

Steven Rand · Marianne Schürenkamp
Bernd Brinkmann

The GEDNAP (German DNA profiling group) blind trial concept

Received: 5 November 2001 / Accepted: 17 December 2001 / Published online: 28 March 2002

© Springer-Verlag 2002

Abstract This paper presents a review of the organisation and background of blind trial systems in general and in particular the system developed in Münster originally for the German Society of Forensic Medicine. This system, known as GEDNAP (German DNA profiling group), has now evolved into a multinational DNA blind trial open to all laboratories involved in paternity and forensic DNA testing.

Keywords GEDNAP · DNA · Blind trial · Quality control · Quality assurance

Introduction

Any laboratory which performs tests and produces results that are to be used in an evaluation, must ensure that these results are correct and that they meet the standards set for acceptance. This is true for all laboratories but is especially true for those which produce results that have consequences of public interest. Forensic science and forensic medicine (in Germany this is combined in the term *Rechtsmedizin*, legal medicine) are both disciplines which produce results for the legal system and therefore have a great responsibility to ensure that very high standards of accuracy and precision are maintained.

Basic principles of the blind trial

The basic principles of the GEDNAP blind trial system are the same as any other system of quality control (Ferrara et al. 1998; Wu et al. 1999; Baselt 2000; IFCC

and WASPaLM 2000) and attempts to evaluate the following problem areas:

1. The ability of an analytical method to produce results for the examination in question
2. To test the specificity of the method by examining the criteria:
 - To test the accuracy of the results
 - To test the precision of the results
 - To test the limits of detection of the method.

The first stage in the validation of any method for use in forensic work is the background research performed by the laboratory which has done the development. In the case of systems for identity or forensic body fluid stain testing, this involves a refinement of the technical and experimental conditions followed by genetic and statistical evaluations of population studies carried out on an adequate number of related and unrelated individuals. The criteria defining what is adequate and which tests have to be performed to validate the method or system have been developed and laid down in a number of publications (Am Soc Hum Genet 1990; Morton and Collins 1995; National Research Council 1996; McGuinness et al. 2000). For the recent development of DNA testing which is now applicable, the criteria have been published mainly in the form of recommendations and guidelines by the DNA Commission of the International Society for Forensic Haemogenetics (recently changed to International Society of Forensic Genetics). These recommendations have been published at regular intervals over the past years to keep pace with the ever-changing repertoire of DNA systems available to the forensic community (DNA Commission 1989, 1992, 1994; Bär et al. 1997).

In all forms of recommendations, guidelines or even regulations, the next stage of any method is the peer-review system. The system must comply with the generally accepted state-of-the-art as laid down by this peer review system. This means the system must not only be proven to be reproducible within the developing laboratory but must also be reproducible in other equally qualified laboratories.

All recommendations go further and regulate what controls must be performed by the laboratory when using the method or system for testing (McEwen and Reilly 1994; Wilson et al. 1994; Hake 1995; Schulz et al. 1995; Tirindelli Danesi et al. 1997; Massari 1998; Clark et al. 1999). The most important of these are:

1. Internal controls which must be included in every test procedure
2. External controls – Participation of the laboratory in a form of blind trial.

This external form of control serves not only to test the ability of the method to come up with the correct answer under the conditions used but also, and this is imperative in this context, to test the ability of the laboratory itself to come to the correct conclusion after having performed the test.

This is a very important aspect of any testing procedure and this blind trial procedure is designed to test the following:

1. Has the laboratory tested the correct stain and are the safety precautions within the laboratory sufficient to avoid confusion or contamination of samples?
2. Has the laboratory arrived at the correct result?
3. Has the laboratory come to the correct interpretation of the result obtained?

All of these aspects must be tested by a blind trial system and therefore serve as a quality control system for the laboratory doing the testing.

It is also expected that participation in a blind trial will stimulate the laboratories to be more self-critical of the standard and quality of their organisation and results. An increased level of awareness of the problems involved will in turn lead to constructive criticism of the blind trial system itself and an improvement in the parameter testing procedure.

Development of the GEDNAP system

The basis for the GEDNAP group (German DNA Profiling Group) began in the early 1980s when a “Stain Commission” was set up by the German Society for Legal Medicine (Deutsche Gesellschaft für Rechtsmedizin) to examine and formulate ways and means of checking the quality of results obtained by laboratories performing forensic testing for the judicial system using the classical systems (e.g. ABO, Gm, enzyme and protein polymorphisms) used at that time for forensic stain analysis. The Commission consisted initially of five members from institutes of legal medicine but later included representatives of the governmental State laboratories (Landeskriminalamt LKA) and the Federal laboratory (Bundeskriminalamt BKA).

