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## Pharmacologically active substances and dietary supplements used by athletes - the European and Italian regulation

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**Abstract.** The nutrition has been supposed as an essential component of physical performance and thus the athletes make use of various substances in an attempt to improve their performance. For this reason, the nutritional supplements are widely used at all levels of sport. They are packed in the form of "doses" and can be used to correct nutritional deficiencies or maintain an adequate intake of certain nutrients even if the excessive intake of vitamins and minerals can be harmful or cause side effects. Faced with disparate regulations of its member countries, the European Commission has established harmonized standards to help ensure the safety and proper labeling of food supplements. The main provisions of the EU about are contained in Directive 2002/46/EC on food supplements containing vitamins and minerals that has been implemented in Italy by Legislative Decree n. 169/2004.

**Key words:** *pharmacologically active substances, dietary supplements, directive.*

### Introduction

Hard training and talent are the main factors contributing to the success of an athlete. Furthermore the sports world is solicited by use of pharmacologically active substances and the use of drugs to enhance performance in sports is termed as doping and is prevalent since ancient times (1). Unfortunately, the use erroneously and abuse of pharmacologically active substances have become so common in daytime sports that the safety, the health and the longevity of far too many athletes are now compromised (2, 3). Athletes, both professionals and amateurs, have not been out of danger. Their trainers, physicians and other assistants, have already given them countless pills, tablets, ointments, injections, vitamins and other potions. The goals are numerous: to stimulate, to calm, to numb the pain caused by a injury, to enhance performance, to reduce inflammation, sometimes to suppress anxiety (4).

Progress in the last few decades in the understanding of the human metabolism and of physical exercise physiology has made clear that a variation in nutritional intake may increase sports

performance positively (2, 5). This knowledge has given rise to an explosion of products specifically designed for each type of physical activity. These substances are more and more used by athletes not only in competitive sports, but also in fitness and recreational sports (1, 5).

Nutritional supplements can be grouped into dietary supplements, ergogenic aids and food for sport. Their use among athletes is very popular: most studies reported that over half of the athletes use supplements (6,7). Some studies reported that 88% of the athletes use one or more nutritional supplements (7). Therefore, although nutrition and doping are important factors in sports and in the performance in the health of athletes and the nutrition is an essential component of any athletic or physical activity program (8, 9). Supplements are consumed for a variety of reasons. Many exercise active individuals utilize supplements to build muscle, gain strength, prevent future disease or illness and improve performance in sport. The choice of supplements depends also on the reason of the exercise program and/or the type of sport (10).

Legality and safety of some dietary supplements remain an issue of concern and their use is closely associated with doping problems [25, 9]. Some supplements or their ingredients, like pro hormones, are considered prohibited by the World Anti-Doping Agency (WADA). Furthermore, athletes who use dietary supplements are susceptible to unintentional ingestion of banned substances (11). Identifying the use of non-approved drugs by cheating athletes has been a great challenge for doping control laboratories.

*Sources of data.* PubMed, using the terms 'dietary supplements' and/or 'pharmacologically active substances' and sport, and official WADA website were reviewed. The research is based on the analysis of the most investigated issues in the studies published in the last years.

### **Risks of nutritional supplements in sports**

Long-term use and the use of multiple-ingredients of dietary supplements were associated with larger number of symptoms and more severe outcome as adverse events (12).

Dietary supplements include vitamins, minerals, herbs, meal supplements, sports nutrition products, natural food supplements, and other related products used to boost the nutritional content of the diet (2).

Some supplements, when used in high doses may do more harm than good: iron supplementation, for example, is potentially harmful. Investigations specifically addressing the supplementation practices of national level athletes are limited, and it is unknown if similar patterns of supplement use occur in elite athletes.

Furthermore, most investigations don't make available details on some of the most valuable information relating to the supplementation practices of athletes: the type of supplements, amounts taken, and rationale for their use, together with issues such as sources of information relating to sports supplements and nutrition knowledge such as sources of information relating to sports supplements and nutrition knowledge (13).

