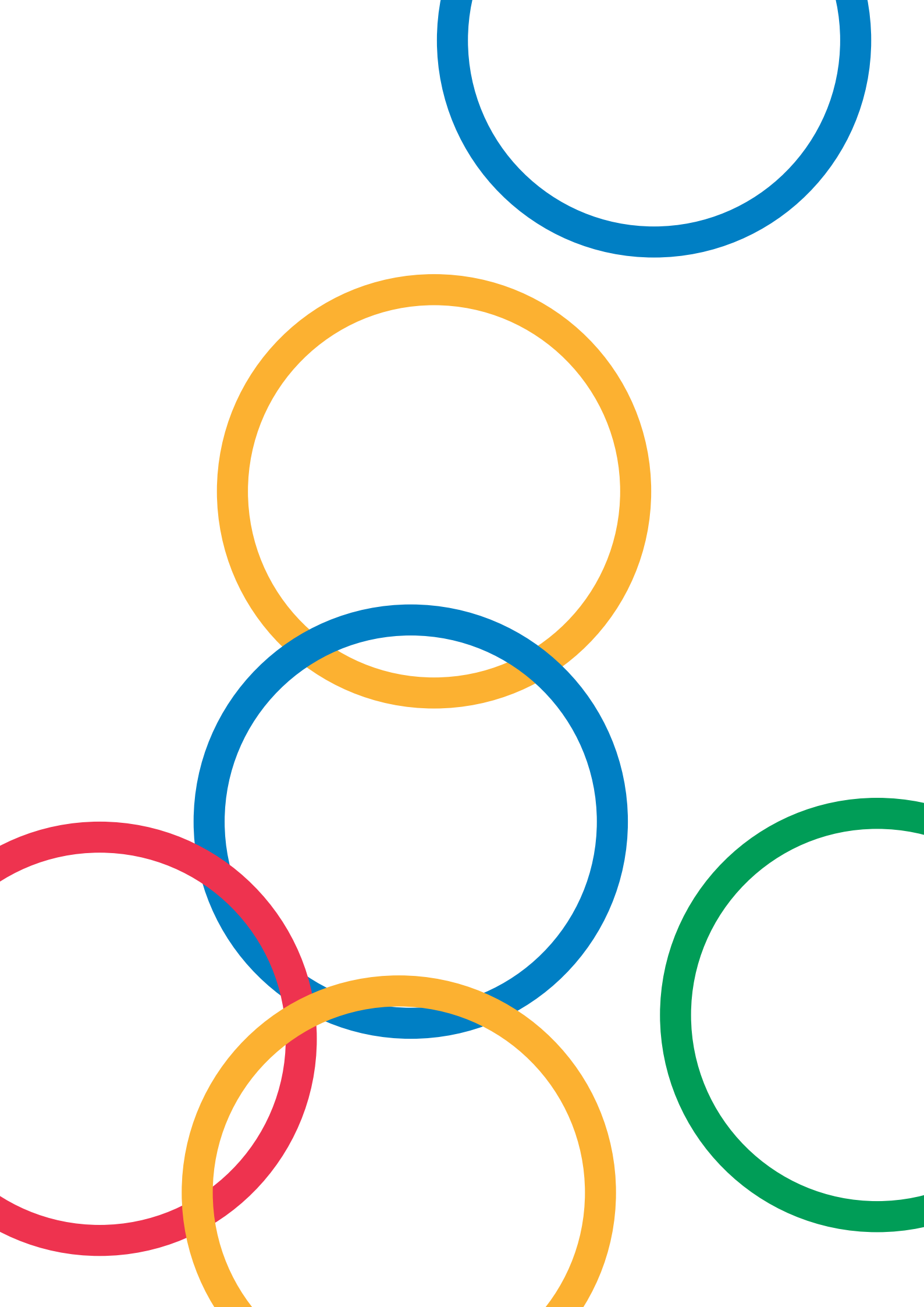


THE ATHLETE BIOLOGICAL PASSPORT:

IS THE ATHLETE BIOLOGICAL PASSPORT AN
EFFECTIVE TOOL IN THE FIGHT AGAINST DOPING?

LAUSANNE, 2013





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EXECUTIVE SUMMARY

BACKGROUND

The ABP program is a new anti-doping testing paradigm based on personalized monitoring of biomarkers of doping. The first of three Biological Passport modules being officially approved by the World Anti-Doping Agency (WADA) end of 2009 was the Athlete Hematological Passport (AHP). It analyzes biomarkers related to the detection of manipulation of production of red blood cells (RBCs), which leads to increased oxygen transfer to the muscles and can enhance significantly the overall physical performance of an athlete. The ABP is hailed as a fundamental step in the fight against doping, able to provide an end to the pharmaceutical race between cheating athletes and anti-doping control. Since then, the program has been implemented by several International Federations (IFs) and Sport Organizations (SOs) according to WADA's requirements, which used the program as well for the London 2012 Olympic Games.

OBJECTIVES

This research analyzes the experiences of several international Sport Organizations (SOs) that have implemented the ABP program as one tool within their anti-doping strategies. The aim is to provide an insight in how these organizations evaluate the effectiveness of this new anti-doping paradigm, especially focusing on advantages, disadvantages and limits as well as their view of the effectiveness of the program.

METHODS

For this purpose, the following research methods have been used: Literature review, expert interviews (personal and by phone) and the analysis of the results of the interviews. 12 organizations have been contributing to the results of this study through interviews with a total of 21 experts, amongst them top level sport governing officials. The scope of this research was restricted to the analysis of the current status of implementation of the ABP by the SOs interviewed, with regards to their goals of implementation, advantages versus disadvantages and limits, their evaluation of effectiveness of the ABP as a tool and lessons learned during the implementation and running of the program in order to give good advice to SOs interested in implementing the program in future. Conclusions have been developed based on the information captured through expert interviews.

RESULTS

The results are based on the experiences of SOs which run the program and participated in this survey. They confirmed the implementation goals of targeting, doping detection, test efficacy, and deterrence and prevention, adding additional objectives such as proofing that the implementation of the tool with limited resources is possible, image enhancements and protection and health of athletes. However, they are well aware that a 100% doping-free sport will not exist: "Doping is like crime in normal society - We should fight against it but never expect to solve it completely" (Verbruggen).

Nevertheless, each organization sees an extensive list of advantages of longitudinal profiling with individual reference values, especially when compared to conventional testing methods. Shifting from blind testing to monitoring of profiles leading to smart test decisions make a higher efficacy on the long term possible. In addition, the passport is a way to make the deterrence visible: Some organizations are monitoring trends of abnormal profiles going back to normal. The possibility to get an overall idea of prevalence in doping in an athletes' population as well as making visible the deterrence effect by following athletes ideally over the period of their professional career is evaluated as a possible enormous optimization in the fight against doping.

However, downsides of this new anti-doping paradigm and limitations are recognized as well: The costliness of the tool, logistical challenges in the process and the number of many experts and stakeholders involved in interpreting the profiles make the management of results is much more demanding and complex than in traditional anti-doping tests. But organizations who implemented the tool state that the effort is worth it.

CONCLUSIONS

In conclusion, SOs that participated in this survey are confident to be on the right path in the fight against doping. However, this is still more a "feeling", as effectiveness is hard to be measured through merely economic analysis by now. This new approach is still in the infancy phase by having implemented one of 3 modules of the program in some organizations. As success can be mentioned that all ABP cases that went to CAS have been won so far, this can be used as proof of robust method for detection of doping. The tool is showing signs of a very promising future by bringing the anti-doping community one step further towards preserving the spirit of sport, the essence of Olympism, of playing true (WADA, Anti-Doping Code 14).

ABOUT THIS RESEARCH

BACKGROUND

The ‘Athletes Biological Passport’ (ABP) program is a new anti-doping testing paradigm based on personalized monitoring of biomarkers of doping. The first of three Biological Passport modules being officially introduced by the World Anti-Doping Agency (WADA) in December 2009 was the Athlete Hematological Passport (AHP). It analyzes biomarkers related to erythropoiesis, the process of producing red blood cells (RBCs). By manipulating the production of RBCs, oxygen transfer to the muscles is increased which can enhance significantly the overall physical performance of an athlete. Since the release of the official guidelines for the AHP module, the program has been implemented by several International Federations (IFs) and Sport Organizations (SOs) according to WADA’s requirements. Six IFs used the program as preparation for and during the London 2012 Olympic Games (OGs), five of them being amongst the 12 SOs interviewed for this paper.