A series of blind trials were set up in which laboratories were required to examine stains commonly encountered in forensic work and to identify the origin of stains (i.e. blood, semen, saliva) using a preliminary or specific

test and to type these stains using the classical systems used in the individual laboratory. In some cases the laboratories were requested to identify the possible donor of the stain by comparison with known control samples supplied in the trial. The initial set of blind trials were distributed by the Institute in Hannover under the auspices of the Stain Commission of the National Society who formulated the rules and regulations for the trials.

When DNA polymorphisms were initially introduced into the repertoire of possible testing systems for forensic use, they were slowly (at first) incorporated into the quality control procedure as performed using a system of blind trials. With the introduction of DNA systems, the evaluation of results became too much for one laboratory and the Institute in Münster was designated to undertake the evaluation of DNA systems.

With the evolution of stain testing in general, classical systems were gradually removed from the repertoire of forensic laboratories and substituted by the current DNA generation so that finally only DNA testing remained.

As a gradual process over a number of years, the number of classical systems included in the GEDNAP blind trial became less and the number of DNA systems became more. The systems for DNA testing have also undergone an evolution over this time period (approx. from 1990 onwards) starting with the SLSs (single locus systems), MLSs (multi-locus systems) were never considered to be a realistic or suitable alternative, through AmpFLPs (amplifiable fragment length polymorphic systems) on to the STRs (short tandem repeats) which are the current state-of-the-art.

At each stage of the development of these DNA systems a specific method was devised by the evaluating laboratory (Institute of Legal Medicine Münster) in collaboration with the Stain Commission and also with the approval of the participating laboratories, to accurately and fairly evaluate the results submitted.

For the SLSs with their continuous allele distribution, a method was developed to accommodate the (acceptable) levels of variation for fragment length measurement. For AmpFLPs this was extended to deal with sequence and electrophoretic variations due to base content (GEDNAP studies, Puers et al. 1992; Bär et al. 1992; Brinkmann et al. 1993; Wiegand et al. 1995).

Throughout the development of the GEDNAP trials, efforts have been made to treat the results with a maximum degree of fairness whilst maintaining a high level of integrity and impartiality to the evaluation. This has been upheld by using firstly an unbiased approach to the evaluation supported by anonymity of the participating laboratories as far as it is possible without being detrimental to the quality of the trial.

GEDNAP is the German-speaking working group of the EDNAP group (European DNA profiling group), which was established in 1989 by a handful of European laboratories in an attempt to harmonise the extremely rapidly developing field of DNA profiling throughout Europe (see Gill et al. 1994 for example). Even in this initial stage it became rapidly obvious that DNA systems for use in

forensic and paternity examinations were being developed at such a rate that soon there would be far too many systems available. This in turn would lead to such a large selection of systems that no two laboratories would use the same package of systems which would make a comparison of results, or checking of results by a second test almost impossible.

The EDNAP group expanded in such a way that each European country could as far as possible have one representative or in some cases more than one depending on the organisation of forensic science in that country. More than one representative for a particular country also has an historical background due to the initial founder member group which grew basically from the brainchild of the UK and Germany. As the number of laboratories performing DNA testing increased, the interest in EDNAP grew and it was decided that wherever possible, (i.e. depending on how many laboratories existed in the particular country) representatives in EDNAP should establish local groups in their own country. These EDNAP representatives should then inform the local working parties of the decisions or recommendations of EDNAP.

Aims and requirements

One of the basic requirements of a blind trial is that all participants receive exactly the same material to be tested enabling a direct comparison with the known standard as well as an interlaboratory comparison to be carried out.

The aims of the blind trial procedure are fourfold:

1. Standardisation of methods and procedures
2. Standardisation of nomenclature
3. Evaluation of the competence of a laboratory to obtain the correct result
4. Elimination of errors in typing.

A blind trial is one essential element of the complete quality assurance programme which a laboratory engaged in DNA typing (or any other type of laboratory) is obliged to conform to. In the field of forensic examinations in general, and DNA typing in particular, this has two main goals:

1. To ensure that results obtained from evidential material which are to be used within the Penal System in a Court of Law, reflect the true nature of this material.
2. That results from DNA investigations, which are to be submitted and stored in a National DNA data bank, are given in a standard form (nomenclature) and have been correctly typed.