When a product contains one or more of banned substances that could lead to a positive doping results. Identifying the use of non-approved drugs by cheating athletes has been a great challenge for doping control laboratories. This is due to the additional complexities associated with identifying relatively unknown and uncharacterized compounds and

their metabolites as opposed to known and well-studied therapeutics (14).

Some supplements contain compounds that will cause an athlete to fail a doping test. Supplement quality assurance programs can reduce, but not entirely eliminate, this risk.

Therefore, most athletes have a massive confusion that leads to trying the "best new supplements", but rarely produces the results promised. Supplements are not the most important aspect of nutrition. Many products have additional compounds that are not listed on the label (15). Doping control laboratories are frequently confronted with new substances that may be misused by athletes. In the Cologne Doping Control Laboratory, different confiscated products and legally obtained nutritional supplements were analyzed in 2009, and various findings were reported including GH-labelled injection vials without any pharmacologically active content; combinations of products indicating the attempt to mask growth hormone abuse; unpurified long-R(3)-IGF-1; nutritional supplements containing the growth hormone releasing peptide-2 (GHRP-2); and ampoules containing the selective androgen receptor modulator Andarine (S-4) (16). Athletes are not vigilant in sourcing reputable information pertaining to dietary supplements, they may be allocating unnecessary resources to unproven products and also exposing themselves to a small but real risk of committing a doping offence. Consequently, athletes should be encouraged to consult sports medicine professionals with specialist knowledge of dietary supplements in regards to issues such as safety, efficacy, potency, and legality of a product prior to initiating any supplementation regime (17).

Therefore, the amount of dietary supplements consumed should be within the recommended range of protein, carbohydrates, and lipids for that particular product. Information on the use of supplements is usually provided by the athletes' coaches and doctors. It is necessary to educate athletes by providing better information about the risks and benefits of consuming dietary supplements. To reduce the risks from the improper use of supplements, physicians, coaches, athletic trainers, parents, health educators, and other sports professionals should inform supplement users about not proven results and provide warnings about the potential harm of such dietary supplements (18).

### The European and Italian regulation

Officially, in 1996 in the United States about 6.5 billion US dollars were spent in general nutritional supplement purchase, reaching in 2002 at 18 billion US dollars, with sports nutritional products covering one-third of the sales. In 1998 worldwide consumption of creatine was 2.7 million kilogrammes (16), and sales of hydroxy-methyl-butyrate (HMB) reached 50-60 million US dollars, despite no evident proof of its efficacy in increasing muscle mass or strength. Use of nutritional supplements, combined with an absence of evidence of their efficacy and a concern for the possibility of "inadvertent" doping (2).

At the European level, the food supplements sector is regulated by the Directive 2002/46/EC, as amended, which was created with the aim of ensuring both a high level of protection of public health, and to allow the free circulation of these products, ensuring also, through adequate and appropriate labeling, better consumer protection [206]. In the preamble to the Directive states that it is increasing the sale of foods containing concentrated sources of nutrients and presented as supplements of nutrients from the normal diet and that the countries of the European community adopt different regulations that may slow down the free circulation of the said products and adversely affect competition. This Directive arises, therefore, as the objective of approximating the laws of the Member States with respect to dietary supplements. The main principles from which to start are that an adequate and varied diet could provide all necessary nutrients for normal development and maintenance of the healthy life and in the presence of particular lifestyle or for other reasons, the consumer may choose to supplement their intake of some nutrients through food supplements but an excessive intake may result in adverse effects and therefore necessitate the setting of maximum safe levels for them in food supplement, as appropriate (19, 20). The maximum amounts of vitamins and mineral in food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following into account: the upper safe level of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups and the intake of vitamins and minerals from other dietary

sources. You must take into account also the reference values for vitamins and minerals for the population (21).

The definition provided by the Directive is as follows "*Food supplements*" means *foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely form such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities* (20).

With regard to labeling, it expressly refers to Directive 2000/13/EC. Adds, nevertheless, that the labeling, the presentation and the advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties. Also, it is forbidden to say that a healthy and balanced diet is not able to make nutritive substances in sufficient quantities.