Recent developments in the availability of doping substances identical to those naturally produced in the human body represent an enormous challenge for traditional anti-doping detection methods. As doping leaves a fingerprint in the athlete’s physiology and the ABP aims to detect exactly these alterations, the ABP is hailed as a robust tool able to provide an end to the pharmaceutical race between cheating athletes and anti-doping control (Sottas, Robinson and Rabin).

RESEARCH OBJECTIVE AND RESEARCH QUESTION

The purpose of this research is to analyze the experiences of these IFs and SOs with special focus on advantages, disadvantages and limits as well as their evaluation of the effectiveness of the program. The aim is to provide the reader with a summary of SOs experiences with the ABP showing if the goals of implementation of the program were actually met or not. The research question is therefore the following:

“The Athlete Biological Passport: Is the ABP an Effective Tool in the Fight against Doping?”

The results were collected through expert interviews and are based on the experiences of several organizations which run the program. The scope of this research was restricted to the analysis of the current status of implementation of the hematological module by the SOs interviewed, with regards to their view on the following points:

- Goals of implementation
- Advantages versus disadvantages and limits
- Their evaluation of the effectiveness of the ABP as a tool
- Lessons learned during the implementation and running of the program in order to give good advice to SOs interested in implementing the program in future

Conclusions have been developed based on the information captured through Expert Interviews.

METHODOLOGY

For this report, the following research methods have been used:

1) LITERATURE REVIEW:

An online research was conducted on Google and Google Scholar using the following keywords: athlete biological passport, hematological profile, steroidal profile, longitudinal profile, indirect doping detection, doping, doping in sport, doping in endurance sports, London 2012 Olympic Games, effectiveness of anti-doping programs. This resulted in the collection of a large range of scientific articles published by renowned research journals of the field of medicine and doping. In addition, web pages of all SOs interviewed were scanned for relevant information, with special focus on press releases of doping cases as well as the information published about anti-doping activities and programs. Relevant literature, presentations and additional reference material provided by the Supervisor of this research, the Interviewees and additional Mentors for this research was taken into account, too.

2) EXPERT INTERVIEWS:

Expert interviews with current stakeholders of the ABP program were conducted. The selection of the SOs was based on the implementation status of the program and/or the special approach they have decided to take with regards to the ABP:

- Anti-Doping responsables of the ABP program at International Sport Organizations who have implemented the hematological passport (UCI-CADF, IAAF, FINA, FISA, ITU, UIPM, and SportAccord, who runs the ABP program for ISMF and CMAS).
- Anti-Doping responsables at FIFA and UEFA, looking at a special approach and view with regards to longitudinal profiling methods.
- Anti-Doping Organizations (WADA, Anti-Doping Switzerland)
- Umbrella Sport Organizations (IOC, SportAccord, ASOIF)

The aim was to provide a 360 degree view from stakeholders which can contribute to a proof of effectiveness of the ABP program. In terms of participation at this survey, the only organization that decided not to take part at the interviews was FINA, due to the preliminary stage of implementation of their ABP pilot program. As type of interview methods, the semi-structured approach was selected using open questions. This interview method has the advantage to be good at uncovering details as unanticipated topics can be explored and questions can be modified, added or eliminated. In that way, the questions set up as interview guidelines were modified depending on the

organization and job responsibilities of the interviewee. The duration per interview with interviewees in operative functions was on average 2 hours, while interviews with presidents or directors of an organization were on average conducted during 30 minutes. The full list of all Experts interviewed can be found below Appendix I. Appendix II shows the interview guidelines set up for interviewees in operative functions, while in Appendix III includes the questions selected for the top management level.

3) ANALYSIS OF INTERVIEW RESULTS:

A situation analysis was done to illustrate the results of the research – the existing views on advantages, disadvantages, limits, effectiveness, wishes, needs, the evaluation of effectiveness of the ABP as a tool as well as the view of the future of the program of the SOs interviewed are grouped and analyzed, and conclusions are derived with regards to the research question.

These three research methods described above have been selected to achieve the following outcomes:

1. To understand the current situation, the goals and status of implementation and special needs of the SOs interviewed.
2. To capture evidence of the effectiveness of the ABP program by identifying advantages, disadvantages, limits SOs definition of effectiveness and future needs and wishes.
3. To derive conclusions based on the evidence identified and contributing to best practice sharing of knowledge between federations.

All literature and materials used for this research have been referenced accordingly within this report.

INTRODUCTION TO THE ABP CONCEPT

“It is an illusion to believe that doping can be completely eliminated. To cheat is part of human nature” (Oswald). Indeed, anti-doping programs seeking to preserve “what is intrinsically valuable about sport: It is the spirit of sport, it is the essence of Olympism, it is how we play true” (WADA, Anti-Doping Code 14) have been moderately successful in the past. “Conventional testing methods have proven to be inefficient – there is no other way than to further develop in doping preventing strategies. The alternative would be the end of sport” SportAccord President Hein Verbruggen says (Verbruggen).

Are regularly blood tests, summarized in a blood passport, a breakthrough in the fight against doping? Will there be only clean athletes in future? This study will show the experiences and view of several International Sport Organizations (SOs) aiming to discover how they evaluate the effectiveness of this new tool in the fight against doping.

HISTORY OF THE BLOOD PASSPORT

Doping can be defined as ‘changing the physiology of an athlete artificially to perform better’ (P.-E. Sottas, WADA Manager Biological Passport). In the 1970s, blood transfusion (BT) became popular amongst elite endurance athletes as an effective means to increase the number of red blood cells (RBC) leading to a higher oxygen transport capacity which significantly improved athletic performance (Giraud, Sottas and Robinson). In the early 1990s, recombinant erythropoietin (rhEPO) replaced BT as the doping method to increase RBC mass – it was easier to administer and less challenging logistic wise – a development which was turned back in 2001 with the introduction of a method for direct detection of rhEPO in urine (Giraud, Sottas and Robinson). Not only since then, researchers and scientists have made significant efforts in finding a direct method to detect performance enhancers similar or identical to substances produced naturally by the human organism, or the detection of autologous BT doping; up to now without considerable success (Giraud, Sottas and Robinson). It was already recognized in the end of 1960s that the detection of substances that are naturally produced by the human body was challenging (Sottas and Vernec). Hence, the prevailing opinion of direct

testing approaches being ineffective as they solely rely on the detection of features dependent on the process of BT (for example the detection of additives and plasticizers released by BT bags) led to a shift in scientists’ focus: To the development and validation of indirect markers of autologous BT (Giraud, Sottas and Robinson).

In the early 2000s, WADA began to further develop and validate the concept of the “Athlete Biological Passport”, a longitudinal approach with a series of test results, together with numerous stakeholders from the world of sport and medical experts with the aim to provide an additional tool for a more sophisticated, intelligent and complementary strategy in the world-wide fight against doping. Recent developments in athletes’ doping behavior, the availability of performance enhancing substances identical to those produced in the human body (such as EPO, testosterone and GH) and the fact that doping regimens became highly scientifically organized, taking full advantage of the weaknesses in conventional detection procedures of prohibited substances in biological samples collected from athletes, underlined the eminent need for an alternative drug-testing paradigm (WADA, ABP Operating Guidelines Version 3.1), (Sottas and Vernec). With the first version of the World Anti-Doping Code (WDAC) published in 2003, allowing the possibility to base an ADRV on biomarkers, the basis for a powerful tool to drive universal tests of blood doping was set (WADA, Anti-Doping Code): The ‘Abnormal Blood Profile Score’ (ABPS) is based on a statistical classification of indirect biomarkers sensitive to any form of blood transfusion, autologous transfusion included. It detects BT three times better than current models and is independent of whether the athlete is taking or stopped the treatment (Sottas, Robinson and Giraud). During the last decade, scientists focused on the implementation and optimization of the sensitivity of the hematological passport by including multiparametric markers specific to blood doping, heterogeneous factors such as gender, age and ethnic origin and the use of probabilistic inference techniques to evaluate longitudinal data (Sottas and Vernec). As the very first International Federation (IF), the International Cycling Union (UCI) implemented the hematological passport in January 2008.

In December 2009, WADA's publication of the first version of the 'Athlete Biological Passport Operating Guidelines' and accompanying Technical Documents set the basis for a world-wide harmonized longitudinal profiling program and methods of gathering biomarkers of doping and related information. The aim of these guidelines was to enable ADOs to pursue ADRVs in accordance with Article 2.2 of the WADC and simultaneously use biological data for intelligent, targeted testing of athletes within a robust and reliable framework ensuring the ability to withstand legal and scientific challenges at the highest level (WADA, ABP Operating Guidelines Version 3.1). Since then, a number of passport cases have been treated by the Court of Arbitration of Sport (CAS) validating the longitudinal method as a reliable means of indirect detection of doping methods (Sottas and Vernec).