Any error in these two categories would have disastrous consequences for the public interest.

Structure of the current GEDNAP blind trials

Participants

The number of participants in the GEDNAP blind trial has risen rapidly and presently (in 2001/2, GEDNAP 22 and 23) stands at 129 laboratories from 28 European countries taking part in 2 blind trials per year. In addition to the original laboratories taking part the member laboratories of the ENFSI group (European Network of Forensic Science Institutes, Gill et al. 2000) have now been integrated.

Participation in the GEDNAP blind trial is basically open to any laboratory, whether private institutes (at present $n=24$), university institutes ($n=55$) or government laboratories ($n=50$) from any country in Europe. Although GEDNAP is, by definition a German working group, the lack of such organisations in certain European countries in the past and the wish of laboratories in these countries to participate in such trials, led to the inclusion of non-German-speaking laboratories which has continued up to the present date. Other EDNAP working parties have followed the same lead set by GEDNAP (Gomez et al. 1997; Gomez and Carracedo 2000).

Construction

The GEDNAP blind trials are organised in such a way that each participating laboratory receives two sets of stains to be tested during the year which is the minimum requirement for a laboratory according to the regulations laid down by the Bundesärztekammer (The Medical Council in Germany) (1988, 1992a, 1992b; Thomas 1998a, 1998b).

The number and the type of samples sent out for each blind trial has varied in the past depending on the number of participating laboratories (in the initial stages of trials), the systems to be tested and public consent.

The DNA systems to be included in the blind trial system have varied depending on the current state-of-the-art and are decided by a unanimous decision between the Stain Commission and a general consensus opinion of the participants. For the present trials the following systems are included as compulsory and additional voluntary or facultative systems:

The compulsory systems are the German DNA data bank systems at present consisting of amelogenin, ACTBP2 (SE33), D21S11, TH01, vWA, FGA (Fibra), D3S1358, D8S1179 and D18S51, the facultative systems are D7S820, DYS19, D16S539, D2S1338, TPOX (HTPO), CSF1PO, D5S818, D19S433 and D13S317.

These facultative systems are all components of commercially available kits such as the SGM Plus kit (Applied Biosystems, Foster City, Calif.), the Profiler and Profiler Plus kits (Promega, Madison, Wisc.) or the MPX 2 kit from Serac (Bad Homburg, Germany) and are now the systems of choice for most forensic laboratories. These have been included because many laboratories use these kits routinely.

At present laboratories receive a total of seven samples for each trial, consisting of three control bloodstains from known and tested individuals and four stains of unknown origin with which they are to be compared.

There are also some laboratories who do not engage in stain analysis but wish to participate in the blind trial. These are mostly engaged in typing samples for the DNA data bank only and will only type the control samples. In GEDNAP 18 and 19 the number was 5 laboratories, in GEDNAP 20 and 21 a total of 7 and for GEDNAP 22 and 23 a total of 10 have registered. This increase reflects the current trend in most countries world-wide.

The stains to be included in a blind trial are decided by the Stain Commission which meets at regular intervals of at least twice a year, taking into account the general opinion of the participants who are consulted on the occasion of the Workshop to present and discuss the results of the preceding trials.

In general, the type and size of the stains are designed to reflect the state-of-the-art of the DNA typing to be tested and attempts to be as near practice oriented as possible.

The setting up of a “fake” or simulated casework situation to be distributed among the participants was seriously considered by the Stain Commission from the very beginning of blind trials. However, because of the vastly differing nature and internal organisation of the laboratories, this was deemed to be extremely difficult to implement from a practical point of view and also to offer no great advantage to the testing procedure.

Planning

The planning for subsequent blind trials is undertaken by the organising laboratory (Münster) in consultation with members of the Stain Commission and also with the participants.

Prior to the Workshop, the Stain Commission convenes to discuss the results and to make suggestions for the subsequent trials based in part on the outcome of the previous trials and on the latest relevant developments in the field.

On the occasion of the presentation of the result of the previous trials, which nowadays takes place at the beginning of February of each year, the participants will be asked for their opinions regarding these aspects. This will then be taken into consideration when the Stain Commission convenes to make the final planning for the forthcoming trials.

A time lapse of approximately 2 months then allows all possible comments to be registered before the final decision is made.

