Summit on Human Performance and Dietary Supplements Summary Report

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The use of dietary supplements to enhance human performance among active individuals, athletes, the military, and other tactical populations is an increasingly popular topic that often is not well understood. There are important differences in nutrient needs between the general public and active adults. The United States has an established regulatory framework for dietary supplements, and the safety and quality of dietary supplements can be strengthened through education, third-party certification programs, and increased attention to serious adverse event reporting. This summary highlights these key issues, as well as research needs, areas for future consideration, and other topics that were discussed during the Human Performance and Dietary Supplements Summit, held August 9 to 10, 2012, in Bethesda, Maryland. Nutr Today. 2014;49(1):7–15

The use of dietary supplements to enhance human performance among athletes, the military, and other tactical populations is an increasingly popular topic that often is not well understood. To review the evidence base and discuss key issues, the National Strength and Conditioning Association, National Institutes of Health Office of Dietary Supplements, the American Society for Nutrition, and the EAS Academy hosted a Human Performance and Dietary Supplements Summit August 9 to 10, 2012, in Bethesda, Maryland (Table 1).

More than 200 professionals from the medical, nutrition, and athletic performance fields, as well as the military, participated in the summit. This summary highlights the key topics covered, research needs, future study considerations, and discussion points as presented at the summit, without further elaboration.

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This article is a summary report of the 2-day Human Performance and Dietary Supplements Summit held August 9 to 10, 2012, in Bethesda, Maryland.

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The authors currently are employed or consulting for the organizations noted. The summit was developed and supported by the National Strength and Conditioning Association, the National Institutes of Health's Office of Dietary Supplements, and the American Society for Nutrition; it was sponsored in part by the EAS Academy of Abbott Nutrition.

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DOI: 10.1097/NT.0000000000000013

TABLE 1	Objectives of the Summit on Human Performance and Dietary Supplements
• Define the nutrition needs of active adults and athletes	
• Discuss dietary supplement use in active adults, elite athletes, and tactical populations	
• Examine the impact of dietary supplements on performance, competition, and training	
• Discuss the translation and application of the available evidence for educating appropriate audiences	
• Review certification, testing, safety issues, and adverse events	
• Identify research gaps and opportunities for further research	

A few decades ago, sports nutrition science was in its infancy. Athletes and fitness enthusiasts struggled for ways to best define their nutrition needs and balance them with the demands of rigorous training and busy lifestyles. Today, science-based solutions are available in the form of sports dietary supplements, conventional foods, and functional foods, developed specifically as sports nutrition products. These products can provide a framework for good nutrition and can offer quality, balanced nutrition, and convenience. The key to understanding the differences in these types of products is to consider the form, composition, labeling, and use of each.

DIETARY SUPPLEMENT REGULATIONS IN THE UNITED STATES

The summit highlighted the dietary supplement regulatory framework in the United States. Like all foods, dietary supplements and conventional foods marketed for sports nutrition are regulated by the US Food and Drug Administration (FDA). Federal law defines dietary supplements as products taken by mouth that contain a "dietary ingredient" and are intended to "supplement" the diet:

- The ingredients in dietary supplements may include vitamins, minerals, herbs, or other botanicals, amino acids, enzymes, organ tissues, glandulars, concentrates, metabolites, constituents, and/or extracts.
- Dietary supplements are available in tablet, capsule, liquid, powder, soft gel, or gel cap form.
- Manufacturers cannot promote these products as conventional foods or for use as the only item of a meal or diet.

The Federal Trade Commission prohibits using unfair or deceptive practices to sell any dietary supplement or conventional food. Dietary supplements also must meet the requirements of 2 amendments of the US Food, Drug, and Cosmetic Act that are specific to dietary supplements.

1994 Dietary Supplement Health and Education Act

The first amendment is the 1994 Dietary Supplement Health and Education Act, which provides the overall regulatory framework for dietary supplements to help ensure safety by establishing specific labeling and notification requirements, authorizing the FDA to develop rules for good manufacturing practices, and giving the FDA authority to remove a dietary supplement from the market if the FDA finds the product is "unsafe."[1]

2006 Dietary Supplement and Nonprescription Drug Consumer Protection Act

This second amendment requires companies that manufacture or distribute dietary supplements to report information about serious adverse events to the FDA.[2]

Labeling requirements for dietary supplements are similar to those of conventional foods. Both must have the following:

- statements of identity/descriptive names; in addition, a dietary supplement also must state that it is a "supplement";
- name and place of business of the company manufacturing, packing, and distributing the product;
- nutrition labeling panel—the Nutrition Facts panel for conventional foods and Supplement Facts panel for dietary supplements;
- complete ingredient listing (Table 2), net contents of the product, and serving size;
- dietary supplements also must list an address and phone number for serious adverse event reporting.

