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Issues of testing for hGH: collection

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Urine has limitations as a substrate for anti-doping efforts and within the last decade sports organizations have begun collecting blood samples in cooperation with anti-doping laboratories. Within the US, authorization to perform a blood draw is determined by the scope-of-practice licensure regulations in each state. Blood collection requires equipment not necessary in standard anti-doping urine collections. There is a need for greater privacy and cleanliness than the usual site for urine collection provides. One of the most challenging aspects of a blood collection is complying with the guidelines for specimen transport. In addition to the standard chain-of-custody protocols that collectors must follow for urine, blood samples call for additional handling to ensure they arrive at the anti-doping laboratory in a condition that allows for analysis. While the invasiveness of the process increases liability risk to the collector, following established standards, guidelines and anti-doping protocols will minimize risk. One significant advantage of blood over urine in anti-doping settings is that specimen adulteration or manipulation is nearly impossible. Therefore, for blood-only collections, sports organizations should explore opportunities for collaboration with the American Red Cross or private blood-collection centres/clinics. Copyright © 2009 John Wiley & Sons, Ltd.

Few athletes can remember a time when anti-doping programmes were not in operation before or after competition. Although doping, the use of banned substances to gain an artificial advantage, has been traced back to some of the earliest times of organized sport, sport has only had the scientific capacity to detect it within the past four decades.

From the beginning of the anti-doping movement, urine has been the substrate used by anti-doping laboratories to detect banned substances. It had and has a number of advantages over other substrates such as blood, hair and sweat. Urine samples are easy to obtain in a sport setting and urine transports without the need for special handling or refrigeration. Hydrated athletes find the urine-collection process to be non-invasive, easy to follow and, aside from limited cases of 'shy bladder', the provision of a urine sample is something that comes quite naturally.

Anti-doping laboratories are built around the use of urine for drug analysis. Urine provides excellent retrospectivity for many of the banned substances. Our scientific foundation for defending legal challenges is built upon years of research using urine.

Urine has limitations as a substrate for anti-doping efforts and within the last decade sports organizations, in cooperation with anti-doping laboratories, have begun collecting blood samples. Within the US, blood collections are quite rare, the primary exception being those testing programs under the authority of the US Anti Doping Agency. However, the lack of a urine-based test for hGH has forced anti-doping organizations to examine the use of blood to detect hGH. For that reason, US sports organizations have begun to study the implementation of blood-collection protocols for their anti-doping initiatives.

According to the American Red Cross, 38 000 blood donations are needed every day in the US, and over 15 million blood donations are conducted each year in the US.^[1] However, in the context of sport there is a level of uneasiness about blood collection. This concern has not been quantified or studied but we may opine that it is related to worry about harm to the athlete during the collection process, the invasiveness of the use of needles or the increase in legal liability to the collector/phlebotomist and anti-doping organization.

Standards for phlebotomy differ by country. In some cases, the standard of practice requires a licensed physician to draw the blood or the presence of a physician is required on site during this process. Within the US, authorization to conduct a blood draw is determined by the scope-of-practice licensure regulations in each state. For example, in California, a limited phlebotomy technician is authorized to do skin-puncture blood collection only; a certified phlebotomy technician I is authorized to do venipuncture and skin punctures, and a certified phlebotomy technician II is authorized to do venipuncture, arterial puncture and skin punctures.^[2] Most states require that phlebotomists be first-aid trained.

Blood collection requires equipment that is not necessary in standard anti-doping urine collections. Additional required equipment includes sterile needles (typically, 21–23 gauge), butterfly needles, disposable syringes, vacutainer tubes, gloves/eye protection, tourniquets, bio-hazard waste and spill equipment, a cold box and temperature-monitoring device and the standard chain-of-custody materials and forms. Early blood-collection protocols required blood samples to be centrifuged prior to transport but this procedure is no longer necessary for blood samples slated for hGH analysis only. If separation is necessary, serum separator tubes may be used or basic mobile centrifuges can be utilized on site

Anti-doping personnel have proven repeatedly that a urine collection can be successfully completed in the most primitive conditions. Blood samples cannot be collected in such settings. There is a need for greater privacy and cleanliness than the usual site for urine collection provides. The venue must be well lit and well ventilated. A comfortable chair or bed for sample provision must be provided. Further, the collection guidelines call for a refrigerator or cool box for blood samples.

The World Anti-Doping Agency guidelines for collecting blood samples from athletes include a period of relaxation and hydration for the athlete prior to the draw.^[3] This period becomes necessary following exercise. The protocol calls for venipuncture of the antecubital vein of the non-dominant arm. The

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collector/phlebotomist must collect enough blood to complete two 5 mL samples (A and B). As a comparison, one US pint equals 500 mL, one ounce is about 30 mL and a standard teaspoon is 5 mL. To protect the athlete, WADA guidelines limit draw attempts to three.

One of the most challenging aspects of a blood collection is complying with the guidelines for specimen transport. In addition to the standard chain-of-custody protocols that collectors must follow for urine, the blood samples call for additional handling to ensure they arrive at the anti-doping laboratory in a condition that allows for analysis. The samples must be stored and transported in a 'cool box'. The 'cool box' must provide the conditions to maintain the samples at 2 $^{\circ}$ C to 8 $^{\circ}$ C (about 36 $^{\circ}$ F to 46 $^{\circ}$ F). The box must include a device to indicate temperature deviation during transport. The samples should arrive at the laboratory no later than 48 hours from collection.

The guidelines for trained phlebotomists, additional equipment, improved facilities and refrigerated transport cause blood collections to be significantly more expensive than urine collections. In the US, a urine collection can cost a few hundred dollars per sample, including the costs of supplies, personnel, on-site expenses and specimen transport. For blood samples, the collection and transport expenses alone can be well over \$1000 per sample (Staffan Sahlstrom, IDTM, Stockholm, Sweden. Personal correspondence). Most, if not all, athletes are ideal blood donors (young, healthy, strong) but venipuncture brings risk of subsequent bruising and soreness. Utilizing well trained and experienced phlebotomists,

appropriate timing of the donation and a well-hydrated donor will significantly minimize problems. The invasiveness of the process increases liability risk to the collector but following established standards, guidelines and anti-doping protocols also will minimize risk. In the case of non-adult athletes, the presence of a parent or witness should be a requirement of the collection protocol.

One significant advantage of blood over urine in anti-doping settings is that specimen adulteration or manipulation is nearly impossible. Unlike urination, where the process requires significant vigilance by the trained collectors and escorts to guard against urine substitution, catheterization, adulteration through the instruction of substances such as oxidizing agents, and so on, phlebotomy simply makes such practices improbable. Therefore, for blood-only collections, sports organizations should explore opportunities for collaboration with the American Red Cross or private blood-collection centres/clinics.

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