Registration

As soon as the decision has been reached, a message is sent to all previous participants and new applicants informing them of the decision and requesting them to reg-

ister for the next set of trials and to reply within a set period of time (usually 2–3 weeks).

In the past the form has always included a question asking the laboratory to state which systems will be tested. This practice has been introduced to allow the organiser to have an overview of the extent of the procedure. This practice will be maintained in the future unless circumstances dictate otherwise.

When confirmation is received from a laboratory either by fax or by mail, the list of participating laboratories is established, whereby each incoming registration is assigned a code number (laboratory number) in chronological order of receipt. This ensures that no bias is given to any laboratory and that laboratories will probably never receive the same number as before and maintains the anonymity of the system. Once a code number has been assigned this will be used in place of the name for all future evaluations.

Preparation of samples

The samples are prepared in the organising laboratory according to the recommendations laid down by the ISFG and other organisations to include a maximum of integrity of the samples and a minimum of contamination (DNA recommendations 1989, 1992, 1994; Bär et al. 1997).

In general, samples are obtained from members of the Institute because the DNA profiles are known and have been thoroughly tested beforehand. For each blind trial different persons or combination of persons are used to avoid duplication (and ipso facto recognition).

1. New cotton cloth is used as the substrate for blood and mixed stains. This is washed 3 times before use to prevent contamination and to remove any traces of chemicals used in the manufacturing process.
2. Stains are prepared in such a way that there is sufficient blank cloth for negative blank cloth controls.
3. Disposable gloves and face-masks are worn at all times. All containers and utensils are sterile and used only once.
4. Blood is taken in sterile citrate containers and the appropriate volume is dispensed using a calibrated pipette.
5. Saliva is collected in sterile Falcon tubes by drainage and vortexed continuously to maintain homogeneity. The appropriate volume is dispensed using a calibrated pipette.
6. Mixtures of body fluids are prepared in a similar way and great care is taken to maintain homogeneity of the sample by vortexing thoroughly between each sampling during the spotting procedure.

The effective relationship between components in a mixture is also checked by a comparison of the peak heights (intensity) after amplification and typing. While this does not give an absolute value, it does reflect the actual relationship as measured under experimental conditions equivalent to those encountered in the trial.

Some examples of stains prepared for the blind trials in the past are blood/blood mixtures in various proportions, blood/body fluid mixtures, semen/saliva mixtures, semen/vaginal fluid mixtures, smoked and unsmoked filter cigarettes, etc.

A variety of stain substrates have also been used including jeans, leather, cardboard, cotton wool swabs, etc.

To illustrate this for the blind trials GEDNAP 20 and 21 the following samples were prepared:

GEDNAP 20

1. Person A: 25 µl blood (female) on cotton cloth
2. Person B: 25 µl blood (male) on cotton cloth
3. Person C: 25 µl blood (male) on cotton cloth
4. Stain 1: unsmoked filter cigarette with 10 µl saliva
5. Stain 2: 25 µl blood mixture (Persons A:B, mixed 1:2 v/v)
6. Stain 3: 25 µl blood mixture (Persons A:C, mixed 3:1 v/v)
7. Stain 4: Buccal swab from Person A.

GEDNAP 21

1. Person D: 25 µl blood (female) on cotton cloth
2. Person E: 25 µl blood (female) on cotton cloth
3. Person F: 25 µl blood (male) on cotton cloth
4. Stain 5: smoked filter cigarette from Person E
5. Stain 6: 1×1 mm piece of a 1-year-old bloodstain on cotton cloth
6. Stain 7: 25 µl blood mixture (Persons D:F, mixed 3:1)
7. Stain 8: used chewing gum, chewed for 30 min by the same person (Person D).

Samples are always prepared in isolation from each other and in different laboratory areas, by spotting onto the substrate which are then air-dried overnight. The individual stains are then cut out (one stain type at a time) and placed in sealed plastic bag labelled with the corresponding number and closed.

In accordance with a recent decision of the Stain Commission, all stains will in future be marked directly on the substrate to enable an identification of the stain at a later date if necessary. This will enable any possible or claimed interchange errors to be clarified. For each laboratory a set of stains is prepared and stapled together. Each package is then checked by an assistant to ensure that the set is complete and correct. The sets are then placed in an envelope labelled with the name and address of the participant and checked again by the section head.

Before sealing the appropriate documentation for submitting the results is also placed in each envelope in turn, check by an observer and the envelopes are sealed.

Distribution of samples

Each set of documents is labelled with the laboratory code only which is entered by the organising laboratory before being sent.