PRINCIPALS

The ABP of an athlete refers to an individual electronic record in which doping test history together with the athletes' own reference ranges are stored as a profile of biomarkers, including also additional information such as exposure to altitude and physiological aspects (e.g. gender, age, ethnic origin). The main characteristic of the ABP might be the elimination of in-between-subject variances in order to personalize the evaluation of the biological data and to detect changes in the physiology of the athlete (Sottas and Vernec). Deviations from the individual reference ranges of a biomarker may indicate either a pathological condition or the abuse of a doping substance; both cases being a good reason for holding back an athlete from competing (Giraud, Sottas and Robinson).

The concept of the ABP is based on regular monitoring of biomarkers of doping over a period of time. Biomarkers of doping aim to detect the biological fingerprint of doping on the biology of an athlete by revealing key modifications in biological parameters induced by the

doping product used using the same logic as biomarkers of a disease detect fingerprints of a disease (Sottas and Vernec). It is now seen as a reliable method to detect indirectly the use of prohibited substances and methods: As opposed to the traditional direct detection methods, the substance or method itself is not detected, but its effects on the body are revealed. Mostly, the drug itself may be quickly excreted or degraded after the act of doping; therefore detection is extremely difficult unless testing is carried out at a very specific point of time (WADA, ABP Operating Guidelines Version 3.1).

Hence, measuring biomarkers of doping over time can show the act of doping by disclosing physiological changes on the athlete's biology, even for performance enhancing drugs to come in future (as not the substance is being detected, but the profile reveals an abnormality) (Sottas and Vernec). Through the longitudinal approach using a series of measurements of biomarkers of blood doping obtained from the same individual, the between-subject variations which were known to be large are eliminated: One athlete is compared to his or her own values and individual reference ranges (Sottas and Vernec). Still with this very sensitive and individualized method of doping detection micro-dosing of doping might be undetectable if the physiological fingerprint remains within the athlete's own reference range (Sottas and Vernec).

MODULES

The ABP program consists of three modules:

1. The Athlete Hematological Passport (AHP), based on blood testing to detect blood doping.
2. The Athlete Steroidological Passport (ASP), based on urine testing, used to detect anabolic steroids.
3. The Athlete Endocrinological Passport (AEP), based on urine testing, aiming to detect growth factors such as GH, IGF-1 and GHRP.

The hematological module was the first one to be implemented by the release of WADA's Guidelines in December 2009 and has been adopted by over 30 ADOs according to WADA's requirements, covering over 10.000 athletes' hematological profiles by the time this report was written (Sottas and Verneq), (P.-E. Sottas, WADA Manager Biological Passport). It measures several blood parameters (hematocrit, hemoglobin, red blood cells, reticulocytes, mean corpuscular volume, hemoglobin and hemoglobin concentration, absolute number of reticulocytes and reticulocytes percentage) which are used to calculate an index of stimulation (OFF-score) and an Abnormal Blood Profile Score. Only the HGB and Off-hr score are taken into account by the Bayesian model used for identifying a possible ADRV (WADA, ABP Operating Guidelines Version 3.1) (Sottas, Robinson and Saugy, The Athlete's Biological Passport and Indirect Markers of Blood Doping).

Research on the steroidal module has significantly advanced over the last years. The plan is to implement this second module of the passport during the course of 2013, which will significantly increase the amount of athletes subject to a longitudinal doping measurement: Basically, every athlete tested will then have an ABP. The implementation of the steroid module will thus require an essential increase of resources, both financially and manpower-wise. By now, the ABP is effective in its fight against blood doping – however, the potential of the modules to come is enormous (Sottas and Verneq).

This report concentrates on the evaluation of the experiences with the hematological module already implemented by several SOs and will therefore not include the future modules to come.

OBJECTIVES OF IMPLEMENTATION

The overall goal of integrating the hematological module of the ABP program as an additional tool in a robust anti-doping program besides of providing proof of a doping offense is to optimize anti-doping programs through intelligent testing, using financial means and manpower in a more efficient way in the fight against doping contributing significantly to the ultimate mission of securing drug-free clean sport and fair competitions. Thus, the purpose is to establish the possible use of a prohibited method or substance indirectly as well as to use biological data to apply traditional doping controls and/or targeting more intelligently (WADA, ABP Operating Guidelines Version 3.1), (Donzé), (Niggli). In summary, it means:

- a) Targeting: Identify and target athletes for specific standard analytical testing such as EPO urine test, CERA blood tests or homologous BT by the interpretation of the blood passport profile
- b) Test efficacy: Increase effectiveness of testing by a more intelligent way of selection of whom to test, resulting in decreasing tests of athletes who show normal blood profiles.
- c) Doping detection: Pursue ADRV's in accordance with the Code Article 2.2.
- d) Deterrence and prevention: Make use of the tool as means for deterrence in order to decrease the prevalence of blood doping for a certain sport or sport in general.

During the expert interviews conducted for this research, it was critically questioned if these objectives have been met for the SOs which run the program today, and how effectiveness for the hematological ABP module is defined by those organizations. The results are displayed within the next chapter of this report.

RESULTS OF EXPERT INTERVIEWS

This chapter summarizes the results captured through the Expert Interviews conducted during the months of August and September 2012. Large knowledge has been gained from the interviews; however, results are going to be displayed only if they are relevant for the research question.

4.1 STATUS AND GOALS OF IMPLEMENTATION

Time wise, the experience with the hematological module of the ABP is very heterogeneous amongst the SOs interviewed.

UCI was the first IF to implement the ABP program early 2008. As an IF, they had already a long-lasting experience with blood testing (FIS was the first IF implementing blood tests in 1995, followed by UCI in 1996 (P.-E. Sottas, WADA Manager Biological Passport). However, also other SOs feature a vast experience in blood testing in- and out of competition, such as FISA (since 2001)

or IAAF (since 2001), before implementing the official blood passport. By now, more than 30 organizations have implemented officially the blood passport (P.-E. Sottas, WADA Manager Biological Passport).

Within this chapter, overviews of the results of the interviews conducted have been created with the purpose to develop an understanding where each SO interviewed stands at the moment with its program. Figure 1 gives an overview of the official start of the program at each SO as well as their special focus of testing.

Figure 1: Overview of Implementation Start

	CMAS*	FISA	IAAF	ISMF*	ITU	UCI	UIPM
Start of ABP program	January 2012	2011	2009	October 2011	2011	January 2008	Beginning of 2012
Program based on	OOC tests for blood profiles introduced from scratch	Mass PC- and OOC testing for blood profiles	Mass PC- and OOC testing for blood profiles	OOC tests for blood profiles introduced from scratch	OOC and PC testing for blood profiles, in addition to IC tests. Shift of urine tests from IC to OOC.	OOC testing as basis for blood profiles, PC and IC are included into profiles. Urine samples for steroid profiles are being collected now, too.	PC testing for blood profiles, in addition to some OOC tests

* managed by SportAccord. Source: Expert Interviews

All SOs interviewed confirmed the implementation goals which were outlined below chapter 2: Targeting, doping detection, test efficacy, and deterrence and prevention. Denis Oswald, ASOIF President, underlines the importance of the deterrence effect: “An athlete can always cheat in one occasion without being detected, but with several measurements this will be visible. Thus, deterrence is one big goal” (Oswald).

However, there are additional objectives which are specific to the nature of the sport or size of the SO. Such an additional objective is, for example, to prove the possibility to run the ABP program with very limited resources and counter the prevailing perception that such a program can only be implemented by rich organizations (Dagouret and Vallini). Code compliancy might be another reason for implementation (Dagouret and Vallini).

In 2011, FIFA also decided to make use of the ABP. With the support of WADA, they are piloting a different approach of the passport at the moment, combining blood profiles with urine longitudinal profiling: During training sessions, unannounced urine tests are conducted on complete teams for setting up a steroid profile, while in competition, only blood samples of 2 selected players per team are taken. With this, in addition to a more intelligent testing and smarter decisions for whom to include into the international registered testing pool (IRTP), their goal is also to manage and reduce costs for In-Competition (IC) tests. Blood tests are taken much faster than urine tests, and can be much better timed in order to avoid the delay of transportation of a whole team and their charter flight which results in better forecasting of costs. The idea is to implement the steroid profile plus blood analysis at the World Championships 2014, in case the pilot proves successful (Dvořák).