Advertisements and labels for dietary supplements cannot make disease claims, such as stating the product will help prevent, treat, cure, or mitigate an illness/disease. However, dietary supplements, like conventional foods, can make health claims. Health claims describe a relationship between a substance and a disease or the reduction of risk for a disease. The FDA must preapprove the health claims, and the product's label must contain a disclaimer specifying that the statements were not evaluated by the FDA. Both dietary supplements and conventional foods also can make nutrient content claims that are preapproved by the FDA (eg, sugar free, low fat, or low sodium).

Dietary supplements and conventional foods can make structure/function claims (eg, calcium builds strong bones, or fiber maintains bowel regularity). However, manufacturers of dietary supplements must provide notification to FDA of these claims (no later than 30 days after marketing a product with a structure/function claim) and add a disclaimer on the product's label that the statements were not evaluated by the FDA. In addition, structure/function claims

TABLE 2 Regulations for Ingredients in Conventional Foods and Dietary Supplements

Ingredient safety
Manufacturers are responsible for ensuring the safety of their products; the regulations governing safety of ingredients used in conventional foods vs dietary supplements differ in several ways.
Ingredients added to conventional foods must meet one of these requirements:
• Have been in general use in foods prior to 1958 (when the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act was enacted) • Comply with a US Food and Drug Administration (FDA)–issued food additive regulation (specifies amount and purpose of ingredient) • Be generally recognized as safe (GRAS) by qualified experts, meaning safe use of the ingredient has been developed under scientific procedures or through common use in food, so there is ''general recognition of safety'' among qualified experts (FDA premarket notification of GRAS ingredients is voluntary—listing available at http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing)
Ingredients used in dietary supplements must meet one of these requirements:
• Have been in general use prior to October 15, 1994 (when the Dietary Supplement Health and Education Act was implemented) • Be in compliance with the notification for a new dietary ingredient (NDI), which requires a 75-d premarket notification to FDA, unless the NDI and any other ingredients in the dietary supplement have been present in the food supply and used for food • For more information about the safety of dietary ingredients, visit http://www.fda.gov/Food/DietarySupplements/Alerts/default.htm and http://ods.od.nih.gov/factsheets/list-all/

Abbreviation: NDI, new dietary ingredient.

are required to have substantiation, supported by competent and reliable scientific evidence.

Four principal issues guide whether a claim is substantiated:

- meaning of the claim being made,
- relationship of the evidence to the claim,
- quality of the evidence, and
- totality of the evidence.

DIFFERENCES BETWEEN NUTRIENT NEEDS OF THE GENERAL PUBLIC AND ACTIVE ADULTS

Another area addressed at the summit was nutrient needs and human performance. When considering the use of dietary supplements for human performance, it is helpful to understand how nutrient needs are estimated and the potential impact of performance activities. Dietary Reference Intakes (DRIs)[3] are calculated using "reference people" of specific height, weight, sex, physical activity, and environmental conditions. However, many active people do not fit into these standard reference categories. The Military DRIs[4] were derived from the DRIs to meet the increased activity levels and greater environmental stresses faced by military populations and are used to develop menu standards for the military.

Some special populations, such as individuals who are very fit and active and/or are performing at environmental extremes (eg, combat personnel, first responders, and professional athletes), may require adjustments in their DRIs. Whereas recommendations for vitamins and minerals remain fairly constant for active versus inactive individuals, needs for water, electrolytes, energy, and, under certain circumstances, macronutrients (carbohydrate, protein, and fat) may differ.

The estimated energy requirement is the average dietary energy intake needed to maintain energy balance in a healthy adult of defined age (in years), sex, height (in meters), weight (in kilograms), and physical activity level (PAL).[3] The PAL factors are based on the activity levels of the general population (Table 3), which are possibly too low for very active people.

