most common ways HIV is passed from one person to another are:

Re-using and sharing needles/sharp objects
Unprotected/unsafe sex (no condoms or other barrier devices)
Mother-to-child

3.1.1 Re-using and sharing of needles

Many HIV infections occur when people share needles/sharp objects to inject heroin, methamphetamine or other drugs. This risk can be greatly reduced by cleaning needles with a bleach solution before re-using them. The risk can be eliminated by using fresh needles each time. Many cities now offer free needle exchange programs. When getting a tattoo or body piercing, always go to licensed health-care providers and make sure the equipment is autoclaved, not just "sterilized" with alcohol.

3.1.2 Un-protected/unsafe sex

Every sexual act that involves sexual fluids of some kind has at least some risks. Barriers, such as condoms (male and female), dental dams, latex gloves and even plastic food wrap (such as Saran Wrap), help reduce risk substantially. Unsafe sex (sex without condoms or barriers) puts you and your partner at risk for HIV or other sexually transmitted diseases (STDs). Safer sex (sex using condoms or other barriers correctly and consistently) protects you and your partner.

Which common sexual activities are most likely to cause HIV transmission when safer sex isn't used?

1. Receptive anal sex ("bottoming") remains the most risky activity, due to the likelihood of direct semen-blood contact. But penetrative anal sex ("topping") with someone can result in HIV transmission, too.
2. Vaginal intercourse puts both partners at risk, but HIV is transmitted from men to women much more easily than from women to men.
3. Oral sex can be risky for the person performing it, particularly if he or she swallows semen, vaginal fluids, or menstrual fluids.
4. Sharing sex toys without sterilizing them can be dangerous.
5. Rimming (licking the anus) is very unlikely to result in HIV infection.

6. Mutual masturbation (hand jobs) and fisting (using a hand to penetrate the anus or vagina) are relatively risk-free, as long as your hand has no open cuts or sores.
7. Sexual assault can result in infection if the assailant is HIV+. The risk increases when rape involves anal penetration, force, and/or multiple assailants. Some forced sexual acts involving wounds can place a victim at very high risk.

In major cities, post-exposure prophylaxis (PEP) is often offered to victims of sexual assault. This month-long treatment reduces the likelihood of HIV infection substantially. It is currently only used on a regular basis for victims of sexual assault and for healthcare workers who have been exposed to HIV on the job. PEP must be started as quickly as possible, always within 72 hours of the exposure. (Kraak , Stricker & Utermohlen, 1994)

3.1.3 Mother-To-Child Transmission

HIV+ mothers can pass the virus to their babies while pregnant, during birth or by breastfeeding. New medical techniques have almost eliminated the risk of a baby getting HIV from its mother when precautions are taken. HIV+ mothers should not breastfeed their babies.

3.1.4 Freak Transmissions

There are a few isolated cases of people infected from using a razor that had just been used by an HIV+ man or in other off-beat ways. To be safe, always avoid direct contact with blood and sexual fluids in any context. Don't worry too much about freak cases. For instance, there is a documented case of transmission from deep or "French" kissing – in two people who had terrible dental problems. The odds of getting HIV from kissing, even when one person is HIV+, are less than the odds of being struck by lightning.

3.2 True versus False Risk of Transmission

HIV cannot be transmitted except when certain bodily fluids are exchanged. Baum, Cassetti & Bonhevi et al) identified the risk of transmission by:

Avoiding contact with sexual fluids by always practicing safer sex
Abstaining from sex unless you and your partner are both HIV- and in a long-term, monogamous relationship
Not using injection drugs, or if you do, always using new or clean needles

Finding out your HIV status if you are planning to get pregnant and working with a knowledgeable doctor and obstetrician if you are HIV+

If you protect yourself in these ways, you do not need to be afraid of getting or passing HIV by casual contact. Remember, HIV is not transmitted by:

Hugs
Dancing
Sharing food or drinks
Using a shower, bath, or bed used by an HIV+ person
Kissing (between people with no significant dental problems)
Sharing exercise equipment

SELF ASSESSMENT EXERCISE

How can we reduce the risk of HIV infection through needles and sharp objects?

4.0 CONCLUSION

In this unit, we illustrated that the most common ways HIV is passed from one person to another are: re-using and sharing of needles, unprotected/unsafe sex (no condoms or other barrier devices), and mother-to-child transmission. We also illustrated the true versus false risk of HIV infection. Thus, we identified that HIV is not transmitted by hugging, dancing, sharing of food or drinks etc.

5.0 SUMMARY

This unit identified the different modes of transmission of HIV. We hope you are now more equipped to make right and life saving decisions.

6.0 TUTOR MARKED ASSIGNMENT

Identify the true versus false risk of HIV transmission

ANSWER TO SELF ASSESSMENT EXERCISE

Many HIV infections occur when people share needles to inject heroin, methamphetamine, or other drugs. This risk can be greatly reduced by cleaning needles with a bleach solution before re-using them. The risk can be eliminated by using fresh needles each time. When getting a

tattoo or body piercing, always go to a licensed professional and make sure the equipment is autoclaved, not just "sterilized" with alcohol.

7.0 REFERENCES/FURTHER READINGS

Centers for Disease Control and Prevention. The Global HIV/AIDS epidemic, 2001. MMWR Morb Mortal Wkly Rep **200**1; 50:434–9.

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UNIT 3 THE HISTORY AND CLASSIFICATION OF HIV/AIDS INFECTION.

CONTENTS

1.0 INTRODUCTION

In this unit, we will look at natural history and classifications of HIV/AIDS as well as symptoms of HIV and AIDS.

2.0 OBJECTIVES

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

Explain the stages of history of HIV/AIDS
Identify symptoms of HIV and AIDS

3.0 MAIN CONTENT

3.1 Classification and History of HIV and AIDS

The history of the HIV infection is divided into the following stages.

Viral transmission, lasting 2–3 weeks
Acute retroviral syndrome, lasting 2–3 weeks Recovery and seroconversion
Asymptomatic chronic HIV infection, lasting an average of 8 years
Symptomatic HIV infection/AIDS defining complication of about 1.3 years
Death

Acute retroviral syndrome develops about 2 weeks after the initial infection and is characterized by a flu-like illness. The features of this syndrome include fever, lymphadenopathy, non exudative pharyngitis, maculopapular rash, diarrhea, headache, nausea and vomiting. In some

cases, certain neurologic manifestations as meningitis and acute encephalitis may appear.

During acute retroviral syndrome, tests that directly detect HIV RNA bypolymerase chain reaction (RNA PCR), DNA PCR, and p24 antigen —are usually positive, but HIV antibody tests are negative. The sensitivity of RNA PCR for diagnosing acute retroviral syndrome approaches 100%, but the specificity is slightly lower (about 98%). HIV RNA level during this syndrome is usually greater than 100,000 copies/ ml. (CDC, 2001)

Kotler, Wang &Pierson (2000) identified possible laboratory abnormalities during acute retroviral syndrome include: thrombocytopenia, lymphopenia, anemia, monocytosis, low level atypical lymphocytosis, thrombocytosis, bandemia and abnormal liver function tests.

The infected individual is most infectious during acute retroviral syndrome because of the high viral replication level. Reports from Malawi have shown that in areas of high HIV prevalence, up to 3% of individuals in high-risk populations, such as those with sexually transmitted infections (STIs), may have acute HIV infection and are potential sources of HIV transmission even though they have negative serology for HIV. This type of situation poses a major public health challenge in resource-limited countries where high-risk individuals may form a significant proportion of blood donors.

The staging of HIV and AIDS disease has important implications for clinical decision making and priority setting for treatment because patients with AIDS, symptomatic disease, and low CD4+ counts usually have more severe disease and therefore require more urgent attention.

SELF ASSESSMENT EXERCISE

The history of the HIV infection (without antiretroviral therapy [ART]) is divided into the following stages……

3.2 Symptoms of HIV and AIDS

The clinical features include fever, headache, malaise, joint pains, pain and tenderness in the muscles (myalgia), diarrhea, maculopapular rash and generalized swollen lymph glands (lymphadenopathy). These symptoms may be accompanied by various self-limiting neurologic manifestations, such as atypical aseptic meningitis and acute encephalitis. Acute retroviral syndrome goes unrecognized in many individuals perhaps because of a lack of suspicion or perhaps because it

is difficult to distinguish these features from a host of other common tropical illnesses, such as malaria, typhoid fever, the common cold, and glandular fever. Acute retroviral syndrome is characterized by high plasma viremia and depressed CD4+ cell numbers and function. Acute retroviral syndrome has also been described in chronically HIV infected patients who are re-infected with another strain of HIV, and a similar clinical syndrome occurs in some patients as a result of virologic rebound following withdrawal of suppressive ART.

During acute retroviral syndrome, tests that directly detect HIV RNA by polymerase chain reaction (RNA PCR) and antigen are usually positive, but HIV antibody tests are negative. The sensitivity of RNA PCR for diagnosing acute retroviral syndrome approaches 100%, but the specificity is slightly lower (about 98%). HIV RNA level during this syndrome is usually greater than 100,000 copies/ml.

4.0 SUMMARY

This unit and also this module discusses the different aspects of HIV/AIDS infections, starting from the objectives of studying the HIV/ AIDS disease, classification, vulnerability, factors fuelling the spread, symptoms, ways of contact and impact of the disease. We hope you enjoyed your studies.

5.0 CONCLUSION

HIV/AIDS is a serious disease that requires federal government, state, local government and the private sector to participate fully in prevention, control, treatment and management of the disease. The proper understanding of HIV/AIDS causes and preventive behaviors by individuals, groups and community members will help a lot in reducing the spread of the disease. All stakeholders must integrate or synergies the various interventions across different level in the country.

6.0 TUTOR MARKED ASSIGNMENT

Discuss different symptoms of HIV/AIDS infection.

ANSWER TO SELF ASSESSMENT EXERCISE

The history of the HIV infection (without antiretroviral therapy [ART]) is divided into the following stages:

Viral transmission, lasting 2–3 weeks
Acute retroviral syndrome, lasting 2–3 weeks Recovery and seroconversion

Asymptomatic chronic HIV infection, lasting an average of 8 years
Symptomatic HIV infection/AIDS defining complication of about 1-3 years
Death

7.0 REFERENCES/FURTHER READINGS

Centers for Disease Control and Prevention. HIV/AIDS—United States, 1981–2000. MMWR Morb Mortal Wkly Rep **200**1; 50:430–4.

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MODULE 2 PSYCHOLOGICAL MANAGEMENT AND COUNSELLING OF HIV/AIDS PATIENTS.

UNIT 1 PSYCHOLOGICAL ISSUES IN HIV/AIDS

CONTENTS

1.0 INTRODUCTION

The main objective of studying counselling as HIV/AIDS management has become a core element in a holistic model of health care, in which psychological issues are recognised as integral part of patient's management. It has also been proved effective in various management and treatment of HIV/AIDS patients worldwide. In this unit, we will look at psychological issues in HIV/AIDS.

2.0 OBJECTIVES

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

Define certain terms relating to counseling and psychological issues of HIV/AIDS
Explain the various psychological responses to HIV/AIDS
Describe psychological response to HIV positive test

3.0 MAIN CONTENT

3.1 Definition of Key Terms

Counselling - A scientific method of relieving pain and improving clients' self capacity to manage the situations or disease.

Depression - A psychological reaction to unpleasant situations or events in the environment

Coping strategies - An individual's methods of resolving certain events without creating more damage to him/her

Counselling programmes - The various interventions put in place to help clients improve their living conditions.

Pre- test Counselling - The initial or baseline counselling information before psycho-social intervention

Post-test counselling - The follow-up counselling after interventions have been given to clients.

3.2 Psychological Issues in HIV/AIDS Counselling

Psychological issues in HIV and AIDS counselling includes:

(A) Shock

- Shock of diagnosis
- Shock of recognition of mortality
- Shock of loss of hope for the future

(B) Fear and anxiety

- Fear and anxiety of uncertain prognosis anxiety of effect of medication and treatment and treatment failure.
- Fear and anxiety of isolation, abandonment and social sexual rejection.
- Fear and anxiety of infecting others and being infected by them.
- Fear and anxiety of partner's reaction.

(C) Depression

- Depression in adjustment to living with a chronic viral condition.
- Depression over absence of a cure.
- Depression over limits imposed by possible ill health.

- Depression of possible social, occupational and sexual rejection.
- Depression if treatment fails.

(D) Anger and frustration

- Anger and frustration over becoming infected.
- Anger and frustration over new and involuntary health/lifestyle restrictions.
- Anger and frustration over incorporating demanding drug regimens and possible side effects into daily life.

(E) Guilt

- Guilt of interpreting HIV as a punishment for example for being gay or using drugs.
- Guilt over anxiety caused to partner/family.

SELF ASSESSMENT EXERCISE

Define the following:

i. Pre-test counselling
ii. Post-test counselling
iii. Coping strategies

3.3 Psychological Responses to HIV Positive Result

Reactions to an HIV positive diagnosis are part of the normal and expected range of responses to news of a chronic potentially life threatening medical condition. Many patients adjust extremely well with minimal intervention while some will exhibit prolonged periods of distress and hostility. Serious psychological maladjustment may indicate pre-existing morbidity and will require psychological/psychiatric assessment and treatment.

Hardman (2001) states that effective counselling requires allowing time for the shock of the news to sink in, there may be a period of emotional ventilation including overt distress. The job of the counsellor is to provide an assurance of strict confidentiality and rehearse, over time, the solutions to practical problems such as who to tell, what needs to be said, discussion around safer sex practices and adherence to drug therapies, clear information about medical and counselling follow up should be given. Counselling may also be of help for the patients' partner and other family members. Depressed patients should also be assessed for suicidal ideation. (W.H.O,1995)

4.0 CONCLUSION

The definitions of several terms presented in this unit could aid your understanding of counselling and psychological issues in HIV and AIDS. Terms like depression, coping management, pre and post-test counselling were briefly defined. Here, pre-test counselling was viewed as the initial or baseline counselling before psychological intervention, while post-test counselling was described as the follow-up counselling after interventions have been given to clients. This unit also tackled several psychological issues in HIV counselling and they included, shock, fear, depression, anger and guilt. Lastly, we also observed that reactions to an HIV positive diagnosis are part of the normal and expected range of responses to news of a chronic potentially life threatening medical condition. Many patients adjust extremely well with minimal intervention while some will exhibit prolonged periods of distress and hostility.

5.0 SUMMARY

We hope you enjoyed your study. This unit provided us with psychological issues in HIV counselling. More of these issues will be discussed further in subsequent units. Ok. Let us attempt the questions below.

6.0 TUTOR MARKED ASSIGNMENT

Identify the psychological issues in HIV/AIDS counselling

ANSWER TO EXERCISE

Coping strategies - An individual's methods of resolving certain events without creating more damage to him/her
Pre- test counselling - The initial or baseline counselling before psychological intervention
Post-test counselling - The follow-up counselling after interventions have been given to clients.

7.0 REFERENCES/FURTHER READINGS

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UNIT 2 COUNSELLING AND HIV/AIDS

CONTENTS

1.0 INTRODUCTION

Various studies have proved that good counselling assisted clients to make informed decisions – such as whether to have an HIV test, helped people living with HIV or AIDS to cope better with their condition, live positive life and it has also helped in the prevention of HIV transmission. Counselling is a core element in the care of HIV/AIDS infected patients. However, many decision makers and service managers such as policy makers in government, CMDs of hospitals or heads of non-governmental organisations (NGO's) know the effectiveness of counselling. Major obstacles to the development and provision of good counselling services include:

Lack of policy approval for establishing counselling services.
Insufficient space or resources provided for counsellors.
Unreasonable demands on the time of counsellors.
Lack of privacy and confidentiality amongst others.

Disseminating the results of studies on the beneficial impact of counselling has helped to overcome the scepticism and strengthen the support given to counselling for the purpose of this work, emphasis shall be laid up on the effect of counselling on HIV/AIDS patients.

2.0 OBJECTIVES

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

Explain the aims of Counselling in HIV/AIDS
Identify different HIV Counselling Programmes and Services
Illustrate coping Strategies in HIV/AIDS
Describe the counselling Process
Identify types of Counselling
Describe pre and post-test Counselling

3.0 MAIN CONTENT

3.1 Aims of Counselling in HIV/AIDS

HIV/AIDS counselling contains the *prevention* of HIV transmission and the *support* of those affected directly and indirectly by HIV. It is vital that HIV counselling should have these dual aims because the spread of HIV can be prevented by changes in behaviour. Preventive counselling has a particular contribution in that it enable frank discussion of sensitive aspects of a patients life, such discussion may be hampered in other settings by the patients concern for confidentiality or anxiety about a judgemental response,(WHO,1994)

Also, when patients know that they have HIV infection or disease, they may suffer great psychosocial stresses through a fear of rejection, social stigma, disease progression and the uncertainties associated with future management of HIV/AIDS. Good clinical management is required to minimise morbidity and reduce its occurrence and counsellors in this field have formal counselling training and they receive regular clinical supervision as part of adherence to good standards of clinical practice.

3.2 Different HIV/AIDS Counselling Programmes.

There are different HIV counselling programmes and services and they include:

Counselling before the test is done.
Counselling after the test for those who are HIV positive and HIV negative.
Risk reduction assessment to help and prevent transmission.
Counselling after a diagnosis of HIV disease has been made.
Family and relationship counselling.
Bereavement counselling
Telephone “Hotline” counselling
Outreach counselling
Crisis intervention
Structured psychological support for those affected by HIV
Support groups counselling

3.3 Coping Strategies

There are different types of strategies that can help people with HIV/AIDS to come to terms with their condition and they include:

Using counselling
Problem solving
Participation in discussions about treatment
Using social and family networks
Use of alternative therapies for example relaxation techniques, massage etc.
Exploring individual potential for control over manageable issues
Disclosure of HIV status and using support options.

The importance of coping strategies involves active participation of patients to the extent the patients can manage themselves and fully empowered in planning of care and in seeking appropriate social support from relevant authorities. Such an approach includes encouraging problem solving, participation in decision about their treatment and care and emphasising self worth and the potential for personal control over manageable issues in life.

3.4 Counselling Process

Kotler, Tierney et al (2001) report that HIV/AIDS counselling is a confidential dialogue between a client and a counsellor aimed at enabling the client to cope with stress and take personal decisions related to HIV/AIDS. The counselling process includes evaluating the personal risk of HIV/AIDS transmission and discussing how to prevent infection. It concentrates specifically on emotional and social issues related to possible or actual infection with HIV/AIDS. With the consent of the client, counselling can be extended to spouses, sex partners and relatives. HIV/AIDS counselling has as its objectives both prevention and care.

A counsellor is a person trained in the skills of the job of listening to the client, asking supportive questions, discussing options, encouraging the client to make his/her own informed decisions, giving practical information and suggesting follow up. Counselling should be a process involving a series of sessions as well as follow-ups, it can also be done in any location that offers peace of mind and confidentiality for the clients.

3.5 Types of Counselling

Two (2) major types of counselling are commonly practised

(a) Clinic-based counselling is a type of counselling provided in a formal session – in a hospital, health centre or clinic by a trained professional such as a doctor, social worker, nurse or psychologist.

(b) Community-based counselling is given in a non-formal environment in a village or urban neighbourhood by one community member trained in counselling to another community or family member.

3.5.1 Pre-Test HIV/AIDS Counselling.

Pre-test HIV/AIDS counselling is often given in connection with a voluntary test. Such counselling helps to prepare the client for the HIV test, explains the implications of knowing that one is or is not infected with HIV, and facilitates discussion about ways to cope with knowing one's HIV status. It also involves a discussion of sexuality, relationships, possible sex and drug-related risk behaviours and how to prevent infection. It helps correct myths and misinformation around the subject of HIV/AIDS. Whenever resources permit, pre-test counselling should be made available to those who desire it. People who do not want or do not have access to pre-test counselling should not be prevented from taking a voluntary HIV test. Informed consent is always required before an HIV test so that the individuals name will be linked to the result.

3.5.2 Post-Test Counselling

Post-test counselling helps the client understand and cope with the HIV test result. In this type of counselling, the counsellor prepares the client for the result, gives the result and then provides the client with any further information required, if necessary refer the person to other services. The two usually discus ways to reduce the risk of infection or transmission of HIV test results should always be given with counselling.

The post-test counselling is that type of counselling where the counsellor explains the test result, whether it is positive, the counsellor needs to tell the client clearly, and as gently and humanly as possible, providing emotional support and discussing with the client on how best to cope, including information on relevant referral services.

Ongoing counselling will help clients accept their HIV status, and take a positive attitude to their lives. Through this ongoing counselling, the infected person may choose to inform a trusted family member to share confidentiality and participate in the counselling. Counselling is also important after a negative result while the client is likely to feel relief, the counsellor must emphasize several points. (Walensley & Paltid, 1997)

Firstly, because of the "window period", a negative result may not mean absence of infection, and the client might wish to consider returning for a repeat test after 3-6 months. Secondly, counsellors need to discuss HIV prevention providing support to help the client adopt and sustain any new safer practices.

4.0 CONCLUSION

Many patients diagnosed with HIV some years ago are now feeling well enough to return to work and to study and are paradoxically, learning to read, just to living, as they had formally adjusted to the possibility of dying. Patients also have to deal with the uncertainty which remains about the long term efficacy of current medical treatment. Even with the significant medical advances in patient's management, counselling remains an integral part of the management of patients with HIV/AIDS, their partners and family.

5.0 SUMMARY

The contraction of HIV/AIDS infection is normally accompanied with various psychological responses such as denial, refusal, cry, disbelief, sometimes suicidal ideation and actual death. Psychological counselling is a vital component of HIV/AIDS prevention and gateway to treatment and management. Hope you enjoyed your studies. As usual, let us attempt the question below.

6.0 TUTOR MARKED ASSIGNMENT

Differentiate between pre-test and post test counselling of HIV/AIDS patients.

Discuss the importance of counselling HIV/AIDS patients.

7.0 REFERENCES/FURTHER READINGS

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UNIT 3 FAMILIES CARE FOR HIV/AIDS PATIENTS.

CONTENTS

1.0 INTRODUCTION

Family care is considered care giving activities and it involves assisting HIV/AIDS within the household. However, family care given mainly in physical terms as custodial or maintenance help or services rendered by a family member for the well being of relatives who cannot perform such activities themselves. Graham (1985) maintains that care goes beyond mere physical assistance, it is the provision of care encompassing the emotional aspect of managing feelings and establishing and maintaining relationships. Caring about family members involves affection and a sense of psychological responsibility, while it also encompasses both the performance of concrete tasks and a sense of psychological responsibility.

2.0 OBJECTIVES

At the end of this unit, you should be able:

Understand the basic concept of family care
To differentiate types of HIV/AIDS family care

3.0 MAIN CONTENT

3.1 HIV/AIDS and Family Care

The advent of HIV and AIDS is not seen simply as the appearance of a new disease that could be easily integrated into an existing order of things. It is perceived as a rupture of society (Duttmann 1996). More than a devastating disease, freighted with profound social and cultural meaning. More than a passing tragedy, it will have long-term, broad-ranging effects on personal relationships, social institutions and cultural

configurations … the effects of the epidemic extend far beyond their medical and economic cost to shape the very ways we organize our individual.

AIDS represents the emergence of a metaphorical illness and the discovery of a perfidious virus. It jeopardizes scientific research, social norms and institutions. It reveals catalyses and increases the flaws and gaps between the rich and the poor and between the north and the south, bringing to the fore social fissures. It awakens long-forgotten intolerant discourses and recalls ancient fears. It prompts the most brave and generous acts, yet provokes the most mean-spirited and non-rational behaviour (Teguis and Ahmed 1992). AIDS has brought about a general awareness of a new situation where the risk of illness is constantly present. People must learn to live with this risk and are likely to become more conscious of it as progress is made in preventive medicine.

Walker et al (1995) point out that conceptualizing family care as the provision of aid/assistance from one or more family members to other family members, beyond that required as part of normal everyday life makes it difficult to distinguish it from aid given as part of the normal exchange in family relationships. Some of the confusion rests in the history and nature of the connection between the care receiver and the caregiver. That is, even when care receivers have similar levels of dependence. The help provided by family caregivers differs by gender and by generation. For example, care giving husbands report giving more care than wives. The authors suggest that caregivers report activities that are not ordinarily for them, or are not part of their normal responsibilities. Since many care giving activities are consistent with everyday household (HH) work that women traditionally perform, caregiving mothers and wives may not consider such tasks to be care giving activities. However, husbands who are less often involved with such activities and who take on such tasks primarily because wives are unable to do so, see themselves as care giving. In the same way, daughters may distinguish between the tasks they do in their own homes from those that they do in the homes of their mothers.

Cleaning the home is women's work, but having to do it in another's house is care giving. Since both helpers and help recipients appear to define care giving relative to gendered responsibilities and tasks, such subjective perceptions make defining care giving difficult. Walker et al (1995) hold that the criterion for care giving should be dependence on another person for any activity essential for daily living. This criterion is based on the functional status of the care receiver rather than on the activities of the caregiver. The criterion of dependence argues that in defining care giving, it is insufficient to ask what caregivers do; one must ask if the family member is dependent on aid. Care giving means

providing assistance above and beyond the aid given to physically and psychologically healthy members. Under this definition, care giving is assistance provided to someone who is dependent on that assistance.

3.2 Types of Family HIV/AIDS Care Activities

Given (1994) distinguish between two forms of assistance:

Direct care and indirect care activities.

Direct care includes the supervision of arrangement for, assistance with, or performance of those self-care and other tasks related to physical comfort for patients. Direct care may include personal care, pain and other symptom management, assistance with medical care activities and emotional care.