Nevertheless, even being convinced about the ABP tool being one important additional tool in world anti-doping strategies, top level sport governing officials do not see things through rose-colored glasses: “Doping is like

crime in normal society - We should fight against it but never expect to solve it completely” (Verbruggen). And: “It is an illusion to believe that doping can be completely eliminated. To cheat is part of human nature” (Oswald).

This is where the mission of a National Anti-Doping Organization (NADO) can contribute massively to educate future elite athletes to come: Dr. Kamber, Director of Anti-Doping Switzerland, sees the goal of his ABP program primarily in the prevention and education of young athletes, and not in the detection, sanctioning and legal prosecution. The earlier an athlete starts with a profile, the better: He can prove that his performance is based on clean sport, and he is prevented from being tempted at one point in his career from abuse of forbidden substances and methods, as this would clearly be visible in his longitudinal profile (Kamber, Director Anti-Doping Switzerland). In addition, with the CleanWater project, Anti-Doping Switzerland together with its cooperation partners and its sponsor provided 10 swimmers the possibility to take part in a pilot ABP program, accompanying the athletes over a period of 2 years until the London 2012 Olympic Games (OG), promoting as such doping free Swiss Swimming. Both Swiss Swimming and participants benefitted from an improved image in the public and the media (Kamber, Director Anti-Doping Switzerland), (CleanWater).

In terms of size, programs also differ considerably. To get an understanding about the size, figures related to the number of athletes subject to the passport (Figure 2), number of tests performed as well as budget (Figure 3) have been collected. Athletes being subject to the passport are mostly athletes from endurance disciplines (Figure 2). The idea is there is to target performance enhancements through blood doping (P.-E. Sottas, WADA Manager Biological Passport). The RTP rules are generally the basis for the selection of an athlete being subject to ABP tests (Figure 2).

Figure 2: Athletes subject to the Program and Selection Criteria

	CMAS*	FISA	IAAF	ISMF*	ITU	UCI	UIPM
Athletes subject to the Passport	6 athletes take part; focus is on the discipline "fin swimming"	All athletes in RTP subject to blood testing	More than 3200 athletes have a profile; approx. 200 athletes are in the focus.	26 athletes have a profile.	All athletes in the RTP (30 male and 30 female athletes)	955 professional road riders now (Pro Tour Teams and Pro Continental Teams) plus 150 athletes of other cycling disciplines.	All senior athletes competing at the World Championships (approx. 100 male and 100 female athletes).
Athlete selection based on	Top ranked athletes in disciplines with doping risk are in the RTP and subject to ABP tests.	RTP rules (Performance-based selection of top-level athletes, athletes who missed tests, abnormal blood results, and origin of a country with low testing history, other reasons, and random selection).	RTP (top ranked athletes, based on statistics on risk factors such as country, discipline, abnormal profile in previous tests, whereabouts, steroid parameters and random selection).	Top ranked athletes in disciplines with doping risk are in the RTP and subject to ABP tests.	Performance and Ranking, Risk assessment (Country with low testing history, problems in other sports), sudden and unexpected performance changes.	Performance, suspicious due to risk assessment (e.g. country, discipline), reinstatement after a suspension, abnormal profile, other sources (from NADOs / other athletes).	Performance and ranking, based on results and random selection.

* managed by SportAccord. Source: Expert Interviews

In addition, the discipline plays a significant role: For example, IAAF sets the focus of their ABP program on endurance disciplines (400m and above, Marathons, Race Walks). Also, IAAF takes into account if an athlete was inscribed to a competition, but did not show up after the announcement of a PC tests for all athletes competing, which was the case at the World Championships in Daegu, Korea, in 2011 (Capdevielle and Garnier)

ITU stated that because of intelligence of the passport program as well as good cooperation with NADOs for performing tests and sharing information, they could reduce the number of athletes in their RTP (Buchanan).

Regarding the number of tests performed and the budget spent (Figure 3), an additional interesting figure to look at is costs per case. A calculation of this figure taking into consideration budget spent by number of tests performed has been done as shown in Figure 2, however, this figure is not comparable between the SOs: The concept included into the budgets given by SOs differ (total anti-doping budget versus only ABP Program, administration costs of the program in- or excluded, etc.), as well as the basis for the number of cases (only blood, OOC or IC, PC and urine tests included), as these values are also used within the ABP program of the SO.

Figure 3: Number of Tests performed and Budget spent

	CMAS*	FISA	IAAF	ISMF*	ITU	UCI	UIPM
ABP tests performed	20 (plan by the end of this year)	Approx. 500 since the start of the program (ca. 250 tests per year).	Approx. 1500 blood tests and approx. 1200 urine tests by IAAF (a total of tests in Athletics: 25.000 since the start of the program).	90 (plan by the end of this year)	2009: 25 tests 2010: 71 tests 2011: 54 tests 2012 so far: 76 (on 30.9.2012) For performing the testing ITU built up good relationship with NADOs.	In 2011, 8.660 ABP tests (4.022 urine and 4.638 blood tests) were conducted. Over 26.000 blood samples collected since the start of the program.	n.a.
Budget spent	Approx. 20.000 Euro for OOC tests (collecting A&B samples for urine and blood).	150.000 CHF total Anti-Doping budget (n.a. % ABP Program).	600.000 US\$ Overall Anti-Doping budget, thereof 150.000 US\$ for ABP program.	28.000 Euro for OOC and IC Tests, collecting samples for urine and blood.	300.000 US\$ in total, thereof approx. 115.000 US\$ for ABP program	7 Mio CHF, thereof 3,9 Mio for the ABP (Collection, transport, Lab analysis, APMU, Lab dock packs, Experts, legal aspects)	n.a.
Costs per Test**	1.000,00 Euro	300,00 CHF	55,56 US\$	311,11 Euro	1.052,63 US\$	808,31 CHF	n.a.
** Costs per case are calculated based on interviewees' information, and therefore not real costs per case. This figure can only be taken as a indicator, as in the budgets given by SOs differ (total Anti-Doping budget vs. only ABP Program, administration costs of the program in- or excluded, etc.), as well as the basis for the number of cases (only blood, OOC or IC, PC and urine tests included).							

* managed by SportAccord. Source: Expert Interviews

Nevertheless, for information purposes these figures still are shown, as they confirm in a way that the program itself is not necessarily expensive: For example, UCI has over 1,100 athlete profiles and is spending yearly approximately 7 Mio CHF. If the number of athletes is reduced, the total costs would be lower, too (Banuls). Also, mass PC tests have proven to be very cost efficient for several IFs. FISA for example organizes mass PC tests as well as OOC testing at training camps and can therefore collect several blood tests efficiently by reducing collection and transport costs per sample (Smith and Lacoste). Still, the perception of the ABP program is that it is an expensive program. ITU stated that in the first place, when their athletes' commission asked for implementation, they were resistant to it because of the perception of high costs. They anyhow decided to implement the tool because of a strong request of their athletes. Now they are convinced about the long-term effectiveness of the tool as one important component of their anti-doping strategy (Buchanan).

Also regarding the financing model interviewed SOs differ in their approach: SportAccord, organizing the ABP program for CMAS and ISMF, has reached an agreement with their event organizers. A certain part of amount of money spent before for IC tests by the organizers has been rededicated to OOC tests. In that way, more OOC take place for the same total budget than before, and

IC test can be conducted more intelligently on targeted athletes. Still, in the view of SportAccord, too many IC tests are done which could be transferred to OOC tests (Dagouret and Vallini). At FISA, today all PC and OOC tests are completely paid by them. IC tests are paid by the event organizers.

IAAF bears all costs today; however, in future, major marathon organizers might contribute to mass testing at major events (now: 10-15 tests are done at a marathon, while future plans are to conduct over 200 tests) (Capdevielle and Garnier). While ITU funds its program at 100% by itself, UCI has found a way to engage to stakeholders to take over a considerable part of the costs of the program: "The biggest financial support is coming from the teams - there is a clear benefit for them to be able show to a sponsor their support in the fight against doping" (Banuls). Today, Pro-Teams and Pro-Continental teams have a total contribution of 4.7 Mio Euro to the costs. Event organizers dedicate 15% of the price money to the fight against doping, while riders contribute with 2% of their price money. UCI itself invests 1.1 Mio Euro (Banuls).

The implementation of the ABP program was overall very well perceived by the stakeholders of the program, as shown in Figure 4. Most athletes prefer blood tests to urine tests, as they are faster and not perceived as intrusion of privacy. Also, athletes like the possibility to be able to demonstrate that they are clean (Capdevielle and Garnier).