For example, a competitive or tactical athlete could expend up to 6000 kcal/d, which may require a PAL of 3 or more. The estimated energy requirement equations for adults are as follows:

$$\text{Adult Men EER} = [662 - (9.53 \times \text{age})] + \text{PA} \times [(15.91 \times \text{weight}) + (539.6 \times \text{height})]$$

$$\text{Adult Women EER} = [354 - (6.91 \times \text{age})] + \text{PA} \times [(9.36 \times \text{weight}) + (726 \times \text{height})]$$

where PA is the physical activity coefficient derived from the PAL (Table 3). Acceptable macronutrient distribution ranges for carbohydrate, protein, and fat are 45% to 65%, 10% to 35%, and 20% to 35% of total calories, respectively. However, different ranges are recommended to meet the carbohydrate and protein needs of very active individuals. The Recommended Dietary Allowance for protein, which covers requirements for nearly all healthy, nonathletic adults, is set at 0.8 g/kg per day. Yet, protein intake recommendations in the sports nutrition literature vary from 1.2 to 2.0 g/kg per day, based on body composition, type of exercise, and health status.[5]

Although the DRIs provide an evidence base from which to derive nutrient recommendations, they are incomplete for athletes and others engaged in strenuous activity. Optimal intakes before, after, and during exercise and specificity for individuals of varying body composition are not addressed by the DRIs. Recommendations are available

TABLE 3 Physical Activity Coefficients (PA values) for Use in Estimated Energy Requirement Equations

	Sedentary (PAL 1.0–1.39) Typical Daily Living Activities	Low Active (PAL: 1.4–1.59) Typical Daily Living Activities, Plus 30–60 min of Daily Moderate Activity	Active (PAL 1.6–1.89) Typical Daily Living Activities, Plus 60 min of Daily Moderate Activity	Very Active (PAL 1.9–2.5) Typical Daily Living Activities, Plus at Least 60 min of Daily Moderate Activity, Plus an Additional 60 min of Vigorous Activity or 120 min of Moderate Activity
Men ≥19 y	1.00	1.11	1.25	1.48
Women ≥19 y	1.00	1.12	1.27	1.45

Abbreviation: PAL, physical activity level.

from other sources, such as the American Academy of Nutrition and Dietetics, the Dietitians of Canada, the American College of Sports Medicine, and many professional journals and publications.

DIETARY SUPPLEMENT USE IN ACTIVE ADULTS, ATHLETES, AND TACTICAL POPULATIONS

The summit explored the uses of dietary supplements by different population groups. There is some research on the efficacy of various dietary supplements and their impact on both health and human performance, but it is limited. The role of dietary supplements in human performance is to support the physiological needs of a metabolic system under stress and to complement the body's effort to mobilize fuel, maintain focus, or accelerate recovery. Several dietary supplements are shown to complement training and human performance, and others still are under study.[3,6] Clear and concise information on dietary supplement strategies that can benefit active populations and influence goal achievement is needed, but reinforcing the role of conventional foods also is important. Following are considerations for several specific populations.

The nutrition needs of very active adults require more study.

Active Adults and Athletes

Active adults and athletes often view dietary supplements as a way to improve their performance, help them achieve a goal faster, and maintain their health. Most active adults and athletes do not question whether the dietary supplements that they take actually are improving their performance. They may take a product simply because of the label "promises." Sports dietitians can help active adults and athletes develop nutritional strategies and plans that evolve according to their individual goals, using an approach such as this multistep process:

- **Step 1:** Provide comprehensive education, helping athletes see how nutritional strategies can help them achieve their goals
- **Step 2:** Offer clear and concise materials to promote understanding of dietary supplement use
- **Step 3:** Provide guidance on how to configure solutions specific to their goals
- **Step 4:** Give follow-up guidance on how to execute their plans.

Professional and Collegiate Athletes

For many athletes, overreaching + overtraining = performance incompetence. For professional athletes, a long in-season grind and short off-season restorative period increase the potential for underrecovery and deconditioning. Sports dietitians often see professional athletes suffering from chronic fatigue because of underresting, stimulant overuse, drug use, and binge alcohol use similar to what occurs in the general population. In addition, some athletes may have off-season binge-eating patterns that can result in chronic dehydration, poor sleep, anxiety, and vulnerability to exertion and environmental stressors.