Indirect care include all those activities which allow the patient to remain at home and receive care there, including cooking, cleaning, shopping, money management and scheduling and transporting patients for treatment.

Brown and Stetz (1994), in their elucidation of the process of care giving in chronic and potentially fatal illness, provide further insights into the intricacies and nuances of family care. Caregiver experiences were termed the labour of care giving (i.e. the ongoing physical, emotional and cognitive work of providing care), which begins with diagnosis and continues for several months after death.

SELF ASSESSMENT EXERCISE

What do you understand by care giving?

3.2.1 Phases of Care giving

The labour of care giving has four phases:

> The initial phase of becoming a caregiver focuses on adjusting to the new role, starting with coming to grips with the diagnosis and the new reality, choosing to provide care, development competency in task performance, and alternating between hope for life and the possibility of death.
>
> The second stage of taking care involved guiding, giving and doing for the ill person to meet his or her needs. This included managing the illness, struggling with the healthcare system, managing the environment and organizing resources, coming to know one's own

strength, handling one's own pain, responding to family issues and preparing for death.

Midwifing the death dealt with providing comfort, managing interactions and orchestrating resources during the final days. While waiting for death, caregivers continued to support and attend to their loved one's need. Since many of them felt that the patients' quality of life during their final days was a reflection of their competence and an ultimate expression of their love, they set the highest standards of performance for themselves.

In the final stage, taking the next step following the patients' death, caregivers sought to bring closure to their care giving role and reconnect with their own lives, a process influenced by the length of their involvement in care giving and strength of identification with and internalization of the care giving role. While experiencing relief from intensive care giving, they attempted to tie up loose ends by completing healthcare payments, returning medical equipment, notifying insurance agencies and so on.

Dealing with regrets over past situations they wished they had handled differently, building a new life away from care giving as well as adjusting to the absence of the care receiver were some important aspects. Brown and Stetz's conceptualization highlights the dimension of care giving beyond the actual tasks involved, focusing on an unfolding trajectory that starts as an insidious, unrecognized and invisible process and ends as a central role for the caregiver. As the preceding paragraphs show, the definition of family care should be comprehensive enough to highlight its multifaceted yet difficult identity within the spectrum of family roles and responsibilities.

Globally, family care is a topic of immense contemporary significance because of the increasing number of families with chronically ill, disabled or elderly members, who are cared for by others in the family. This trend is due to the profound changes in the way these individuals are served while in the past long-term institutionalization of such people was the option for families, in recent times community care is being promoted as the preferred alternative. To some extent, it is policies of mainstreaming and integration which suggest that care receivers benefit from living in a family setting located in the general population that are responsible. On the other hand, cutbacks in social welfare expenditure which make the provision of quality care for large numbers of people economically unfeasible for institutions also play a role. As a result, individuals in need of care live in the community and are supported by their families.

Medications also help such individuals to participate in many activities associated with normal people on a daily basis, with less risk of disrupting their daily routines. The family therefore, has an expanded set of responsibilities as the interface between the affected individual and the larger society. The net effect of these trends is that the family plays a considerably more pivotal role in the care of individuals than it did in the past (Seltzer and Heller 1997).

4.0 CONCLUSION

In this unit, family care was conceptualized as the provision of aid/assistance from one or more family members to other family members beyond that required as part of normal everyday life. We also looked at direct and indirect family care of HIV/AIDS.

5.0 SUMMARY

This unit tackled basic concepts of HIV/AIDS and family care, illustrating the forms and phases of family care. Hope you found this unit helpful. Now let us try these exercises.

6.0 TUTOR MARKED ASSIGNMENT

Distinguish between direct and indirect family care giving of HIV/AIDS patients

ANSWER TO SELF ASSESSMENT EXERCISE

Care giving is assistance provided to someone who is dependent on that assistance.

7.0 REFERENCES/FURTHER READINGS

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UNIT 4 HIV/AIDS FAMILY CARE, ROLES AND RELATIONSHIPS

CONTENTS

1.0 INTRODUCTION

We all know that caring for sick relations exerts tremendous physical, social and emotional strain on both the care giver and the receiver. In this unit, we will discuss the concesequences of HIV/AIDS family care.

2.0 OBJECTIVES

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

Describe consequences of HIV/AIDS family care
Describe family care giving relationship with the patient

3.0 MAIN CONTENT

3.1 Consequences of HIV/AIDS Family Care

The negative consequences of the care giving experience have been described under the word *'burden'*, a concept first developed and measured by Grad and Sainsbury (1963). Burden refers to 'the physical, psychological or emotional, social and financial problems' that may be experienced by family members caring for a relative with a disability or impairment (George and Gwyther 1986: 253).

Theoretical efforts to define the concept of burden more precisely led to the distinction between objective and subjective burden made by Hoeing and Hamilton in (1966).

Objective burden refers to the reality demands that confront the family members who takes on the caregiver role, whereas;

Subjective burden encompasses the feelings aroused in family members as they fulfill their care giving functions.

It is also widely acknowledged that the experience of burden is phenomenological, i.e., it lies in the interpretation of the caregiver, and hence what is burdensome to one may not be similarly perceived by another.

Many authors provide a comprehensive review of the experience of objective burden, which includes dimensions such as:

The impact of the care receiver's symptomatic behaviour
Deterioration in the caregiver's physical health
Economic pressures
Employment restrictions
Reduction of leisure and social relationships.

Through their review which covers a range of illness, Hooyman and Gonyea underscores the difficulties and constraints that care giving engenders for the care provider. Subjectively, caregivers go through a complex mix of emotions which included love and compassion on the one hand, and denial, shame, fear, frustration, anger, depression and guilt on the other. These feelings arise on hearing the diagnosis, in relation to the care receiver and the suffering that he/she goes through on account of the illness which brings about changes in the caregiver-care receiver relationship, in response to the challenges from other family members.

3.2 Differentiation of Family Roles

Montgomery et al (1985) and Barber et al (1990) found objective and subjective burden to be distinct entities, poorly correlated with each other and with different correlates. According to Montgomery et al (1985), objective burden is related to the characteristics of care giving behaviours and the presence of helpers, while subjective burden is related to the characteristics of the caregiver. Barber et al (1990) concluded that while both objective and subjective burden are correlated with the caregiver's health status, guilt as a result of receiving help from others, and the extent to which the caregiver perceives that others do not understand what it is like to care for a patient. Objective burden is related to the number of hours of care and subjective burden to patient impairment and quality of the patient-caregiver relationship. The predictors of subjective burden include the patient's disruptive behaviour and degree of closeness of the caregiver-patient relationship. The predictors of objective burden are the extent to which caregivers perceive that those rendering support do not understand what it is like to

care for a patient, the patient's impaired social functioning, and the amount of guilt the caregiver feels when help is needed from others.

Various studies have examined the factors related to burden characteristics of the caregiver such as age, sex, social support, locus of control and coping strategy as having a bearing on burden the caregiver burden as related to the caregiver's support and coping but not to age, sex, income, education and patient's residence.

Caregivers' strain has been found to be related to patient impairment, amount of care required, affection, nature of the relationship with the patient and thee caregiver's reaction to patient impairment, while the caregiver's negative emotions are linked to interpersonal conflict, level of impairment and the caregiver's reaction to patient impairment.

The effects of the strain of caring for a sick relative could be determined by caregiver age and education; caregiver physical, social and financial resources; caregiver coping (namely, problem/emotion/relationship-focused strategies); the duration of care giving; and patient functional status on caregiver depression and satisfaction. The use of problem and positive relationship-focused strategies report more caregiver satisfaction but show no relation to depression. The use of emotion and negative relationship-focused strategies report greater depression but are not linked to satisfaction. Factors predicting depression include memory and behaviour problems, caregiver age, caregiver resources and emotion-focused coping. Factors predicting satisfaction comprise caregiver age, caregiver resources, problem and positive relationship-focused coping.

Boss et al (1990) consider caregiver perceptions to play an important role in his/her experience of depression and coping. Examining this in caregivers of patients with Alzheimer's dementia (AD), they found that the caregiver perception of high boundary ambiguity (arising from the patient's physical presence and psychological absence) associated with AD hinders his/her sense of mastery and control over the situation, leading to depression and burden. While mastery is the strongest predictor of depression, ambiguity links patient functioning to mastery since it facilitates uncertainty.

Greenberg et al (1995) examined the relationship between subjective burden and caregiver physical health in the context of parents caring for an adult child with mental illness. The research focused on four conceptualizations of subjective burden found in the mental illness literature, viz, stigma, worries, loss and fear. The negative relationship between health and stigma and worry was significant, while that of health fear was not.

Greenberg et al (1995) speak of the role contextual factors in influencing caregiver burden. According to Seltzer and Heller, four aspects define the care giving context. The cultural context i.e., the family's racial or ethnic group influences a lot of factors that affect the care giving process, including how the family conceptualizes the meaning of disability, the role of the extended family in providing care, the availability of economic resources and the access to the service system. The type of disability is another important factor because although there are similarities in the experience of all patients regardless of the type of illness, there are also unique demands specific to the illness/socio-demographic characteristics of the family such as gender and age play a role, as do the formal services family receive. Hooyman and Gonyea (1995) delineate various demographic and societal factors. The number of adults requiring long-term care has increased, largely because of the success of medical technology. Public policy advocates family care as a cost effective solution to the deinstitutionalization campaign. At the same time, the capability of traditional family caregivers to provide care is altered due to factors such as geographic mobility, escalating divorce rate, greater public acceptance of single and homosexual lifestyles, and larger numbers of women entering the workforce, growth in unemployment and underemployment and poverty.

Gender differences in care giving and burden: Wives care for spouses who are generally older than themselves, perceive less reciprocity from the impaired spouse and provide greater help with instrumental activities of daily living (IADL), thereby experiencing greater burden. Care giving husbands are older, perceive more reciprocity and more help with IADL tasks from their impaired spouses, and hence experience less burden. Care giving wives have more living children bit share caregivng responsibilities with fewer formal helpers. For caregiver husbands, the greater the number of hours and the more the IADL tasks with which care is provided, the greater the burden. For wives, the greater the recipient's age, the greater the activities of daily living (ADL) impairments and the greater the number of hours of care provided, the greater the burden reported. Similarly, the greater the perceived health of the recipient and the greater the caregiver's age, perceived health and perceived reciprocity, the lower the burden for care giving wives.

Gender differences in the psychological costs of providing care to a patient with AD in relation to the caregiver's coping style, social supports and sense of control. The researchers discovered that (a) women had a higher self-report of stress than did men, although the two groups did not differ significantly in terms of depression or anxiety; and (b) women predominantly used fantasy to cope, whereas withdrawal was the more common technique for men. Perhaps more interesting is the

differential effectiveness of these coping strategies for men and women in adapting to the caregiver role. Significant predictors of anxiety among the women were external sense of control and the use of internalization as a coping style, which predicted feelings of resentment, but internalization was not a significant predictor among the men, anxiety was predicted by lack of social support coupled with the use of either fantasy or withdrawal as a dominant coping style

Kramer (1993b) examined the effects of caregiver age; duration of care giving; marital history of the care giving spouse; caregiver's quality of prior relation with the ailing spouse, caregiver's physical, social and financial resources; caregiver's cognitive appraisal of situation; and patient's level of impairment on caregiver depression, satisfaction and quality of life. She concluded that a history of one or more prior marriages is associated with increased depression and lower satisfaction and quality of life. Lower prior relationship quality is associated with increased depression, lower quality of life and care giving satisfaction.

Lower caregiving physical and social resources and negative appraisal of stressors reported higher depression and lower quality of life. Caregiver social resources were significantly associated with caregiving satisfaction. Marital history and quality of prior relationship as well as personal resources and appraisal of stressors were predictors of depression and quality of life. Marital history and quality of earlier relationship were the only significant predictors of caregiving satisfaction.

SELF ASSESSMENT EXERCISE

What do you understand by objective and subjective burden of care?

3.3 Family Care Giver Relationship with the Patients

The quality of the caregiving relationship is found to play a mediating role in determining whether care receiver cognitive impairments or care receiver functional impairments have a greater effect on caregiver well being. Studies have shown that filial caregivers and spousal caregivers of elderly people, greater cognitive impairment (but not greater functional impairment) was related to less emotional closeness in the caregiving dyad, which in turn was associated with the caregiver's perception of their care-giving efforts as being less effective. These results indicate that the mental, behavioural and personality changes that are typically part of cognitive impairment have a unique potential to erode positive emotional bonds between caregivers and care recipients. Consequently, the diminished positive ties between caregivers and care recipients undermine the caregivers' sense of effectiveness.

HIV/AIDS research has focused on temporality, uncertainty, risk-management and body control. This help to understand what it means to have a positive status. To be HIV-positive is to learn that you are carrying a transmissible lethal virus, though you may not be already sick, you are dangerous to yourself and to others, and you know neither when nor how you will fall ill. As a result, certain risks must be managed in a situation of uncertainty.

The shadow of stigma is never far from HIV/AIDS, arising from its initial association with 'risk groups', from its sexual mode of transmission, contagious nature and fatal consequences. Stigma has brought to light numerous complex issues, such as the importance of confidentiality, the management and consequences of secrecy, the biases within society and within the health profession, the limits on positive people's expectations of care and support and the pain of experiencing discrimination. The result of perceiving HIV/AIDS as the adversary is to consider positive people as casualties and victims, exacerbating a sense of hopelessness and impotency. Victims are placed on a continuum of 'innocence' or 'guilt', which determines their worthiness of our compassion and of deservedness or non-deservedness of the disease.

It is an indisputable fact that dealing with a disease such as HIV/AIDS constitutes an enormous challenge, which can be met only through a broad interdisciplinary approach that spans prevention, treatment, care and rehabilitation. Particularly in the absence of a biomedical solution, it becomes the mandate of social scientists to deliver ever-increasing contributions for the adequate conception and assessment of prevention and care.

4.0 CONCLUSION

This unit thus illustrates that the consequences of the care giving experience have been described under the word *'burden'*, which refers to 'the physical, psychological or emotional, social and financial problems' that may be experienced by family members caring for a relative with a disability or impairment. This unit also identified and distinguished between subjective and objective burden and also tackled family care giving relationships.

5.0 SUMMARY

In this unit, we discussed the consequences of care giving on the family ex-raying different perceptions of care giving and HIV/AIDS. Now let us attempt the question below.

6.0 TUTOR MARKED ASSIGNMENT

The quality of the caregiver-care-receiver relationship plays a major role in mental and physical well-being of the dependent patient: Discus.

ANSWER TO SELF ASSESSMENT EXERCISE

Objective burden refers to the reality demands that confront the family members who take on the caregiver role; whereas *Subjective burden* encompasses the feelings aroused in family members as they fulfill their care giving functions

7.0 REFERENCES/FURTHER READINGS

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MODULE 3 NUTRITIONAL MANAGEMENT OF HIV/ AIDS

UNIT 1 IMPORTANCE OF HIV/AIDS NUTRITIONAL MANAGEMENT

CONTENTS

1.0 INTRODUCTION

Nutrition is the process of absorbing nutrient from food and processing them in the body in other to keep healthy; it can also be seen as the study of how food affects the health and survival of human body. Nutrition is integral to everybody especially to those infected with HIV AIDS which is one of the most deadly diseases in the world with approximately 42 million people worldwide infected with HIV/AIDS and more people getting infected everyday. In this unit, we will look at importance of nutritional management in HIV/AIDS.

2.0 OBJECTIVES

At the end of this unit, students should be able to:

Identify importance of nutrition management in HIV/AIDS
Explain Nutritional consequences of HIV/AIDS
Know HIV/AIDS: Nutritional Assessment

3.0 MAIN CONTENT

3.1 Importance of HIV/AIDS Nutrition

Nutrition is highly important in an individual life because it enhances the development of the individual, and it helps to maintain good health both physically and psychologically throughout life. Nutrition improves cognitive development in an individual which concerns mental growth including memory, perception and logical reasoning, problem-solving skill, numerical understanding, intelligence and hypothetical thinking. Nutrition is also important because it helps avoid diet-deficiency diseases which are caused by lack of a specific nutrient, such as protein, vitamin or mineral.

Malnutrition is a dietary condition caused by a deficiency or excess of one or more essential nutrients in diet and it is mostly characterized by extreme weight loss, stunted growth, weakened resistance to infection, and impairment of intellect in which severe cases leads to death. Finally nutrition is good for physical fitness because energy expenditure depends on nutrition; if diet is inadequate the fitness will drop so nutrition is highly important for the development of a person.

3.2 General Nutritional Management in HIV/AIDS

Nutritional management is an important aspect in the care of all HIV-infected patients; about 42 million people worldwide are estimated to be infected with the HIV with an estimate of one out of four adults carry the virus. During the course of HIV infection, several nutritional issues are likely to arise, including the need for education about the following:

Healthy dietary principles.
Maintenance of lean body mass and normal growth in children, and the treatment of wasting.
Management of metabolic complications due to drug therapies.
Management of drug and food or nutrient interactions.
Management of gastrointestinal symptoms that may influence the types and amount of food ingested.
Appropriate use of herbal and/or nutritional supplements.
Cultural and ethnic beliefs related to diet and food.
Role of exercise.
Relationship between substance abuse and nutrition.
Food safety.
Nutrition during pregnancy.
Access to infant formula and food as an alternative to breast-feeding.

HIV-infected patients may be at nutritional risk at any point in their illness, severe malnutrition and weight loss, particularly loss of tissue, and delayed weight gain and height velocity in children can affect morbidity and mortality. Fear of developing fat-redistribution Syndrome with central obesity and loss of subcutaneous fat may prevent patients from beginning or continuing potent antiretroviral therapies Development of hyperglycemia and lipid abnormalities may increase the risk of diabetes, heart disease and stroke. The appearance of these metabolic changes may induce patients to cease HAART (highly active antiretroviral therapy) or to change to less effective antiretroviral regimens. Food and drug interactions are an important issue for effectiveness and tolerability of HAART regimens.

The presence of food in the gastrointestinal tract can influence the absorption of several HIV medications such as didanosine, indinavir, saquinavir, and nelfinavir. Drug-food interactions can influence serum drug concentrations, thus increasing the likelihood of side effects when serum concentrations are too high and increasing the risk for viral resistance and loss of durable viral suppression when serum concentrations are too low. In addition, complicated medical and food schedules as well as side effects of the medications can compromise adherence to and tolerability of the regimen with antiretroviral medications.

It is important for health care professionals to be knowledgeable about these interactions so they can help patients with timing of their anti-retroviral regimens with regard to food. Anorexia and oral or gastrointestinal symptoms such as pain, nausea, vomiting, malabsorption, and diarrhea may arise from HIV infection, secondary infections, and encephalopathy, or drug therapies. Inability to eat food secondary to complicated medical regimens or fatigue adds to the nutritional risk.

Clinically, these symptoms may prevent adequate nutritional intake resulting in continued weight and lean tissue loss, vitamin or mineral deficiencies, and poor nutritional status. Chemical dependency and socio-economic factors can limit access to proper food and nutrition that can itself contribute to an increased immuno-compromised state.

SELF ASSESSMENT EXERCISE

HIV-infected patients may be at nutritional risk at any point in their illness. Identify the reasons

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3.3 Nutritional Consequences of HIV/AIDS

Weight loss, loss of lean body mass, fat accumulation and metabolic changes are common in HIV disease, but determining the cause of these changes is not so easy. Chronic immune system stimulation, however, is one likely cause.

When the immune system is stimulated due to acute trauma, infection, chronic disease, or an inflammatory process, it causes a series of physiologic and metabolic changes known as the **acute phase response** (APR). Cytokines, produced when the immune system is activated, initiate the APR, which redistributes resources to maximize function. The end result is metabolic catabolism.

The APR is characterised by fever, skeletal muscle catabolism, inflammation, liver synthesis of acute phase proteins (e.g., prealbumin, retinal-binding protein, complement, fibrinogen, C-reactive protein), alternations in hormone production, increases in neutrophils and other immune cells, and changes in serum levels of trace elements and antioxidants. (Johann-Liang, O'Neill & Cervia , et al.2000)

The liver responds to the APR by increasing uptake of protein, which can be broken down and resynthesized into acute phase proteins or used for energy. The sources of this protein are albumin, muscles, skin, and the gastrointestinal (GI) tract. Clinically, there will be decline in serum albumin even if nutrition intake is adequate. The liver will also increase uptake of iron and zinc, lowering serum levels of these nutrients, while levels of serum copper and ceruloplasmin increase by 50% to 100%. It is thought that copper acts as a "scavenger" to destroy highly charged particles produced during phagocytosis, thereby preventing cellular damage.

Antioxidants, necessary to neutralize the greater number of free radicals produced during phagocytosis, are used at a faster rate, and serum levels of lycopene, beta-carotene, alpha-carotene, and total carotenoids decline.

In an APR, the level of C-reactive protein is increased above 1.5 milligrams per decilitre with a corresponding decrease in serum, albumin, thyroxine-binding prealbumin, and zinc. As long as C-reactive protein is elevated, serum albumin stays depressed.

However, there is an increase in C-reactive protein with any inflammation, whether it is related to a chronic or acute condition. A long-term elevation of C-reactive protein, without an acute cause, is called a chronic phase response (CPR).

The bottom line is that an immune response has nutritional consequences. The APR induces catabolism and increases the need for nutrients. The CPR also increases nutrient needs, but to a lesser degree. Should a nutrient deficiency or marginal deficiency be present, the body's ability to mount an effective fight is compromised. The greater the deficiency or deficiencies, the weaker the immune response.

3.4 HIV/AIDS: Roles of nutrition therapy providers

HIV medical nutrition therapy requires specialized knowledge of nutrition, especially in relation to HIV disease, medications, complications, and sensitivity to the infected and affected populations served (Zuin, Comi, Fontana, et al (1994) The number of qualified medical nutrition therapy providers is inadequate, and there are scanty opportunities for training. HIV medical nutrition therapy providers can do the following:

Work in concert with the HIV medical team.

Receive continuing education each year, to include HIV medical, pharmacological, and nutritional updates as well as updates in any other relevant area.

Be targeted for education and ongoing training through the Ryan White CARE Act, AIDS Education and Training Centers, or other comparable systems. The education and training of other health care professionals should include at least basic nutrition for patients with HIV.

Baum, Shor Posner , Zhang et al. (1997) and The Food and Nutrition Board and Institute of Medicine (IOM) Committee on Nutrition Services for Medicare Beneficiaries issued a report in December 1999 evaluating the benefits and costs of the provision of nutrition services, including the services of an RD, to Medicare beneficiaries. The IOM report found that the RDs are currently the single identifiable group of health care professionals with standardized education, clinical training, continuing education, and national credentialing requirements necessary to be directly reimbursed as a provider of nutrition therapy. The committee also recognized that other health care professionals could in the future submit evidence to be evaluated by the Centers for Medicare and Medicaid Services for consideration as reimbursable providers.

4.0 CONCLUSION

In this unit, we illustrated that nutrition is the process of absorbing nutrient from food and processing them in the body in other to keep healthy; it can also be seen as the study of how food affects the health and survival of human body. Nutrition is integral to everybody

especially to those infected with HIV AIDS. This unit thus looked at importance of nutrition management in HIV/AIDS as well as consequences of poor nutrition on HIV/AIDS.

5.0 SUMMARY

We have thus seen the unquantifiable importance of nutritional management in HIV/AIDS. Need we say more? Now let us attempt the questions below.

6.0 TUTOR MARKED ASSIGNMENT

Nutritional management is an important aspect in the care of all HIV-infected patients: Discuss

ANSWER TO SELF ASSESSMENT EXERCISE

Severe malnutrition and weight loss, loss of tissue, delayed weight, loss of subcutaneous, development of hyperglycemia and lipid abnormalities, may increase the risk of diabetes, heart disease and stroke.

7.0 REFERENCES/FURTHER READINGS

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UNIT 2 LEVELS OF NUTRITIONAL CARE

CONTENTS

1.0 INTRODUCTION

Because of the rapidly changing picture of HIV disease, the CDC classification by CD4 count and clinical signs and symptoms may not be appropriate for nutritional complications or referrals. Rather, defining levels of risk for nutritional com-promise as the trigger for nutrition referral and intervention may be more practical, given current resources. Ideally, all patients infected with HIV should have access to a registered dietitian (RD). Nutritional and medical assessments are needed for optimal individualized care. The initial visit of a new HIV-positive patient should include screening for nutritional risk. A validated screening tool is needed to assess the degree of nutritional risk. The purpose of screening is to categorize a patient's nutritional needs as low, moderate, or high risk for nutritional compromise. If indicated, referral to an RD for nutrition assessment and development of an individualized care plan should be made. Follow-up visits of stable HIV-positive patients should include an annual screening for nutritional risk.