Figure 4: Communication at Implementation and Reaction

	CMAS*	FISA	IAAF	ISMF*	ITU	UCI	UIPM
Communication at Implementation	Standard information letter to athletes. SportAccord informs its members regularly about the experience with the implementation of the passport.	No direct information to Athletes	Information on web site. Announcement to athletes at World Championships in Daegu, Korea.	Standard information letter to athletes. SportAccord informs its members regularly about the experience with the implementation of the passport.	Introduction of was requested by the athletes' commission, therefore the presentation to the athletes was very brief.	Official communication was done to teams, press releases to public and UCI internal presentations. Regular and transparent information on web-site (e.g. yearly business report).	Information published in medical guidelines. Briefing of athletes at World Championship Finals athletes.
Reactions to Passport Program	No reaction yet.	Athletes are positive to FISA efforts on clean sport and fair competitions.	No complains, no questions, as blood testing was not new to athletes.	Event organizers reacted very positively. Athletes also gave very positive feedback.	Very positive reaction from athletes and event organizers.	Riders were very positive. They use it as a tool of proof of their clean performance to a potential new team.	Reaction was very positive.

* managed by SportAccord. Source: Expert Interviews

Regarding difficulties faced at implementation, comments were received on the need to learn to use the ABP Software (since September 2012 included in ADAMS), setting up the structure to manage the program, learning how an APMU works and how responsibilities are distributed between organizations involved (Smith and Lacoste). Also, finding trustful Sample Collection Agencies and Blood Collection Officers (BCOs) alongside with the logistical challenge was an issue (Capdevielle and Garnier). With the introduction of the whereabouts in ADAMS from 2007 onwards collecting whereabouts was still difficult at the beginning, as many all athletes were not using the system before. Now for UCI collecting whereabouts information works very well, as teams support with including information into the system (Banuls). However, other SOs state that the provision of whereabouts remains challenging still today: Several NADOS and therefore a number of athletes are still not using ADAMS, as other systems are in place (e.g. SIMON).

This year, 5 of the SOs interviewed used their ABP program to support the IOC's values and mission to provide the cleanest field of play possible during the London 2012

Olympic Games (OG). All IFs were very satisfied with the experience of anti-doping activities before and during the OGs and stated that their expectations using the program were met and remarked the very good collaboration with WADA, IOC, LOCOG and local authorities. Out of the 400 blood passport tests performed at the OG, 200 were done in Athletics. In addition, steroid and endocrine parameters were analyzed, too (Capdevielle and Garnier). For FISA, 80 samples were collected and analyzed. Targeted conventional urine tests were performed upon profile analysis, no ADRV was found (Smith and Lacoste). ITU treated the OG anti-doping procedure as any other routine mission. 15 male and 15 female athletes (27% of total athletes participating) were tested in PC tests 2 days before the event at the OG. Based on the results, 3 athletes (2 female, 1 male) were targeted with conventional urine tests - and not found positive (Buchanan). UCI performed 50 PC tests, analyzed the profiles, and provided the IOC with useful information for target test purposes. Those tests had normal routine impact (Banuls). For UIPM, 30 males and 30 females (more than 50% of the athletes participating) were tested in PC tests. No abnormal profiles were found (Borrione).

4.2 ADVANTAGES, DISADVANTAGES AND LIMITS

After developing an understanding of where the surveyed IFs stand with their program, their views on advantages, disadvantages and limits are analyzed.

All SOs interviewed are convinced about the importance of the ABP as an additional tool in the fight against doping and the advantages a longitudinal profiling with individual reference values brings in comparison to conventional testing methods. “The Armstrong case proves that current doping controls have failed. The ABP is a logical development to strengthen the efficacy of anti-doping programs” (Verbruggen). And: “The strategy of doping controls has been designed 30 to 40 years ago - now there is the need to adapt these to the actual situation and to the future to come” (Dvořák).

In the view of the SOs, the shift from blind testing to monitoring of profiles which at a certain point leads to intelligent and smart test decisions not only can lead to a higher efficacy in using the budget spent, but in specific cases to cost reductions: This is the case for FISA and UIPM. Both organizations say that with the ABP, they were able to test more athletes than with conventional testing. Reason is, as explained above, the organization of mass PC tests as well as for FISA, OOC testing at training camps. A clear advantage of the ABP is that the passport is a way to make the deterrence visible: Some organizations, such as detailed in the next chapter, have seen the trend of abnormal profiles going back to normal.

Figure 5: Advantages and Benefits

Advantages and Benefits

- Intelligent testing (Quality instead of Quantity), possibility to reduce number of tests
- Efficient testing (Budget spent is used more efficiently, taking smarter decisions)
- Long term-view (blood profile) is effectively combined with snapshot view (urine tests). With the direct detection method it is much more difficult to detect doping.
- Adds credibility and state-to-the-art technology to the anti-doping program
- Very good for targeting and not targeting (the decision that there is no need to concentrate on an athlete)
- Deterrence effect is high – ABP is a way to make deterrence effect visible
- Cheaper analysis cost, thus reaching more athletes with same budget
- Bigger window of detection
- Short time to collect a sample
- Get an overall good idea of a prevalence in doping of an athletes' population
- Ethics: Pathology can be found based on the profile. However, the ABP is not a health check
- Prevention of false positives, using individual limits and not population limits any more
- Very positive comments from athletes (more chances to perform well, to compete fairly)
- An athlete can be monitored even if a country does not cooperate with WADA (e.g. Russia, China, North Korea)
- High preventive effect for the youth; not only following a control approach
- Image enhancements in the public and media (“we don't say only that we are clean, do something about it”).

Source: Expert Interviews

Furthermore, for the first time SOs can really see what is happening in an athletes' population. For example, due to PC testing of all participants of the IAAF World Championships in Daegu, Korea, (1800 blood tests were conducted: 800 female, 1000 male), a broad picture of the athletes population could be derived: It showed amongst other results that 72% of the abnormal blood profiles were female, and only 28% male (Capdevielle and Garnier). Figure 5 gives an overview of the advantages the organizations are experiencing while using the program.

Despite the long list of benefits, organizations also see the downside of the program as displayed in Figure 6. Criticism on the process side required by WADA form one part of the disadvantages mentioned by the organizations: Logistical challenges due to the geographical spread-out of athletes over the world in connection with the requirement to analyze a sample within 36 hours at an accredited or recognized laboratory and therefore the high

OOC testing costs. In addition, the case by case approach where experts need to set a scenario around the profile of the athlete, with all documents, whereabouts, lab doc packages, altitude, supplementary doping forms, and further material used, is very consuming and also costly, and leads to the perception that the ABP is affordable only for wealthy SOs. Especially with the new modules of the ABP program also other SOs will be able to join and the perception will hopefully change (Donzé).

As this research is concerned with determining whether the ABP is effective as a tool in the fight against doping or not, the attention to an additional disadvantage is driven: Most SOs agree that the effectiveness of the tool is extremely difficult to assess. For example, if an abnormal profile returns to normal, it is not known if it is due better doping methods or due to the deterrence effect of the passport. Effectiveness and how to assess it will be discussed further in the next chapter of this report.

Figure 6: Disadvantages

Disadvantages

- Logistical challenge due to geographical distribution of the athletes
- Short transport time (36h to get the sample to the lab)
- Limited number of labs which can be used
- OOC-Sample collection is expensive
- Difficulty to prosecute a case: No automatic ADVR from a blood passport, like for a prohibited substance in an urine sample. Long time from flagging till opening a case based on the passport.
- Costly tool (as case by case approach is needed). It is much more demanding, but it is worth it.
- All experts have to agree, and this can be a challenge as false positives must be avoided.
- It is a new way of thinking, thus education is still needed
- It takes time for setting up this program: To have usable profiles it takes around 2 years to have enough samples per profile.
- Expert panel need a scenario (with all documents, whereabouts, lab doc packages, altitude, supplementary doping forms, etc.). It's a very time consuming process. The quality of lab packs also differs.
- The perception that the ABP is expensive and only for wealthy IFs.
- Future and implementation of steroid module not clear
- The effectiveness of the tool is extremely difficult to assess.
- And finally: The tool might be efficient - finding results can be very political

Moreover, there is still need of education: The “old” believe that only with being positive a sanction can be received needs to be changed.