The National Collegiate Athletic Association (NCAA) has established specific sports nutrition rules that govern how teams can feed their players (eg, specifying institutions may provide only 1 training table meal per day to a student athlete, but that institutions may provide fruit, nuts, and bagels at any time).

The NCAA also has rules that allow student athletes to receive nutritional supplements for additional calories and electrolytes. Permissible nutritional supplements cannot contain any NCAA-banned substances and are identified according to classes—carbohydrate/electrolyte drinks, energy bars, carbohydrate boosters, and vitamins and minerals. The NCAA recently adopted a policy that schools must designate an individual as the athletic department's resource for questions related to nutritional supplements,

although no specific criteria for knowledge or training were specified.[7]

Youth Athletes

American youth represent a growing segment of consumers who can spend billions of dollars annually on dietary supplements, including those products aimed at improving physical performance, fighting fatigue, and modifying body composition. For example, energy drink and energy shot sales were a $12 billion industry in 2010, and it is possible that teenagers accounted for a large proportion of all purchases.[8,9]

Data from the 2007 National Health Interview Survey estimated that approximately 3.9% of children (1–18 years of age) were using nonvitamin, nonmineral, natural dietary supplement products, such as fish oil, creatine, and *Echinacea*.[10] Data from the 1999–2002 National Health and Nutrition Examination Survey report that 31.8% of children (1–18 years of age) used multivitamins and minerals, vitamin C, vitamin D, and calcium supplements.[11]

Few clinical trials have examined the suitability and efficacy of using dietary supplements to improve athletic performance in adolescents. Teens often do not check the specific ingredients in dietary supplements that they are ingesting and do not always follow product directions. Sports dietitians can serve an important role in educating and advising youth athletes on evidence-based nutrition and training strategies for safely optimizing physical performance.

Tactical Athletes

Elite tactical athletes are members of the military special operation forces, the tactical law enforcement teams of the Coast Guard, and civilian special weapons and tactics (SWAT) teams. These groups often appear similar to other athletes, but their cost of failure to perform can prove catastrophic. Tactical athletes face many of the same increased nutrition needs and challenges as other elite athletes, but they usually work under highly stressful conditions, face strong peer pressure to perform, must often perform for extended periods, and may have limited or delayed access to basic hydration and refueling resources. These conditions often can leave tactical athletes dehydrated and hungry during missions and without a way to refuel.

Many tactical athletes self-report using dietary supplements to achieve a range of goals, including increasing size or mass, strength or power, energy, and overall health; gaining an edge in semiannual physical fitness tests; and/or staying awake or alert for long periods during missions. The types of dietary supplements used include carbohydrate and protein powders, weight gain products, creatine, preworkout powders, branched-chain amino acids, vitamins, low-carbohydrate protein powders, and thermogenics/fat burners.

Four nutritional strategies are used for mission success:

- developing a workable plan for team/individual,
- practicing implementation of the plan and adjusting when necessary,
- assessing local dining facilities and hours of operation, and
- maintaining hydration.

Each tactical athlete population has a specific operational footprint. However, adequate fueling of SWAT teams is a particular challenge because of the varied nature of their operations. Unlike military teams who are sent on deployments, law enforcement SWAT teams do not know when they will need to respond to real-world crises—"game day" often is totally unexpected, so their season is 365/24/7, frequently with no "off" days. Thus, SWAT teams always must stay prepared.

EDUCATING ACTIVE ADULTS, ATHLETES, AND TACTICAL POPULATIONS

The summit outlined education strategies for various population groups. Nutrition education can help alleviate the general confusion that often surrounds the use of dietary supplements. For practitioners, the education goal is applying research to develop practical, easily implemented, science-based recommendations that fit into the athlete's goals. Sports dietitians can serve as a valuable resource for personal trainers and strength coaches, who may have limited nutrition backgrounds. Scientific journals, Web sites (government/military—http://www.nutritioninmedicine.net/neppphp/champ.php), educational institutions, professional organizations (http://www.usada.org/supplement411), industry academies, health associations, third-party certifiers (http://www.usp.org/sites/default/files/video/uspvConsumerEducation/index.html), and trusted colleagues also are good resources.

In developing a performance nutrition plan, the sports dietitian should consider information from the following:

- the strength coach, athletic trainer, physician, manager, and/or agent;
- a health and medical history for complaints of cramping and musculoskeletal injuries;
- a diet record of 3 or more days;
- laboratory results;
- records of past and current diet, weight, body fat, and dietary supplement use;
- lifestyle; and
- most importantly, the athlete's goals.