The envelope containing the set of samples and the documentation necessary for returning the results are prepared for posting and sent via the university postal system.

Typing of samples

In accordance with recent discussions laboratories are now requested to retain an adequate part of the sample for future testing in case of any disagreements over the identity or claims of contamination prior to the sample being received by the participant.

Laboratories are expected to comply with the international recommendations for DNA typing (DNA Commission 1989, 1992, 1994; Bär et al. 1997) and include all the appropriate positive and negative controls as well as the various ladders (internal and external where appropriate), but this is no longer laid down as a prerequisite. It is up to the individual laboratories to fulfil this condition. In the past it was necessary to include in the documentation a list of all standards required in order to make a comparison of the results. While this was true for the SLSs or AmpFLPs this is no longer necessary for the present day STRs in use which have been exactly defined and are mostly contained in commercially available kits with standard ladders and are typed using capillary electrophoresis and denaturing gels. This was also a problem for sequence variants run on native gel systems (e.g. FES 11 and 11a variants) but this information was always requested in order that no false interpretation of the results would occur.

It was also previously necessary to make a statistical appraisal of the measured fragment length as compared to the true length and to establish a consensus opinion of the actual size. This was the case with SLSs with a continuous distribution of fragment sizes and with sequence variations detectable on native gel systems. This is no longer necessary for the majority of STR systems.

The only system included in the trial where this is appropriate is ACTBP2 (SE33) which is at present one of the data bank systems in Germany. This system exhibits inter-alleles with 1 or 3 base pair (bp) variants (e.g. 18.1 or 18.3) and sequence variants, most of which are rare but do exist to an appreciable degree which cannot be ignored. In the case of ACTBP2 it was necessary to make a preliminary study using selected laboratories to test if these could be reliably distinguished from the more common alleles (such as alleles 18 or 18.2) using routine methods. From the experience gained from this study it was found that in order to accurately type alleles in this system some extra controls should be included in every run at least once at the beginning and once at the end. If separation can be achieved then the run is valid. The Stain Commission recommends that for this system a mixture (compound) standard should be included which contains the alleles 14.3, 21, 21.1, 31.3 in order to cover the spectrum of variant alleles from the low to the high fragment sizes. This is also commercially available from Serac (Bad Homburg, Germany) which produces a kit containing the German data bank systems.

All ACTBP2 alleles in samples sent out for blind trials have been previously sequenced to establish the correct number of bases as a guideline for typing.

Not all alleles in all systems are sequenced before the samples are sent but this does apply to all alleles which are off-ladder or rare or show any other sort of variation.

Returning samples

Participants are requested to return the results by the closing deadline of 1st December of the year in question to allow the organising laboratory sufficient time to evaluate and present the results at the Workshop in February of the following year.

If results are received after this date they may be included if there is sufficient time. However, once the statistical evaluation has been made, no more results can be included.

Laboratories were previously requested to also submit the raw data (print-out or original gels) when returning the results, so that possible error sources could be identified. In order to refute any possible suggestion of collaboration between participating laboratories or biased evaluation by the organising laboratory, the submission of the raw data is now obligatory. This can be done by e-mail or other forms of electronic data storage (e.g. discs, ZIP, CD ROM) if desired.

When the results are received the date is entered and the results are filed under the appropriate laboratory code number before being processed.

The results for each individual laboratory are then entered by one person into an excel file.

When all the results have been received (or the deadline has passed) and entered into the appropriate file for the lab code number, a print-out is made and the results are double checked by comparing the original data (from the laboratory) with the data entered in the excel file.

Any errors in the excel file are corrected.

Results

Evaluation of results

All data in the excel files are then rechecked by the section head by comparison of the original data with the excel files.

At this stage any errors or discrepancies from the established values made by the participating laboratory are checked (if possible) by referring to the raw data submitted.

In previous blind trials the non-detection of weaker alleles in a mixture was not penalised. However, due to the development of more sensitive techniques it was decided by the Stain Commission that for mixtures it would be reasonable to expect that alleles should be detected if they are present in more than 20% as a mixture component based on the proportion of alleles in the mixture.

Example: GEDNAP 19 Stain 6: ACTBP2 Person E 24.2/27.2 and Person F 30.2/31.2). A mixture relationship of 1:4 (i.e. 20%:80%) results in alleles 24.2 and 27.2 each with 10% and alleles 30.2 and 31.2 each with 40% assuming an equal degree of efficiency of the amplification and equal number of cells containing DNA in the sample.

