Assessment of the Options Paper and Update Paper Prepared by Queensland Health Forensic and Scientific Services (QHFSS)

Requested by Commission of Inquiry
into Forensic DNA Testing in Queensland

Prepared by Bruce Budowle, Ph.D.

19 September 2022

Introduction

1. This Report addresses a number of topics regarding "A review of the automatic concentration of DNA extracts using Microcon® Centrifugal Filter Devices: Options for QPS Consideration" (what has been called and will be referred to herein as the "Options Paper") and "Assessment of Low Quantification Value DNA Samples" (what has been called and will be referred to herein as the "Update Paper") which were written by the Queensland Health Forensic and Scientific Services (QHFSS) and provided to the police. The information in the Options Paper ultimately established a basis for a policy on processing low quantity samples (in 2018). The Update Paper assessed the efficacy of concentration of low quantity samples that were requested for further analysis by the police since the enactment of the 2018 policy. This policy (described below) is being investigated, and the Commission of Inquiry into Forensic DNA Testing in Queensland has identified a number of topics upon which they would like to have some guidance.

2. The opinion in this Report is based on:

    a. Options Paper QHFSS Project #184 on A review of the automatic concentration of DNA extracts using Microcon® Centrifugal Filter Devices: Options for QPS Consideration (prepared by Justin Howes and Cathie Allen), January 2018

    b. Update Paper –Assessment of Low Quantification Value DNA Samples (prepared by Cathie Allen, Justin Howes and Paula Brisotto), 21 June 2022

    c. QHFSS Project #163 Report on Assessment of Results Obtained from 'Automatic-Microcon' Samples (prepared by Josie Entwistle, Allison Lloyd, Kylie Rika, Thomas Nurthen, and Cathie Allen), August 2015

    d. Email chain regarding concerns from FSG

    e. Report Evaluation of the efficacy of Mirocons v1KDR feedback

    f. AJR Report Evaluation of the efficacy of Mirocons v1

    g. Excel spreadsheet of feedback

    h. Ewen Taylor statement

    i. Dale Frieberg statement

3. It appears that in 2012, QHFSS established a policy that samples yielding concentrations of DNA between 0.00214 ng/µl and 0.0088 ng/µl would automatically be subjected to a concentration step.

4. The reasoning for concentrating DNA in this quantitation range is:

    a. Out of the 100 µl of extract derived for each sample, at most 15 µl can be placed in the amplification process (known as PCR for polymerase chain reaction). Thus, the maximum amount of DNA that can be analyzed for any particular sample is 0.132 ng

(that is 0.0088 ng/µl x 15 µl = 0.132 ng). QHFSS has stated that analyses with less than 0.132 ng "exhibit marked stochastic effects" (for example see Project #184). Moreover, as the amount of DNA placed into a PCR decreases, stochastic effects are further exacerbated, and the resultant DNA profile may yield partial or no results which is especially so for low quality samples. Therefore, the chances of obtaining usable information can be increased if more DNA sample can be placed into a PCR. While there are aspects to concentrating DNA to consider when developing and implementing a concentration methodology (see Review and Assessment of the Appropriateness of Not Concentrating Low Quantity DNA Samples by Queensland Health Forensic and Scientific Services (QHFSS), date 13 September 2022), the logic of concentration generally is correct and appropriate for obtaining better results and having more samples yield usable data.

b. In 2015, QHFSS undertook a study (Project #163) to assess the value of further processing samples yielding quantitation values between 0.00214 ng/µl and 0.0088 ng/µl. The motivation for the assessment was based on anecdotal observation that samples in this quantitation range "often yield a DNA profile result which is unsuitable for interpretation or comparison (deemed non-informative)" (see Project #163). An anecdotal observation can be a starting point for investigation of a potential issue. Collecting data to support or refute that observation should follow. QHFSS carried out a study to assess the performance of low quantity samples subjected to concentration. Out of a collection 1001 samples (deemed assessable), 184 samples yielded a result that was considered informative (~18.4%). The assessment determined that (on page 16, section 5, first paragraph):

> This assessment has indicated that there has been value in the automatic-microcon process, with informative results and NCIDD uploads obtained across the quantification value range, including the lowest value ranges, albeit with a high number of non-informative results, which declined as the quantification value increased.

5. Thus, this assessment would appear to be supportive of the process of automatic micro concentration of sample within that range.

6. There were suggestions for process change in the Project #163 report (see page 16, section 5.1). One was that samples in this quantitation range be concentrated to half volume instead of full volume to preserve some sample (first paragraph). It is not clear if all samples were processed to full volume beginning 2012 (and if so when the policy changed to allow half volume concentration), whether samples were processed to full or half volume at analyst discretion (later in the Project #163 Report half volume is mentioned as if it was operational), or whether there were criteria to decide on which volume option was best suited for a sample. More recent protocols and studies tend to focus more so on concentrating to half volume.