This information shapes an individualized plan that includes a variety of foods to promote training adaptations, speed recovery, and support overall health. Ultimately, the plan becomes what the athlete eats every day.

Military dietitians working with tactical populations have a similar scope of practice—helping service members

with performance, as well as weight management, eating disorders, and/or other conditions and diseases requiring medical nutrition therapy. New recruits often lack basic nutrition knowledge and may not know what to expect when eating family style in a large dining facility, how to use military rations, or how to best fuel themselves for training and missions. In addition, they may face the challenge of staying within military fitness and weight-for-height standards.

Military dietitians must help develop nutrition education programs that promote healthier food choices and work to ensure that dining facilities provide healthy foods that fuel the warrior athlete. When evaluating dietary supplements, military dietitians often determine if they meet specific criteria by asking "are they **S**afe, **L**egal, **E**thical, and do they **W**ork" (SLEW)? Education is important, but will rarely prove effective if tactical athletes are simply told to "stay away from something." Engaging in a discussion of the pros and cons of particular dietary supplements can help these athletes make more informed decisions. Opportunities for education include existing education programs, one-on-one counseling with dietitians, educational materials developed by sports dietitians, and information provided by other medical and food service professionals. In addition, the US Department of Defense's online Human Performance Resource Center (http://www.hprc-online.org) provides an interactive resource for tactical athletes.

THIRD-PARTY CERTIFICATION: IMPORTANCE AND UNDERSTANDING

The summit considered third-party certification and its role in dietary supplement safety and quality. The safety and quality of dietary supplements are important for all athletes, especially professional, collegiate, and tactical athletes who may need to pass regular drug screening tests. Some dietary supplements are manufactured by established pharmaceutical companies that already have rigorous quality control systems in place, whereas others are produced by companies that may have more limited experience with quality standards. Although all dietary supplement manufacturers are required to follow the FDA's current Good Manufacturing Practices (cGMPs), manufacturers' own quality control standards can vary, potentially resulting in contamination, adulteration, and inappropriate labeling.

One way to enhance the quality of dietary supplements is through third-party certification or verification. This involves an independent third-party agency/organization conducting a quality review of a manufacturer's products and processes to ensure that they meet FDA requirements at the facilities where the products are manufactured. Product quality and appropriate labeling are confirmed by analytical testing.

The FDA published guidance for third-party certifiers in 2009,[12] and since then, an increasing number of manufacturers are voluntarily taking part in certification programs. Products that pass all certification requirements may receive specific recognition and/or a particular seal of participation/certification.

Third-party certification helps ensure quality of dietary supplements.

The 5 primary third-party certifiers in the United States (Figure 1) have developed their own specific approaches, criteria, and processes for evaluating and authenticating products. Each one differs in some ways, but all follow current FDA guidance.

Key elements required by a third-party certifier include documentation from the manufacturer that the

- ingredients are consistent with those listed on the label in the declared potency and amounts,
- product does not contain harmful levels of specified contaminants,
- product will dissolve, disintegrate, and be released into the body within a specified time period,
- product was made according to FDA cGMPs under sanitary and well-controlled procedures, and
- manufacturing plant is in good regulatory standing with the FDA.

Some certifiers also screen for banned substances and conduct random off-the-shelf tests on approved products. This screening process is very important for athletes and military service members, as some dietary supplements can cause positive drug urinalysis tests because of adulteration or the presence of banned/illegal substances. Although certification does not ensure effectiveness or safety, such programs do help promote integrity in the manufacturing process.

Specifically, independent third-party certification can help mitigate some public health concerns about potential contamination and adulteration of dietary supplements. Certification can promote consumer confidence by helping individuals make educated decisions when choosing tested and vetted products. Certification also allows the responsible brands to separate themselves, so that consumers who

Five U.S. primary "certifiers/verifiers"

1) U.S. Pharmacopeial Convention (USP) | www.usp.org
2) NSF International (NSF) | www.nsf.org
3) Informed-Choice | www.informed-choice.org
4) Banned Substances Control Group (BSCG) | www.bscg.org
5) Consumer Lab | www.consumerlab.com

FIGURE 1. Primary third-party certifiers/verifiers of dietary supplements.

are concerned or skeptical can choose the best products. In addition, it gives drug-tested populations the peace of mind that when they use products that are certified, they have less risk of having an accidental doping charge.