Looking at the limitations the organizations see with the ABP program as listed in Figure 7, the following topics are pointed out:

Figure 7: Limitations

Limitations of the ABP Program

- Not all NADOs include test results into ADAMS, sharing of data is difficult. Some athletes have several passports.
- Whereabouts not centralized in ADAMS (e.g. USADA uses SIMON)
- Limits of ADAMS: From an operational point of view, the software is complicated. SIMON, another system used by organizations, is better designed for managing the activities of the athletes (whereabouts).
- From now on: ABP software is only available with using Adams. So now NADOS are obliged to use ADAMS if they want to use the ABP software. This approach is criticized by NADOS.
- Manpower and capacity: the more data collected, the more documentation exists, the more complex it gets
- Still at the very beginning what interpretations of the profiles is concerned.
- Scientific uncertainty, various interpretations between experts, need of future assessment and scientific development.
- Access to calendar of the athlete needed
- Depending country laws and regulations (e.g. for blood collection, sample transport and data protection)
- An athlete can have two whereabouts failures before being sanctioned for the third
- Testing is not conducted b/w 23:00h and 6:00h so micro-dosing is possible during the night
- Possibility to hemodilute when not coming directly to the doping control after being notified for a PC testing
- An athlete could cheat by constantly using micro doses of EPO, by monitoring the values in ADAMS (knowing that they are just on their limits)
- Transparency of results in ADAMS - a delay of the release to athletes is favored
- Guidelines for PC-Testing do not exist

Source: Expert Interviews

One limitation that can be highlighted is the fact that not all NADOs and therefore athletes use ADAMS today, mainly due to data protection issues and system advantages (e.g. USADA uses SIMON, a system used by several NADOs which has advantages in managing the activities of the athletes (whereabouts)). This can lead to one athlete having several passports (e.g. Lance Armstrong could have 4 passports by now: WTC (Ironman), ITU, UCI and USADA), and if test results want to be shared between organizations, they have to be managed manually via data down-and upload using excel files. WADA therefore wants to give priority to the concept of “one athlete - one passport” (P.-E. Sottas, WADA Manager Biological Passport). Since September 2012, the ABP software within ADAMS and export and import functions have been deactivated. This approach to centralize all data in ADAMS and oblige NADOs to use the system is classified as a disadvantage by national organizations (because of data protection laws in certain countries, automatic data sharing and use of ADAMS is not possible) (Kamber, Director Anti-Doping Switzerland). Now, several NADOs are working on a stand alone solution for the ABP software – which is the worst solution WADA could want to achieve.

By NADOs not using ADAMS, also whereabouts information of athletes is more difficult to access for the SOs in charge of organizing the OOC tests. Also the transparency of the results towards the athletes is criticized by most organizations, as they fear that athletes are monitoring their values and try to adapt their doping behavior accordingly. However, WADA does not agree with this view, as firstly, most athletes already measure their values on a regular basis themselves and know therefore where they stand, and secondly, the individual reference values calculated by the adaptive model are not given to the

athletes: They only receive raw data. At this moment the consensus is to wait at least a month to release the data to the athlete (P.-E. Sottas, WADA Manager Biological Passport).

In addition, limitations regarding interpretation of the profiles, manpower used for it and amount of data collected over time which make the process even more complex, have been raised. Furthermore, limitations of the ABP program regarding the possibility of an athlete to cheat the system have been mentioned: There exists the possibility to hemodilute when not coming directly to the doping control after being notified for a PC testing. Also, testing is not conducted between 23:00pm and 6:00am, so micro dosing is possible during the night. It is feared that an athlete could cheat by constantly using micro doses of EPO, by monitoring the values (for example in ADAMS) knowing that they are just on their limits. Cheating by micro dosing is still undetectable because the effect on the physiology is close to natural levels in the body. Therefore, most SOs are in favor of releasing the test results only after a certain delay of time to the athlete, as discussed above. IAAF would prefer to give athletes access to their data only on request - this would mean that there would be an additional indicator when targeting or flagging athletes' behavior (Capdevielle and Garnier).

In addition to the points mentioned above, there is a discussion of ethics on the passport: When monitoring test values, pathologies could be detected. It was debated if in case pathology is seen in an athlete's profile, the obligation of the IF exists to inform the athlete. Generally, an anti-doping control is not a medical health check, however, it is WADAs position that if pathology is identified, the athlete should be informed immediately (Donzé).

4.3 RESULTS AND EFFECTIVENESS

In this chapter, current results of the passport tests as well as evidence for effectiveness of the tool as such are discussed.

“Blood doping has decreased thanks to the passport – although it can not be deducted that the sport is clean now: A shift to other doping forms is taking place (e.g. growth hormones). With the ABP, all new kind of doping influencing the red blood cells can be detected - this means that for the first time in history, the doping controllers are ahead of the dopers” (P.-E. Sottas, WADA Manager Biological Passport).

The following overview shows the results in terms of ADRV found and targeted athletes of the ABP program so far (Figure 8):

Figure 8: Results of the ABP Program

	CMAS*	FISA	IAAF	ISMF*	ITU	UCI	UIPM
ADRV based on ABP Program	No case so far	On abnormal blood profile: No case. On targeted conventional testing: 1 case	On abnormal blood profile: 6 athletes sanctioned; 2 more cases ongoing and further cases expected to come. On targeted conventional testing: 1 case.	No case so far	No case so far	On abnormal blood profile: 10 opened (4 riders sanctioned at national level; did not appeal / 4 riders sanctioned by CAS / 1 case closed at national level / 1 case pending at national level).	No case so far
Athletes targeted with abnormal profiles	At the moment 2 athletes	approx. 30	Many athletes are subject to targeted conventional testing based on ABP profiles.	At the moment 4 athletes	non	Many athletes are subject to targeted conventional testing based on ABP profiles.	non

* managed by SportAccord. Source: Expert Interviews

Overall, compared to the budget invested the number of positive cases found seems quite low, even for an organization like UCI who has the longest experience with the tool. However, all ABP cases that went to CAS have been won so far. This shows that it is a robust method that can be used for detection of doping (Niggli). Also, as seen in the previous chapter, the SOs are convinced that the ABP is the right approach for reaching a long-term effectiveness in anti-doping strategies. But how can effectiveness of the tool be measured?

This is a key question not only for SOs that are running the program, but also organizations that are interested in strengthening their anti-doping policy and following closely the experiences of other organizations with the tool. “The investment (financially and also resources) for such a program must be justified by a noticeable and worthwhile improvement in detection and deterrence” (Vouillamoz and Earl).

Figure 9 shows a summary of the ways SOs determine the effectiveness of the ABP program.

The idea of setting up a cost-benefit calculation on figures such as number of tests conducted by number of opened disciplinary proceedings would raise several questions: Would then an increase or a decrease of ADRVs found be a proof of enhancement of anti-doping program effectiveness over time? On the one hand evidence of intelligent testing with an increase in successful ADRV could be shown, and on the other hand, the deterrence with a decrease in ADRV could be measured. Would a higher number of positive cases detected through conventional methods be a sign of moving towards intelligent testing?

For example, since 2008, the UCI could convict more than 25 athletes included in the ABP program based on traditional direct detection methods (Zorzoli, The Athlete Biological Passport from the perspective of an anti-doping organization).

Figure 9: How to determine Effectiveness?

How to determine Effectiveness of the ABP tool?

- Number of tests conducted and budget spent, number of CAS cases won.
- Based on the number of positive cases: Very difficult and too early for an evaluation.
- With the same amount of money, having a more intelligent program (to know who to test. In future it could be one measurement the number of AAF coming from the program. This would mean that smarter decisions are taken of who to target). In 2009, the huge numbers of positives to EPO especially in cycling show the big success of target testing of the ABP program.
- If a program is cost effective or not highly depends on the management of the program (planning of the tests, outsourcing not as cost effective as doing it in-house).
- Effectiveness is reached by the higher number of athletes covered. This sends a strong message to the athletes.
- The program is cost effective if there is an additional deterrence effect compared to the previous urine testing program (Abnormal profiles going back to normal, and parallel measurement of performance of the athlete: Has the performance decreased since athlete is being tested?)
- There is evidence of effectiveness: Clear improvements of the profiles can be seen. Deterrence effect is visible through evolution of the blood parameters.
- ABP program is only effective if as many additional information as possible is collected to assure correct interpretation of the profile.
- Acceptance of the athletes, successful education to a new procedure.
- Estimation of the prevalence of doping (through the ABP program it can be seen how many athletes of a population are doping, e.g. IAAF prevalence in 2006: 11% in endurance sports. In some countries: more than 50%). It can be measured over time of how it varies within time within a population (blood doping decreased in a population).
- Performance decrease in some sports (e.g. cycling) - it is under discussion to use performance markers which could be used for target testing, although it is extremely difficult to do that.
- Evidence coming from collaboration with police and customs (EPO is rarely found nowadays, seizures have notably decreased. Instead, growth hormones and peptides are found). Preventive approach being highlighted in the media.