2.0 OBJECTIVES

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

Explain levels of nutritional risk in HIV/AIDS
Discuss nutritional education for HIV/AIDS

3.0 MAIN CONTENT

3.1 Levels of Nutritional Risk

The timing for the referral to an RD is made on the basis of these guidelines and expert opinion. In general, they apply to all age groups and both sexes. Levels of nutritional risk are categorized as ***low, moderate, and high risk*** for nutritional compromise. The risk reflects consideration of multiple factors that may lead to nutritional compromise. The spectrum of nutritional intervention includes ensuring basic education on healthy diets, identifying common practices and diseases that traditionally require nutrition counseling or intervention and assessing conditions that are specifically seen in HIV disease that are known to affect morbidity and mortality if nutritional intervention does not occur. Many of these factors span the spectrum of HIV disease; therefore individualized assessment, rather than stage by stage of HIV disease, is recommended. The following categories are based on those published by the American Dietetic Association. The priority timeline for referral for patients categorized by nutritional risk is as follows:

High risk, to be seen by an RD within 1week;
Moderate risk, to be seen by an RD within 1 month;
Low risk, to be seen by an RD as needed. Detailed descriptions of the categories appear below:

3.1.1 High risk (RD within 1 week).

A. Poorly controlled diabetes mellitus.
B. Pregnancy (mother's nutrition; infant: artificial infant formula).
C. Poor growth, lack of weight gain, or failure to thrive in pediatric patients.
D. 1 10% unintentional weight loss over 4–6 months.
E. 1 5% unintentional weight loss within 4 weeks or in conjunction with
    1. Chronic oral [or esophageal] thrush.
    2. Dental problems.
    3. Dysphagia.
    4. Chronic nausea or vomiting.
    5. Chronic diarrhea.
    6. CNS disease.
    7. Intercurrent illness or active opportunistic infection.
F. Severe dysphagia.
G. Enteral or parenteral feedings.
H. Two or more medical co-morbidities, or dialysis.
I. Complicated food-drug-nutrient interactions.

J. Severely dysfunctional psychosocial situation (especially in children).

3.1.2 Moderate risk (see RD within 1 month).

A. Obesity.
B. Evidence for body fat redistribution.
C. Elevated cholesterol (200 mg/dL) or triglycerides (250 mg/dL), or cholesterol 100mg/dL.
D. Osteoporosis.
E. Diabetes mellitus, controlled or new diagnosis.
F. Hypertension.
G. Evidence for hyper vitaminoses or excessive supplement intake.
H. Inappropriate use of diet pills, laxatives, or other over-the-counter medications.
I. Substance abuse in the recovery phase.
J. Possible food-drug-nutrient interactions.
K. Food allergies and intolerance.
L. Single medical comorbidity.
M. Oral thrush.
N. Dental problems.
O. Chronic nausea or vomiting.
P. Chronic diarrhea.
Q. CNS disease resulting in a decrease in functional capacity.
R. Chronic pain other than oral/gastrointestinal tract source.
S. Eating disorder.
T. Evidence for sedentary lifestyle or excessive exercise regimen.
U. Unstable psychosocial situation (especially in children).

3.1.3 Low risk (RD as needed).

A. Stable weight.
B. Appropriate weight gain, growth, and weight-for-height in pediatric patients.
C. Adequate and balanced diet.
D. Normal levels of cholesterol, triglycerides, albumin, and glucose.
E. Stable HIV disease (with no active inter-current infections).
F. Regular exercise regimen.
G. Normal hepatic and renal function.
H. Psychosocial issues stable (especially in children).

All patients of all levels of risk should be educated about healthy, balanced diets for their given lifestyle and physiologic requirements. Medical nutrition therapy should take into account the patient's age, sex, and physiological state, with special attention paid to pediatric growth and development, pregnancy, obesity, quality of dentition, and exercise

practices. During nutrition assessment, family and medical history should be considered, particularly regarding diabetes, coronary artery disease, hypertension, and other cardiac risk factors. Recommendations (individualized care plans) should be adapted to stage of HIV progression, from asymptomatic to advanced stages with active General Nutrition Management in HIV secondary infections. Socioeconomic, cultural, and ethnic back-ground should be considered, including a history of mental health disorders or substance abuse as well as literacy level and financial status. Nutritional counseling or medical nutrition therapy should also be tailored to make the most of available access to care.

SELF ASSESSMENT EXERCISE

Levels of nutritional risk in HIV/AIDS are --------, ---------- and --------

3.2 Nutrition Education for HIV/AIDS

Nutrients provide the support necessary for the immune system to mount an immune response. Every component of the immune system appears susceptible to nutritional deficiencies, including non-specific responses such as phagocytosis and killing activity, as well as cell-medicated and humoral immune functions. Therefore, nutritional deficiencies increase susceptibility to infection.

HIV disease is a complex condition, and individuals have nutritional and educational needs based on their own body's reaction to the virus. By understanding how HIV alters immunity, metabolism, physiology, and nutrient needs, you can create an educational plan that meets the needs of the patients.

AIDS is caused by HIV, which invades and kills specific immune cells, causing abnormal immune function and increasing susceptibility to infection and cancer. HIV is transmitted sexually, through blood and bodily fluid exchanges, from a woman to her fetus, or from a mother to her baby via breast milk. Transmission of the virus may not result in infection. Those who are infected (sero-positive) have antibodies to the virus in their blood.

A properly functioning immune system exists in balance between competing activities: the growth and proliferation of immune cells vs. cellular death (apoptosis); proinflammatory cytokines; procachectic vs. anticachectic cytokines; and nutrient supply vs. needs. Nutritional status can influence each of these and thereby affects the balance of immune function toward the positive or negative. (For instance, if there is too much inflammation, an immune response – healthy tissues are damaged.

Decreasing inflammation, through nutrition or drugs, brings back the balance and prevents damage due to excessive inflammation.

In the HIV – positive or AIDS patient, the disease itself impairs immunity while nutrient needs and nutrient intake. Understanding the interactions of the immune system, metabolism, nutrient needs, and prescription drugs will allow us to bring to use nutrition to influence the course of this disease.

Malnutrition for instance is one consequence of AIDS. Increased nutrient needs for an activated immune system, often with decreased intake and altered digestion, absorption, utilization, and metabolism, cause nutritional deficiencies, weight loss, and tissue – wasting often seen in AIDS patients. Nutrient deficiencies seen in HIV disease occur even in asymptomatic HIV–positive individuals. Nutrients most commonly deficient include zinc and selenium.

4.0 CONCLUSION

HIV disease is indeed a complex condition, and individuals have nutritional and educational needs based on their own body's reaction to the virus. This unit thus identified three levels of nutritional risks in HIV/AIDS, which includes: high, moderate and low risks.

5.0 SUMMARY

We hope you enjoyed your studies. This unit provided a broad view of nutritional risks in HIV/AIDS as well as need for nutrition based education for HIV/AIDS patients. Now let us attempt the question below.

6.0 TUTOR MARKED ASSIGNMENT

Identify and discuss levels of nutritional risks in HIV/AIDS

7.0 REFERENCES/FURTHER READING

CDC (2004). Inadequate dietary intake and altered nutrition status in early HIV infection. Nutrition; 10: 16–20.

UNIT 3 HIV/AIDS NUTRITION COUNSELLING AND INTERVENTION

CONTENTS

1.0 INTRODUCTION

Nutrition counselling works. As long as caloric intake increases, it does not matter if the increase is from food or nutritional supplements, as both will increase weight. There is a subgroup of individuals with HIV or AIDS who do not gain weight when their caloric intake is increased. In these individuals, their metabolism may be so altered from an infection that calories alone will not allow them to gain weight. They may need anabolic agents or nutrients such as omega-3 fatty acids that decrease inflammation.

2.0 OBJECTIVES

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

Identify the need for nutritional counselling in HIV/AIDS
Illustrate the relevance of HIV/AIDS dietary counselling
Identify outcomes of nutritional intervention
Identify hormonal agent in anabolic action: Testosterone
Illustrate the importance of vitamins and minerals in HIV nutritional management

3.0 MAIN CONTENT

3.1 Nutritional Counselling

Nutritional counselling above all should be non-judgemental. In the role of nutritional counsellor, the counsellor is a facilitator for the patient, assisting with solutions for nutritional problems. A counsellor need to be objective and open-minded in finding solutions to problems that are either directly related to the bio-chemistry and physiology of AIDS or have psychosocial components. This is especially true in clients with lipo-dystrophy. In addition to living with HIV disease, their body shape may drastically change and they no longer feel good about themselves. Counsellor should work with clients, not against them, even if the counsellor beliefs and values do not agree with theirs.

Counsellor's priorities may not be shared by the client. Many people with AIDS are interested in supplements and alternative therapies. It is important to stay informed about these therapies so as to establish a rapport and gain credibility. If one cannot answer a questions, research them and be sure to follow up.

Above all, HIV-positive and AIDS patients need education on food safety issues. People with a healthy immune system are able to fight off bacteria from contaminated foods, but AIDS patients are more susceptible to infection from Salmonella, Campylobacter jejuni, and listeria monocytogenes. For instance, Salmonellosis occurs almost 100 times more frequently in persons with AIDS than in otherwise healthy persons while Campylobacter infections occur 35 times more frequently.

When determining nutrition counselling needs, one should look at the stages of the illness and how needs might differ among the groups. Since many HIV-positive people believe in the value of supplements, and nutrient levels fall early in the disease, start supplementation early. Do not megadose, but start with 100% to 200% of the recommended Dietary Allowance for most nutrients. Antioxidant nutrients such as vitamins E, A, and C; selenium; and zinc may need to be supplemented in higher amounts.

Individuals who have symptoms but may not have progressed to AIDS will need more help developing a nutritional plan for management of disease symptoms such as relieving nausea, vomiting, and diarrhea and increasing appetite when the individual isn't feeling well or when he or she has diarrhea, constipation, nausea, or vomiting. Newer issues include dealing with weight gain, redistribution of body fat, and elevated cholesterol, triglyceride and glucose levels.

Those with acute infections, complications, or chronic stages of disability have more severe nutritional problems that may necessitate manipulation of the types of foods and methods of feeding. Should mechanical problems associated with eating be an issue, changing the texture of foods may help. Use soft or liquid foods that are easy to swallow and need little chewing. Increase nutrients by using powdered supplements or skim milk powder. Some foods irritate the mouth, throat, and oesophagus and should be avoided. Using a straw helps by pass sore areas of the mouth.

Mal-absorption of fats and sugars may necessitate a low-fat, lactose-free diet to increase absorption. In some individuals, high fiber will help, while in others it may make the problem worse.

SELF ASSESSMENT EXERCISE 1

When determining nutrition counselling needs, one should look at
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3.2 HIV/AIDS Dietary Counselling and Management

Intensive nutritional intervention is recommended early in the course of HIV infection to maintain nutritional status. When weight loss has occurred, nutritional intervention with or without oral supplementation, enteral-nasogastric nutrition, percutaneous endoscopic gastrostomy nutrition and parenteral nutrition has been trialled with varying degrees of success in increasing weight and improving body composition.

Few studies have examined the effect of nutritional counselling alone to improve dietary intake and weight in people with HIV/AIDS. Dowling et al. conducted a prospective study to investigate the effect of dietary counselling on dietary intake, weight and body composition in 34 people with HIV/AIDS over 12 weeks. While nutrient intake increased, body composition was not significantly altered. Chlebowski et al examined the effect of dietary counselling in 108 people with HIV/AIDS over a six-month period in a prospective cohort study. Weight declined despite adequate energy intake.

Other research investigated the role of oral nutritional supplementation in addition to nutritional counselling. Rabeneck et al. compared dietary counselling with oral nutritional supplementation (treatment group) to dietary counselling without nutritional supplementation (control group) over a six-week period in 118 people with HIV/AIDS who had lost weight. They found no significant differences in the change from

baseline in weight or body composition between the two groups; mean weight decreased by 0.1 kg in both groups; fat free mass increased in the treatment group by 0.9 kg and decreased in the control group by 0.4 kg

Schwenk et al. examined the effects of dietary counselling to increase intake with and without the addition of oral supplements. They found a significant increase in fat free mass over eight weeks in both groups. However, the weight change was not significant. Berneis et al. also investigated the effects of nutritional supplements with dietary counselling (n = 8) or dietary counselling alone on body composition and whole body protein catabolism in people with HIV/AIDS. In contrast, they found only the group receiving the oral supplement with dietary counselling had significant increases in fat free mass (2%) and a significant reduction in protein catabolism. In most cases, dietary counselling for weight gain was described as education regarding a high energy, high protein diet with individual modifications to minimise symptoms (e.g. foods low in fat and insoluble fibre in order to minimise diarrhea). In some of these studies the education was poorly described and referred to as following standard nutritional principles.

Specialized supplements have also been trialled for their effectiveness in promoting weight gain and immune improvement in people with HIV/AIDS. A small pilot study in three HIV-positive subjects showed weight gains of 2 kg to 7 kg over three months when taking whey protein supplements. Whey protein supplementation for 14 weeks resulted in significant increases in weight (both fat free and fat mass) in HIV-positive women.

A combination of [beta]-hydroxy [beta]-methylbutyrate, glutamine and arginine has also been shown to increase weight and fat free mass when compared with placebo in a double-blind study of HIV-positive people with weight loss over an eight-week intervention period. Pharmacological agents in the management of HIV-associated appetite and weight loss several pharmacological agents, usually marketed for some other conventional use, have been investigated for their capacity to stimulate appetite and/or promote therapeutic weight gain in people with HIV/AIDS.

SELF ASSESSMENT EXERCISE 2

Identify the qualities of a good nutrition counselor

3.3 Outcome of Nutritional Interventions

The aim of this unit is also to address the current nutritional management guidelines for people with HIV/AIDS. The treatments

discussed here are complimentary to the nutritional issues associated with weight loss treatment. Weight loss still occurs in people with HIV/ AIDS even in patients receiving highly active antiretroviral therapy (HAART) although the prevalence is not clear. Many people with HIV/ AIDS already had advanced disease before HAART was introduced, and even in those who respond to treatment, viral resistance may develop thus reducing the effectiveness of the drugs. Due to the side effects of HAART and lifestyle changes necessary to take this treatment effectively, some people choose not to take therapy or despite a good virological response, do not tolerate therapy. For these people with HIV/ AIDS, nutritionalmanagement remains focused on maintaining nutritional status and treating the symptoms of disease. Management strategies for weight loss have progressed since they were last published in this Journal and so they are discussed in detail below. (Chlebowsk, Grosvenor, & Bernhard 2001)

3.4 Hormonal Agents with Anabolic Action: Testosterone

Hypotestosteronaemia was a frequent finding in HIV-positive men prior to the HAART era. Pre-HAART estimates suggested approximately 50% of HIV-positive males were likely to experience hypogonadism related to under nutrition, chronic illness or medications. Data relating to the degree of hypogonadism since the HAART era are limited but Berger et al. suggest the prevalence of hypogonadism may be diminishing with more effective therapy (17.3% of 127 studied).

3.5 Vitamin and Mineral for HIV Transmission and Disease Progression

HIV-1 infection is having a devastating impact on people in developing countries. Poor nutrition and HIV-related adverse health outcomes contribute to a vicious cycle that may be slowed down by using nutritional interventions, including vitamins and minerals.

Among children, periodic supplementation with vitamin A starting at 6 month of age has been shown to be beneficial in reducing mortality and morbidity among both HIV-infected and uninfected children. Limited data exist on the role of other nutrient supplements among children. Among HIV-infected adults, the safety and the efficacy of vitamin A supplements need further study, although adequate dietary intake of this essential nutrient is recommended.

Multivitamin supplements were efficacious in reducing adverse pregnancy outcomes and early childhood infections, and is currently provided to pregnant HIV-infected pregnant women in many programs. The efficacy of such supplements among HIV-negative pregnant women

needs further study. Daily multivitamin supplements were found to reduce HIV disease progression among men and women in several observational studies and randomized trials, and to provide an important low-cost intervention that could be provided to adults in early stages of HIV disease to prolong the time before antiretroviral therapy is recommended (Kotler, Tierney, & Wang, et al 2005)

4.0 CONCLUSION

This unit looked at nutritional counseling in HIV/AIDS. It thus illustrated the role of nutrition and counseling in HIV/AIDS. Above all, nutrition counselor should be well vast in dietary knowledge that could aid nutritional management of HIV/AIDS as well as be objective, friendly and accommodating.

Nutritional management is highly essential for HIV aids patients because it helps in prolonging the life of a HIV patient and reducing the progression of the disease to AIDS from HIV. A balanced food diet is to be taken to prevent loss of weight, sickness and malnutrition although there is no documented evidence that any specific food of any description, on its own, can alter the course of the disease or for that matter be effective in the treatment of malnutrition,(Guenter, Muurahainen & Simons, et al, 2000).

Micronutrients supplementation is only useful in combination with an adequate and well-balanced diet and can never replace the need for adequate food intake. Multivitamin supplements should not exceed two to three times the recommended daily allowance until such time that more data and experience becomes available.

5.0 SUMMARY

This unit provided information on nutritional counselling, HIV/AIDS dietary counselling, outcome of nutritional intervention, hormonal agent in anabolic action: Testosterone and Vitamin and Minerals for HIV transmission and disease progression. We hope you enjoyed your studies. Let us, as usual attempt the questions below.

6.0 TUTOR MARKED ASSIGNMENT

Identify the need for nutritional counselling in HIV/AIDS

ANSWER TO SELF ASSESSMENT EXERCISE

Self Assessment Exercise 1

When determining nutrition counselling needs, one should look at: *stages of the illness and how needs might differ among the groups*

Self Assessment Exercise 2

Qualities of a good HIV nutrition counselor: Nutritional counselling above all should be non-judgemental. The counsellor is a facilitator for the patient, assisting with solutions for nutritional problems. A counsellor need to be objective and open-minded in finding solutions to problems that are either directly related to the bio-chemistry and physiology of AIDS or have psychosocial components. Counsellor should work with clients, not against them, even if the counsellor beliefs and values do not agree with theirs. Counsellor's priorities may not be shared by the client. Many people with AIDS are interested in supplements and alternative therapies. It is important to stay informed about these therapies so as to establish a rapport and gain credibility. If one cannot answer a questions, research them and be sure to follow up. Above all, HIV-positive and AIDS patients need education on food safety issues.

7.0 REFERENCES/FURTHER READINGS

Kotler DP, Tierney AR, Wang J, et al.(2005) Magnitude of body mass de-pletion and the timing of death from wasting in AIDS. J Clin Nutr 1; 50:444–7.

Chlebowski RT, Grosvenor MB, Bernhard NH, et al.(2001) Nutritional status, astrointestinal dysfunction, and survival in patients with AIDS. Journal of Gastroenterol; 4:1288–92.

Guenter P, Muurahainen N, Simons G, et al (2000). Relationships among nutritional status disease progression, and survival in HIV infection. J Acquir Defic Syndr; 6:1130–8.

UNIT 4 NUTRITION SCREENING TOOLS FOR HIVAIDS PATIENTS

CONTENTS

1.0 INTRODUCTION

In this unit, we will tackle several screening tools used for assessment of risk for nutritional problems. These tools will thus be identified and briefly explained.

2.0 OBJECTIVES

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

Identify screening tools for assessment of nutritional problems in HIV/AIDS
Explain the role of nutritional problem on HIV/AIDS management

3.0 MAIN CONTENT

3.1 Screening tools for nutritional assessment

Several screening tools are used for assessment of risk for nutritional problems. After a review of the literature for nutrition screening of HIV-infected individuals, the following tools were identified.

Only the Revised Subjective Global Assessment has been studied and reported for use in HIV-infected populations. The others, however, have been adopted and adapted for use in the screening of HIV/AIDS patients. They are as follows (descriptions follow):

- Scored Patient-Generated Subjective Global Assessment
- Revised Subjective Global Assessment for HIV-Infected Individuals
- Quick Nutrition Screen.
- Nutrition Referral Criteria for Adults and for Pediatrics.
- Nutrition Screening Initiative.
- HIV/AIDS Medical Nutrition Therapy Protocol.

3.1.1 Patient-Generated Subjective Global Assessment

The Scored Patient-Generated Subjective Global Assessment (PG-SGA) is validated for use in oncology patients. It is a widely used screening form that can also be used in the context of a comprehensive assessment. There are 2 sections to the PG-SGA.

The first is generated by the patient and includes components of patient history with an assigned prognostic value, history of weight status, list of food intake, a checklist of symptoms that impede food intake, and a measure of functional capacity.

The remainder of the form is generated by the health care provider and includes diagnosis, stress level, physical findings, and a score based on comprehensive review of the information. The form was designed to be administered by RDs, registered nurses, physician assistants, physicians and other medical health providers.

3.1.2 Revised SGA for HIV-Infected Individuals

(Bowers and Dols) revised the SGA and used it to evaluate the nutritional status of 36 HIV-positive patients. The revised SGA is an effective evaluation tool for stratifying patients into categories according to their nutritional status. Weight loss history, dietary intake, wasting, functional impairment, and gastrointestinal symptoms identified through the revised SGA relate directly to malnutrition. It can be used in a variety of settings, including homes, hospitals, home-care settings, doctors' offices, and nurse-run clinics.

3.1.3 Quick Nutrition Screen

The Quick Nutrition Screen was published in the Health Care and HIV Nutrition Guide for Providers and Clients by the Bureau of Primary

Health Care and distributed for the use by its Ryan White CARE Act grantees. It was developed and reviewed by HIV nutrition, nursing, other health care professionals and community representatives from both non-government and government agencies. Completed by clients, this screening tool has been adopted and adapted in numerous agencies across the country, as published in 1996, it requires updating.

3.1.4 Nutrition Referral Criteria for Adults and Children with HIV/AIDS

Nutrition Referral Criteria for Adults (18 or more years) with HIV/AIDS and Nutrition Referral Criteria for Pediatrics (18 years) with HIV/AIDS were screening tools originally developed in 1997 by Dietitians in AIDS Care, a networking group in Los Angeles, as part of the nutrition standards of care, approved by the Los Angeles County Commission on HIV Health Services. It had been reviewed by the multidisciplinary Standards of Care Committee of the Commission and subsequently adapted by agencies within Los Angeles County and throughout the country. It contains both time and symptoms and conditions that trigger nutrition referral to an RD.

3.1.5 Public Awareness Checklist of the Nutrition Screening Initiative

The Nutrition Screening Initiative formed in 1990, is a broad, multidisciplinary effort led by the American Academy of Family Physicians, the American Dietetic Association, the National Council on the Aging, and a coalition of 125 national health, aging and medical associations. The Nutrition Screening Initiative developed the Public Awareness Checklist, a series of screening tools (Level I and Level II), along with a manual for professionals. This simple test was intended to increase the nutrition awareness of elderly people and not to diagnose malnutrition. The initiative validated the usefulness of the checklist as a public awareness tool. The Public Awareness Checklist, however, is the basis of nutrition screening tools developed for HIV and other disease conditions.

A Clinician's Guide to Nutrition in *HIV and AIDS* adapted both Nutrition Screening Initiative Levels I and II screening tools as its recommended screening tool for identifying persons at risk for nutritional problems. There has been no report of its validation in HIV.

3.1.6 HIV/AIDS Medical Nutrition Therapy Protocols

The purpose of HIV/AIDS Medical Nutrition Therapy protocols is to clearly define the level, content, and frequency of nutrition care needed

in HIV disease. Originally developed and reviewed by members of HIV/AIDS and Pediatric Dietetic Practice Groups and the American Dietetic Association, it was published in 1996.

The screening criteria for nutrition referral are based on the following:

I. Time considerations, starting with a nutrition assessment at baseline and thereafter according to the individual's level of care, defined in the protocol.

   A. For adults:
      1. Asymptomatic HIV infection: 1–2 times a year.
      2. HIV/AIDS symptomatic but stable: 2–6 times a year.
      3. HIV/AIDS acute: 2–6 times a year.
      4. Palliative: 2–6 times a year.
   B. For children/adolescents:
      1. No signs/symptoms or mild signs/symptoms: 1–4 times a year.
      2. Moderate signs/symptoms: 4–12 times per year
      3. Severe signs/symptoms: 6–12 times a year.

II. New or ongoing clinical conditions,
III. The individual's ability to understand and incorporate nutrition management skills.

Although the protocol does not list specific screening conditions, it assumes that the health care team will base referrals on assessment factors spelled out in the protocols. To date, no validation studies of the Medical Nutrition Therapy protocols have been reported. The Nutrition Guidelines for Agencies Providing Food to People with HIV/AIDS refers to the protocols given above as the guide RDs should follow to provide medical nutrition therapy to persons with HIV/AIDS.

Heller et al. have recently reported on an instrument to assess nutritional risk in HIV-infected children. Fifteen providers evaluated 39 children. Information collected included medical history and socio-demographic, dietary, anthropometric, and biochemical data. Medical, dietary, and anthropometric data were found to be good predictors of nutritional risk. In spite of the small sample size, the instrument was found to be valid and a good predictor of nutritional risk in HIV-infected children.

SELF ASSESSMENT EXERCISE

screening tools used for assessment of risk for nutritional problems in HIV/AIDS are

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3.2 The Role of Nutritional Problems

There is a similarity between the immune deficiency, multiple infections, and severe weigh loss seen in AIDS patients, and the association of protein caloric malnutrition (PCM) with reduced resistance to infection observed in malnourished children, particularly in the Third World." "It is also possible that nutritional deficiency may play a significant role in the clinical course of the immuno-deficient state." "These similarities between AIDS and PCM suggest that nutrition may contribute to the immuno-deficient state. The immunodeficiency in children with PCM can be reversed by nutritional rehabilitation, which suggests that restoration of nutritional state may be a useful adjunct to therapy for AIDS patients".

As described above, the immunological alterations found in PCM are practically identical to those of AIDS; impaired delayed cutaneous hypersensitivity, lymphocyte proliferation response to mitogens, complement activity and secondary response to antigens. There is also a reduced number of resetting T lymphocytes, increased deoxynucleotidyl transferase activity, decreased serum thymic factor, fewer helper T cells, impaired production of interferon gamma and interleukins 1 and 2, reduced antibody affinity, impaired secretory immunoglobulin A (IgA) antibody response and phagocyte dysfunction. The proportion of helper/ inducer T lymphocytes recognized by the presence of CD4 positive antigen on the cell surface is markedly decreased. The ratio CD4/CD8 is significantly decreased. Lymphoid atrophy is a prominent feature of nutritional deprivation. Serum antibody responses are generally intact in PCM. Most complement components are decreased, especially C3, C5, factor B and total hemolytic activity.