The labeling, in fact, shall contains the name of the categories of nutrients or substances that characterize the product or an indication of the nature of those nutrients or substances, the portion of the product recommend for daily consumption, a warning not exceed the stated recommended daily dose, a statement to the effect that food supplements should not be used as a substitute for a varied diet, a statement to the effect that the products should be stored out of the reach of young children (20, 22).

With regard to Italian legislation, the first act was the Legislative Decree No. 111 of 1992 implementing Directive 89/398/EEC laying down rules on of the only products intended for particular nutritional uses, such as foods for infants and products dietary and that also included dietary supplements and foods containing added vitamins and minerals. Later, in 2004 the Legislative Decree n. 169 has implemented Directive 2002/46/EC. Article 7 of the Decree provides that in case of supplements touted as adjuvant hypo caloric diets aimed at weight reduction, it is forbidden any reference to the timing and amount of weight loss resulting from the intake of the aforementioned supplements. Indeed, the advertisements must invoke the need to follow, in any case, an adequate hypo caloric diet and remove sedentary lifestyles (23).

Moreover, in case of presence of other ingredients such as plants or other natural substances, the advertising must contain the warning that may be incurred in the unwanted side effects. For the purpose, also, of the first marketing of the supplements, the undertaking concerned shall inform the Ministry of Health by forwarding it a model of the label used for the product. For foreign products, the marketing is only allowed 90 days after the receipt of the label, without any observation of the Ministry. In the case in which the Ministry has doubts on the safety of the product, it may request additional documentation and may request that changes are made-labeling, as well as the inclusion of some warnings. The product has received marketing authorization will be entered in a special register that the Ministry of Public Health and constantly updated. If, however, the Ministry believes that the product is dangerous for your health, prohibits the marketing and immediately inform the European Commission. Finally, the Decree, Article 15 provides for a series of penalties for violations of its provisions. Decree 169 was supplemented by the Decree of the Ministry of Health of 09/07/2012 which allows the use of substances and preparations listed in the annex to the decree. In 2006 the EC Directive n.1925 on foods with added vitamins and minerals (22). At the same time the EC Directive was enacted n.1924 on nutrition and health claims provide the products supplied, the so-called claims, which apply to all foods, including supplements. A nutritional claim suggests a food has beneficial nutritional properties, such as "low fat", "no added sugar" and "higher in fiber".

A health claim is a statement that suggests a relationship between food and health. This Directive, however, considers supplements, only those products that do not have a significant impact on food intake in terms of energy, i.e. calories.

Therefore, the products previously considered as "energy supplements" and "protein supplements" to caloric significant impact, such as the bar that are consumed by athletes, are excluded from the scope of Directive EC 1924, falling within the scope of Directive EC 1925 .

To try to make things clear, in the Italian Ministry of Health has issued the Circular of 11/05/2009 - replacing the previous circular of 11/30/2005 - whose Annex I is devoted to products intended to meet the intent muscular effort, especially for sportsmen. According to the said Annex, the

products must submit a composition nutritionally adapted to the particular needs of sportsmen and be appropriate for the specific uses for which they are proposed. If there are vitamins and minerals, the content of the portion should not be less than 15% of its RDA.

In any case, through self-control plans should be excluded even in the presence of traces of possible doping contaminants and/or substances included in the list referred to in Law no. 376 of 2000 relating to the regulation of the health protection of sport and the fight against doping. As a general rule, formulated products to meet the specific nutritional needs of athletes can be traced to the following categories: energy products, protein-concentrated amino acids to support the nitrogen demand, products intended to replenish the losses idrosaline due to profuse sweating, other products specifically adapted (22, 23).

### Conclusion

Reasons for nutritional supplements usage were supported scientifically in some cases (e.g., muscle gain upon protein supplementation), but others did not have a scientific basis (e. g., use of glutamine and magnesium) (24). While athletes may periodically attempt to promote skeletal muscle hypertrophy, key nutritional issues are broader than those pertinent to hypertrophy and include an appreciation of the sports supplement industry, the strategic timing of nutrient intake to maximize fuelling and recovery objectives, plus achievement of pre-competition body mass requirements (25).

