Clinical Research Rotation

The IRB Protocol

A Prospective Pilot Study Describing the Use of Performance-Enhancing Drugs in Adolescent and Young Adult (AYA) Male Oncology Patients

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A. Study Purpose and Rationale

The use of performance-enhancing drugs (PEDs) is increasingly common among adolescent males. For teens, the most commonly used PEDs include creatine, anabolic steroids and steroid precursors. Adolescents, males in particular, use PEDs to gain muscle mass or strength, address negative body image or pressures regarding weight, cope with insecurities and deal with societal or peer pressure.

When it comes to medical treatment, it is common for the patients not to self-disclose their use of PEDs to the treating physician. However, PEDs cause significant side effects such as weight gain, nausea, muscle cramps and kidney damage (creatine), heart and liver damage, halt bone growth (anabolic steroids and steroid precursors). In cancer treatment, serious and potentially fatal consequences can also result from the complex interactions between PEDs and cancer chemotherapy. The rate of PEDs usage reporting to the treating doctors is estimated to be 2 % (to be confirmed by a chart review of the past oncology patients filling the inclusion criteria). The true prevalence of the PEDS usage in the male AYA population seen at CUMC oncology department is estimated to be around 10-20%.This study aims to describe the use of PEDs among the adolescent male cancer patients as reported to an independent observer and compare it to what is reported to the oncologist.

The primary aim of this study is:

- To describe the prevalence and patterns in use of PEDs among male AYA oncology patients seen at the CUMC and any discrepancy in reporting it to the medical practitioners.

The secondary aims of this study are:

- To describe the overall usage of OTC nutritional supplements as well as illicit substances among male AYA oncology patients seen at CUMC
- To educate AYA about the risks and interactions of unregulated supplements during cancer therapy
- To explore symptoms and side effects associated with the use of PEDs and other nutritional substances.

B. Study Design and Statistical Analysis

There will be one group in this study. This will consist of adolescent and young adult (AYA) males (13-21 years old) seeking treatment with the CUMC pediatric oncology department for the first time. The sample size is set to 45 subjects to allow for loss to follow up. This is based on one-sample chi-square analysis at for 80% power at $p<0.05$ requires 43 subjects for the effect size of 13% (2% reported vs. 15% prevalence). CUMC sees approximately 130 new pediatric oncology patients annually, 20% (26) of which are estimated to be eligible for the study. Due to resource constraints, we expect to be able to approach

90% of the new patients, 80 % of which are expected to consent to the study yielding 19 patients annually.

Primary Aim 1: To describe the prevalence and patterns in use of PEDs among male AYA oncology patients seen at the CUMC and any discrepancy in reporting it to the medical practitioners.

The association between variables such as age, ethnicity, diagnosis, socioeconomic status, type of protocol and side effects with the use of different PEDs and reporting to doctor will be analyzed using a multiple regression model.

Secondary Aim 1: To describe the overall usage of OTC nutritional supplements as well as illicit substances among male AYA oncology patients seen at CUMC

The association between variables such as age, ethnicity, diagnosis, socioeconomic status, type of protocol and side effects with the use of supplements and reporting to the doctor will be analyzed using a multiple regression model.

Secondary Aim 2: To educate AYA about the risks and interactions of unregulated supplements during cancer therapy

Patients will be provided with educational materials about the interactions of unregulated supplements and urged to discuss them with their oncologist

Secondary Aim 3: To explore symptoms and side effects associated with the use of PEDs and other nutritional substances.

The incidence of expected side effects will be estimated and exact 95% confidence interval constructed based on a Poisson distribution.

C. Study Procedure

Within two weeks of initiation of cancer treatment at CUMC consented patients have a confidential interview with a community health worker discussing any nutritional supplements and illicit substances they take in detail (approximately 45 minutes). At the same time the patient fills a demographic data sheet and Memorial Systems Assessment Scale (MSAS). He is also offered voluntary biochemical testing (such as blood and urine toxicology screening). The patient will be asked to fill an MSAS monthly and a shorter interview to update nutritional supplement info (approximately 20 minutes) will take place at 1 month and six months. The patients are also educated about the risks and interactions of PEDs and chemotherapy and urged to check with their doctor or the investigator before starting or stopping any nutritional supplements. The study period is 6 months.

D. Study Drugs

There are no study drugs in this study.

E. Medical Device

There are no medical devices in this study.

F. Study Questionnaires

The study questionnaire is a comprehensive review of all nutritional supplements and other substances the patients have used during the past 6 months and continue to use during their cancer treatments. The questionnaire is drafted at the 6^{th} grade reading level and includes colloquial and street names for various substances.

G. Study Subjects

Inclusion criteria:

- A new patient seeking treatment at the CUMC Pediatric oncology department
- Male, 13-21 years old at the beginning of the study

Exclusion criteria:

- Estimated treatment of survival is expected to be less than 6 months.

H. Recruitment of Subjects

All new patients seeking treatment at the CUMC Pediatric oncology department who fulfill the study requirements are eligible for the study. After obtaining an approval from the patient's primary physician, he will be approached during his first appointment. The study will be explained to the patient in detail and if the patient consents, a confidential interview with a community health worker will take place within the first two weeks after consenting.

I. Confidentiality of Study Data

Study data will be coded with a unique code number. The study data is only available to the investigators. It is not shared with the treatment team unless it is deemed by the investigators that not doing so would severely harm the patient or affect his medical treatment.

J. Potential Conflict of Interest

None.

K. Location of the Study

The study is carried out at the CUMC pediatric oncology inpatient ward and clinic in conjunction of scheduled appointments. No additional appointments or visits are required for the study.

L. Potential Risks

The risks to the subject are minimal. Potential risks include loss of confidentiality of patient's data.

M. Potential Benefits

The subject may or may not benefit as a result of his or her participation in this study. Potential benefits include recognition and reduction of chemotherapy interactions with non-prescribed supplements.

N. Alternative Therapies

Not applicable.

O. Compensation to Subjects

No compensation will be provided to the subjects.

P. Costs to Subjects

The subjects will not incur any additional costs as a result of participating in the study.

Q. Minors as Research Subjects

The study involves the participation of minors. Approval from the Department of Pediatrics Committee on Human Investigation will be obtained.

R. Radiation or Radioactive Substances

Not applicable to this study.