Nutritional problems have been a part of the clinical aspects of AIDS from its earliest recognition as a new disease" "In fact, in many AIDS patients, death seams to be determined more by the individual's nutritional status than by any particular opportunistic infection. This is, when wasting of lean body mass approaches 55% of normal for age, sex, and height, death is imminent regardless of the forces resulting is such profound malnutrition". Furthermore, the severity of the clinical

manifestations of AIDS is proportional to the degree of the nutritional deficiencies.

Macronutrients are related to wasting and energy balance in HIV-infected patients, while micronutrients play different roles in immune function" In addition to supporting optimal function of the immune system, nutrition is especially critical in children, as it provides the best opportunity for normal growth and development. All persons with HIV infection should be screened for nutritional problems and concerns at the time of their first contact with a health care professional, and routine monitoring should be performed on an ongoing basis. Scientific evidence strongly suggests that nutritional and antioxidant deficiencies are a requisite prior to both reacting positively on the tests for HIV and for progressing to AIDS.

4.0 CONCLUSION

Finally it is important to the health of persons with HIV/AIDS to have access to the services of a nutritionist whose knowledge in the area of nutrition for HIV/AIDS is current, and that each program have practitioners in some capacity as full time, part time, or in consultation who will provides nutritional assessment, appropriate nutrition intervention counseling with appropriate educational materials for good and effective nutritional management.

5.0 SUMMARY

In this unit, we looked at:

Patient generated subjective global assessment
Revised Sga for HIV-infected individual
Quick nutritional screen
Nutritional referral criteria for adults and children with HIV/AIDS
Public awareness checklist of the nutrition screening initiative
HIV/AIDS medical nutrition therapy protocols
The role of nutritional problem on HIV/AIDS management.

Hope you enjoyed your studies. Let us tackle the questions below.

6.0 TUTOR MARKED ASSIGNMENT

List and briefly describe the screening tools used for assessment of risk for nutritional problems in HIV/AIDS

7.0 REFERENCE/FURTHER READINGS

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MODULE 4 CHEMOTHERAPEUTIC MANAGEMENT OF HIV/AIDS

UNIT 1 ANTIRETROVIRAL THERAPY OF HIV/AIDS

CONTENTS

1.0 INTRODUCTION

Antiretroviral therapy (ART) has significantly reduced morbidity and mortality, prolonged life expectancy, and improved quality of life among people with HIV infection. ART has also been effective in the prevention of mother-to-child transmission of HIV (PMTCT). The increasing availability of ART has created a major incentive to participate in voluntary counseling and testing and has broadened and enhanced prevention efforts by reducing stigma and increasing uptake of behavior change communication messages. Effective ART may reduce overall transmission at the population level.

Comprehensive care, including antiretroviral (ARVs), treatment of opportunistic infections, and the use of prophylactic agents, benefits the individual, the community, and the country. The provision of affordable, accessible, and good quality treatment and care on a global scale for people living with HIV is essential for tackling the epidemic, improving lives, and protecting the significant development gains of the past 20 years.

Addressing the care and treatment needs of HIV-infected people is also a critical component of achieving the millennium development goals of

the next decade. Until 2005, only 5% of the six million people who required ARVs in resource-limited countries could access these drugs.

Between 2003 and the end of 2005, however, these numbers rose three-fold mainly from the massive scaling up of programs supported by the 3 by 5 Initiative of the World Health Organization (WHO); the Global Fund to Fight AIDS, Tuberculosis and Malaria; the World Bank; and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). Nigeria, with a national sero-prevalence of 5% and an estimated four to six million people living with HIV, has at least 800,000 people in urgent need of ART. Only about 5% of those in need are currently receiving ART, but this number is expected to rise sharply with the 2005 presidential directive to treat 250,000 individuals by the end of 2006.

2.0 OBJECTIVES

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

Identify goals of ART
Identify actions required to achieve durable ART
Identify limitations of ART

3.0 MAIN CONTENT

3.1 Goals of Highly Active Antiretroviral Therapy

The goal of HIV therapy is to provide optimal and individualized treatment for HIV-infected people at all stages of disease. ART for HIV became available in 1987 with the approval of AZT, a reverse transcriptase inhibitor and nucleoside analogue now known as zidovudine. While zidovudine monotherapy prolonged life, its beneficial effects were short-lived and within months the disease would again progress.

Combination therapy with two nucleoside analogues offered some improvement. However, the benefits were again time-limited regardless of the specific combination. It was not until new classes of ARVs the non-nucleoside reverse transcriptase and protease inhibitors—became available and were used in combination with two nucleosides that sustained results were achieved. The use of three ARVs from two drug classes has been termed triple-combination therapy or "highly active antiretroviral therapy" (HAART). HAART use is associated with sustained suppression of plasma HIV RNA (viral load) as measured by PCR, and significant improvement in immune status as measured by absolute and percentage

CD4+ counts. These results have led to increased survival, reduced morbidity, and decreased vertical and sexual transmission.

HAART may also be used to prevent infection following inadvertent exposure to HIV. Although HAART has produced dramatic benefits by increasing healthy survival, eradication of the virus in any individual has been elusive. The apparent invincibility of HIV, even in the face of HAART, has been aided by complex viral and cellular kinetics that allow it to persist in long-lived cells such as latently infected CD4+ T lymphocytes and tissue-bound macrophages. In addition, there are potential "sanctuary" sites such as the brain, testes, and retina, where the presence of blood-tissue barriers limits entry of otherwise potent ARVs. Therapy must often be tailored to fit the needs of individual patients; however, ***the goals of ART remain the same***:

- **Clinical:** Prevent progression of disease, prolong life and improve the quality of life.
- **Virologic:** Maximally suppress plasma HIV RNA (viral load).
- **Immunologic:** Reconstitute the immune system with an increase in the quantity and quality of CD4+ cells.
- **Therapeutic:** Provide the most convenient HAART regimen with a low pill burden, few food requirements or limitations, and an infrequent dosing schedule, and enhance adherence.
- **Toxicity:** Select a regimen with the fewest acute and chronic adverse effects.
- **Pharmocokinetic:** Choose regimens with favorable pharmacokinetic properties and a high threshold for development of resistance.
- **Public health:** Reduce infectiousness in the population.

HAART has become the standard of care for treatment of HIV infection. The key to successful HAART in a resource-limited country such as Nigeria is the concept of durability. A durable regimen is one in which the potency of the drug—defined by its ability to suppress virus below levels of detection (< 50 or < 400 HIV RNA copies per ml, depending on the assays used—is maintained over a long period of time. A durable regimen can prevent the emergence of resistance, promote health, reduce the complexities of care, and ensure health cost savings. Current knowledge of the mechanisms of action, toxicity, drug resistance and pharmacokinetic profile of available ARVs should inform the development of a durable regimen.

Other key issues that will influence the development of durable regimens in resource-limited countries include knowledge of the effectiveness of available regimens, patterns of resistance, and the presence of co-morbidities, such as tuberculosis and hepatitis B or C.

Monitoring and evaluating ART programs to ensure they produce the desirable outcomes is also important for enhancing durability.

SELF ASSESSMENT EXERCISE

Identify the goals of ART

3.2 Actions required to achieve durable ART

Action required to achieve durable ART include

- Maximized adherence to the ARV regimen;
- Select sequential ARVs in a rational manner, starting with the most potent, locally proved combinations;
- Preserved future treatment options;
- Select drug combinations with high mutational thresholds;
- Use resistance testing in selected clinical settings;
- Select drugs with similar pharmacokinetic profiles;
- Limit the use of drug combinations with high toxicity;
- Use combinations with low pill burden, food requirements, and refrigeration storage needs; and
- Avoid adding single agents to a failing drug regimen.

3.2 Risks and Limitations of ART

It should be noted that ART has many risks and limitations:

First, early and delayed adverse effects, such as metabolic disorders, mitochondrial toxicities, and numerous organ-specific adverse reactions are continual concerns. The scope of these adverse effects is rather broad, and our understanding of their pathogenesis and clinical presentations continues to evolve.

Second, HIV clinicians and researchers now view the late 1990s as a period of irrational optimism about the possibility of a cure for HIV. It has since become clear, however, that such a feat is unachievable because of the complexity of the regimens, the difficulties of maintaining long-term adherence, viral mutation, and toxicity. Even in the absence of systemic replication, latently infected resting CD4+ T cell populations persist in lymph nodes and other organs. Prolonged ART appears to impair the development of HIV-1–specific immune responses because it reduces systemic HIV that would otherwise serve as the antigenic stimulant of such responses. Therefore, plasma viremia inevitably rebounds whenever treatment is stopped.

ARVs do not cure HIV infection and therefore must be taken for life. They can result in major toxicities and drug interactions, and drug

resistance can develop if adherence is poor. The cost of ARVs and laboratory monitoring pose major financial challenges, particularly in resource-poor countries. The lack of an adequate health infrastructure and insufficient human resources create serious obstacles to providing ART in an effective, durable, and sustainable manner. Furthermore, increased commitment to treatment and care may lead to the neglect of prevention efforts and programs aimed at reducing the social and economic impact of HIV.

4.0 CONCLUSION

The goals of HIV therapy are to provide optimal and individualized treatment for HIV-infected people at all stages of disease. Goals thus includes preventing progression of disease, prolong life, and improve the quality of life and maximally suppress plasma HIV RNA (viral load). This unit further looked at Actions required to achieve durable ART which includes maximized adherence to the ARV regimen, selection of drug combination with high mutation threshold amongst others. Risks and limitations of ART were further identified

5.0 SUMMARY

We hope you enjoyed your studies. This unit took a broad look at ART, goals and limitations. Let us attempt the following questions below.

6.0 TUTOR MARKED ASSIGNMENT

Identify the risks and limitations of ART

ANSWER TO SELF ASSESSMENT EXERCISE

Goals of ART are:

- **Clinical:** Prevent progression of disease, prolong life, and improve the quality of life.
- **Virologic:** Maximally suppress plasma HIV RNA (viral load).
- Immunologic**:** Reconstitute the immune system with an increase in the quantity and quality of CD4+ cells.
- **Therapeutic:** Provide the most convenient HAART regimen with a low pill burden, few food requirements or limitations, and an infrequent dosing schedule, and enhance adherence.
- **Toxicity:** Select a regimen with the fewest acute and chronic adverse effects.
- **Pharmocokinetic:** Choose regimens with favorable pharmacokinetic properties and a high threshold for development of resistance.

- **Public health:** Reduce infectiousness in the population.

7.0 REFERENCES/FURTHER READINGS

Antiretroviral Agents for Adults (DHHS**), (**2005). The (DHHS) Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents. (The Living Document: October 6. Available at http://www.aidsinfo.nih.gov/guidelines/

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UNIT 2 CLASSES OF ANTIRETROVIRAL AND MODES OF ACTION

CONTENTS

1.0 INTRODUCTION

This unit follows logically with the previous ones. Remember that the previous unit looked at the goals and limitations of ART. In this unit we will look at classes of ART, choice of ART regimes, NRTI backbones and co formulated NRTI combination.

2.0 OBJECTIVES

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

Identify classes of ART
Explain choice of ART
Explain NRTI backbones
Identify co formulated NRTI combination

3.0 MAIN CONTENT

3.1 Classes of ART

The major classes of ARVs are:

Nucleoside reverse transcriptase inhibitors (NRTIs)
Nucleotide reverse transcriptase inhibitors (NtRTIs);
Non-nucleoside reverse transcriptase inhibitors (NNRTIs);
Protease inhibitors (PIs);
Fusion inhibitors.

The drugs in each of these classes interfere with specific steps in the HIV replication cycle. NNRTIs are synthetic nucleoside analogues that are inactive until taken up by infected cells and converted to the triphosphate compound through the action of cellular enzymes. The active triphosphate forms inhibit HIV-1 replication by incorporating into the viral DNA chain and competing with deoxynucleotide triphosphate (DNTP), which is the natural substrate for HIV reverse transcriptase (RT). This terminates the growing DNA strand, leading to incomplete replication of the virus. The only NtRTI that is used for HIV treatment is tenofovir disoproxil fumarate (tenofovir DF). Tenofovir DF requires initial diester hydrolysis for conversion to tenofovir. Tenofovir is then taken up by cells and is phosphorylated to tenofovir diphosphate, which competes with the natural substrate (deoxyadenosine 5-triphosphate) for incorporation into viral DNA. This causes premature DNA chain termination and incomplete replication of the virus.

NNRTIs do not require intracellular phosphorylation to be active. Instead, these agents bind to a hydrophobic pocket of RT that is distinct, but close to the dNTP binding site. Thus, they do not compete with template or nucleoside triphosphates, but rather exert non-competitive inhibition of RT. These agents are active against HIV-1, but not HIV-2. Normal HIV replication involves the action of two groups of proteases. First, there are cellular proteases that cleave envelope precursor polyprotein, leading to the formation of the glycoprotein spikes that are on the surface of the virus. Viral proteases are responsible for cleaving Gag and Gag-pol precursor polyproteins with formation of the remaining viral proteins, including RT, protease, and integrase.

The only fusion inhibitor in use at this time is enfuvirtide (T-20). This agent inhibits the fusion between HIV and cellular membranes by binding to the gp41 portion of the HIV glycoprotein envelope, preventing the conformational changes that are necessary for the fusion of HIV to cellular membranes. Currently investigational ARV drug classes include co receptor antagonists and maturation inhibitors. CCR5 and CXCR4 are co receptors for the binding of HIV to target cells; thus, agents that antagonize them have the potential to interfere with this critical step in the lifecycle of the virus.

However, one potential limitation of CCR5 antagonists is that they are only likely to be effective against CCR5-tropic HIV, while CXCR4 antagonists are expected to be effective only against CXCR4-tropic virus. It is uncertain whether the use of CCR5 antagonists will cause selection of CXCR4-tropic virus, or conversely, whether selection of CCR5-tropic virus will occur with the use of CXCR4 antagonists.

3.2 Choice of Antiretroviral Regimens

While there are many effective HAART regimens that are used to treat HIV infection, the initial strategy must be based on specific drug and patient factors such as proven potency, ease of administration, potential drug toxicities, pharmacokinetics, resistance threshold, expense, and availability. The current Nigerian ART guidelines recommend starting with an initial HAART regimen that includes two NRTIs plus one NNRTI or a PI. The preferred first-line regimen is zidovudine or stavudine, plus lamivudine; or emtricitabine, plus nevirapine or efavirenz. Three alternative first-line regimens are also recommended: tenofovir, plus lamivudine or emtricitabine, plus nevirapine or efavirenz; abacavir, plus lamivudine or emtricitabine, plus nevirapine or efavirenz; or zidovudine or stavudine, plus lamivudine or emtricitabine, plus tenofovir or abacavir. Previous reports have shown that the potency of NNRTI-containing regimens was equivalent to that of PI-containing regimens. As an initial strategy, if a PI-containing regimen is chosen; most PIs can be combined with ritonavir for pharmacokinetic enhancement.

Although enhancement of a PI-based regimen with ritonavir is likely to be more effective than using another PI alone, it may cause more side effects. A review of several clinical trials indicates that the most potent HAART regimens include efavirenz or lopinavir/ritonavir in combination with two NRTIs. Based on a review of data from a number of studies, the preferred initial HAART combinations for adults are: efavirenz in combination with lamivudine and either zidovudine, stavudine, or tenofovir; or lopinavir/ritonavir in combination with lamivudine and either zidovudine or stavudine.

A number of alternative regimens are less preferred because of the increased pill burden, potential adverse events, or limited efficacy data. Clinicians try to avoid stavudine as a first-line therapy because of its long-term, cumulative toxic effects.

SELF ASSESSMENT EXERCISE

Identify the major classes of ART

3.3 NRTI Backbones

Multiple options are now available for the initial choice of dual NRTIs, the “NRTI backbone”. The Nigerian guidelines recommend four of them: *stavudine plus lamivudine, zidovudine plus lamivudine, tenofovir plus lamuvidine/emtricitabine, or abacavir plus lamuvidine*. All of the backbone combinations are effective when combined with an NNRTI or

PI, but their side effect profiles are different. Didanosine, although a very effective drug, should be avoided as an initial therapy because of the potential for developing neuropathy and pancreatitis, which can be fatal.

The NRTI, tenofovir, plus either lamivudine or emtricitabine, has been shown to be well tolerated and as effective as stavudine plus lamivudine. To date, it appears that effects of long-term toxicity such as lipoatrophy and hypertriglyceridemia occur less frequently with tenofovir than with stavudinebased treatment. The coformulation of a tenofovir/emtricitabine (Truvada®) tablet means that this combination can be taken once daily with efavirenz with only two pills. Compared to Combivir®, the coformulation Truvada, when given in combination with efavirenz, had a superior virologic effect, less toxicity, and no tenofovir resistance.

The Truvada/efavirenz combination is now widely used in Western countries because of its high virologic success and low toxicity rates. Stavudine plus lamivudine is well tolerated in the short term; however, over time, some patients develop peripheral neuropathy and/or peripheral and facial lipoatrophy. Zidovudine plus lamivudine is associated with gastrointestinal side effects, anemia, and neutropenia; however, it is not associated with peripheral neuropathy and is associated with less peripheral and facial lipoatrophy than stavudine-containing regimens. Because of the high prevalence of anaemia in Nigeria, the hemoglobin of all patients commencing treatment with zidovudine must be checked; zidovudine is contraindicated if the hemoglobin is less than 8 gm/dl.

The combination of abacavir and lamivudine is well tolerated, is usually not associated with mitochondrial toxicity, and can be dosed once or twice daily. A coformulation of the two drugs (Epzicom®) has been used successfully in a number of clinical trials. One major limitation of the widespread use of abacavir, however, is the occurrence of hypersensitivity reaction (HSR) in 5% to 10% of patients, which may occur in the first few weeks of therapy.

Thus, physicians need to be trained to distinguish abacavir hypersensitivity rash from nevirapine-associated rash. Moreover, subsequent re-challenge after initial hypersensitivity can lead to death. HLA haplotype B-5701 has been associated with abacavir HSR, but the magnitude of the association is uncertain since many patients with the HSR lack HLA B-5701. It has also been suggested that heat shock proteins (Hsp 70) represent an early component of the abacavir-specific immune response, which is sensitive to inhibition of type 1 alcohol dehydrogenase and influences interferon-gamma expression. It appears

that African ethnicity, male gender, and CDC class C disease are associated with reduced risk. A preliminary report suggested that the incidence of severe HSR may be higher with once daily dosing compared to twice daily dosing.

3.4 Coformulated NRTI Combinations

There are currently three coformulated dual NRTI combinations: zidovudine/lamivudine (Combivir), abacavir/lamivudine (Epzicom), and tenofovir/emtricitabine (Truvada). When combined with an NRTI or a PI, these formulations offer reduced pill burden, improved adherence, and preserved potency. A notable disadvantage is the lack of flexibility in dosing: if changes are needed, the patient must revert to the individual drugs.

Unlike the traditional thymidine NRTI backbones, failures with the abacavir/lamivudine and tenofovir/emtricitabine backbones are associated with M184V mutations with or without the L74 or K65, which leaves some plausible sequencing options. Interestingly, individuals developing the K65R mutation who experience virologic failure are still able to maintain a mean viral load decrease of 0.9 log from baseline as observed in the Gilead 903 study. In this study, using both virtual phenotype and true phenotype, patients with K65R mutation were hypersensitive to zidovudine and stavudine and had full or partial susceptibility to abacavir, and in many cases, based on the results of testing resistance alone, remained sensitive to tenofovir and didanosine. This occurred in the absence or presence of the M184V mutation, which is known in vitro to hypersensitize the virus to tenofovir. Therefore, patients experiencing failure with a K65R mutation may have virologic success with a second regimen, including one containing tenofovir.

4.0 CONCLUSION

In this unit, we identified classes of ART and they include: nucleoside reverse transcriptase inhibitors (NRTIs), nucleotide reverse transcriptase inhibitors (NtRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs) and fusion inhibitors. We also observed that while there are many effective HAART regimens that are used to treat HIV infection, the initial strategy must be based on specific drug and patient factors such as proven potency, ease of administration, potential drug toxicities, pharmacokinetics, resistance threshold, expense, and availability. Hope you enjoyed this unit.

5.0 SUMMARY

This unit looked at classes of ART, why the choice for ART regimes, NRTI backbones and co formulated NRTI combinations. Now let us test our understanding and attempt the questions below.

6.0 TUTOR MARKED ASSIGNMENT

Explain factors influencing choice of ART

ANSWER TO SELF ASSESSMENT EXERCISE

The major classes of ARVs are:

nucleoside reverse transcriptase inhibitors (NRTIs)
nucleotide reverse transcriptase inhibitors (NtRTIs);
non-nucleoside reverse transcriptase inhibitors (NNRTIs);
protease inhibitors (PIs);
fusion inhibitors.

7.0 REFERENCES/FURTHER READINGS

Antiretroviral Agents for Adults (DHHS**),** **(**2005). The (DHHS) Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents. (The Living Document: October 6. Available at http://www.aidsinfo.nih.gov/guidelines/

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UNIT 3 OTHER NRTI COMBINATIONS

CONTENTS

1.0 INTRODUCTION

This unit is also a follow-up on the previous one. Here we will discuss other NRTI drugs, identify their advantages and disadvantages. Happy reading!

2.0 OBJECTIVES

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

Identify other NRTI combinations
Illustrate the advantages and disadvantages of identified NRTI drugs
Illustrate the aims of selecting the third drug

3.0 MAIN CONTENT

3.1 Other NRTI Combination

Alternative double nucleoside choices exist; however, their use is limited by availability constraints or potential toxicity. The combination of stavudine plus didanosine has been shown to be quite effective. However, toxicity from the combination is unacceptable with excessive rates of pancreatitis, lipoatro- phy, peripheral neuropathy, and lactic acidosis. Tenofovir plus didanosine is generally inappropriate for initial regimens, and should be avoided in salvage regimens, if alternatives are

available. When used together, didanosine dose should be reduced. Tenofovir plus abacavir should be avoided; this combination has been associated with an increased risk of virologic failure, especially in patients with a viral load of more than 100,000 copies/ml and a CD4+ count of fewer than 200 cells/mm.

Even among some people who achieve viral suppression, a paradoxical decline in CD4+ count occurs, which is poorly understood.

It is worth noting that inappropriate dosing of didanosine was a common finding in patients with adverse outcomes Lamivudine plus didanosine has been demonstrated to be an effective NRTI backbone in many studies. However, potential problems with this regimen include pancreatitis and peripheral neuropathy due to didanosine and probably increased risk of some manifestations of mitochondrial toxicity. Thus, it is not used in initial regimens. Emtricitabine has also shown to be effective when combined with didanosine and efavirenz once daily in treatment-naive patients but this combination is not used in initial regimens because of toxicity. Zidovudine plus didanosine is usually used in second-line regimens after failure of initial therapy.

3.2 Advantages and disadvantages of different NRTI combinations

THIRD HAART DRUGS	ADVANTAGES	DISADVANTAGES
Nevirapine (a recommended choice)	Inexpensive	Rash, hepatotoxicity
Efavirenz(a recommended choice)	Inexpensive, Available	Central nervous system effects, Potential fatal abnormalities
Lopinavir/Ritonavir(an Alternative choice)	Potent, relatively tolerated	Gastrointestinal, hyper Lipidema, abdominal truncal fat accumulation
Indivanir with or without Ritonavir	Inexpensive to protease inhibitors	Skin disorders, glucose intolerance, abdominal truncal fat accumulation
Atazanavir with or without ritonavir(an Alternative choice)	No effect on serum lipids, unique resistance profile	Indirect hyperbilirubinema
Nelfinavir(an alternative choice not Recommended for first-	Low potency	Gastrointestinal effect, less effective than other protease

line therapy)		inhibitors
Saquinavir(an alternative choice not Recommended for first-line therapy	Less effect on lipids than other protease inhibitors	Abdominal and truncal fat accumulation

3.3 Selecting the Third Drug

In addition to the NRTI backbone, the third drug of a HAART regimen is a critical choice and should be chosen based on potency, pharmacokinetics, adverse event profile, and availability. The most common third drug added to a HAART regimen is a non-nucleoside, either nevirapine or efavirenz. Both drugs have favorable pharmacokinetic profiles, are dosed infrequently (typically once daily), and have been shown to be effective. Both drugs are inducers of the cytochrome P450 (CYP450) system and may lower the effective concentrations of hepatically metabolized drugs in the blood, although to different degrees.

The largest study to date comparing efavirenz-containing and nevirapine-containing regimens (the 2NN trial) found that both had similar virologic and immunologic efficacy. The major difference between these drugs is their toxicity profiles. Efavirenz was better tolerated with lower incidence of severe hepatic and cutaneous toxicity. Delavirdine, a third approved non-nucleoside, is infrequently used because of a higher pill burden and a lack of central nervous system penetration. Delavirdine is an inhibitor of CYP450. Non-nucleoside drugs should not be used together and should only be used in combination with two other ARVs.

3.3.1 Nevirapine

Nevirapine, the first non-nucleoside to be approved, is associated with rash in approximately 17% of patients. One-half of the rashes are mild, characterized by intact skin and absence of blistering, skin desquamation, involvement of mucous membranes, angioedema, or systemic signs (body aches, arthalgias, myalgias, fevers, lymphadenopathy or significantly elevated hepatic transaminases). It is usually self-limited and does not require discontinuation of the drug. Antihistamines may offer some symptomatic relief. In approximately 0.5% of patients, the rash can be serious and includes potentially fatal Stevens-Johnson syndrome or toxic epidermal necrolysis. Following the recommended lead-in dosing reduces the likelihood of developing nevirapine-associated rash.