A lot of study showed that the use of dietary supplements varies with each individual professional athlete for several reasons. When asked about their use of supplements and their reasons for consumption, a majority of athletes expressed their desire to improve health and performance (26). Use of nutritional supplements, combined with an absence of evidence of their efficacy and a concern for the possibility of "inadvertent" doping. Market regulation is complicated by the increasing popularity of Internet sales.

There is evidence that some of the apparently legitimate dietary supplements contain ingredients that are not declared on the label, which are prohibited by the doping regulations of the International Olympic Committee and the World Anti-Doping Agency (WADA). Consequently, it is recommended to use the certified nutritional supplements.

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## Pattern of sports injuries and physiotherapy interventions at the 23<sup>rd</sup> Nigerian University Games

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**Abstract.** *Introduction.* Sports injuries represent the most significant adverse consequences of sports activities and a common reason for non performance and non participation at sport events. This study investigated the pattern of sports injuries and physiotherapy interventions during the 23<sup>rd</sup> Nigerian University Games (NUGA). *Material and Method.* A retrospective case charts review of incidences of sports injuries recorded at the 23<sup>rd</sup> NUGA held between March 16<sup>th</sup> to 27<sup>th</sup> 2011 at the University of Benin was carried out. Data were gleaned on age, sex, type of sport, type of injury, anatomical location affected and physiotherapy intervention received. Data were summarized using descriptive statistics. *Results.* Sports injuries constituted 51.5% (188/365) of all reported medical conditions with a female to male ratio of 1:1.7. Football had the highest incidence (20.2%) of sports injuries followed by athletics (13.8%). Soft tissue injuries were prevalent in both contact (79.3%) and non-contact (82.1%) sports. The most injured anatomical parts were the head 22 (18.2%) and knee joints 17 (14.0%) in contact sports; the knee 14 (21.2%) and ankle 9 (13.6%) joints in non-contact sports. Cryotherapy was the mainstay of physiotherapy for sports injuries (47.2%) and was mostly in combination with soft tissue massage and bandaging (13.8%). *Conclusion.* Sports injuries were common medical conditions in the Nigerian University Games and it constitutes a significant burden for physiotherapy interventions. The observed sports injuries profile are consistent with most epidemiological reports. Advocacy for policy to minimize injuries and institutionalize physiotherapy interventions at subsequent NUGA is warranted.

**Key words:** *sports injuries, sports activities, physiotherapy.*

### Introduction

Sports injuries has become increasingly a public health challenge (1,2) and represent the most significant adverse consequence of sports activities and a common reason for non performance and non participation at sport events (2-6). Injuries resulting from sports are *sine qua non* of an intricate interaction between intrinsic (athlete-related) and extrinsic (environmental) risk factors (7-10). Some studies posit that the extrinsic factors play a more dominant role in the aetiology of sports injuries (9-11).

The occurrence and pattern of sports injuries are sport specific (11-13). Each sport has its characteristic injury profile and degree of risk (13-16) with severity ranging from mild to lifelong physical impairment, disability and even death (4, 8, 17, 18).

Consequent to the foregoing, it is believed that injury surveillance and profiling in multi-sports events are of immense advantage in providing epidemiological information, policy formulations aimed at injury prevention and proper

management programme and the opportunity to monitor long-term changes in incidences of injuries (19-21).

Injury surveillance studies at local, national, continental and world level are being advocated as the first step in the process to reduce the incidence of sports injuries (22-24). In spite of the rapid growth of amateur and professional sports in Nigeria, there is still paucity of studies on pattern of injuries and management during local and national single and multi-sports events. Therefore, the objective of this study was to investigate the pattern of sports injuries and physiotherapy interventions during the 23<sup>rd</sup> Nigerian University Games (NUGA).

### Material and Method

A retrospective study of incidence of sports injuries recorded at the 23<sup>rd</sup> NUGA which held at the University of Benin (Edo State, Nigeria) between March 16<sup>th</sup> to 27<sup>th</sup>, 2011.