7. The Project #163 also notes benefits and risks under different scenarios. For example, Consideration 1 (pages 16-17, section 5.1) stated that proceeding with concentration posed the least risk of loss of information and facilitates estimating the number of contributors in mixture profiles. Disadvantages primarily were reported to be cost, labor and time. Consideration 2 (pages 17-18, section 5.2) entertained not automatically concentrating the samples in this quantitation range with the benefit being reduced time, cost and labor; however, disadvantages noted were loss of information and less opportunity for possible improvement on obtaining informative results.

8. In January 2018, QHFSS produced a Report on Project #184 which was another study to assess the efficacy of concentrating samples in a similar concentration range as the previous study (this time 0.001 ng/µl and 0.0088 ng/µl). Again, QHFSS states a similar motivation that "Anecdotally, the suitability to provide QPS with DNA profile Intelligence from extracts that have been concentrated has been noted to be limited. Furthermore, extracts that are of low quant value that have been automatically concentrated have been observed to rarely yield DNA information for QPS" (see page 5 first full paragraph). In Project #184 a collection of 1449 samples that underwent concentration was reviewed, and 10.6% of these samples were deemed successful (see pages 9-10). QHFSS further evaluated the success data and drilled down "to the samples that had some NCIDD interaction and in particular, where they were the only samples in the case that were NCIDD-suitable for that particular profile." The laboratory determined that only 1.45% of all concentrated samples would provide "*new* intelligence" (see pages 9-10). Note that selection of being the only samples suitable for NCIDD upload could restrict the analysis to a smaller portion of samples and thus impact this figure downward.

9. A few points are noted with Project #184. The concentration seems to be targeted to 35 µl. It is unclear if any samples were concentrated to full volume, and there was no guidance on the decision process to opt for one volume or the other. QHFSS does indicate that ~89% of the samples did not yield meaningful interpretation results. Based on these results QHFSS recommended to cease automatically concentrating Priority 2 and Priority 3 case samples (see #1 on page 19). There are no data or analyses on whether a 10.6% success is beneficial to the criminal justice system or to greater Queensland. The success/failure percentages were different between Projects #163 and #184 but there were no data analyses on potential reasons regarding the differences. Such an analysis could help determine if the processes accessing samples and assessing performance were similar, as well as could be informative for improving laboratory practices.

10. In February 2018, the police accepted the QHFSS option that recommended to cease automatically concentrating Priority 2 and Priority 3 case samples and that low quantity samples would not be worked unless requested by the police on a case-by-case basis (which was Option 2 of the Options Paper). It was not explicitly stated in the Options Paper if scientists could request further working of Priority 2 and Priority 3 evidence with

quantitation values in the low quantity range. However, the statement by Dale Frieberg (paragraph 39) indicates that he believed that scientists would continue to request additional processing. The Options Paper contains the same data as in Project #184. When considering continuing or discontinuing concentration of low quantity samples the Options Paper identifies the 1.45% figure as relevant to the decision process but does not discuss the 10.6% finding (although the data are included in the body of the Options Paper). It is unknown what was discussed in any detail during the meeting with the police and how comprehensive was the exchange of information on the success rate, what was deemed a good success rate, and whether or not there were limitations associated with the study of the data generated. However, the statement by Ewen Taylor (paragraph 18) indicates that his understanding was QHFSS conveyed that the 1.45% figure was relevant regarding obtaining a result.

11. Subsequently, the police have been compiling data on the success rate on the samples they have requested to be concentrated. The percentage has been approaching 30%. As a result, QHFSS prepared an updated "Assessment of Low Quantification Value DNA Samples" dated 21 June 2022. There were 650 samples identified for the time frame between 2018 and 2021 and 25.4% of these samples were categorized suitable for comparison purposes. It has not been disclosed why there are differences in the percentage success in the three analyses, but they can be in part due to sampling, different search parameters, changes in the way analysts are interpreting data, a bias in ascertainment in the selection of samples for concentration, and bias by analysts to scrutinize more so these requested samples, to name a few.

Commission Tasks

12. Each task that the Commission asked me to address will be stated and followed with a response.

Question 1

13. From a laboratory management perspective, is the presentation of an Options Paper to police a standard way to implement a change in process of this nature? Why/Why not?

Response to Question 1

14. There are many different laboratory systems to include being part of a police agency (for example the FBI Laboratory), independent (for example my laboratory from which I recently retired and the Houston Forensic Science Center), commercial fee for service (for example Bode Technology) and that structure can drive the relationship, the accountability of service, and who might weigh in on the decision-making process. There are examples of these various systems around the world, and many seem to function well. It is difficult to opine on best practices from an international perspective, but one can assess the process

that was used in this particular laboratory system. QHFSS performed an analysis, provided the findings to its primary customer (the police), provided data in a report, and gave options for the police to consider. In principle, this approach is informative and collaborative and seeks input from the client. If properly undertaken, the approach would be acceptable.