Source: Expert Interviews

Nevertheless, SOs think that a measurement based on “hard facts” is too early: “At this moment, there can’t be done an economic analysis of facts; however, the feeling is that with the ABP program much higher cost effectiveness is reached over time” (Dvořák). FISA and IAAF, both amongst the first SOs to implement the passport, say that “effectiveness based on number of cases is too early to evaluate” (Smith and Lacoste), and “calculating efficiency based on number of positive cases is firstly very difficult, and secondly too early” (Capdevielle and Garnier).

UCI states that a calculation of effectiveness taking into account the number of positive cases is not appropriate – however, from analyzing the data, it looks like the number of abnormal blood values is diminishing (Rossi): UCI examined 10 years of values from cyclists’ anti-doping tests and found that one of the most reliable markers of blood doping, RET%, has fallen dramatically since 2009, the year after the passport was implemented (Zorzoli and Rossi, Implementation of the biological passport: The experience of the International Cycling Union). UCI is not the only Federation who confirms that the passport is a way to make deterrence visible: IAAF has found a trend in at least 15 athlete profiles going from abnormal back to normal. For the first time, the prevalence of doping can be seen in an athletes’ population. IAAF had this idea in mind when deciding to do PC tests of 100% of the athletes participating at the World Championships in Daegu, Korea, in 2011 (Capdevielle and Garnier). FISA states that for successful deterrence, it is important that the athlete feels that he can be tested any time, anywhere (Smith and Lacoste).

For cyclists, the passport has developed to an additional tool when negotiating a new contract with a team: To the teams as well as sponsors the importance of scandal-free and therefore doping-free sport is high, and there are cases known to UCI where athletes with a suspicious profile have been refused by a new team (Zorzoli, The Athlete Biological Passport from the perspective of an anti-doping organization). Preserving image is also one of the reasons why at UCI, as mentioned before, all stakeholders such as teams, event organizers and contribute to the funding of the program. The effect of an introduction of a longitudinal profiling approach in image enhancement for the athlete himself, the sport and even a country is confirmed by Anti-Doping Switzerland, based on their experience with the project CleanWater (CleanWater), (Kamber, Director Anti-Doping Switzerland).

It can be summarized that advantages and benefits are seen by the SOs, however a noticeable improvement in detection and deterrence is still very difficult to quantify and measure right now. IOC believes that to prove the effectiveness not only through a “feeling” by the SOs to be on the right path, but through an economic analysis, still at least 3 more years of experience with the tool are needed (Schamasch, IOC Medical and Scientific Director). In addition, to determine the effectiveness in the fight against doping, the complete anti-doping strategy of an organization, including education and prevention activities, should be taken into account (Dagouret and Vallini). By now, IOC believes that anti-doping strategies are moving in the right direction and that the ABP could be one of the solutions support significantly the mission of fair play and equal rights for athletes in future (Schamasch, IOC Medical and Scientific Director).

4.4 LEARNING AND FUTURE OUTLOOK

There have been several points discussed during the Expert Interviews which have been learned when introducing the program and which could serve as advice to other SOs interested. As a first point, having a low budget is not an obstacle to start the program. SportAccord's advice is to start small: It is better to target fewer athletes and conduct more tests on one athlete than testing a lot of athletes. An additional advice is to integrate stakeholders such as organizers and sponsors, and shift the anti-doping strategy from direct tests in competition to OOC tests for indirect profiling. Also, in terms of effectiveness, the ABP program should not be considered separately from the other anti-doping programs, but be treated as a tool in the global program (Dagouret and Vallini). FISA recommends strongly starting the program with a risk assessment and a screening of the athletes' population. "By focusing on PC tests at the beginning, an overall impression of the situation within the athlete population can be obtained while keeping costs low" (Smith and Lacoste). In addition to the screening, a risk assessment of who is more likely to be exposed to doping should also be conducted. After that, decisions of whom to target and who not to concentrate on can be taken, using resources in an optimized way. "The selection of athletes is of primary importance" (Capdevielle and Garnier).

As the program is complex and requires considerable preparation from all involved stakeholders, and building up profiles with enough samples per athlete to be usable for targeting, UIPM suggests to any organization interested in the implementation having a one to two years period of training before the official introduction. During that time, education of athletes can take place, internal processes and organizational requirements can be set up, the expert panel can be established and the organization can learn how to interpret the profiles (Borrione). ITU also adds that getting advice and learning from other IFs that run the program is of very valuable help, and all resources available should be used (Buchanan). Understanding the interrelations between all involved organizations, and work out own detailed processes saves a lot of time and money, FISA says (Smith and Lacoste). Also, several organizations recommend collecting directly an A and a B sample even if for the passport, this is not a required procedure (WADA, ABP Operating Guidelines Version 3.1). In this way, a profiling sample can also be used as means for direct detection in case of necessity

(Capdevielle and Garnier), (Zorzoli, UCI Head of Medical Section).

Coming to the future outlook, organizations such as the IOC see the future of anti-doping in the longitudinal approach, as traditional direct detection methods have shown their limitations in success and efficiency (Schamasch, IOC Medical and Scientific Director). They believe in the future of monitoring of athletes values, most of them not only for blood, but also for endocrinological and steroidal parameters. Some of the organizations are already collection these values and waiting for more clarification and guidance from WADA as to evaluation of results. WADA's plan is to officially release the guidelines and related technical documents for the steroid module in 2013, which would lead to a passport based on the steroid module for practically all athletes (P.-E. Sottas, WADA Manager Biological Passport).

From here to the vision of test all athletes at the entrance of the Olympic Village for the Rio 2016 OGs in order to ensure the cleanest field of play possible it is a long walk. To realize this idea, appraised by the Dr. Schamasch as a tool that could ensure that only clean athletes compete at the OG (Schamasch, IOC Medical and Scientific Director), however has still practical hick-ups: too many athletes would need to be closely followed by taking several samples, the right and timely interpretation of the profiles is difficult (Verbruggen).

"The future of anti-doping is a combination of the passport including his future modules to come and a closer cooperation with police, customs and Interpol which should lead to an even more sophisticated system" (Donzé). The highly preventive use of the passport in the context of anti-doping education of youth and junior athletes, the cooperation with the pharmacy industry by getting information related to substances which could be potentially used for doping in advance to market release, and further use of forensic science (a multi-disciplinary scientific approach to gather analytical and non-analytical evidence to establish facts that can be presented in a legal proceeding) could further strengthen the anti-doping approach in future. IOC emphasizes their expectation that more IFs and NADOS jump into the program, which probably is more a financing question than any other (Schamasch, IOC Medical and Scientific Director).

CONCLUSIONS

The implementation of the hematological module of the ABP is seen as being for the first time a step ahead of cheaters in the race between athletes and anti-doping controllers. By combining efficiently conventional direct testing methods (snapshot – view: detecting a substance in the body) with the more subtle and indirect method (long-term view: evaluating the effect of a forbidden substance or doping method on the physiology of the athlete), international anti-doping controllers feel to be moving from merely blind testing to intelligent targeting of athletes.

The advantages of the ABP compared to traditional doping detection methods are therefore clearly seen in the intelligence leading to ‘quality instead of quantity’ and expected higher cost efficiency on the long term, adding credibility and state-to-the-art technology to the anti-doping program.

Additionally, practical aspects such as longer detection windows and shorter collection time for samples are stressed. Apart from the high preventive effect for the youth especially highlighted by the NADO interviewed, the possibility to get an overall idea of prevalence in doping in an athletes’ population as well as making visible the deterrence effect by following athletes ideally over the period of their professional career with the ABP tool is evaluated as a possible enormous optimization in the fight against doping. Athletes’ as well as other stakeholders’ feedback to organizations who implemented the program is very positive; athletes seeing the opportunity to prove their clean performance and fairness in competition, organizers and sponsors benefitting from the image enhancement supporting clean sport can bring in public and media.

There are, however, downsides of this new anti-doping paradigm. The ABP is a costly tool, because a case by case approach is needed. Logistical challenges in the process of sample collection and transportation are faced which may lead to complications for world-wide roll out at some organizations; many experts and stakeholders are involved in order to collect and interpret all information

about an athlete, and the management of results is much more demanding and complex than in traditional anti-doping tests. But organizations who implemented the tool state that the effort is worth it.