Mild asymptomatic liver enzyme elevations (LEE) are relatively common, often self-limited, and do not require treatment discontinuation. Liver enzymes should be checked regularly until they have returned to normal. Symptomatic elevations of ALT and hepatic failure also occur with nevirapine, particularly during the first six weeks of treatment. Reported symptoms, including nausea, vomiting, and abdominal pain, are similar to those that occur in patients with pancreatitis and lactic acidosis therefore, these conditions should be excluded. About half of the patients with nevirapine-associated hepatotoxicity have rash with or without other manifestations of autoimmune disease, strengthening the theory that it is essentially a hypersensitivity phenomenon. Risk factors for this rash-associated hepatitis include female with CD4+ counts greater than 250 cells/mm3 and male with CD4+ counts greater than 400 cells/mm3.

Therapy should be discontinued in patients with symptomatic LEE (with or without manifestations of hypersensitivity), liver failure, or lactic acidosis. Therapy with ARVs that are less hepatotoxic may be cautiously restarted after resolution of the LEE. Required supportive therapy should be given. Fatal hepatic failure has been reported but is rare. Although nevirapine is not absolutely contraindicated in patients co-infected with HIV and hepatitis C virus (HCV), it should be used with caution because of preliminary reports that suggest an accelerated rate of hepatic fibrosis in such patients.

Choosing another agent may be prudent to reduce the risk of necro-inflammation and fibrosis in some patients. Also, the use of nevirapine in post-exposure prophylaxis (PEP) regimens is discouraged because of its propensity to cause hepatotoxicity in patients with intact immune systems. For HIV-infected patients who are co-infected with hepatitis B virus (HBV) or HVC, it is usually difficult to distinguish liver enzyme abnormalities caused by ARV hepatotoxicity or hypersensitivity from those caused by a flare of HBV or HCV due to immune reconstitution. It is important to make this distinction correctly, however, since it directly impacts the decision to continue or interrupt HAART. A helpful strategy involves close monitoring of the patient’s laboratory and clinical course: patients who remain asymptomatic and have improving liver enzymes while receiving the same ART regimen probably have immune reconstitution hepatitis flare, in which case therapy can be cautiously continued.

Therapy should be interrupted in those who are symptomatic and those who experience progressive worsening laboratory results on ART, because they probably have hepatotoxicity or hypersensitivity. A distinct advantage of nevirapine is its lack of adverse effects on the fetus and newborn, hence its use for prevention of vertical transmission. A

potential disadvantage is an interaction with rifampicin, which precludes the use of the two drugs together.

3.3.2 Efavirenz

Efavirenz also is associated with rash, but this is usually less severe than with nevirapine and only infrequently leads to drug discontinuation. The primary problems associated with efavirenz use are central nervous system side effects and potential fetal abnormalities, specifically neural tube defects. The neurological effects associated with efavirenz include mood alterations, sleep disorders, unusual dreams, hypomania, and anxiety. Usually these effects are self-limited and resolve after several days or weeks.

The potential adverse effects on the fetus, efavirenz should not be administered during pregnancy or in women contemplating pregnancy. The interaction with rifampicin is less than that of nevirapine. When the drugs are used together, the efavirenz dose is usually increased from 600 to 800 mg daily, although this may not be necessary in all patients. In one randomized, controlled study among Thai patients with tuberculosis and an average body weight below 60 kilograms, there was no significant difference in virologic and immunologic outcomes between patients who received 600 mg of rifampicin and those who received 800 mg in combination with an efavirenz-containing HAART regimen

The patients received HAART regimens of efavirenz, didanosine, and lamivudine, while tuberculosis was treated with a rifampicin-containing regimen. Although there was wide variability in its plasma concentrations, efavirenz at a dose of 600 mg/day was found to be efficacious, with virologic success, immunologic success, and weight gain. The rifampicin dose did not require adjustment.

3.3.3 Protease Inhibitors

An effective alternative to the non-nucleoside approach is the addition of a PI as the third drug in a HAART regimen. The most effective and practical PIs to be considered for first-line therapy includes lopinavir/ritonavir (Kaletra®), indinavir with or without ritonavir, and atazanavir with or without ritonavir. Nelfinavir is also an option, but it has been demonstrated to be less effective than lopinavir/ ritonavir-based therapy. Pharmacokinetic enhancement of nelfinavir with ritonavir is less effective than with the other PIs and is associated with unacceptable gastrointestinal intolerance.

Saquinavir hard gel (Invirase®) is an alternative only when co-administered with ritonavir. Amprenavir and its newer prodrug form,

fosamprenavir, are not yet available in Nigeria. Unfortunately, at their regular doses many PIs have trough levels close to the lowest concentration at which they exert antiviral activity, thus providing opportunities for viral replication and resistance. Ritonavir is a unique PI in that at very small doses, it alters the metabolism of other PIs by inhibiting gastrointestinal and hepatic CYP450 enzyme system. This improves pharmacokinetic parameters of coadministered PIs such as peak plasma concentration (Cmax), half-life, and trough concentration (Cmin). The area under the plasma concentration versus time curve (AUC), which determines the overall viral exposure to the PI, is also increased, often allowing a reduction in the dose needed for effective treatment.

Also, the inhibitory quotient the ratio of Cmin to the concentration needed to inhibit viral replication by 50% (IC50), which influences the likelihood of developing resistance mutations is improved with ritonavir-boosted PIs. For these reasons, ritonavir-boosted PIs generally have improved potency and greater pharmacokinetic barriers to resistance. In contrast to some unboosted PI regimens, failure of ritonavir-boosted, PI-based regimens in previously PI–naive patients is unlikely to be due to development of resistance to the boosted PI. This was well illustrated when lopinavir/ritonavir plus two NRTIs were compared to nelfinavir plus similar NRTIs. The “anti-resistance” characteristic, which has been demonstrated with other boosted PIs, including atazanavir/ritonavir and fosamprenavir/ritonavir, underlies some of the strongest arguments in favor of boosted PI regimens. Also, ritonavir-boosting can be used to overcome low-level resistance to PIs.

SELF ASSESSMENT EXERCISE

The neurological effects associated with efavirenz include: ……., ……., and ……

3.3.4 Triple Nucleoside Regimens

Triple nucleoside combinations also have been studied as first-line HAART. These combinations allow sparing of NNRTIs and PIs. Although these combinations are convenient and cause fewer drug interactions, the potency of the fixed combination of zidovudine/lamivudine/abacavir has been inferior to nonnucleoside– and PI–based regimens. Therefore, triple nucleoside combinations should only be used in circumstances in which NNRTIs and PIs are either not available or not tolerated.

Conversely, the combinations of tenofovir/lamivudine/abacavir tenofovir/lamivudine/didanosine should be avoided because they failed

in two studies. Resistance testing in both studies showed the emergence of both M184 and K65R mutations in patients with evidence of virologic failure. Preliminary reports from the DART study of the evaluation of tenofovir/lamivudine/zidovudine have shown promising results. The good response with this particular regimen appears directly related to the presence of zidovudine and tenofovir, a combination that has bidirectional protection against resistance.

One concern with the use of the DART regimen in some resource-limited settings, however, is the apparently increased risk of anemia. Nonetheless, the DART regimen is particularly promising in settings with high rates of tuberculosis co-infection, because it does not contain NNRTIs or PIs that are responsible for the drug interactions that complicate the management of both infections.

Some quadruple NRTI regimens that contain zidovudine and tenofovir also have shown some promise in preliminary trials, but there are lingering concerns about broad NRTI resistance and a clear role for the regimen remains undefined. It should be noted that the DART study has no comparative treatment arm and results must be interpreted with caution at this time.

4.0 CONCLUSION

This unit provided us with materials on other NRTI combinations, as well as the feature, goals, advantages and disadvantages of identified NRTI combinations.

5.0 SUMMARY

In this unit, we identified other NRTI combinations, their features, advantages and disadvantages. OK! Let us attempt the questions below.

6.0 TUTOR MARKED ASSIGNMENT

Identify the advantages and disadvantages of identified NRTI combinations

ANSWER TO SELF ASSESSMENT EXERCISE

The neurological effects associated with efavirenz include: mood alterations, sleep disorders, unusual dreams, hypomania, and anxiety.

7.0 REFERENCES/FURTHER READINGS

Antiretroviral Agents for Adults (DHHS**), (**2005). The (DHHS) Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents. (The Living Document: October 6. Available at http://www.aidsinfo.nih.gov/guidelines/

Antiretroviral Agents for Adults **(IAS-USA):** Yeni PG et al. Treatment for Adult HIV Infection: 2004 Recommendations of the *International AIDS Society-USA Panel. JAMA.* 2004;292(2): 251-65.

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UNIT 4 STEPS TO INITIATE ANTIRETROVIRAL THERAPY

CONTENTS

1.0 INTRODUCTION

In previous unit, we identified the goals and classes of ART. This unit will look at steps to initiate antiretroviral therapy. Specifically, it will tackle assessing patients for ART regime, criteria for commencement of ART and monitoring ART and patient follow-up.

2.0 OBJECTIVES

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

Identify assessment steps taken before commencement of ART
Identify assessment criteria for ART
Identify the skills needed for ART monitoring and patient follow-up

3.0 MAIN CONTENT

3.1 Assessment Steps taken before commencement of ART

Several patient-related factors may influence the choice and outcome of ART in resource-limited countries. In Nigeria, many patients may delay visiting a clinic until they present with advanced HIV disease (WHO stage III or IV) because of the prevailing stigma and the absence of widespread counseling and testing.

Patients may present with coexisting morbidities such as anemia, malaria, tuberculosis, or hepatitis, which may affect the choice of the drug regimen due to potential drug interactions and toxicities. A 2001 sentinel survey conducted by the Federal Ministry of Health found 23%

of tuberculosis patients to be HIV positive. Most patients are poor, and financial constraints can cause treatment interruptions.

A detailed clinical evaluation of the patient should be made at baseline and every three to six months subsequently. Each visit should include a review of current symptoms and concomitant illnesses. Clinical features and diseases should be categorized as HIV-related or AIDS-defining. The patient should also be screened for the presence of co-infections, including malaria, tuberculosis, HBV and STIs.

A detailed medical history, including a history of any high-risk sexual behavior and the number of sex partners, should be elicited from the patient. The history should also include the sexual and other relevant history of the patient's sexual partner or partners, as this information can be useful in determining the patient's relative risks for other infections, such as with the hepatitis B, hepatitis C, and human papilloma viruses. Other important information includes a history of any previous blood transfusions and, in women, the history of previous pregnancies, antenatal care, and deliveries.

Many patients in Africa may be taking traditional medications for HIV-related disease. Identifying the remedies a patient may be taking is important, as these drugs may cause drug interactions or affect liver or kidney function, the ultimate pathways for the metabolism and excretion of most ARVs.

The initial physical examination of the patient should be detailed and should include: measuring weight, temperature, and vital signs; checking the skin for rashes, ulcers, and lesions; checking the oral cavity for thrush and sore throat; assessing mental and emotional status; and making appropriate assessments of the following organs or systems: lymph nodes, chest and cardiovascular, abdominal and gastrointestinal, genitourinary and rectal, gynecologic (women), neurological, and ophthalmic.

Baseline laboratory investigations should include a chest X-ray for tuberculosis and pneumonia; microbiologic tests for tuberculosis, including a sputum smear and cultures; a full blood count; a fasting blood sugar; kidney and liver function tests; a lipid profile, including triglycerides and cholesterol; a pap smear for women; appropriate swabs for STIs; hepatitis B and C antibody tests; a syphilis test; a pregnancy test if indicated; a CD4+ count; and a HIV viral load if available.

After the initial work-up of the patient, the physician should have the information needed to determine the patient's stage of HIV disease and to assess other factors that will influence treatment decisions, such as the

presence of HIV-related diseases and other concomitant illnesses, like hypertension or diabetes; the patient's weight profile; and concomitant medications, including any traditional medications. The decision of when to start ART and what regimen to choose in Nigeria is complicated by prevailing factors such as pregnancy, the presence of co-morbidities (tuberculosis, HBV, or HCV), anemia, consideration of uninfected partners, and the availability and cost of the drugs. A successful HAART regimen should be tailored to the patient. For instance, in patients with a significant psychiatric history, efavirenz may not be the optimal choice because of its associated central nervous system effects.

In women who are likely to get pregnant during treatment, efavirenz should be avoided because of the potential for fetal abnormality. Patients who are malnourished and anemic prior to treatment are not good candidates for therapy with zidovudine. Knowledge about the drugs and the full background of the patient is essential in designing the most acceptable and adhered to HAART regimen. The physician should see the patient at subsequent visits to discuss treatment options, including the risks and benefits of ART, and to choose the optimal ART regimen.

A treatment plan must be developed that the patient understands and to which he or she will be committed. Patient education and preparation are keys to subsequent commitment and adherence to the administered regimen. There should be no rush to start patients on ART as this can lead to non-commitment, dropouts, and the generation of drug resistance. Clinicians should assess the patient's readiness for medication before initiation of therapy, potentially during multiple consultations. Patient education should include discussion of the goals of ART as well as the expected outcomes based on clinical, CD4+ cell, and viral load responses. It is critical for patients to understand that the first regimen has the best chance of long-term success. In addition, education and counseling should incorporate a detailed discussion of the need for adherence and possibly a detailed adherence plan, including the use of treatment partners.

Adherence should be monitored and assessed at each clinic follow-up visit because there is evidence that adherence wanes over time. Patients should be encouraged to join support groups as both peer education and support from members strengthen adherence among patients on ARVs.

Furthermore, adherence goals should be built into all patients' treatment plans and interventions. Toxicities are the most common reasons for poor adherence to medications. When the treatment regimen is chosen, patients must be counseled on how to take the specific medications,

what side effects could potentially occur, what to do in the event of an adverse effect, and where to go with any treatment or disease-related questions.

SELF ASSESSMENT EXERCISE

Identify the necessary steps taken before commencement of ART

3.2 Criteria for commencement of ART

The criteria for commencement of ART according to the Nigerian guidelines in both adults and adolescents are:

- WHO Stage IV disease (AIDS) irrespective of CD4+ count;
- WHO Stage III disease (symptomatic HIV) with CD4+ counts of less than 350/mm3
- WHO Stage I or II disease with CD4+ counts of less than or equal to 200/mm3.

3.3 Monitoring Antiretroviral Therapy and Patient Follow-Up

Before initiating therapy, the clinician and patient must agree on a schedule for monitoring the progress and effects of therapy. At a minimum, the physician should evaluate stable patients every three months and other laboratory assessments twice annually.

At treatment initiation, at the time of any treatment change, or with concurrent illnesses, monitoring should take place more frequently. The first return visit to the clinic should be scheduled two weeks after the patient starts HAART. At this time, it is wise to assess the patient's tolerance of and adherence to the medications, especially any side effects related to nevirapine or efavirenz use, which occurs in the first few weeks of therapy.

A brief physical exam should be performed and, if indicated, a complete blood count and chemistry should be done to assess any potential adverse effects on blood count and hepatic function in particular. If the patient on nevirapine-containing regimen does not have a rash or any medication-related side effects, the dose of nevirapine should be increased from 200 mg/day to 200 mg twice daily. If a rash is present in any form, the 200 mg dose should be continued until resolution, at which time the dose can then be increased. The patient should again return to the clinic every four weeks to pick up drugs.

This schedule ensures supervision of drug therapy and provides opportunities for adherence counseling and contact tracing for patients who miss their appointments. A brief and targeted physical examination should be performed. In resource-poor settings like Nigeria, it is not practical to carry out plasma HIV RNA (viral load) at four weeks to assess early efficacy because of costs and the unavailability of the tests in most ART centers. However, CD4+ counts and plasma HIV RNA levels should be monitored 12 weeks after commencing therapy and subsequently every 24 weeks if patients are stable. Unstable patients may require more frequent monitoring.

The standard of care in Nigeria for monitoring ART is CD4+ cell enumeration and plasma viral load quantification. Plasma viral load correlates with disease progression and is a critical parameter for assessing virologic failure. In tertiary and referral centers that have the necessary infrastructure and trained personnel to perform this assay, viral load quantification will provide the physician and patient with critical information on virologic status during ART and will indicate when virologic failure has occurred. In points of care where this assay is not available, CD4+ cell enumeration and clinical monitoring can be substituted.

Targeted physical examinations should be done every 12 weeks and a detailed examination every 24 weeks. Comprehensive laboratory monitoring should be done every 24 weeks for stable patients. This should include a complete blood count and blood chemistry including liver enzymes, renal function, serum lipids, a CD4+ count, and plasma HIV RNA (where available). Every attempt should be made to discuss the laboratory results at follow-up visits, as this is an important part of promoting adherence and commitment to therapy. As much as possible, these results should be used in making decisions about drug management, as patients are often encouraged by a decline in HIV RNA and lack of toxicity.

Patients should be instructed to return to the clinic at any time between scheduled appointments if they have treatment-related questions or problems. In the event they believe they are experiencing a drug-related serious adverse event and yet cannot visit the clinic, they should be instructed to stop all ARVs until they seek the advice of a professional in the clinic.

4.0 CONCLUSION

We hope you found this unit interesting and insightful. This unit provided us with fundamental issues on steps taken before ART and

monitoring and follow-up of patients on ART. Let us, as usual attempt the question below.

5.0 SUMMARY

We have seen that there is indeed a crucial need to initiate several steps before commencement of ART. This is because patients may present with coexisting morbidities such as anemia, malaria, tuberculosis, or hepatitis, which may affect the choice of the drug regimen due to potential drug interactions and toxicities. This unit also illustrated other criteria for commencement of ART as well as monitoring ART and patient follow-up.

6.0 TUTOR MARKED ASSIGNMENT

What do you understand by monitoring of ART and patient follow-up?

ANSWER TO SELF ASSESSMENT EXERCISE

Assess co-existing morbidity
Obtain detailed medical and physical history
Identify patient's stage of HIV infection
Check pregnancy status of female patients
Carry the patient along

7.0 REFERENCE/FURTHER READING

Antiretroviral Agents for Adults (DHHS**),** **(**2005). The (DHHS) Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents. (The Living Document: October 6. Available at http://www.aidsinfo.nih.gov/guidelines/

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MODULE 5 PATIENTS ADHERENCE AND HIV/AIDS TREATMENT SUPPORT

UNIT 1 WHAT IS TREATMENT ADHERENCE AND SUPPORT

CONTENTS

1.0 INTRODUCTION

In the previous module, we looked at chemotherapeutic management of HIV/AIDS as well as nutritional needs and assessment tools for HIV/AIDS management. This unit will logically tackle the issue of treatment adherence and treatment support. We will start by defining treatment adherence and support. This unit will be a short one, which also serves as a form of respite from the previous long and tedious ones. Happy reading!

2.0 OBJECTIVES

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

Define treatment adherence
Identify factors influencing adherence
Explain treatment support

3.0 MAIN CONTENT

3.1 What Is Treatment Adherence?

Success with any medication depends not only on the intrinsic properties of the drugs, but also on the ability of the patient to take the medications. HIV infection is one of the most difficult chronic diseases to treat optimally. Multiple drugs must be administered, the pill burden may be high, the regimen may be complicated, toxicities are common, drug interactions may occur, food restrictions may be required, medications are expensive, the regimen carries an enormous social and psychological burden for many, and therapy is lifelong. HAART is lifesaving, yet it is anything but easy and it is very unforgiving. Less than 95% adherence to a regimen can lead to viral resistance and ultimately treatment failure. It has been estimated that every 10% decrease in adherence leads to a corresponding 16% increase in mortality.

3.1.1 Factors Influencing Treatment Adherence

A number of factors affect adherence.

These include the patient's belief systems regarding the etiology, as well as their knowledge of the management and treatment of HIV infection.

Other factors include the social, emotional, and financial status of the patient as well as the tolerability, dosing schedule, and pill burden of the drug regimen.

Active use of injected drugs or alcohol, psychiatric disease, and depression are also important factors promoting non-adherence.

Young people and those with a disruptive social life are also likely to be non-adherent to ART. Studies among HIV-infected patients have indicated a strong preference for once-daily dosing and compact regimens.

Furthermore, several reports have observed a significant correlation between low pill burden and improved virologic response. Despite the difficulties of taking lifelong treatment, improving patient adherence is possible. It is imperative to provide the patient with basic knowledge about ARVs and HIV disease and to stress the overall importance of adherence prior to initiating ART. Over the course of several visits before initiating therapy, clinicians can take a number of steps to

improve the chances of good adherence, such as discussing cultural beliefs and myths about HIV and ART; discussing the risks and benefits of ART, including dosing schedules and side effects associated with different regimens; establishing readiness and full commitment to therapy; fostering trust in the health care team; recruiting family and friends for disclosure and treatment support; and developing support groups for people living with HIV/AIDS. Activities that engage family and community members in adherence education and treatment support can both promote adherence and minimize stigma.

Upon initiating ART, clinicians can take further steps to improve the likelihood of good adherence, such as tailoring the regimen to the patient's lifestyle; familiarizing the patient with the pills and dosing schedule; scheduling follow-up visits soon after initiation to discuss side effects and any other obstacles to taking the drugs; promptly responding to any problems by adjusting, changing, or stopping medications when needed; and treating associated conditions, such as depression, anxiety, psychotic disorders, and drug addiction.

3.2 Treatment Support

Facilitating family-based care in which all infected members of the family are seen together at follow-up clinics for ART is another useful strategy for enhancing adherence and successful ART. The potential for improved adherence is also maximized when clinicians develop long-term plans for treatment and are careful to select regimens that will avoid drug interactions and side effects to the extent possible.

Prescribing regimens with low pill burdens, infrequent dosing, minimal toxicities, and no food interactions are all associated with optimal adherence. Fixed dose combinations, pill boxes, and blister packs have all been found to be successful in increasing adherence to drugs in various resource-limited settings. Pagers and alarm clocks can also help to remind patients to take their medication. Tracking defaulters with pharmacy logs and home visits by clinic staff can be particularly useful in preventing prolonged periods of poor adherence and addressing potential problems with adherence as they arise.

Other factors that may enhance adherence to ART include providing medications free of charge for those who cannot afford them. It has been suggested that a cost-sharing program could facilitate adherence to ART, although a recent report from Senegal does not support such an approach. Directly observed therapy (DOT) is another way to ensure adherence, but the logistical requirements of this are often daunting, especially because HIV, unlike active tuberculosis, requires lifelong treatment.

DOT is relatively easy to administer in controlled environments such as prisons, but it can also be implemented at the community level. For example, a large community-based ART program is used by community health workers who visited patients daily. All patients gained weight, and fewer than 5% required medication changes due to side effects or toxicity. Among patients for whom viral load was tested, 86% had suppressed viral loads. Various cohort studies with DOT have observed that high therapeutic success can be achieved with PI based triple therapy regimens. The potential application of DOT-HAART in the Nigerian setting has shown promising preliminary results.

Adherence should be measured periodically; ideally, at every clinic visit. The most commonly used method is direct patient interview, which tends to overestimate adherence. Patient-reported poor adherence is usually accurate, however. A clinician's estimate of the likelihood of adherence is often unreliable.

SELF ASSESSMENT EXERCISE

Identify the steps taken by physicians to improve the likelihood of good adherence

4.0 CONCLUSION

In this unit, we saw that success with any medication depends not only on the intrinsic properties of the drugs, but also on the ability of the patient to take the medications. Factors influencing adherence include among many, patient's belief systems regarding the etiology, as well as their knowledge of the management and treatment of HIV infection

5.0 SUMMARY

This unit provided us with information of treatment adherence and support. Hope you enjoyed your studies. Let us attempt the question below.

6.0 TUTOR MARKED ASSIGNMENT

Identify factors influencing adherence

ANSWER TO SELF ASSESSMENT EXERCISE

Upon initiating ART, clinicians can take further steps to improve the likelihood of good adherence, such as tailoring the regimen to the patient's lifestyle; familiarizing the patient with the pills and dosing

schedule; scheduling follow-up visits soon after initiation to discuss side effects and any other obstacles to taking the drugs; promptly responding to any problems by adjusting, changing, or stopping medications when needed; and treating associated conditions, such as depression, anxiety, psychotic disorders, and drug addiction.

7.0 REFERENCES/FURTHER READINGS

Antiretroviral Agents in Pregnancy**, (**2005) Public Health Service Task Force Recommendations for the Use of Antiretroviral Drugs in Pregnant HIV-1 Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States. The Living Document: November 17. Available at http://www.aidsinfo.nih.gov/.

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Prophylaxis of Occupational Exposure **(**2005) Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis--September 30, *MMWR Recomm and Rep* 2005;54(RR-9):1

UNIT 2 DRUG RESISTANCE

CONTENTS

1.0 INTRODUCTION

Adherence is the most important factor in determining whether resistance emerges during treatment. The relationship between adherence and the accumulation of drug resistance is complex and variable. Drug resistance occurs at a range of adherence between 60% and 80%. Drug-resistance mutations that are associated with reduced viral fitness and virulence may lead to a fairly durable treatment benefit but also delay the need to modify therapy, thus allowing high-level resistance to emerge. Other mutations are associated with reducing (cross-resistance) or enhancing (hypersensitivity) the activity of some ARVs in the same or other classes. In this unit, we will shed more light on variations of drug resistance.