ADVERSE EVENT REPORTING

Another area addressed at the summit that is important for dietary supplement safety and quality was adverse event reporting. Some dietary supplements that have claimed they were helpful for weight loss, body building, sexual enhancement, performance boosting, or diabetes were later shown to illegally contain prescription/nonprescription medications, steroids, and stimulants. Such contaminants and/or adulterants or a supplement's ingredients alone may cause minor to serious illness/injury or other adverse events (Table 4). Contaminants and/or adulterants or dietary supplements also may interact with other supplement ingredients and/or prescription/over-the-counter medications to cause illness/injury.

The potential adverse events or illnesses/injuries associated with dietary supplements can include (but are not limited to) cardiac events, exertional heat stroke, seizures, rhabdomyolysis, liver and kidney failure, syncope, psychoses, and even death.[14] It is only through reporting of adverse events that it is possible to detect a signal of harm.

The 2006 Dietary Supplement and Nonprescription Drug Consumer Protection Act requires manufacturers, packers, or distributors to submit to the FDA all serious adverse event reports associated with the use of a dietary supplement. Serious adverse event reports (using the standard FDA MedWatch form FDA 3500A—Mandatory Reporting Form, available at http://www.fda.gov/safety/medwatch/howtoreport/downloadforms/ucm149238.htm) must be mailed to the FDA along with the product label.

In addition, the submitter must provide the FDA with a follow-up report of any related new medical information received within 1 year of the initial serious adverse event report. Dietary supplement manufacturers must maintain records for 6 years related to all adverse event reports they receive. Subsequent to the 2006 act, the FDA issued specific guidance for implementation of adverse event reporting.[15,16]

TABLE 4 Definitions for Adverse Events[13]

Adverse event
''Any health-related event associated with the use of a dietary supplement that is adverse.''
Serious adverse event
''An adverse health consequence that results in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity; or a congenital anomaly or birth defect; or an incident that ''requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described above.''

Adverse event reporting is important, and everyone involved should know how to report adverse events.

Whereas dietary supplement manufacturers are mandated to report serious adverse events to the FDA, reporting by health professionals is voluntary (see steps outlined in Figure 2). A recent survey of military physicians suggests that 3 of 4 physician respondents do not know how or where to report serious adverse events associated with dietary supplements.[14] If physicians do not know where to report adverse events, it is likely consumers have even less knowledge. It is possible that many consumers report serious adverse events to local poison control centers, but unfortunately, the FDA's MedWatch system and poison control centers do not share information with each other. Another way health professionals and consumers can report serious adverse events is through Natural Medicines Watch (Figure 3). This adverse event–reporting tool is specifically designed to include dietary supplements and is integrated with the Natural Medicines Comprehensive Database (http://naturaldatabase.therapeuticresearch.com/content.aspx?page=natmedwatch&xsl=generic&ref=rhmenu). This system eliminates many of the barriers for reporting, allowing quick access to information about commercial products and instructions on how to complete the adverse events reporting form. Importantly, Natural Medicines Watch information is shared with the FDA and is available for research and public health evaluation.

Other governmental systems (eg, Consumer Product Safety Commission), manufacturers, private organizations (eg, American Association of Poison Control Centers), and trade associations (eg, the American Chemistry Council and Consumer Specialty Products Association) capture serious adverse event data on dietary supplements, but at different points on the continuum. These data are not necessarily reported to the FDA. Unfortunately, some of these systems have considerable limitations, and few specifically focus on dietary supplements. Although serious adverse event data are obtainable, it generally is isolated, difficult to access, or in a form that is unusable or hard to analyze. Without a consolidated repository of serious adverse event data on dietary supplements, signal detection is severely compromised. Although existing rules and regulations should adequately protect consumers if manufacturers fully comply with cGMPs and serious adverse event–reporting requirements, the number of serious adverse event reports on dietary supplements is limited. It is estimated that less than 1% of serious adverse

Reporting Serious Adverse Events to the FDA:

Manufacturers are ***required*** to report by completing MedWatch Form 3500A and mailing it with a product label to the FDA.