In this case the laboratory would not be penalised if the alleles 24.2 and 27.2 were not detected in this mixture.

All errors are classified into categories in an attempt to identify the most common source of errors. The types of errors are classified as:

1. Errors due to poor quality results
2. Errors due to over interpretation of stutter bands
3. Errors due to over interpretation of very weak bands
4. Errors due to false alignment to the ladder
5. Errors due to transcription

Criteria for categorisation

After checking all results, each individual result for each system and for each stain is categorised according to the following criteria:

Category 1 No errors

Category 2 Mixture not detected

Category 3 Error in typing but would not be reported

Category 4 Error in typing which would be reported

Only errors classified under Category 4 are considered to be true errors for the final evaluation.

Presentation of results

Each laboratory receives a copy of the results which are presented beforehand at the Workshop. In order to simplify the results not all results are given, only the code numbers are given of those who have made errors from categories 2–4.

Informing participants of results

The results are presented at the workshop held every year in February at a predefined location (usually proposed at the previous Workshop and finally decided by the Stain Commission). The results are made public in the form of a verbal presentation illustrated using overhead projection and/or slides. Over the past years it has become impractical to present all the results for all laboratories and for all systems: with more than 100 participating laboratories this is unfeasible but all the results can be made available on request.

The complete files containing all the results submitted are brought to the Workshop to enable immediate checking if so desired. The various categories are demonstrated and the laboratory code numbers where errors have been made are given, usually together with examples, so that each affected laboratory has the chance to see the problem. After the presentation each laboratory receives a copy of the relevant tables.

Laboratories are given the chance to appeal if they feel that their results have been incorrectly classified or if they have been unfairly treated. This is made clear at the Workshop and all laboratories are given the right to appeal if they wish to do so.

Laboratories also have the right to receive more of a particular sample if they wish to retype a stain in order to check the method or to convince themselves that nothing untoward has occurred.

In the event of any problem with typing or if a participant requests that the sample in question be retested, the following procedure has been invoked in accordance with the decision of the Stain Commission:

1. The portion of the sample which was retained by the laboratory will be returned to a member of the Stain Commission selected by the participating laboratory (a list of members and contact information can be supplied on demand).
2. The member of the Commission selected should be from an Institute of Legal Medicine if the participant is a government laboratory and vice versa but the choice lies with the participant.
3. A private laboratory has a free choice.
4. The selected laboratory will then carry out the desired testing and report the findings back to the Commission and if necessary, consult with the organising laboratory before a decision is made.

Certification

A certificate is then issued by the organising laboratory in which it states that the laboratory in question has successfully completed the blind trial in the named systems. False results (errors) are not explicitly named but are not included in the list.

The certificates are completed by an assistant in the organising laboratory based on the final evaluation of the Workshop and include all alterations which have been agreed and validated after making the results public, counter-checked by the department head and signed by the Chairman of the Stain Commission who is also Director of the organising laboratory.

Laboratories also have the right to appeal at this stage if a typographical error has been made by the issuing laboratory and when the certificate is sent out, information to this effect is included in the accompanying letter.

All the documentation sent for analysis to the organising laboratory will in future be returned with the certificate. The participating laboratory is responsible for archiving and storage for an as yet undefined period of time.

State-of-the-art

At the present state-of-the-art the STR systems form the backbone of the blind trial and are expected to do so for some time to come. Newly developed and/or possible candidates for inclusion in the blind trial system will be considered by the Stain Commission and a decision will be reached after consultation with the participants in general. The decision will obviously depend on general availability and technical aspects. This system has been employed and has proved successful during the previous

stages of GEDNAP and will be employed in the future as long as the participants are in agreement.

Future developments

One of the main areas of development is the field of mitochondrial DNA testing of hairs and other materials (e.g. Carracedo et al. 2000). This has already been considered by the Stain Commission although the numbers of laboratories who can use this system is limited. Nevertheless, it is the duty of the Stain Commission of the German Society of Legal Medicine to consider all systems which are in forensic use and an appropriate blind trial system must be established. This is in progress. As in the past, all new developments in the field of forensic investigations must be evaluated and if deemed necessary included in the scope of the blind trial system.

