Department of Pharmacy

Retrospective Analysis of Guideline Recommended Antiretroviral Regimens and Vaccination Schedules for Adult Patients with Human Immunodeficiency Virus (HIV) in an Infectious Diseases Clinic

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PURPOSE

This study will evaluate the management of patients diagnosed with HIV in an outpatient infectious diseases practice compared to evidence based guidelines. The 2018 guidelines from the International Antiviral Society (IAS) recognize three treatment regimens as "Recommended Initial Regimens for Most People with HIV." These are listed below. Demographic information of this patient population will be collected to determine which factors, if any, are significantly different for patients on less strongly recommended antiretroviral medications. The percentage of patients who received first line recommended antiretroviral regimens will be reported to assess the adherence with current guidelines. Rates of increased viral load above 200 HIV RNA copies/mL and CD4 cell counts below 200 cells/mm3 will be characterized and analyzed for this patient population. A qualitative analysis will be completed to identify the rationale behind the initiation of each patient's antiretroviral regimen. These described contraindications will be compared with the IAS guideline recommendations to act as an objective measure for appropriateness of care. Percentage of patients who received recommended vaccines will also be evaluated as patients with HIV are at an increased risk for vaccine preventable diseases due to the nature of immunosuppression.

PREFERRED ANTIRETROVIRAL REGIMENS FOR THE TREATMENT OF HIV

Based on the International Antiviral Society 2018 guideline recommendations

Available in a single pill formulation that contains an integrase inhibitor

Listed in alphabetical order by generic name of the integrase inhibitor component:

- Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide fumarate)
- Triumeq (dolutegravir/abacavir/lamivudine)
- Genvoya (elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide fumarate)

PRIMARY OBJECTIVE

Determine if there is a difference in demographic information associated with patient populations on certain treatment regimens for HIV.

SECONDARY OBJECTIVES

- Calculate the percentage of patients at this outpatient infectious diseases clinic whom were receiving first line recommended medications as of their most recent office visit on or before June 30th, 2018
- Of those patients not on first line recommended regimens, determine the various contraindications to first-line recommended therapy (Qualitative analysis)
- Characterize the distribution of most recent CD4 cell counts of all patients
- Calculate the percentage of patients with undetectable viral load
- Compare the viral loads between patients on various regimens
- Compare the CD4 cell counts between patients on various regimens
- Calculate the percentage of patients who have received each of the recommended vaccinations according to ACIP guidelines

METHODS

Retrospective chart review utilizing EPIC electronic medical record of patients who are:

- HIV positive
- Managed at LVPG outpatient infectious diseases clinic

Charts will be reviewed for antiretroviral regimen, vaccination history, and laboratory values using clinician notes, prescription lists, and medication administration records between February 1, 2015 and June 30, 2018.

INCLUSION CRITERIA

Inclusion in the study will be limited to a maximum of 100 patients. If more than 100 patients are eligible for inclusion, the 100 patients with appointment dates chronologically closest to June 30, 2018 will be included in the analysis.

- Age older than 18 years
- Diagnosis of HIV-1
- Attended appointment at least once between July 1, 2017 and June 30, 2018

DEMOGRAPHIC DATA TO BE COLLECTED

Age	Hepatitis B Virus (HBV)
Gender	Hepatitis C Virus (HCV)
Race	Type 1 Diabetes Mellitus
Weight	Type 2 Diabetes Mellitus
Current Insurance Status	Hypertension (HTN)
	Hyperlipidemia (HLD)
Sexual Orientation	Atherosclerotic Cardiovascular Disease (ASCVD)
	Tuberculosis (TB)
Time since HIV Diagnosis	Chronic Lung Disease (CLD)
	History of Transplant Surgery
Substance Use	History of Splenectomy

IMMUNIZATION RECOMMENDATIONS

Recommend the administration of vaccines at the same schedules in all individuals regardless of CD4 count except for certain live virus vaccines

Based on the Advisory Committee on Immunization Practices (ACIP) Adult Immunization Recommendations.

Live viruses that should be avoided when the CD4 count is ≤ 200 cells/mm3

- Mumps/measles/rubella vaccine
- Varicella (chicken pox) vaccine
- Herpes zoster vaccine

ASSESSED VACCINATIONS

- Influenza
- Pneumococcal conjugate
- Pneumococcal polysaccharide
- Tetanus toxoid/diphtheria/pertussis
- Human Papilloma Virus
- Varicella
- Hepatitis A
- Hepatitis B
- Meningococcal
- Mumps/measles/rubella
- Herpes Zoster Virus

STATISTICAL ANALYSIS

Descriptive statistics for the sample as a whole will be calculated and presented.

Statistical comparisons between the demographic variables between groups, based on the various treatment regimens, will then be completed.

- Chi-square Test of Independence will be used for categorical variables
  - If > 20% of the expected cell counts are found to be < 5, the Fisher's Exact Test will alternatively be used
- ANOVA will be used to compare continuous variables between groups
  - If the distribution of variables in any of the groups is skewed, the Kruskal-Wallis Test will alternatively be used

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