The NUGA also called “University Games” is a biannual sports competition founded in 1966 at the University of Ibadan, Nigeria.

NUGA is the foremost platform to showcase young elite athletes and has since served as a breeding ground and springboard for world class athletes in Nigeria. NUGA typically comprises of 16 sporting events involving the track and field, badminton, basketball, chess, cricket, football, handball, hockey, judo, soccer, squash, swimming, table tennis, taekwondo, tennis and volleyball.

This retrospective review was delimited to cases of sports injuries recorded by the NUGA clinic for which physiotherapy intervention was received. Information were gleaned on age, sex, type of sport, type of injury, anatomical location affected and the type physiotherapy treatment received. For the purpose of analysis, sports injuries sustained were classified as fracture, head injuries, spinal cord injuries, soft tissue injuries, chest injuries, abdominal injuries, peripheral injuries and ocular injuries respectively (6). Ethical approval for this study was obtained from Ethics and Research Committee of Obafemi Awolowo University Teaching Hospitals Complex, Ile-Ife, Nigeria. Permission of the Head of the NUGA Medical Team was obtained to facilitate access to the case notes of the participants.

*Data Analysis.* Data was analysed using descriptive statistics of mean and standard deviation, frequency and percentage using Statistical Package for Social Sciences software version 16.0 (SPSS Inc., Chicago, USA).

## Results

A total of 365 case notes of athletes reporting various medical conditions were reviewed. However, only 188 (51.5%) - 119 (63.3%) males and 69 (36.7%) females cases, with a female to male ratio of 1:1.7, met the eligibility criteria. The age range of all injured athletes was 17-32 years (mean  $22.75 \pm 2.88$  years) (table I).

Table II showed the incidences of sports injuries by sports types. Football had the highest incidence with 38 (20.2%) reported cases, followed by athletics 26 (13.8%). However, swimming and badminton had the least reported cases of sports injuries of 0.5% respectively (table II).

Type of sports injuries is presented in table III. The result of this study showed that some athletes

had multiple types of injuries or more than one diagnosis at a time. However, 151 (81.3%) athletes had soft tissue injuries, 22 (11.8%) had head injuries while 7 (3.8%) had spinal injuries.

Distribution of sports injuries by contact and non-contact sports categories is presented in table IV. The result of this study showed that contact sports such as football and hockey had 96 (79.3%) athletes reporting soft tissue injuries and 1(0.5%) athlete reporting fracture of the bone.

Also 3 (2.5%) athletes reported spinal injuries, 18 (14.9%) athletes reported head injuries, while 2 (1.7%) athletes reported chest injuries (table IV). The result of this study also showed that soft tissue injuries 55 (82.1%) was the most common injury type among non-contact athletes followed by 4 (6.0%) head injuries (table IV).

The distribution of sports injuries by anatomical parts are presented in table V. The knee joint was the most injured anatomical part with 31 (16.6%) incidences, followed by the head 26 (13.9%). 12(6.4%) athletes had injuries to multiple anatomical sites. 11 (5.9%) athletes each sustained injuries to the foot, hand and thorax. 7 (3.7%) athletes each sustained injuries to the spine and shoulder joint while 3 (1.6%) athletes sustained injuries to the wrist joint (table V).

Distribution of sports injuries by anatomical parts by contact and non-contact sports categories is presented in table VI. The result showed that most of the athletes in contact sports had sports injuries affecting the head 22 (18.2%) and knee joints 17 (14.0%) respectively. On the other hand, non-contact sports athletes had injuries affecting the knee 14 (21.2%) and ankle 9 (13.6%) joints respectively (table VI).

The pattern of physiotherapy for the injured athletes is presented in table VII. The result showed that most athletes were treated by combination of different modalities. Cryotherapy was the mainstay of physiotherapy for sports injuries (47.2%). Cryotherapy was often in combination with soft tissue massage and bandaging 26 (13.8%), followed by a combination with soft tissue massage only 24 (12.8%) while a combination of cryotherapy, bandaging, exercise and rest was received by 9 (4.8%) athletes. However, 14 (7.4%) athletes received cryotherapy only.