Up to now the organising laboratory has also participated in the blind trial. While this situation is not optimal, the organising laboratory has always attempted to treat these samples in an impartial way and the testing is performed by another person independent of the preparation of the trial samples. In addition another independent governmental laboratory sends other unknown samples to the organising laboratory for testing in a similar way to the official blind trial. It has now been unanimously decided that additional samples would be provided to the organising laboratory by Dr. Schmitter (BKA Wiesbaden) which would then be tested and evaluated using the same criteria as employed in the blind trial. The organising laboratory also participates in the EDNAP trials so that the quality of results produced is also open to official scrutiny from external sources.

Conclusions

Since the blind trial system was first conceived in its present form, there have been many changes in the construction and implementation of the system as well as the several generations of DNA systems. The organising laboratory took over the sole responsibility of distribution, collection and evaluation of the blind trial but decisions as to which systems and which samples were to be tested were always made and will be made in the future by full consultation with the members of the Stain Commission and with the participating laboratories. This system has proved invaluable in the past for the selection of systems as well as for solving problems which may have arisen at any stage of the process. The complete feed-back regarding criticism of performance and implementation, problems and solutions together with an open discussion of all aspects at the Workshop, has proved to be a successful combination and will be maintained as long as the forum so desires.

The organising laboratory has also gained a great deal of experience over this period of time which has been put to practical use in the various aspects of management.

Review of the GEDNAP proficiency testing programme

In November 2000, a review of the GEDNAP procedure was carried out by Dr. B. Budowle of the FBI as part of an overall review of the databank system organised by the BKA. This included a visit to the organising laboratory where all phases of the procedure were examined for possible sources of error or inconsistencies in the system. A report was made and submitted to Prof. Dr. Kube, head of the Forensic Science Institute of the BKA. There were no major criticisms but some recommendations were made to improve the standing and validity which have now been incorporated into this document and into the blind trial system.