However, to be on the right path in the fight against doping is still more a “feeling” than provable by a cost-benefit analysis. It is at the moment too early to take into account this kind of economic evaluation, being with this new approach still in starting phase by having implemented one of 3 modules of the program in some organizations. Compared to the budget invested the number of positive cases found seems quite low; as success however can be mentioned that all ABP cases that went to CAS have been won so far, which can be used as proof of robust method for detection of doping. Despite the difficulties to measure the positive effects of the program there are ways to do so: A deterrence effect can be seen by watching abnormal profiles getting back to normal, which several federations monitor for suspicious athletes over time.

Financially, several organizations have proven that the mere cost of implementation and running of such a program is not a reason for not introducing the tool. Involving event organizers, sponsors, athletes and other stakeholders can help financing the program. Also, intelligent set up such as a athlete population screen and risk assessment prior to official implementation, selecting test venues where a number of athletes come together (e.g. Pre-Competition or at training camps) and using and sharing data with NADOs can lead to an even cheaper program than conventional testing, with the effect that more athletes can be tested and tests are not performed blindly.

In summary, it seems that the ABP is still in its infancy phase showing signs of a very promising future by bringing the anti-doping community one step further towards preserving the spirit of sport, the essence of Olympism, of playing true (WADA, Anti-Doping Code 14).

APPENDICES

6.1 - LIST OF EXPERT INTERVIEWS

ASOIF	Denis Oswald, President, Telephone Interview
FIFA	Prof. Jiří Dvořák, Chief Medical Officer, Telephone Interview
FISA	Matt Smith, Executive Director, Personal Interview
FISA	Dr. Alain Lacoste, Head of the Medical Section, Personal Interview
IAAF	Thomas Capdevielle, Anti-Doping Results Manager, Telephone Interview
IAAF	Dr. Pierre-Yves Garnier, Medical & ABP Manager, Telephone Interview
IOC	Dr. Patrick Schamasch, Medical and Scientific Director, Telephone Interview
ITU	Leslie Buchanan, Anti-Doping Manager, Telephone Interview
NADO	Dr. Matthias Kamber, Director Anti-Doping Switzerland, Telephone Interview
SportAccord	Hein Verbruggen, President, Personal Interview
SportAccord	Françoise Dagouret, Manager Doping Free Sport Unit, Personal Interview
SportAccord	Matteo Vallini, Project Officer Doping Free Sport Unit, Personal Interview
UCI (CADF)	Francesca Rossi, Director UCI Anti-Doping Services CADF, Telephone Interview
UCI (CADF)	Olivier Banuls, CADF Operations and Project Manager, Personal Interview
UCI (CADF)	Dr. Mario Zorzoli, Head of Medical Section, Personal Interview
UEFA	Marc Vouillamoz, Head of Match Operations / Head of Anti-Doping Unit, written answers to Interview Guide
UEFA	Mike Earl, Medical and Anti-Doping Manager, written answers to Interview Guide
UIPM	Paolo Borrione, Medical delegate for UIPM, Telephone Interview
WADA	Olivier Niggli, Legal Council, Personal Interview
WADA	Frédéric Donzé, Director of European Regional Office and International Federations Relations, Personal Interview
WADA	Pierre-Edouard Sottas, Manager Biological Passport, Personal Interview

6.2 – INTERVIEW GUIDELINE (OPERATIVE LEVEL)*

1. About the implementation status:

- 1.1 When did you implement the program?
- 1.2 Why did you decide to start the program?
- 1.3 In which way does the ABP Program support your IF's Anti-Doping Policy?
How is your experience with the program in general?
- 1.4 How did you implement and communicate the start of the program?
- 1.5 What was the reaction of the stakeholders when starting the program?
- 1.6 Are you informing internally / externally about your experience and results of your ABP program?
- 1.7 How did you use the program at London 2012 Olympic Games?
What are your expectations of the impact of the ABP program regarding London 2012 Olympic Games?
- 1.8 Which service providers do you use for collecting the samples, transportation, laboratory & analysis services and panel of experts? Who is your APMU (Athlete Passport Management Unit)?

2. About the athlete and the testing results:

- 2.1 Which athletes are subject to the ABP Program (now and at the start)?
- 2.2 How do you select the athletes and who is involved in the decision when, where, and what to test?
- 2.3 How can an athlete be targeted? Which information is used?
- 2.4 How are you informing the athlete that he is going to take part at the ABP program?
- 2.5 Does the athlete have access to his data, and if yes, through which way?
- 2.6 Where are all passport results stored, and to whom does this information belong?
- 2.7 In which step in the process is WADA informed about abnormalities in the profile?
- 2.8 On which criteria does the expert panel base their judgments?
- 2.9 How do you guarantee the independence of the expert panel? By whom are they compensated?
- 2.10 Is there a possibility to challenge the decision of the expert panel, and if yes, which is the way to do so?
- 2.11 How many tests are performed (yearly or in total since start of the program)?
- 2.12 In how many cases the passport has been used to target an athlete?
- 2.13 How many of them have been found AAF?
- 2.14 In how many cases was the demonstration of the use of a forbidden substance through the passport sufficient for a disciplinary sanction?

3. Advantages versus disadvantages:

- 3.1 What has this new approach brought to the fight against doping in sport compared to urine samples?
- 3.2 What would have happened within your sport without the implementation of the ABP Program?
- 3.3 Where do you see the advantages of the ABP Program?
- 3.4 Where do you see the disadvantages of the ABP Program?
- 3.5 Where do you see limitations?
- 3.6 Where do you feel an athlete could cheat the system (now and in future)?

4. Evidence of effectiveness of the ABP Program:

- 4.1 How would you define effectiveness of the ABP Program?
- 4.2 Is the program effective today? By which evidence can your view be supported?
- 4.3 How would you determine the cost / benefit ratio of the program?
- 4.4 How could effectiveness of the program be objectively measured?

5. About the budget and costs:

- 5.1 What is the yearly budget for the ABP program? What is its share of the overall Anti-Doping Budget in %?
- 5.2 What are the costs per case?
- 5.3 What is your current financing model of the program?
Which stakeholders are concerned and what is their contribution to the costs?

6. Learning during the implementation of the program:

- 6.1 Which were the difficulties you faced during the implementation?
- 6.2 What would you do differently if you would implement it again?
- 6.3 What would be your advice to other Federations interested in implementing the program?

7. Future of the program:

- 7.1 Where do you see the ABP program evolving within your sport (near and far future)?
- 7.2 Where would you see possibilities of cost reduction or synergies for future?
What would be prerequisite for realizing them?
- 7.3 How could a future financing model look like? What would be prerequisite for implementing it?
- 7.4 How could disadvantages and limits be tackled in future?
- 7.5 What would be your needs / wishes concerning the future of the ABP program?

* Questions were modified according to the nature of the organization as well as functional responsibilities of the interviewee.

6.3 – INTERVIEW GUIDELINE (TOP MANAGEMENT LEVEL)*

1. What is your general impression about the ABP program?
2. What has this new approach brought to the fight against doping in sport?
3. What would have happened within the sport without the implementation of the ABP Program?
4. What are the goals of implementation of the ABP program?
5. Why should an organization implement it?
6. What were your expectations of the impact of the ABP program regarding London 2012 Olympic Games? Have they been met?
7. Where do you see the advantages of the program?
8. Where do you see the disadvantages of the program?
9. Where are the limits and how could they be tackled in future?
10. Where do you see room for improvement for the program?
11. How would you determine the cost / benefit ratio of the program?
12. Effectiveness: When is the program effective in your view?
13. Successfulness: When is the program successful in your view?
14. Where do we stay today: Is it effective / successful today? By which evidence can your view be supported?
15. Where do you see the ABP program evolving within the sport (near and far future)?

* Questions were modified according to the nature of the organization as well as functional responsibilities of the interviewee.

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ACKNOWLEDGEMENTS

THIS REPORT WAS WRITTEN BY ANJA SUTTER AND WAS SUPERVISED BY DR. MARTIAL SAUGY, DIRECTOR OF THE SWISS LABORATORY FOR DOPING ANALYSES AND NEIL ROBINSON, LABORATORY SUPERVISOR OF THE SWISS LABORATORY FOR DOPING ANALYSES. MENTORED BY DR LAURENT RIVIER, SCIENTIFIC CONSULTING.

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Published by the Association of Summer Olympic International Federations (ASOIF)

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