2.0 OBJECTIVES

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

Describe drug resistance
Explain testing for drug resistance
Illustrate drug toxicity
Explain antiretroviral therapy and acquired drug resistance
Describe transmitted drug resistance
Describe key drug-drug interaction
Describe switching drugs

3.0 MAIN CONTENT

3.1 Drug Resistance

With a virion half-life of 30 minutes and a daily production of up to 109 virions, HIV reverse transcriptase enzyme incorporates approximately one mutation per genome per replication cycle. The higher the viral replication, the more frequent the mutations, with almost every single point mutation occurring daily. These mutations produce a population of diverse, yet related viral variants referred to as "quasispecies," which are generated by the error-prone viral RNA-dependent polymerase.

Whenever a mutation occurs, the fitness or replicative capacity of the altered virus may be enhanced, unchanged, or reduced, depending on the specific mutation and its interactions with the host immune system and the presence or absence of ARVs.

Approximately half of the virus population in plasma is cleared and replaced each day. The high turnover allows a rapid emergence of drug-resistant variants under selective pressure. To maximize its chances of survival, HIV, like other pathogenic organisms, evolves toward strains with the greatest ability to replicate in a given environment. Therefore, evolution toward wild-type virus, which typically has high replicative capacity, is favored in the absence of ARV pressure. On the other hand, when a patient is taking ARVs, viral evolution favors strains that are best able to replicate in that environment, that is, strains that are resistant to the particular drug or drugs. If the selected drug-resistant strain is of appropriate fitness, it may eventually become the dominant strain, although resistant variants are usually replaced by residual wild-type virus if the drug selective pressure is removed.

The most effective way to interrupt the cycle of viral replication and mutation is to attain complete, durable viral suppression. Incomplete viral suppression encourages viral mutation and resistance.

The factors contributing to incomplete suppression of virus replication *include poor adherence, pharmacologic factors, host factors, inadequate ARV potency, and transmitted drug resistance.* Mechanisms that result in HIV drug resistance include decreased drug binding, increased enzyme efficiency, nucleotide excision, increased target concentration, altered (co)receptor affinity, and altered drug transport.

The factors linked to detection of resistance mutations are:

- A high baseline viral load or low baseline CD4+ count;

- Substantial but imperfect adherence (highest-risk patients);
- Injection drug use; and
- Use of drugs with low resistance development thresholds.

Drug resistance is a major problem for HIV-infected patients on ART. Among treatment-naive subjects initiating HAART, 25% developed drug-resistance mutations during a 30-month follow-up, while multi-class resistance was noted in about 10%. Resistance testing has been observed to improve treatment outcome in patients receiving ART. Mutations on the reverse transcriptase and protease genes can be mapped to specific codon changes that are often correlated with viral resistance to a specific drug, subclass of drugs, or class of drugs. While measuring resistance has become more common in the developed world, resistance testing is expensive and not available in many resource-poor countries like Nigeria. However, a fundamental understanding of viral resistance is required to treat patients, particularly those who have not responded to or failed a prior treatment regimen. Therefore, resistance testing should be embraced in tertiary health institutions as part of the process of monitoring Individuals on ART in Nigeria.

3.2 Transmitted Drug Resistance

As ARV use becomes widespread in a given area, one might expect an increase in the proportion of patients who become infected with drug-resistant HIV strains. However, the emerging trend in places with a long history of ART is that transmitted resistance is low if HAART is comprehensive and widely available. Epidemiologic data from the CATCH study found the overall prevalence of HIV strains resistant to at least one ARV was 9.6%. The prevalence of drug-resistant HIV among patients infected for a year or less was 10.9%, compared to 7.5% among patients infected for more than one year. Data from the United States have demonstrated similar results. Among patients with primary HIV infection, 11.5% had resistance to at least one ARV compared to 7.5% among patients with chronic HIV infection. In both studies, the most common resistance was to NRTIs. Historical models have been used to predict that over the next decade, the rate of transmission of drug-resistant virus in Africa would remain below 5% and that most resistant strains would result from acquired, not transmitted, resistance.

SELF ASSESSMENT EXERCISE

The factors contributing to incomplete suppression of virus replication include----------
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3.3 Antiretroviral Therapy and Acquired Drug Resistance.

The choice of HAART regimen may help to avoid resistance. Regimens that promote adherence by using pills with low toxicity, doses of one or two times a day, and fixed dose combinations will delay the onset of resistance. Other factors promoting a durable regimen include drugs that are potent, have favorable pharmacokinetic properties, and have a high barrier to resistance. The choice of the first regimen may determine future treatment options by determining the resistance pathways. There is, therefore, a need for studies to determine optimal regimens for the Nigerian ARV program. Nevirapine-containing regimens for PMTCT in the country also need to be evaluated in view of the reports of high-level resistance from the use of single-dose nevirapine and the poor response due to resistance of these patients to subsequent nevirapine-containing HAART combinations.

3.4 Testing for Resistance

Drug resistance can be determined by two main techniques:

Genotypic and phenotypic testing. Genotypic testing detects specific mutations in the reverse transcriptase and/or protease genes. Phenotypic testing determines the relative amount of drug needed to suppress viral replication compared to a reference wild-type virus. These tests are most reliable when the viral load is greater than 1,000 copies/ml. Genotypic tests are more readily available, have a quicker turnaround time, are less technically demanding to perform, and are relatively less costly. Another important advantage of genotyping is the ability to detect mutations that are in the process of back mutation (from resistant virus to wild-type, or “revertant” mutants), and whose amino acid sequences are between those of resistant virus and wild type virus.

These partially revertant mutants may not influence phenotype, but their identification on genotypic testing offers valuable information. Genotyping has limited usefulness if the clinical significance of detected mutation has not been previously characterized, and if the mutations are multiple and complex, genotyping requires expert interpretation.

Phenotypic tests measure drug susceptibility directly. However, the assay is technically more demanding, limited in availability, and relatively expensive, and determining clinically relevant cut-offs or breakpoints is often difficult and variable. Advantages of phenotypic resistance assays include ease of interpretation and provision of meaningful information when multiple mutations are present in the same sample. Thus, phenotypic testing may be preferred to genotyping in

heavily treatment-experienced patients, who harbor multiple, complex resistance mutations.

The usefulness of resistance testing is in the identification of drugs that are likely to work and, independently, not to work. These determinations may be imperfect, however, because clinically relevant mutations may not be detected by standard resistance tests if they constitute a very small proportion of the total viral pool. The more "active" drugs contained in a regimen, the greater the likelihood that the therapy will succeed. The following situations warrant resistance testing consideration:

- Before initiating therapy in a patient exposed to possibly resistant virus, such as when a patient has been exposed to single-dose nevirapine or has had a sexual partner who was exposed;
- In patients who fail to adequately respond to first-line or second-line therapy; and
- In patients who experience viral "rebound" or a return of HIV RNA toward baseline.

Several caveats need to be considered about resistance testing: tests are most useful when the patient is on an ARV regimen; the absence of resistance to a drug that a patient has previously taken does not eliminate the possibility that the virus is resistant to that drug; if resistance to a drug is ever documented, it is assumed that the patient is likely to archive resistance virus indefinitely, regardless of subsequent test results; and expert advice is often required to interpret resistance test results.

3.5 Drug Toxicity

The use of ART for treating HIV infected people in developing countries has increased significantly in the past few years and has already witnessed the gains of reduced mortality and morbidity seen in the developed world in the mid-1990s. Even though the adverse events of these drugs have been well documented, experience in developing countries, particularly Nigeria, has been limited because of inadequate data gathering and the short duration of experience in the country.

3.6 Key Drug-Drug Interactions

The use of ARVs is complex. Drug-drug interactions can occur, posing a major challenge for treating HIV positive individuals. Interaction among drugs used in combination therapy, with other drugs, and even with food may affect the absorption, distribution, metabolism, and excretion of the various drugs used in the regimen. In general, clinically

significant drug interactions occur when a change of not less than 25% of the drug concentration occurs.

The most studied interactions have been between drugs using the CYP450 enzyme system for drug metabolism in the liver. Because NNRTIs and PIs are metabolized through this system, many clinically relevant drug interactions occur with the use of these drugs. The interaction may take place via one of three pathways: as a substrate; as an inhibitor; or as an inducer. Rifampicin, rifapentine, and rifabutin all have significant interactions with NNRTIs and PIs by virtue of their ability to act as inducers of the CYP450 enzyme in the liver. Blood levels of NNRTIs and PIs are significantly reduced when combined with rifamycins. However, the effect is least with rifabutin, hence the recommendation that rifabutin be used with NNRTIs and PIs in patients coinfected with HIV and tuberculosis. Rifabutin is metabolized by CYP3A; therefore, its serum concentration is increased by PIs and delavirdine, which are inhibitors of the enzyme. As a result, rifabutin's dose has to be reduced if it is used with PIs or delavirdine. On the other hand, since efavirenz induces CYP3A and reduces serum concentrations of rifabutin, the dose of rifabutin has to be increased when they are used together.

Rifampicin and rifapentine are not substrates for CYP3A, and their levels are not significantly affected by inhibitors or inducers of the enzyme. No significant interactions occur between rifamycins and NRTIs. Rifapentine is not recommended in HIV-infected patients with tuberculosis, because it is associated with rifamycin-monoresistant relapse.

Double-boosted PIs are now increasingly used to treat heavily experienced patients in whom it is critical to suppress viral load. Lopinavir/ritonavir should not be combined with amprenavir or fosamprenavir, because reports have indicated that this combination leads to profound reduction in plasma concentrations of the drugs. Similarly, the concentrations of lopinavir and indinavir are reduced when boosted lopinavir is used in the combination.

It is not necessary to increase the dose of ritonavir when saquinavir is co-administered with lopinavir/ritonavir. Co-administration of a newer PI, tipranavir, lowers the concentrations of boosted saquinavir, lopinavir, and amprenavir. A number of tenofovir-related interactions have also been observed. Tenofovir increases the concentration of didanosine. Therefore, the enteric-coated form of didanosine at a reduced dosage of 250 mg/day should be used in combination with tenofovir. Atazanavir and lopinavir/ritonavir each increase the levels of

tenofovir, hence patients receiving HAART combinations of these drugs must be monitored because of possible adverse effects.

On the other hand, tenofovir causes significant reduction in the plasma concentration of atazanavir, and ritonavir boosting is recommended whenever they are used together. The absorption of atazanavir requires low gastric pH. Thus, it should not be used with proton pump inhibitors. However, preliminary results suggest that some H2-blockers such as famotidine can be safely administered with ritonavir-boosted atazanavir, although dosing may need to be altered.

The combination of tenofovir DF, lamivudine, and abacivir or tenofovir DF, lamivudine, and didanosine resulted in dramatic failures in virologic suppression, throwing into doubt the possible use of these drugs for once-daily regimens. Studies suggest that the drug interactions arising from the use of these combinations may arise from genetic barriers, rather than plasma (pharmaco-dynamic) interactions between the individual drugs

3.7 Switching Drugs

Numerous reports have alluded to intolerability as the most common reason for failure of the first drug combination. A significant percentage (21%) of patients in the Italian ICONA study stopped their drugs because of toxicity. These observations—coupled with evidence linking PIs to lipid abnormalities and the effect of adherence on treatment outcomes motivated physicians to switch patients already well suppressed from one class of ARVs to another. The most reasons for physicians to consider ARV switching are:

- To improve adherence by reducing the pill burden, removing food requirements, and reducing the dosing frequency of various drug combinations, which can be achieved by using a compact, once daily regimen;

- To manage actual or possible toxicity; this includes not only morphologic and metabolic disturbance, but also other important adverse events, such as anemia, hypersensitivity reactions, and peripheral neuropathy;

- To reduce the risk of clinically important drug interactions, such as between nevirapine and rifampicin; and

- To take advantage of the more convenient new fixed dose formulations.

The main outcomes determining likely success of switching include: maintenance of virologic control; maintenance of CD4+ count response (and immune function); improvement, resolution, or prevention of toxicity; and improvement in patient adherence and quality of life.

People with HIV infection appear to have a strong preference for once-daily dosing and compact therapy. Clinical studies indicate that potential once-daily ARV regimens are as effective as past standard-of-care regimens. Once-daily therapy is not always superior to twice-daily regimens, however. One concern with once-daily dosing is the potential consequence of a missed dose, a phenomenon that has been described as "pharmacokinetic forgiveness." Pharmacokinetic forgiveness of a drug is the likelihood of maintaining therapeutic concentrations of the drug despite occasional missed doses.

This concept is critical when comparing once-daily regimens with twice-daily regimens. Although once-daily regimens are associated with a higher overall adherence percentage than twice-daily dosing, an important difference is that those on once-daily regimens appear more likely to miss two consecutive doses. Since missing consecutive doses of ARVs may be a more significant factor for resistance development than missing single doses, it cannot be assumed that the higher adherence percentage of once-daily regimens makes them better than twice-daily regimens in all situations. The relevance of these preliminary observations to the clinical outcomes of patients is being investigated.

Thymidine analogues have an increased relative risk of adverse events within the NRTI class; hence, switching to a better-tolerated agent abacavir or tenofovir DF may help avoid or ameliorate thymidine-analogue–associated toxicities. In this regard, stavudine carries a higher relative risk than other NRTIs for mitochondrial toxicities, including morphologic changes from lipodystrophy and lactic acidosis.

In contrast, lamivudine, emtricitabine, abacavir, and tenofovir DF do not appear to be associated with limb fat loss and are less likely to induce lactic acidosis.

Switching from stavudine to tenofovir DF, but not to abacavir, is associated with lipid improvements.

A newly approved once daily PI, atazanavir, which has little or no effect on lipid, has added another switch option. These two strategies represent new treatment approaches to lipid management. NRTIs are associated with few clinically important drug interactions, and most can be managed by dose modification rather than drug substitution. The

exception is the switch from didanosine to an alternative NRTI in patients planning to start hepatitis C therapy with ribavirin. The fixed-dose coformulations of abacavir/lamivudine and tenofovir DF/emtricitabine are attractive not only for treatment initiation and switching for virologically suppressed patients but also for patients coinfected with HIV and HBV. Lamivudine, tenofovir, and emtricitabine all have dual activity on HIV and HBV, and these effects may be synergistic Since all NRTIs except abacavir are mainly renally excreted, the dose of these drugs should be reduced in patients with renal insufficiency. Therefore, fixed-dose coformulations are usually inappropriate in such patients.

4.0 CONCLUSION

This unit provided variations of drug resistance. We also saw that adherence is the most important factor in determining whether resistance emerges during treatment. The relationship between adherence and the accumulation of drug resistance is complex and variable.

5.0 SUMMARY

In this unit, we tackled several variation of drug resistance which includes among many, transmitted drug resistance. We hope you did not find this unit long and technical. Not to worry, no knowledge is a waste. OK! Let us tackle our 'infamous exercises'

6.0 TUTOR MARKED ASSIGNMENT

Drug resistance can be determined by two main techniques. Identify and briefly explain these techniques.

ANSWER TO SELF ASSESSMENT EXERCISE

The factors contributing to incomplete suppression of virus replication include *poor adherence, pharmacologic factors, host factors, inadequate ARV potency, and transmitted drug resistance.*

7.0 REFERENCES/FURTHER READING

Antiretroviral Agents in Pregnancy, **(**2005) Public Health Service Task Force Recommendations for the Use of Antiretroviral Drugs in Pregnant HIV-1 Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States. The Living Document: November 17. Available at http://www.aidsinfo.nih.gov/.

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UNIT 3 DEFINING ANTIRETROVIRAL SUCCESS AND FAILURE

CONTENTS

1.0 INTRODUCTION

In this unit, we will look at antiretroviral success and failure. Successful ART indicates positive response to treatment, which is associated with decline in plasma HIV RNA and increase in CD4+ count. This unit will also look at viral blips and second line salvage therapy.

2.0 OBJECTIVES

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

Define antiretroviral success and failure
Explain viral blip
Explain second line and salvage therapy

3.0 MAIN CONTENT

3.1 Defining Antiretroviral Success and failure

Successful ART implies that a patient has taken his or her drugs and responded to treatment. A successful response is associated with a rapid decline in plasma HIV RNA and a corresponding increase in CD4+ count. After one month of starting a successful HAART regimen, the plasma HIV RNA should have declined at least 10-fold, or one log10 copies/ml, while the CD4+ count should have risen above the starting point. Within 12 weeks of starting therapy, approximately 80% of patients will have HIV RNA less than 400copies/ml and the CD4+ count should have increased by approximately 50 cells/mm3. The maximal effect of treatment should be observed in most patients by 24 weeks.

More than 95% should have plasma HIV RNA below 400 or 50 copies/ml, depending on the assay used, and the CD4+ count increased by 50–100 cells/mm3. There is greater variability in the change in CD4+ count, especially early in treatment. Of note, approximately 10% of patients have a disconnection of response in HIV RNA and CD4+ counts in that HIV RNA declines, but the CD4+ count increase is blunted. Factors associated with such reduced CD4+ cell response include: older age, a lower baselineCD4+ count, and a very low nadir CD4+ count (98). Also, tuberculosis and, less strongly, malaria have been associated with decreased CD4+ cell counts. These patients may require continued prophylaxis with cotrimoxazle for opportunistic infections if the CD4+ cell count is below 200. If the plasma HIV RNA does not decrease steadily over the first three months or it rebounds to within 0.5 log10 copies/ml of pre-therapy values, then the HAART regimen is failing. By 24 weeks if the HIV RNA has not decreased to levels below detection (fewer than 400 copies/ml), the patient should be considered as having failed the therapy.

In addition to the laboratory changes in HIV markers, within the first few months of therapy, patients should feel better clinically if they were symptomatic prior to therapy. Typically patients describe an improved sense of well-being, weight gain, and less fatigue. They may note a decrease in oral or vaginal candidiasis, fewer herpes simplex outbreaks, and improvement in skin and/or hair texture, regression of condylomata, and regression of Kaposi's sarcoma. Serum cholesterol levels may increase and triglycerides levels may decrease, corresponding to a return to pre-HIV infection status.

Patients who do not respond, or patients who have responded and are now experiencing a rebound in their plasma HIV RNA, are considered virologic or clinical treatment failures. Treatment failure has multiple causes. The most common cause is an ineffective treatment regimen either because the regimen prescribed in the first place was suboptimal or because the patient did not take the pills as instructed. Continued use of ARVs administered suboptimally will quickly lead to viral resistance and failure. Typical scenarios include: stopping just one medication because of drug intolerance or cost concerns; losing one or more medications; forgetting to take doses; sharing medications with family or friends; and selling parts of the regimen. The reason is not as important as the result*:* treatment failure and viral resistance.

Suboptimal adherence is not the only reason for treatment failure. Patients who fail to respond to the original regimen may actually have been infected with a resistant virus. This is particularly true in patients more recently infected in a community where ARVs are being used. For example, viral resistance to nevirapine may occur in areas where this

drug is used to decrease mother-to-child transmission rates. Up to 23% of women who have taken single-dose nevirapine to decrease transmission rates may develop resistant virus, which can be transferred to their sexual partners and/or infants. In this setting, ideally, resistance testing should be done; if unavailable, treatment should be changed to a PI-based therapy as soon as possible.

Other reasons for treatment failure include suboptimal potency, such as triple nucleoside regimens like zidovudine/lamivudine/abacavir, stavudine/didanosine/lamivudine, tenofovir/lamivudine/abacavir, and tenofovir/lamivudine/didanosine. Studies have also observed that the combination of didanosine plus tenofovir plus an NNRTI results in high virologic failure rates in ARV-naive, HIV-positive patients. Failure rates were similar to those reported for triple-NRTI therapy with several resistance mutations identified; a didanosine plus tenofovir plus NNRTI combination therapy is therefore not recommended.

Other less potent regimens include nelfinavir or saquinavir (unboosted)-based treatment.

The most common situation involving suboptimal potency is prior use of regimens that do not qualify as HAART, such as single or dual nucleoside regimens, single PI regimens, or PIs given with just one nucleoside analogue. Non-HAART regimens should never be used except when administered in certain PMTCT strategies.

Poor pharmacokinetics with suboptimal drug concentrations can also cause treatment failure. Poor absorption, drug-drug interactions at the gut level, inappropriate food administration, and metabolic induction by CYP450 I induced by concomitant medications are all potential causes of treatment failure. Examples include: rifampicin, nevirapine, and efavirenz decrease most PI concentrations; tenofovir decreases atazanavir concentrations; didanosine and indinavir taken with food results in low concentrations; lopinavir/ritonavir, atazanavir, and tenofovir must be taken with food or concentrations are reduced; lopinavir/ritonavir and amprenavir decrease each other’s concentrations when taken together. In addition, the use of numerous traditional medicines in addition to HAART regimes may cause many yet unidentified drug interactions, which could affect the potency of the regimens.

SELF ASSESSMENT EXERCISE

Successful ART implies that:----------
----------A

successful response is associated with:----------

3.2 Viral Blips

It is important to separate patients who are experiencing viral blips from those who have virologic failure. "Viral blip" *refers to a transient increase in viral load to more than 50 copies/ml in a person with chronic viral suppression.* It is usually random, fewer than 500 copies/ml or fewer than 1,000 depending on the assay used and readily returns to fewer than 50 (or fewer than 400) copies/ml without any change in treatment. The frequency of these blips is approximately 30% to 50% in patients on different chronically suppressive regimens, whether PI-based or NNRTI-based. Possible explanations for the blips include: a transient release of drug-sensitive virus from latent reservoirs; an increase in target cells during infection or post vaccination; a transient increase in viral replication in relation to changes in ARV levels; and peculiar host factors.

Viral blips were initially thought to represent release of resistant virus, but this notion has been disputed by the current consensus that they usually do not predict development of resistance or virologic failure. However, it has been suggested that viral blips are more common in people with very low CD4+ T cell counts at baseline (102). Moreover, patients with frequent blips have been found to have somewhat impaired CD4+ T cell recovery compared to those without blips. Like many aspects of the pathogenesis of HIV, our understanding of this phenomenon is evolving.

The best way to respond to these blips is still unclear because most patients who experience this phenomenon return to undetectable viral loads. The role of blips in predicting treatment failure also is not clear. The current recommendation for any rebound in viral load is to confirm the rise with a second test performed, two weeks or a month later, and in the interval to attempt to identify potential causes of the blip. Clinicians also recommend delaying viral load testing for at least two weeks to one month after vaccination or an infection.

3.3 Second-Line and Salvage Therapy

Changing therapy in patients already receiving treatment is done for one of two main reasons: toxicity or virologic failure. If patients become intolerant to a specific drug or regimen, substitutions can usually be found within the same class or from a different class. The more

complicated situation involves switching from a virologic-failing regimen to a new and effective regimen, or "salvage therapy." The choice of which salvage therapy to use is even more difficult if drug resistance data are not readily available.

When treatment fails, a comprehensive evaluation of why a patient failed including a thorough treatment history must be performed. For instance, if a patient was non-adherent because the regimen was too complex, it is unlikely that that person would respond to an even more complex "salvage" regimen. This type of patient may require significant in-depth counseling prior to starting a new therapeutic approach. The first treatment failure is the one that is easiest to salvage. Typically, patients are starting a non-nucleoside- based treatment. In Nigeria, that regimen would include nevirapine or efavirenz in most patients. When nevirapine fails, typically efavirenz will not work either, and vice versa. The alternative then is to initiate a PI-based treatment. Preferred at this junction is a ritonavir-boosted regimen, either lopinavir/ritonavir, indinavir/ritonavir, atazanavir/ritonavir, or saquinavir/ritonavir .

The nucleosides may also need to be replaced. Lamivudine was likely to be included in the first regimen and therefore the likely mutation associated with resistance is M184V. Thymidine analogue mutations, or TAMs, may also be present, particularly if the patient remained on the failing regimen for a prolonged period. A likely substitution in this situation with M184V and TAMs is the combination of abacavir plus didanosine or tenofovir plus zidovudine with or without lamivudine as an NRTI backbone.

Although lamivudine loses its direct virologic potency in the presence of M184V mutation, it may be retained in the regimen as a third NRTI, because it allows for the persistence of M184V mutants that replicate poorly because of reduced viral fitness. The second treatment failure is even more difficult to manage, especially without resistance testing. Typically, more than three drugs have to be taken. If possible, a new class of drug should be given, such as a fusion inhibitor like enfuvirtide. This drug, which is prohibitively expensive and in limited supply is unlikely to be used in Nigeria in the near future. A newer PI, tipranavir-ritonavir, is active against many viral strains that are resistant to earlier PIs, but it is also unavailable in Nigeria at this time.

In the same way, the promise of investigational drugs that are in advanced stages of development such as CCR5 receptor antagonists TMC 114 and TMC 125 is unlikely to extend to Nigeria in the immediate future. Other strategies depend on how desperate the situation has become. "Giga-HAART"or the administration of six or more drugs, regardless of susceptibility has been used with modest

success. In heavily treatment-experienced patients with multiple resistance mutations who are unable to achieve complete suppression of viremia, treatment goals become restricted to maintenance of immunologic function and prevention of clinical deterioration.

In this population, ongoing HAART with even modest virologic suppression has been shown to reduce the fitness or replicative capacity of the virus and improve clinical outcomes (105). Structured treatment interruption is generally not recommended in patients with advanced HIV/AIDS because it is associated with rapid CD4+ decline. Most studies have shown similar adverse outcomes, although one CD4+ guided study demonstrated a good response to HAART in HIV-infected patients with high CD4+ cell counts. Vigilant prophylaxis against opportunistic infections, prompt management of treatable infections and malignancies, and palliative care may be the only remaining options in these situations for many such people.