References

- A joint policy statement by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the World Association of Societies of Pathology and Laboratory Medicine (WASPALM) (2000) Principles of clinical laboratory accreditation. *Clin Lab* 46:201–203
- Ad Hoc Committee on Individual Identification by DNA Analysis, The American Society of Human Genetics (1990) Individual identification by DNA analysis: points to consider. *Am J Hum Genet* 46:631–634
- Bär W, Brinkmann B, German U, Henke L, Kratzer A, Puers C, Scheithauer R, Wenzel R, Wiegand P (1992) GEDNAP (German-DNA-Profiling-Group) II. *Rechtsmedizin* 3:6–9
- Bär W, Brinkmann B, Budowle B, Carracedo A, Gill P, Lincoln P, Mayr W, Olaisen B (1997) DNA recommendations. Further report of the DNA commission of the ISFH regarding the use of short tandem repeat systems. *Int J Legal Med* 110:175–176
- Baselt RC (2000) Commentary on Wu AHB, Hill DW, Crouch D, Hodnett CN, McCurdy HH. Minimal standards for the performance and interpretation of toxicology tests in legal proceedings. *J Forensic Sci* 1999; 44:516–522
- Brinkmann B, Bär W, Feuerbach M, Henke L, Hochmeister M, Kratzer A, Rand S, Rothämel T, Weisser HJ, Wiegand P (1993) GEDNAP III – Dritter Spurenringsversuch der Deutschen Gesellschaft für Rechtsmedizin. *Rechtsmedizin* 3:33–39
- Bundesärztekammer (1988) Richtlinien der Bundesärztekammer zur Qualitätssicherung in medizinischen Laboratorien. *Dtsch Arztebl* 85:699–712
- Bundesärztekammer (1992a) Richtlinien der Bundesärztekammer zur Qualitätssicherung in der Immunhämatologie. *Dtsch Arztebl* 89:479–482
- Bundesärztekammer (1992b) Richtlinien der Bundesärztekammer zur Qualitätssicherung in der Mikrobiologie. *Dtsch Arztebl* 89:1871–1878
- Carracedo A, Bär W, Lincoln PJ, Mayr W, Morling N, Olaisen B, Schneider P, Budowle B, Brinkmann B, Gill P, Holland M, Tully G, Wilson M (2000) DNA commission of the international society for forensic genetics: guidelines for mitochondrial DNA typing. *Forensic Sci Int* 110:79–85
- Clark HD, Wells GA, Huet C, McAlister FA, Salmi LR, Fergusson D, Laupacis A (1999) Assessing the quality of randomized trials: reliability of the Jadad scale. *Control Clin Trials* 20:448–452
- DNA Commission of the International Society for Forensic Haemogenetics (1992) Second DNA recommendations. 1991 report concerning recommendations of the DNA commission of the International Society for Forensic Haemogenetics relating to the use of DNA polymorphisms. *Int J Legal Med* 104:361–364
- DNA Commission of the International Society of Forensic Haemogenetics (1994) DNA recommendations – 1994 report concerning further recommendations of the DNA commission of the ISFH regarding PCR-based polymorphisms in STR (short tandem repeat) systems. *Int J Legal Med* 107:159–160
- Editorial (1989) Recommendations of the Society for Forensic Haemogenetics concerning DNA polymorphisms. *Forensic Sci Int* 43:109–111
- Ferrara DS, Tedeschi L, Frison G, Brusini G (1998) Quality control in toxicological analysis. *J Chromatogr B Biomed Sci Appl* 713:227–243
- Gill P, Kimpton C, D'Aloja E, et al, (1994) Report of the European DNA profiling group (EDNAP) – towards standardisation of short tandem repeat loci. *Forensic Sci Int* 65:51–59
- Gill P, Sparkes R, Fereday L, Werrett DJ (2000) Report of the European Network of Forensic Science Institutes (ENFSI): formulation and testing of principles to evaluate STR multiplexes. *Forensic Sci Int* 108:1–29
- Gomez J, Carracedo A (2000) The 1998–1999 collaborative exercises and proficiency testing program on DNA typing of the Spanish and Portuguese Working Group of the International Society for Forensic Genetics (GEP-ISFG). *Forensic Sci Int* 114:21–30
- Gomez J, Rodriguez-Calvo MS, Albarrañ C, et al, (1997) A review of the collaborative exercises on DNA typing of the Spanish and Portuguese ISFH Working Group. *International Society for Forensic Haemogenetics*. *Int J Legal Med* 110:273–277
- Hake S (1995) Akkreditierung von medizinischen Laboratorien – ein sinnvolles und notwendiges Verfahren? *Clin Lab* 41:529–534
- Massari C (1998) A general guide for conducting in-process inspections. *Qual Assur* 6:97–105
- McEwen JE, Reilly PR (1994) A review of state legislation on DNA forensic data banking. *Am J Hum Genet* 54:941–958
- McGuinness C, Seccombe DW, Fröhlich JJ, Ehnholm C, Sundvall J, Steiner G (2000) Laboratory standardization of a large international clinical trial: the DAIS experience. *DAIS Project Group. Diabetes Atherosclerosis Intervention Study. Clin Biochem* 33:15–24
- Morton NE, Collins AE (1995) Statistical and genetic aspects of quality control for DNA identification. *Electrophoresis* 16:1670–1677
- National Research Council (1996) The evaluation of forensic DNA evidence. *National Academy Press, Washington DC*
- Puers C, Wiegand P, Bär W, Brinkmann B, Gujer HR, Kloosterman AD, Rand S, Rothämel T, Schmitter H, Weisser HJ (1992) GE-DNA-P (German DNA Profiling Group)-Studie. *Rechtsmedizin* 2:99–103
- Schulz KF, Chalmers I, Hayes RJ, Altman DG (1995) Empirical evidence of bias. Dimensions of methodological quality associated with estimates of treatment effects in controlled trials. *JAMA* 273:408–412
- Thomas L (ed) (1998a) Qualitätssicherung quantitativer Bestimmungen. In: *Labor und Diagnose. TH-Books, Frankfurt/Main*, pp 1427–1437
- Thomas L (ed) (1998b) Referenzmaterialien und Richtlinien zur Standardisierung labor diagnostischer Methoden. *TH-Books, Frankfurt/Main*, pp 1438–1463
- Tirindelli Danesi D, Spano M, Altavista P, et al, (1997) Quality control study of the Italian Group of Cytometry on flow cytometry DNA content measurements: II Factors affecting inter- and intralaboratory variability. *Cytometry* 30:85–97
- Wiegand P, Ambach E, Augustin C, et al, (1995) GEDNAP IV and V. The 4th and 5th stain blind trials using DNA technology. *Int J Legal Med* 108:79–84
- Wilson RB, Ferrara JL, Baum HJ, Shaler RC (1994) Guidelines for internal validation of the HLA-DQ alpha DNA typing system. *Forensic Sci Int* 66:9–22
- Wu AHB, Hill DW, Crouch D, Hodnett CN, McCurdy HH (1999) Minimal standards for the performance and interpretation of toxicology tests in legal proceedings. *J Forensic Sci* 44:516–522