Healthcare professionals and consumers can ***voluntarily*** report to the FDA with the paper Voluntary Reporting Form 3500 (Request form by telephone at 1-800-FDA-1088 or online) in one of three ways:

1) Online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm

2) Via Fax to 1-800-FDA-0178 or

3) By mail using the form's postage-paid address

FIGURE 2. How to report serious adverse events for dietary supplements to the Food and Drug Administration.

events are reported,[18] and recent reports indicate some manufacturers underreport adverse events and do not comply with cGMPs.[19] This underscores the need for enhanced enforcement to ensure all manufacturers act responsibly. Healthcare professionals need to talk to their patients about dietary supplements to educate them about product use and the importance of identifying and reporting any potential health concerns using tools such as

- taking a dietary supplement history (http://hprc-online.org/dietary-supplements/files/guidelines-for-taking-a-comprehensive-dietary-supplement-history-pdf) and
- reporting dietary supplement serious adverse events (http://hprc-online.org/dietary-supplements/resources-1/files/HPRC_Reporting_Adverse_Events_2.pdf).

RESEARCH CONSIDERATIONS

The final area addressed at the summit was dietary supplement research and future study considerations. Research provides the evidence base for healthcare professionals and practitioners to make sound recommendations on dietary supplement use for active adults, adolescents, athletes, and tactical populations. It is important to first identify possible performance determinants and outcomes, whether at the basic level of energy metabolism or cellular homoeostasis or, more generally, at the whole limb or whole body level. To ensure scientific rigor, protocols for measuring performance and a strong and experienced research team are needed. The strength of the evidence comes with consistency of outcomes published in a body of research, later confirmed through consensus among experts, and culminating in scholarly reviews and position papers of professional organizations. Verification and certification of product ingredients are an essential part of any dietary supplement study.

Populations (generalizability), responders/nonresponders, timing and duration, end points, and doses are just some of the challenges facing dietary supplement research. Most studies are a snapshot in time, which may not reflect consistent effects over the longer term. The use of multiple dietary supplements within a study may create interactions that are impossible to adequately parse out and evaluate. Long-term safety studies on individual supplements to evaluate interactions with other products, genes, and the environment often are lacking.

The National Institutes of Health's Office of Dietary Supplements has supported multiple evidence-based systematic reviews on the safety and efficacy of dietary supplements to define the current level of science and inform future research needs and directions. The Office of Dietary Supplements also supports an Analytical Methods and Reference Materials Program to enhance methods development and validation and to develop reference materials for use in clinical and research studies.

Ongoing challenges in dietary supplements research include the following:

- overcoming strongly held beliefs regarding the efficiency of supplements,
- the need to differentiate a supplement's response in relation to the background diet,
- selection and enhancement of appropriate study or experimental designs, and
- the continual handicap of interpreting studies with small sample sizes.

Research consortia among government, industry, and academia may hold promise for research on dietary supplements and improvement of human performance.

One of the recommendations from the Human Performance and Dietary Supplements Summit was to consider a consortium approach (ie, industry/academia/government partnership) to conduct and support long-term studies on human performance and dietary supplements.

Serious adverse events can be reported through Natural Medicines Watch

https://naturaldatabase.therapeuticresearch.com/nd/adverseevent.aspx

All serious adverse events reported through Natural Medicines Watch are sent to the FDA's MedWatch

FIGURE 3. Reporting serious adverse events for dietary supplements to Natural Medicines Watch.[17]

Summit attendees identified the following areas for future research:

- understanding unique training and education needs related to dietary supplements and human performance for specific populations—elite athletes (both adults and youth), tactical athletes, and active individuals;
- underrecovery, overtraining, and the impact of fuel timing;
- safety, efficacy, and long-term use of dietary supplements in youth populations; and
- improved neurocognitive performance, improved recovery from training, correction of sleep disturbances, and increased protein needs during caloric deficit.

SUMMARY

The summit reported that continued research is needed to define the nutrition needs of active adults, athletes of all ages, war fighters, tactical units, and first responders and to identify specific strategies, including the use of dietary supplements, to optimize their performance. Third-party certification programs and increased attention to serious adverse event reporting can help strengthen the safety and quality of dietary supplements. Finally, education is fundamental to the most effective use of dietary supplements and should become a primary goal of medical, nutrition, and performance professionals in their work to help active adults, athletes, and tactical populations meet their unique performance goals.

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