4.0 CONCLUSION

In this unit, we touched on antiretroviral success and failure. Successful ART indicates positive response to treatment. We also describe “Viral blip” refers to a transient increase in viral load to more than 50 copies/ml in a person with chronic viral suppression. We also saw that complicated situations involve switching from a virologic-failing regimen to a new and effective regimen, or “salvage therapy.”

5.0 SUMMARY

This unit provided information on ART success and failure as while touch on the concept of ‘viral blip’ and ‘salvage therapy’ Hope you enjoyed your studies. Let us attempt the questions below.

6.0 TUTOR MARKED ASSIGNMENT

1. Define Viral Blip
2. Define ‘salvage therapy’ and identify conditions necessitating its usage.

7.0 REFERENCES/FURTHER READINGS

Antiretroviral Agents for Adults (DHHS**),** **(**2005). The (DHHS) Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents. (The Living Document: October 6. Available at http://www.aidsinfo.nih.gov/guidelines/

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UNIT 4 ANTIRETROVIRAL THERAPY IN CHILDREN/ WOMEN/HIV-INFECTED PATIENTS WITH TB

CONTENTS

1.0 INTRODUCTION

In the previous unit, we discussed ART success and failure. This unit thus tackles ART therapy in specific groups, namely, women, children and HIV-infected persons with TB.

2.0 OBJECTIVES

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

Discuss antiretroviral therapy in children
Discuss antiretroviral therapy in pregnancy
Discuss antiretroviral therapy in HIV-infected patients with TB.

3.0 MAIN CONTENT

3.1 Antiretroviral Therapy in Children

The decision to initiate ART in a child depends on his or her age and the availability of virologic testing. Serologic diagnosis is unreliable in children younger than 18 months because maternally derived antibody may persist in the child. The clinical features of HIV infection may resemble those of many other prevalent conditions, such as malaria and malnutrition.

For HIV-sero-positive children younger than 18 months with proven HIV status (DNA PCR), ART is recommended when the child has: WHO Pediatric Stage III disease irrespective of the CD4+ percentage;

WHO Pediatric Stage II disease, with consideration of using CD4+ less than 20% to assist in decision-making; or WHO Pediatric Stage I (asymptomatic) and CD4+ less than 20%. If HIV sero-positive status is not virologically proven but CD4+ cell assays are available, ART can be initiated when the child has WHO Stage II or III disease and CD4+ less than 20%. In such cases, HIV antibody testing must be repeated at 18 months of age to confirm HIV infection; only children with confirmed infection should continue with ART. For HIV-sero-positive children aged 18 months or older, ART can be initiated when the child has: WHO Pediatric Stage III disease (clinical AIDS) irrespective of the CD4+ percentage; WHO Pediatric Stage II disease with CD4+ less than 15%; or WHO Pediatric Stage I (asymptomatic) and CD4+ less than 15. For children older than eight years, adult criteria for initiation of therapy are applicable. The ideal goal of treatment is full suppression of virus to plasma HIV RNA to fewer than 50 or fewer than 400 copies/ml. This almost always means the use of HAART: an NNRTI and two NRTIs as recommended in the Nigerian ARV guidelines.

Full suppression is not always attainable, particularly in children. Partial suppression is usually much better than no treatment at all. As in adults, pediatric treatment is life long. The first treatment regimen has the greatest chance of success, while subsequent regimens are usually more toxic and less tolerable. According to the Nigerian guidelines, the judgment about when to start ART depends on age, clinical staging, and CD4+ cell count, while the decision when to switch ARVs depends on clinical and laboratory staging, observation of toxicity, CD4+ cell count, and viral load. A limited number of treatment options are available for children. If children can be taught to take tablets or capsules, their options increase. Successful treatment also requires education of the parents or guardians. Successful treatment of older children may require disclosure to the child about his or her HIV status, drug education, and adherence counseling.

3.2 Antiretroviral Therapy during Pregnancy

The decision to use ART in pregnancy is based on the premise that ART is beneficial to such women unless the adverse effects outweigh the benefits. The considerations for the use of ART should be based on four considerations: the need to use appropriate ARVs; the effects of ARV on pregnancy; the effect on transmission of HIV from the mother to the child; and the effect of the drug on the fetus.

The major goal of ART in pregnancy is to achieve maximal suppression of plasma viral load to undetectable levels, even though there is evidence that woman with plasma HIV RNA of less than 1,000 have minimal levels of transmission to their babies. Some evidence now

supports the possibility of teratogenic effect of efavirenz in humans, in addition to the ample evidence in animal models. Therefore, efavirenz is best avoided in early pregnancy. When there are no alternatives, an efavirenz-containing regimen maybe instituted after the second trimester in pregnant HIV-positive women coinfected with tuberculosis.

HIV-positive pregnant women who meet the criteria for ART should begin therapy after the first trimester. According to the Nigerian PMTCT guidelines, zidovudine should be included as a component of ART whenever possible. Treatment should commence early enough to ensure good virologic control in patients enjoying HAART. The choice of drugs in pregnancy should include a review of prior exposure, drug resistance, and the clinical and immunological status of the mother.

HIV-infected pregnant women already on ART should continue on therapy with a switch of treatment in the first trimester to include nevirapine but exclude efavirenz. HIV-positive pregnant women who do not meet the criteria for ART should have zidovudine prophylaxis from 28 weeks of pregnancy with chemoprophylaxis for the baby. The blood count of patients taking zidovudine should be monitored regularly because of the development of anemia, a common complication of pregnancy in Nigeria.

SELF ASSESSMENT EXERCISE

The considerations for the use of ART should be based on four considerations namely:

3.3 Antiretroviral Therapy in HIV-Infected Patients with Tuberculosis

The incidence of tuberculosis has dramatically increased since the mid-1980s both in industrialized and developing countries. In Nigeria, reports from AIDS treatment centers in Jos and Lagos have observed high levels of tuberculosis coinfection among patients with HIV. Tuberculosis is the leading cause of morbidity and mortality among HIV patients in Nigeria. Without treatment, more than half of HIV infected patients coinfected with tuberculosis are likely to die. With the correct treatment, such patients are cured after taking appropriate tuberculosis drugs for at least six months. Proper treatment and isoniazid prophylaxis also prevents the spread of tuberculosis, because it makes people noninfectious.

Concomitant treatment of tuberculosis and HIV is compounded, however, by the drug interactions between NNRTIs and PIs with rifampicin. Rifampicin is a potent stimulator of the P450 cytochrome enzyme in the liver and leads to dramatic reduction of the blood levels of NNRTIs and PIs to sub-therapeutic levels. Pharmacokinetic levels of efavirenz can be maintained by increasing the dose to 800 mg. The use of rifabutin in place of rifampicin has been recommended for people taking ART. Rifabutin is expensive, though, and scarce in resource-limited settings such as Nigeria.

Other important issues in the treatment of tuberculosis/HIV–coinfected patients include pill burden, toxicity, and adherence issue Paradoxical worsening of tuberculosis is defined as a transient worsening of disease at a pre-existing site or the development of new tuberculosis lesions while a patient is on appropriate anti-tuberculosis therapy. It is thought to be due to improved *M. tuberculosis*–specific immune responses. Risk factors for paradoxical reaction include: a low baseline CD4+ T cell count, a high viral load, and initiation of ART within two months of initiating anti-tuberculosis therapy. These reactions, which may be seen in 7% to 30% of patients, tend to occur within days to weeks of initiating ART, but may be delayed for several months. Moreover, they may occur in one-third of HIV-infected patients started on ART and tuberculosis therapy at the same time.

Possible manifestations are worsening adenopathy, enlarging central nervous system lesions, or increased pulmonary infiltrate. Patients may have an increase in the size of the cutaneous response to tuberculin tests, while those who were previously anergic may develop a cutaneous response to tuberculin. Other previously described manifestations are tenosynovitis, pleural effusion, meningitis, superior vena cava syndrome, and peritonitis. These reactions are indicative neither of drug resistance nor treatment failure, and they usually subside spontaneously after about 10 to 40 days. Moreover, non-steroidal anti-inflammatory agents may provide some relief. Severe cases may require temporary interruption of HAART; however, no change in tuberculosis treatment is needed except in the most severe cases.

The approach to tuberculosis diagnosis and treatment differ markedly between developed and resource-limited countries. In many resource-limited settings, positive sputum smear alone is used for tuberculosis diagnosis, and additional information is derived from chest X-ray. mycobacterial culture and resistance testing are often unavailable, or are available but prohibitively expensive. Empiric treatment for tuberculosis is common.

Routine laboratory tests to monitor the adverse effects of tuberculosis treatment may be unavailable. Instead, patients are educated about symptoms of drug toxicity to facilitate early reporting and appropriate treatment. Detailed information about treatment of tuberculosis in resource-limited settings can be obtained from WHO treatment guidelines.

Another significant difference between resource-limited and developed countries is the use of primary prophylaxis or secondary prophylaxis after full treatment for active tuberculosis. Primary prophylaxis is recommended in patients with positive Mantous test if active tuberculosis can be definitively excluded.

However, several studies in resource-limited areas of tuberculosis endemicity have suggested that secondary tuberculosis prophylaxis may also be efficacious. The first study, conducted in Zaire, found decreased relapse rates when rifampin and isoniazid were given for an additional six months after completing a standard course of treatment. In a study in Abidjan, Côte d'Ivoire, HIV-infected patients who completed treatment for active tuberculosis were randomized to isoniazid plus sulphadoxine-pyrimethamine or placebo.

Compliance with isoniazid was poorer than with sulphadoxine-pyrimethamine, but patients who received the combined prophylactic regimen had a significant trend toward improved survival. While these and other studies suggest a potential beneficial effect of secondary prophylaxis, they do not provide answers to several critical issues, such as the impact of HAART on the apparent benefits, the optimal regimen for secondary prophylaxis, and the impact of secondary prophylaxis on the emergence of drug-resistant *M. tuberculosis*. The WHO does not yet endorse secondary prophylaxis, and additional studies are needed before secondary prophylaxis can be included in routine care standards.

4.0 CONCLUSION

We have seen that the decision to initiate ART in a child depends on his or her age and the availability of virologic testing. Serologic diagnosis is unreliable in children younger than 18 months because maternally derived antibody may persist in the child. This unit also illustrates that the decision to use ART in pregnancy is based on the premise that ART is beneficial to such women unless the adverse effects outweigh the benefits. Tuberculosis is also the leading cause of morbidity and mortality among HIV patients in Nigeria. Without treatment, more than half of HIV infected patients coinfected with tuberculosis are likely to die. With the correct treatment, such patients are cured after taking appropriate tuberculosis drugs for at least six months.

5.0 SUMMARY

In this unit, we looked at ART therapy in children, women and HIV-infected patients with TB. We hope you found this unit very helpful. Let us attempt the questions below.

6.0 TUTOR MARKED ASSIGNMENT

Discuss antiretroviral therapy in children

ANSWER TO SELF ASSESSMENT EXERCISE

The considerations for the use of ART should be based on four considerations:

the need to use appropriate ARVs
the effects of ARV on pregnancy
the effect on transmission of HIV from the mother to the child
and the effect of the drug on the fetus

7.0 REFERENCES/FURTHER READINGS

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UNIT 5 ANTIRETROVIRAL THERAPY IN DUAL INFECTIONS WITH HIV AND HEPATITIS

CONTENTS

1.0 INTRODUCTION

This unit will look at ART in dual infection with HIV and Hepatitis. This is thus a follow-up on the previous unit. Enjoy your studies.

2.0 OBJECTIVES

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

Illustrate ART in dual infection with HIV and Hepatitis
Describe effects of Hepatitis B on HIV infection
Describe effects of Hepatitis C on HIV infection
Explain post exposure prophylaxis

3.0 MAIN CONTENT

3.1 Antiretroviral Therapy in Dual Infections with HIV and Hepatitis

Nigeria's high HIV-1 sero-prevalence rate of 5.0% (5) and its high HBV carriage rate of 10.3% in the general population have created opportunities for coinfection with HIV and HBV. This is made possible because HIV and HBV (and HCV) share the same modes of transmission. The prevalence of HBV in HIV infected individual's ranges from 20% to 42% in Nigeria. Important virologic, epidemiological, and clinical interactions between HIV and HBV have been described. For example, people with HIV/HBV coinfection have a

greater rate of chronic liver disease, higher viral loads of HBV, and accelerated progression of liver disease.

3.1.1 Effects of Hepatitis B Virus on HIV Infection

The primary goal of treating chronic HBV is to halt progression of liver disease by suppressing viral replication. Until recently, the only antiviral agents available for treatment for HBV were lamivudine and interferon-alpha 2a and -alpha 2b. The availability of tenofovir, adefovir, and entecavir has expanded HBV treatment options. Tenofovir, lamivudine, and emtricitabine are effective against both HBV and HIV. Yet HBV lamivudine resistance occurs at a rate of approximately 20% per year, while resistance to tenofovir is much less frequent. Tenofovir is effective against lamivudine-resistant and probably emtricitabine-resistant strains of the virus.

Preliminary studies have suggested that regimens that contain both lamivudine and tenofovir produce better HBV suppression than those with lamivudine alone. Emtricitabine plus tenofovir probably has similar effects. Thus, HAART regimens that contain tenofovir; emtricitabine or lamivudine; and a third agent have the potential to render multiple benefits for coinfected patients. Since the introduction of suppressive combination ART, survival in HIV-infected people has been extended.

Data are scarce on the clinical course of prolonged HIV/HBV coinfection and the effects of HAART in this setting. Nonetheless, a study of people coinfected with HIV and HBV has revealed that responses to HAART were inferior relative to those of people infected only with HIV. Although both patient groups achieved similarly significant immunologic responses to treatment, coinfection was associated with excess risk of virologic failure and of death.

Virologic response was impaired in coinfected subjects, however, frequently as a result of interruptions in treatment driven by hepatic complication. Furthermore, coinfected patients are more likely to develop hepatitis after HAART initiation, and they face a higher risk of hepatic decompensation and hyperbilirubinemia.

SELF ASSESSMENT EXERCISE

The primary goal of treating chronic Hepatitis B Virus is

3.1.2 Patients with HIV/Hepatitis C Coinfection

HCV is a flavivirus with single-stranded RNA that is capable of very rapid replication, leading to the daily production of approximately 1012 virions. This replication rate is faster in HIV/HCV–coinfected people than in HCV mono-infected patients, and HAART has been shown to drive HCV's genetic diversity. Six genotypes have been characterized with significant geographic variation.

Previous reports have observed that HIV/HCV–coinfected people experience more rapid progression of liver fibrosis and greater morbidity and mortality from liver disease than those infected with HCV alone. The accelerated pace of hepatic decline in HCV/HIV–coinfected patients occurs in part because they have diminished cellular immune responses to HCV infection, characterized by weak HCV-specific CD8+ T cell and CD4+ T cell immune activity. Thus, they are less able to clear HCV viremia after initial infection. Because of this, liver cirrhosis occurs in 15% to 25% of coinfected patients within 10 to 15 years after HCV infection compared to only 2% to 6% of people with HCV infection alone. Liver-related mortality is also greater in coinfected patients. Factors that predict progression to advanced liver fibrosis (the most prognostic indicator of the development of cirrhosis) in people coinfected with HIV and HCV include: CD4+ T cell counts of fewer than 200 cells/mm3; alcohol consumption; and an HCV infection duration of more than 40 years.

HCV does not appear to alter the natural course of HIV infection in any significant way. However, it was initially suggested that the recovery of CD4+ T cells in response to potent HAART was blunted in those who were HCV/HIV coinfected; subsequent studies failed to show similar findings. On the other hand, the initiation of HAART is often accompanied by a paradoxical increase in HCV viremia in coinfected patients, which explains some of the immune reconstitution hepatitis flare. It appears that an initial increase occurs in all patients, but it is prolonged only in those with low CD4+ cell counts. The biological explanation for this increase is still uncertain.

Nonetheless, there is increasing evidence that immune restoration through HAART may slow the course of liver disease progression in individuals with HIV/HCV coinfection. It has therefore been recommended that hepatitis C should be treated aggressively in coinfected patients. Best results occur among those with a pre-treatment CD4+ cell count of greater than 350 cells/mm3. However, treatment of coinfected patients is complicated by drug interactions and poor

tolerance of therapy. Potential toxicities may outweigh the benefits when the pretreatment CD4+ cell count is less than 200 cells/mm3.

Three large randomized controlled trials of interferon-based therapy in patients who were coinfected With HIV and HCV have now been completed: the AIDS Clinical Trials Group study; the APRICOT (AIDS Peginterferon Ribavirin International Co-infection Trial) study; and the RIBAVIC study. These studies compared recombinant interferon alpha-2b plus ribavirin to peginterferon alfa-2b plus ribavirin. Overall, the results of these studies showed that patients who were treated with peginterferon had a better-sustained virologic response than with standard interferon.

The sustained virologic response was less in coinfected patients than previously seen in HCV mono-infected patients. Treatment in the RIBAVIC study was discontinued in 42% of patients, and 31% had severe adverse events, suggesting that therapy was tolerated relatively poorly in this group. Toxicity may be enhanced in individuals treated with HAART, and even more in those treated concurrently with HAART and the combination of interferon and ribavirin. Ribavirin should not be coadministered with didanosine because of a drug-drug interaction that has been associated with potentially fatal hepatic decompensation, pancreatitis, and lactic acidosis.

3.2 Post-Exposure Prophylaxis

The magnitude of risk associated with a particular exposure to HIV tends to be influenced by the nature of the exposure and the status of HIV disease in the source patient. The risk of transmission following percutaneous occupational exposure is about 0.3% (158), which is lower than the risk of transmitting HBV or HCV. This risk can be reduced if ARVs are immediately administered and continued for the recommended one month. Post-exposure prophylaxis (PEP) is unnecessary if the exposed worker is already known to be HIV sero-positive. For all others, baseline HIV tests should be performed and PEP initiated as soon as possible. Rapid HIV tests can be used to determine the HIV sero-status of the source person. However, the tests may be falsely negative during the window period, which is the time between detectable HIV antigens and the development of HIV antibody.

For occupational exposures, the health care worker and index patient should be tested for HIV before administration of PEP. A three-drug regimen should be provided as soon as possible to the health care worker for four weeks. Complete blood count and chemistry should be done after two weeks with HIV testing conducted at 12 and 24 weeks. If

negative at 24 weeks, the health care worker can be considered to be uninfected.

Rigorous evaluations of PEP programs have not been done, although such programs are not 100% efficacious in preventing infection. In an analysis of 57 voluntarily reported cases of occupationally acquired HIV infection, 14% of the health care workers acquired HIV infection despite receiving PEP. Although poor adherence due to the adverse effects of ARV drugs was implicated in some prophylaxis failures, other patients failed because the infecting virus was resistant to the prophylactic ARV drugs. Therefore, choosing the initial regimen should involve careful consideration, ideally with expert consultation, of the source patient's treatment experience and the local epidemiology of ARV resistance. The choice of a PEP regimen should be based on the type of exposure and the status of the source patient. Also, drug resistance that is known or suspected to be present in the source patient should be considered.

A three-drug regimen should be recommended when the source person is known to be infected with HIV and has markers of high infectiousness such as symptomatic disease, a high viral load, or a low CD4+ cell count. Three-drug regimens are also preferred if exposure involves a large-bore needle, deep injury, or visible blood on the needle, or if the needle was just removed from the source person's blood vessel. The three-drug regimens are generally similar to standard HAART regimens, but example, nevirapine has been associated with severe cases of hypersensitivity reaction when used for prophylaxis. Since some of these reactions have been fatal, the use of nevirapine in PEP regimens should be avoided. The adverse events associated with nevirapine—including life-threatening rash and hepatic failure—are more common in HIV-uninfected, immuno-competent individuals. If possible, an alternative drug should be substituted, such as efavirenz, remembering that efavirenz cannot be used in patients who are pregnant or contemplating pregnancy. Alternative drugs include any PI-based three-drug regimens and even triple nucleoside regimens, such as zidovudine/lamivudine/abacavir (Trizivir®) or zidovudine/lamivudine/tenofovir.

A two-drug regimen may be considered if exposure is limited to a few drops or splash on mucous membrane or disrupted skin, provided the source patient does not have any marker of high infectiousness. The two-drug regimens typically consist of two NRTIs (such as zidovudine plus lamivudine). Even in relatively low-risk situations, some clinicians prefer three-drug regimens, although there are no proven advantages and toxicity may be increased. In situations in which the HIV sero-status of the source person is unknown, prophylaxis may be prudent after careful assessment of the specific situation.

A complete blood count and chemistry should be done after two weeks of PEP, and testing for HIV should be repeated at 12 and 24 weeks. If negative at 24 weeks, the health care worker can be considered to be uninfected. Low risk exposures such as body fluid contact with intact skin do not require prophylaxis. Although pregnancy is not a contraindication to PEP, it is necessary to closely monitor for adverse effects.

PEP following unprotected intercourse has not been studied in depth, although some health departments and treatment centers do provide such services. If clinically appropriate, the same regimen as the above should be employed. A similar approach has been taken in many areas of the world when a man suspected of being HIV positive has raped a woman. The inability of PEP to prevent HIV transmission 100% of the time emphasizes the importance of using strategies that prevent exposure in the first place. Since accidental HIV exposure is a source of emotional turmoil, all patients should be offered psychological support and education on how to avoid future exposure. STI treatment, hepatitis prophylaxis, and emergency contraception may be important, depending on the nature of the exposure.

4.0 CONCLUSION

In this unit, we saw that people with HIV/Hepatitis B, C, virus co-infection have a greater rate of chronic liver disease, higher viral loads of HBV, and accelerated progression of liver disease, so care should be taken in their management.

5.0 SUMMARY

This unit took a look at effects of HIV/Hepatitis B, C, co-infection on patients management. This unit also looked at post exposure prophylaxis. We hope you enjoyed your studies. Following are exercises we need to attempt.

6.0 TUTOR MARKED ASSIGNMENT

Discuss the effects of ART on HIV/Hepatitis C co infection

ANSWER TO SELF ASSESSMENT EXERCISE

The primary goal of treating chronic Hepatitis B Virus is to halt progression of liver disease by suppressing viral replication

7.0 REFERENCES/FURTHER READINGS

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MODULE 6 HIV/AIDS PALLIATIVE CARE

UNIT 1 DEFINING PALLIATIVE CARE

CONTENTS

1.0 INTRODUCTION

Over 60 million men, women and children have been infected with HIV to date and more than 22 million people have died of AIDS. AIDS is now the primary cause of death in Africa.[1] Prevention efforts initially dominated the public health agenda as the most realistic approach to reducing morbidity and mortality. Currently, however, attention to the need for care and treatment is increasing, allowing for the integration of these approaches into national health policies and priorities.

There is an urgent need to extend the benefits of disease-specific therapy to people living with HIV/AIDS in developing countries. This includes antiretroviral therapy (HAART) and prophylaxis and treatment of opportunistic infections. Increased availability of these therapies should not only have a positive impact on survival; such treatment should also promote the key palliative care goals of pain and symptom management and improved quality of life, since disease specific therapies in HIV/AIDS should have desirable effects on, and go hand-in-hand with additional care for, the palliation of suffering. As efforts to provide HIV-specific therapies to resource-poor countries continue, there

remains a critical need to provide palliative care for the large numbers of HIV-infected persons in these countries who may or may not have access to anti-retroviral and other new therapies.

Palliative care is crucial in every care setting, rich or poor, for it is a philosophy of care that centers on improving quality of life for patients and their families. In this unit, we focus attention on the need to integrate palliative care into national government strategies in order to address the pandemic in resource-poor settings, which includes many developing countries and low-income areas in some industrialized countries.

2.0 OBJECTIVES

At the end of this unit, unit should be able to:

Define palliative care
Illustrate palliative care in industrialized and developing countries
Identify barriers to implementing palliative care in resource poor settings

3.0 MAIN CONTENT

3.1 Defining Palliative Care

The World Health Organization (WHO) initially defined the term "palliative care" in connection with its initiatives to develop National Cancer Control Programs.[6] According to WHO:

Palliative care is the active total care of patients whose disease is not responsive to curative treatment. Control of pain, of other symptoms, and of psychological, social and spiritual problems is paramount. The goal of palliative care is the achievement of the best possible quality of life for patients and their families. Many aspects of palliative care are applicable earlier in the course of the illness, in conjunction with [other] treatment. Palliative care:

Affirms life and regards dying as a normal process
Neither hastens nor postpones death
Provides relief from pain and other distressing symptoms Integrates the psychological and spiritual aspects of patient care Offers a support system to help patients live as actively as possible until death
Offers a support system to help the family cope during the patient's illness and in their own bereavement

WHO recently updated this definition to reflect the full scope of palliative care, defining it as *"an approach which improves quality of life of patients and their families facing life-threatening illness through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual"*

3.2 Palliative Care Services in Industrialized and Developing Countries

Palliative care services need to be integrated and balanced with other care services to address the needs of patients and their families. Symptom control and supportive therapies are necessary throughout a patient's illness, although the proportion of palliative care services varies with the patients' trajectory of illness and the setting in which they receive care. For example, in developing countries, where many patients with cancer and/or HIV/AIDS first seek treatment when they are already in a far advanced stage of disease, palliative care may be the major form of therapy provided to control a patient's symptoms, support the patient and family, address their psychological, cultural and existential distress, and serve as a prevention intervention.

In settings with early diagnosis where disease-specific therapies are available, palliative care services will support such therapies, increasing as needed along the disease trajectory. For many people with HIV/AIDS, the lack of available disease-specific therapies increases their need for symptom control and supportive therapies to improve their quality of life. In resource-poor countries, where both cancer and AIDS are typically diagnosed very late in the course of a patient's illness, palliative care services may dominate the available services. In settings where disease-specific therapies are available, palliative care services are balanced with disease-specific therapies.

It is important to stress that National AIDS Programs should avoid viewing palliative care and disease-specific therapies as an either/or phenomenon. The more modern and ethically appropriate approach is to view active disease-specific therapies and palliative care as part of a continuum in which patient needs and available resources determine the prioritization and balanced use of care strategies. Attention must also be given to how the available resources can be fairly distributed to the largest population in a cost-effective and efficient system of healthcare delivery.

SELF ASSESSMENT EXERCISE

Palliative care is----------

The goal of palliative care is----------

3.3 Barriers to Implementing Palliative Care in Resource-Poor Settings

Numerous reports have outlined the major barriers in resource-poor settings to implementing the key elements of HIV/AIDS care and support. These barriers range from serious limitations posed by scarce monetary, nutritional, and human resources to the low priority placed on AIDS care in national health budgets. Medical, religious, gender, social, and cultural barriers also exist including the social- and self-stigmatization of HIV/AIDS, as well as behaviors and practices that impede the implementation of prevention and care policies.

People with HIV/AIDS often suffer significant psychosocial distress related to their experience of serious life-threatening illness at an early age, social ostracism associated with their illness, and the common and concurrent organic mental disorders caused by the HIV infection. They also suffer significant physical distress due to complications of opportunistic infections and tumors, which may include major symptoms such as pain, nausea and vomiting, fatigue, insomnia, anxiety, depression, and delirium. In addition, major environmental and geographical factors may add barriers to providing HIV/AIDS care and treatment; for example, many people living with HIV/AIDS in the developing world reside in rural areas far from available treatment resources.

An estimated 50% to 60% of people with HIV/AIDS worldwide have no access to healthcare professionals to address their medical needs. In Nigeria, for instance, 88% of the population lives more than 10 kilometers from any kind of health facility, and many of these facilities lack trained personnel and the most basic medical supplies and medications. This lack of medical resources occurs in a setting where many people are also deprived of the most basic necessities of food, water, housing, and income.

WHO and UNAIDS have summarized major barriers to implementing the key components of HIV/AIDS care and support: They are:

Low priority of financial support to the health sector nationally and internationally
Low priority of HIV care within national health budgets
Globalization policies that prohibit a strong emphasis on HIV care in practice
Lack of investments in building infrastructure
Serious managerial weaknesses at all levels of the health sector
Insufficient remuneration and support for care professionals Loss of staff due to high HIV-related mortality and morbidity Shortages of relevant HIV information and HIV training opportunities
Irregular and inadequate supplies of drugs, reagents, and equipment
Insufficient local production of drugs and other commodities, given the weakness of local pharmaceutical manufacturers, markets and patent protection
Lack of essential drug lists and drug procurement not adapted to needs of people with HIV/AIDS

4.0 CONCLUSION

In this unit, palliative care was defined as the active total care of patients whose disease is not responsive to curative treatment. Control of pain, of other symptoms, and of psychological, social and spiritual problems is thus paramount. We also saw the tilt that exist in palliative care of developed and developing countries. Low priority of financial support to the health sector nationally and internationally low priority of HIV care within national health budgets was identified as one of the barriers of palliative care in resource poor settings.

5.0 SUMMARY

This unit took a broad view of palliative care, its definition, services in developed and developing countries and barriers to its implementation in resource poor settings. Now let us attempt the exercise below.

6.0 TUTOR MARKED ASSIGNMENT

Identify barriers to implementing palliative care in resource-poor settings

ANSWER TO SELF ASSESSMENT EXERCISE

Palliative care is the active total care of patients whose disease is not responsive to curative treatment. Control of pain, of other symptoms, and of psychological, social and spiritual problems is paramount. The goal of palliative care is the achievement of the best possible quality of life for patients and their families.

7.0 REFERENCES/FURTHER READINGS

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UNIT 2 NATIONAL PUBLIC HEALTH APPROACH TO PALLIATIVE CARE

CONTENTS

1.0 INTRODUCTION

Although it is far beyond the scope of this unit to address ways of eliminating these barriers, we can offer some models for providing palliative care in developing nations. Against what appear to be overwhelming odds, several model programs suggest that care and treatment can be provided and that palliative care services can readily be instituted for the care of patients; however, a national strategy is needed to implement these models effectively.

2.0 OBJECTIVES

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

Explain national palliative care policy
Describe integrated home care and community palliative care.

3.0 MAIN CONTENT

3.1 National Public Health Approach to Palliative Care

WHO endorses a national program strategy that requires an initial three-part process for improving palliative care. The foundation measures for this public health approach are:

1. Governmental policy: adoption of a national palliative care policy
2. Education: training of healthcare professionals and the public
3. Drug availability: assuring availability of drugs for pain control and symptom management provides a schematic representation of this three-pronged approach, which is discussed in the following

sections. All three of these foundation measures together are necessary, along with committed leadership, to achieve an effective national program.

National palliative care policies and programmes do not need to be specific to HIV/AIDS; they can address the needs of patients with any serious life-threatening illness, such as AIDS, cancer, congestive heart failure, neuro-degenerative disorders, and cerebrovascular disease. In fact, generic palliative care programs can allow for the coordination of a variety of policy agendas and may help reduce stigma associated with AIDS care. A strategic national program for palliative care offers the most rational and effective means of improving the quality of life for the greatest number of patients and families, even where resources are severely limited.

SELF ASSESSMENT EXERCISE

Identify the WHO endorsed three-part process for improving palliative care.

3.1.1 Adoption of a National Palliative Care Policy

STEP 1: GOVERNMENTALPOLICY

Establishment of a national policy for palliative care is the best way to ensure quality standards, funding, and accessibility of adequate care for the greatest number of patients and families. A national policy serves as the official recognition of a commitment of financial support; it can play a major role in facilitating the availability of essential drugs, as well as the necessary educational initiatives for healthcare professionals and the public alike, as part of its mandate. Numerous governments have already adopted a national palliative care policy, including Australia, Canada, Spain, Uganda and the United Kingdom.

A national policy should set priorities that address access to palliative care across all healthcare settings, including hospitals, clinics, and home-based care. Palliative care needs to be available in both urban centers and rural areas as an integral part of the essential primary healthcare services that people can expect. These palliative care services should be sustainable and supported by healthcare professionals. Government budgets should appropriately address the need for essential drugs and provide medications and services ranging from durable medical goods to counseling programs.

A number of resources exist to aid the development of a national health policy. WHO's *National HIV/AIDS Control Programs: Policies and Managerial Guidelines* can be used as a model for the development of specific policies, as well as national palliative care and/or AIDS programs in general.

To integrate palliative care into a national healthcare policy, governments should ensure that:

Palliative care programs are incorporated into their existing healthcare systems
Healthcare workers are adequately trained in palliative care and the relief of HIV/AIDS-related pain
National health policies are revised so that equitable support is provided for programs including home-based palliative care
Hospitals are able to offer appropriate back-up and support for home-based care
Both opioid and nonopioid analgesics, particularly morphine for oral administration, are available

Establishment of a national program, in which national healthcare policy is situated, may include the following activities:

Identification and consideration of the capacities of existing healthcare systems
Consultation with non-governmental organizations (NGOs)
Inclusion of steps to ensure community involvement
Recruitment of leaders
Reviewing the role of existing organizations
Identification of resources
Development of a communication strategy
Preparation of a draft national plan
Drawing up a budget for palliative care
Organization of a national conference
Changing legislation if needed
Launching the program with workshops

The functions of an established national program to provide palliative care are to:

Recommend legislative action
Recommend priorities for the investment of additional resources
Encourage the systematic development and coordination of specific palliative care activities to ensure the best use of available resources for the whole population

Forecast future trends and coordinate the strategic development of health services, health systems such as quality assurance systems, and training and supply of health professionals
Develop and support palliative care programs for smaller populations for jurisdictions within the area it covers
Coordinate the work of all agencies that can contribute to palliative care in the area

UNAIDS has developed a four-guide series for the strategic planning process for a national response to HIV/AIDS, including situation analysis, response analysis, strategic plan formulation, and resource mobilization. The Canadian Palliative Care Association's consensus document on *Standardized Principles and Practice of Palliative Care* presents guidelines for national committees to follow in developing palliative care standards; it is a clear framework for this process, with sample goals, objectives, essential steps, accompanying policies and procedures, and desirable outcomes (http://www.cpca.net).

3.2 Integrated Community- and Home-based Care Policy

In order to make services sustainable, the national policy should allocate resources to home-based care as well as to in-patient palliative care services and outpatient clinic services. Successful national HIV/AIDS palliative care programs that focus attention on integrated community- and home-based care are seen as the most efficient and cost-effective approach to healthcare delivery.

Throughout Africa, model programmes are demonstrating the beneficial integration of hospice, community and home-based care for people with HIV/AIDS. For example, the South Africa, developed an integrated care program in which patients with HIV/AIDS are referred to teams of nurses and trained community caregivers who care for them in their own homes. The program has halved average patient stays at the local hospital, and extended care provided at home costs less than a 2-day stay in the hospital. The Hospice Association of South Africa (HASA) was supported by the National Department of Health to replicate this model in seven pilot programs.

People with HIV/AIDS and their families are cared for by and in their immediate communities with help from outside agencies and healthcare professionals who are committed to implementing palliative care standards. HASA is now demonstrating the physical, financial, and social benefits of linking micro-community and hospice care to the formal care system of hospitals and clinics, empowering communities to better deal with the burden of disease as well as to decrease incidence

and stigma. HASA's integrated community-based home care model is depicted.

Hospice Uganda promotes similar work through its government-supported community-based hospice program, providing home care and serving as a resource center to the community for healthcare professional training, public education, and advocacy for hospice services.

4.0 CONCLUSION

We have seen that establishment of a national policy for palliative care is the best way to ensure quality standards, funding, and accessibility of adequate care for the greatest number of patients and families. A national policy serves as the official recognition of a commitment of financial support; it can play a major role in facilitating the availability of essential drugs, as well as the necessary educational initiatives for healthcare professionals and the public alike, as part of its mandate.

5.0 SUMMARY

In this unit, we saw the need for a national program strategy that requires an initial three-part process for improving palliative care. Step 1 of this programme is discussed in this unit, while steps 2 and 3 will be discussed in subsequent unit.

6.0 TUTOR MARKED ASSIGNMENT

To integrate palliative care into a national healthcare policy, governments should ensure that----------
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Establishment of a national program, in which national healthcare policy is situated, may include the following activities:----------
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ANSWER TO SELF ASSESSMENT EXERCISE

Governmental policy: adoption of a national palliative care policy
Education: training of healthcare professionals and the public
Drug availability:

7.0 REFERENCES/FURTHER READINGS

Osborne, CM HIV/AIDS in resource-poor settings: comprehensive care across a continuum. *AIDS* 10 (suppl 3):S61-7, 1996.

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UNIT 3 TRAINING HEALTHCARE WORKERS

CONTENTS

1.0 INTRODUCTION

Remember that the previous unit looked at Governmental policy: adoption of a national palliative care policy, which is also the first step identified. This unit will look at step of national public health approach to palliative care which is education: training of health care workers and the public.

2.0 OBJECTIVES

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

Identify the need for training health care workers for palliative care
Identify the six major sets of training in palliative care
Identify the WHO multi-dimensional education recommendations

3.0 MAIN CONTENT

3.1 Training Healthcare Workers

STEP 2: EDUCATION

The second foundation measure in a national public health approach to palliative care involves healthcare worker training and public education.

Education of healthcare professionals is crucial for the dissemination and implementation of existing palliative care knowledge. Training programs should exist for medical students, residents, practicing physicians, nurses, pharmacists, social workers, pastors, community-based home-care workers, and rural health workers. Successful experiences in several countries indicate that palliative care education

can be incorporated into existing healthcare system training programs. Distance learning and certification programs developed for each group of healthcare workers will further increase education coverage. Education must be appropriate to the situation in which they are performing their activities.

Training in palliative care focuses on six major skill sets:

1. Communication
2. Decision-making
3. Management of complications of treatment and the disease
4. Symptom control
5. Psychosocial care of patient and family
6. Care of the dying

WHO recommends that multi-dimensional education include at least a minimum of learning in three important areas:

1. Attitudes, beliefs and values:

- The philosophy and ethics of palliative care
- Personal attitudes towards HIV/AIDS, pain, dying, death, and
- bereavement
- Illness as a complex state with physical, psychological, social, and
- spiritual dimensions
- Multi-professional team-work
- The family as the unit of care

Knowledge base:

- Principles of effective communication
- Pathophysiology of the common symptoms of advanced disease
- Assessment and management of pain and other symptoms
- Psychological and spiritual needs of seriously ill and dying patients
- Treatment of emotional and spiritual distress
- Psychological needs of the family and other key people
- Availability of community resources to assist patients and their families
- Physiological and psychological responses to bereavement

Skills. Opportunities should be provided for the application of learned knowledge through practice in the classroom, making use of role-plays and discussion of real case-histories. Important areas for practice include:

- Goal-setting in physical, psychological, social and spiritual

dimensions.

- Development of a family care plan
- Monitoring of pain and symptom management

Various programs in resource-poor settings for the training of healthcare professionals have illustrated how the above-mentioned program components can be implemented. HASA initiated a model program for medical student training with a Diploma in Palliative Medicine at the University of Cape Town. With no palliative medicine journals, minimal undergraduate and postgraduate training, and very few palliative care physicians in the country, this program is beginning to develop a standardized knowledge base within a group of educated professionals. HASA also trains professional nurses in palliative care at nine campuses in South Africa.

The Mildmay Centre for AIDS palliative care in Uganda provides specialist outpatient palliative care and rehabilitation, using a train-the-trainer approach to disseminate its program and philosophy of symptom control throughout sub-Saharan Africa.[11, 26, 27]

SELF ASSESSMENT EXERCISE

Training in palliative care focuses on six major skill sets, namely----------

4.0 CONCLUSION

This unit looked at the second foundation measure in a national public health approach to palliative care which involves healthcare worker training and public education. We also saw that training in palliative care should focus of six areas and WHO recommends that multi-dimensional education include at least a minimum of learning in three important areas namely knowledge, skill and attitude.

5.0 SUMMARY

This unit tackled the second step of national public health approach to palliative care. Hope you find it interesting. Ok! Let us attempt the questions below.

6.0 TUTOR MARKED ASSIGNMENT

WHO recommends that multi-dimensional education include at least a minimum of learning in three important areas: Identify the areas with examples

ANSWER TO SELF ASSESSMENT EXERCISE

Communication
Decision-making
Management of complications of treatment and the disease
Symptom control
Psychosocial care of patient and family
Care of the dying

7.0 REFERENCES/FURTHER READINGS

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UNIT 4 EDUCATING FAMILY AND VOLUNTEER CAREGIVERS

CONTENTS

1.0 INTRODUCTION

In developing countries, empowerment of family members and volunteers to be effective palliative caregivers may be the most realistic approach for meaningful coverage, especially in rural areas. Experts emphasize that home care should not become a version of acute care delivery at home: it should rather "encompass personal care, personal services, social companionship, and applied medical care," as reflected in education and training.[4] Training for volunteer caregivers is available through hospices and other care-giving bodies. St. Luke's Hospital in South Africa, for example, runs intensive trainings for community volunteers who will work with professional teams to provide care in home-based settings. This unit thus serves as a follow-up on the previous one.

2.0 OBJECTIVES

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

Identify resources for education
Explain need for educating traditional healers
Identify the need for public education

3.0 MAIN CONTENT

3.1 Resources for Education

WHO's Palliative Care Unit developed a series of monographs addressing the principles and practice of palliative care for both child

and adult cancer patients, which can be adapted for National AIDS Programs. These include publications on cancer pain relief, guidelines for opioid availability, symptom relief in terminal illness, and palliative care for children, all suitable for professional education in palliative care for HIV/AIDS.

Professionals. In addition to the WHO monographs, the following international documents are available for the education of professionals worldwide.

The Education of Physicians in End of Life Care (EPEC) is a train-the-trainer curriculum comprising four 30-minute plenary modules and 12 45-minute workshop modules, available on CD-ROM (www.epec.net).

The *Oxford Textbook of Palliative Medicine* is a useful comprehensive medical textbook with chapters devoted to AIDS and various cultural settings.[32]

A Canadian training module is available, devoted exclusively to palliative care for HIV disease.[33]

The International Association for the Study of Pain published a core curriculum for professional education in pain.[34]

Guides for the use of analgesics also exist and should be widely distributed.

Pediatric clinicians. In the arena of pediatric palliative care education, the US National Pediatric and Family HIV Resource Center (NPHRC), a non-profit educational center, has focused on educating professionals who care for children and families affected by HIV/AIDS (www.pedhivaids.org). NPHRC's François-Xavier Bagnoud International Pediatric HIV Training Program has trained nearly 120 doctors, nurses, social workers, and other healthcare professionals from around the world in the care of children with HIV/AID. Training resources are available specifically for nurses and midwives that are particularly useful in resource-poor settings.

The International Society of Nurses in Cancer Care has a core curriculum in palliative nursing care.

A train-the-trainer course similar to EPEC for nurses, *End of Life Nursing Education Consortium (ELNEC) Project*, consists of nine content modules available on CD-ROM (www.aacn.nche.edu/elnec)

WHO created a series of 13 fact sheets for nurses and midwives including a module on palliative care with general key issues, challenges and detailed information on care-provision issues. WHO encourages programs to disseminate these documents, adding illustrations and/or adapting the information to fit specific contexts.

SELF ASSESSMENT EXERCISE

Identify the importance of education resources for palliative care

3.2 Educating Traditional Healers

In developing countries, traditional healers are a potential professional resource for the dissemination of palliative care knowledge. Government-sponsored education of these healers has sought to increase coverage areas of effective palliative care and symptom control awareness in Nigeria. The AIDS Foundation's collaboration with traditional healers resulted in a training curriculum to increase the impact of AIDS prevention, education and management.

3.2 Public Education

Palliative care education needs to be made available at the family, community and national levels. Patients, families and caregivers need good information regarding the illness, symptom control, options for care and how care can be provided. Community and religious leaders, legislators and other community members, as well as government officials, policymakers and NGOs, need information about the essential components of palliative care and how and where it is provided to allow them to be effective supporters and advocates of palliative care at both the community and national levels.

There is a major need for public education campaigns to facilitate community members' awareness of the nature of HIV disease and to provide them with information and knowledge for choosing care options when disease-specific therapies are unavailable or no longer appropriate. Such campaigns must emphasize that palliative care is focused on preventing needless suffering. There is also a particular need to educate the public about the role and appropriate use of analgesic drugs in pain management. According to WHO, it is essential that the public be made aware of the following:

Palliative care will improve a patient's quality of life, even when disease is incurable.
There is no need for patients to suffer prolonged and intolerable pain or other distressing symptoms.
Treatments exist that can relieve pain and many other symptoms of advanced disease.
Drug therapy is vital to pain management.
Drugs for pain relief can be taken indefinitely without losing their effectiveness.

Psychological dependence ("addiction") does not occur when morphine is taken to relieve pain.
The medical use of morphine does not lead to abuse.

Public palliative care education need not be AIDS-specific. It must be delivered in a culturally sensitive manner that is accessible to every segment of the population. Media campaigns can be effective in promoting awareness of palliative care issues, as can resource centers and overall community participation in care. Where illiteracy precludes written educational materials, video and theater are possible dissemination options. In settings where written materials are typically unavailable and radio is a common method of communicating information, major radio campaigns would be appropriate. "Scribes" or literate members of volunteer groups may also participate in education efforts. All arenas of public education should give special consideration to stigma reduction. Distance learning and certificate programs for volunteer caregivers in the community can further advance education efforts.

4.0 CONCLUSION

In this unit, we saw the need for education resources to palliative care. Also in developing countries, traditional healers are a potential professional resource for the dissemination of palliative care knowledge, so education should geared towards making them more competent. Palliative care education needs also to be made available at the family, community and national levels. Patients, families and caregivers need good information regarding the illness, symptom control, options for care and how care can be provided.

5.0 SUMMARY

This unit, which is a continuation of the previous one looked at education and palliative care. Hope you find it interesting also. Let us attempt the questions below.

6.0 TUTOR MARKED ASSIGNMENT

Palliative care education needs to be made available at the family, community and national levels: Discuss

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UNIT 5 NATIONAL POLICY FOR HIV/AIDS DRUG AVAILABILITY

CONTENTS

1.0 INTRODUCTION

This unit looks at the third and final foundation measures for public health approach. Remember we identified such measures as: Governmental policy: adoption of a national palliative care policy; Education: training of healthcare professionals and the public, and Drug availability.

2.0 OBJECTIVES

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

Describe national policy for drug availability

3.0 MAIN CONTENT

3.1 National Policy for Drug Availability

STEP 3:

A NATIONAL POLICY FOR DRUG AVAILABILITY

A national palliative care strategy should include basic directives that focus on both the necessary legislation and the administration process for drugs essential to the care and treatment of people with HIV/AIDS. To provide appropriate symptom control and supportive therapy, a national palliative care program must include policy measures regarding the need for a wide range of drugs to effectively address and control opportunistic infections and the major symptoms that patients with HIV/ AIDS report, including pain, nausea and vomiting, delirium and agitation, insomnia, fatigue, depression and anxiety. Such national policies should reflect laws that address the importation and distribution

of needed supplies, and also determine the appropriate amount of drugs to be imported and distributed.

Particular attention should be given to pain management. Numerous studies suggest that more than 80% of HIV/AIDS patients with advanced illness have significant pain, which is currently both under-assessed and under-treated. In a recent study in Uganda, hospice members found that pain was the first major source of distress for both cancer and AIDS patients and their relatives.[20] An excellent resource for the necessary legislative and administrative process for pain medications is the *Guide To Opioid Availability*, published in the WHO monograph *Cancer Pain Relief*. This document can help governments focus attention on developing a national policy for drug availability for palliative care drugs, particularly opioids.

Psychological symptoms vary in prevalence, occurring in 10% to 60% of patients during the course of their illness. Both delirium and dementia are common features of advanced AIDS, and the use of psychotropic drugs to manage these symptoms must be included in a country's Essential Drug List. (The WHO Action Programme on Essential Drugs recommends that every country maintain an Essential Drug List that includes the basic drugs needed to treat the diseases and conditions in that country. This assures that decisions regarding resource priorities are based on medical needs of the majority of the population.)

Other variables in this unit described a wide range of drug regimens for particular symptoms in patients with HIV/AIDS. These drugs, preferably in their generic form when available, should be incorporated into Essential Drug Lists. Essential Drug Lists should also include medications for patients' palliative care needs, such as non-opioids, opioids, and adjuvant analgesic drugs based on the WHO three-step analgesic ladder. A model Essential Drug List for cancer patients can be easily adapted for patients with HIV/AIDS but should also include cost-effective drugs for the treatment of opportunistic infections and their serious side effects, antidepressants, neuroleptics and anti-convulsants.

National drug policy should address the handling of medications. A model of such a document is Uganda's *Guidelines for Handling Class A Drugs*.[44] WHO has suggested essential components for guidelines that regulate health professionals who dispense opioid drugs.

1. *Legal authority*. Physicians, nurses and pharmacists should be legally empowered to prescribe, dispense and administer opioids to patients in accordance with local needs.

2. *Accountability*. They must dispense opioids for medical purposes only and must be held responsible in law if they dispense them for non-medical purposes.
3. *Prescriptions*. A prescription for opioids should contain at least the following information:

- Patient's name and address
- Date of issue
- Drug name, dosage strength and form, quantity prescribed
- Directions for use
- Physician's name and business address
- Physician's signature

Patient access. Opioids should be available in locations that will be accessible to as many patients as possible.
Medical decisions. Decisions concerning the type of drug to be used, the amount of the prescription and the duration of therapy are best made by medical professionals on the basis of individual patients' needs, and not by regulation.
Dependence. Physical dependence, which may develop when opioids are used to treat chronic pain, should not be confused with psychological dependence.

Financing must be secured for essential drugs. In Latin America, the "South-South Cooperation" Initiative is using a strategy of partnership among neighboring countries to become more powerful advocates for cheaper medications, particularly AIDS drugs. The Bamako Initiative is a revolving fund for financing essential drugs, with countries joining together to decrease prices and maintain commitment to buy and distribute them. In India, the production of cheap immediate-release morphine has aided the distribution and affordability of this essential drug. The cooperation of the pharmaceutical industry is needed to spread this practice to other nations.

Drug availability must include medications appropriate for pain relief and symptom control, regardless of the availability of other types of treatment. Access to palliative care services will always be essential, whether or not people have had access to other therapies including ART. In 1997, the UNAIDS HIV Drug Access Initiative (DAI) was developed to improve access to ART in resource-poor areas. Until 1999, DAI focused exclusively on ART, but it now is also promoting other means of treatment—including palliative care (see www.unaids.org/)

SELF ASSESSMENT EXERCISE

National drug policy should address the handling of medications. Identify the guidelines by WHO that regulate health professionals who dispense opioid drugs----------
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4.0 CONCLUSION

This unit illustrates that a national palliative care strategy should include basic directives that focus on both the necessary legislation and the administration process for drugs essential to the care and treatment of people with HIV/AIDS. It also highlighted guidelines for handling certain category of drugs.

5.0 SUMMARY

This unit which serves a follow-up to previous ones in this module looked at the concept of national policy for drug availability. Hope you enjoyed your studies.

6.0 TUTOR MARKED ASSIGNMENT

A national palliative care strategy should include basic directives that focus on both the necessary legislation and the administration process for drugs essential to the care and treatment of people with HIV/AIDS. Discuss

7.0 REFERENCES/FURTHER READINGS

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