15. The limitation of this approach is that police may not have the requisite experience to render scientific judgement, and they have a different responsibility than that of a laboratory. Substantial effort is needed to ensure the police understand enough to be able to opine on quality science decisions. Additionally, while the police are paying for the laboratory services, there are other stakeholders, such as the legal system and victim services, that should be consulted within this particular system who may have different perspectives on what constitutes success or need. Having said that, the priority of a laboratory should first and foremost be to obtain as much usable data as possible in a quality fashion. Once that is determined, then cost/benefit analyses (to include legal constraints) can be undertaken to determine if the processes are acceptable and sustainable.

Question 2

16. Provide any comments you have on the relationship between FSS and QPS evidenced in the correspondence regarding the Options Paper.

Response to Question 2

17. The initial correspondence after the Options Paper was presented seems to be appropriate. The decision was made and documented. Subsequently, there appears to be some tension between QHFSS and the police which is evident in email exchanges once Inspector Neville began asking about the success rate (see 14 November 2018, 2:47 PM email from David Neville and 15 November 2018, 3:24 PM, 9:20 AM email from Gerard Simpfendorfer and responses by Cathie Allen in emails 15 November 2018 and 16 November 2018, 4:01 PM) (which is further substantiated in discussion personally with Inspector Neville on 21 August 2022). In a Quality System, issues raised by clients should be addressed in a non-confrontational manner. In the "Email chain regarding concerns from FSG" (cited above) some of the exchange is informative and helpful (a good process) and some of the exchange does not seem to be responsive or constructive. Herein my response focuses on the non-responsive communications. Inspector Neville initially observed 3 out of 4 samples requested for concentration yielded useful information suggesting that more than ~2% of samples initially determined in the Options Paper may yield results. An observation with such a limited sampling of four samples could be simply sampling error, but it did raise the interest of the police. QHFSS should have presented data of performance over the 10-month period since the policy was enacted as well as continued monitoring of the results. Whether Inspector Neville's observation was simply a sampling phenomenon or an indication of a different success rate could have been able to be readily assessed and discussed. In Project #184 QHFSS stated (#3 on page 19) that:

> After a six month period of processing, re-analyse samples that have had a Microcon® process performed and were in the initial Quantification range greater than 0.0088ng/uL, to evaluate whether the range from Recommendation 1 can be extended.

18. It is unknown if QHFSS performed the follow up after the six-month period; but the only data made available are in the Update Paper three years later in response to police inquiries. QHFSS did respond with "Automatic progression of samples through the Microcon process means that all available DNA extract will be consumed, so no further testing can be conducted on these samples after this step." This statement seems at odds with the fact that in most documentation the 35µl half volume option is treated with the most emphasis during validation, as well as in standard operating protocols. Half of the sample would still be available. Perhaps "Automatic" means that full concentration is automatically performed. The concentration options being discussed are unclear and explaining the process would have helped. In an exchange with Gerard Simpfendor (15 November 2018, 3:24 PM, 9:20 AM email from Gerard Simpfendorfer and response by Cathie Allen in email 16 November 2018, 4:01 PM) who asked for clarification of the process, part of the response from QHFSS is "Reporting scientists are questioned under oath about the scientific decisions that they have made and provide answers based on scientific principles." This response seems odd and non-responsive to a workflow process question. An adversarial tone is captured when Justin Howes comments to Cathie Allen and Paula Brisotto that the email exchange with the police as a "great email" (email 21 November 2018, 12:29 PM). Cathie Allen to her credit does not agree with Justin (email 21 November 12>31 PM). Lastly, in the same vein as Inspector Neville who initially raised concerns that 3 out of 4 samples being successful (email 14 November, 2:47 PM) which might have been the result of sampling error (early on espoused by Justin Howes), Justin Howes takes the opposite position and comments to Cathie Allen and Paula Brisotto that 5 samples yielded no results (email 21 November 2018, 12:37 PM) – also ignoring the possibility of sampling error. The better approach would have been to collect data, which should have been ongoing since the 2018 policy was enacted, to provide an informed response and within QHFSS to be informed on best practice.

Question 3

19. Identify any problems or concerns you have regarding
    a. The data that were selected for inclusion in the Options Paper; and
    b. How the data were presented and/or interpreted

Response to Question 3

20. It is difficult to address how the data were selected for the Options Paper because there is insufficient detail on what constitutes usable data. The broad categories of, for example, partial, do not address case needs or investigative needs. At times low level data can be

interpretable, either as single source or a minor in a mixture. The resulting likelihood ratio (LR) may be large or small. Even if small, in context the information could be useful. What is determined as usable is very complex and that the broad categorization used for the Options Paper may not be sufficient. Currently, it is unknown what was the depth of the assessment to be able to determine if the process was adequate or inadequate.

21. As far as presentation and/or interpretation it is unknown to me regarding the depth of discussion between QHFSS and the police during their February 2018 Options Paper meeting. However, based on the Ewen Taylor and Dale Frieberg statements (see paragraph 10 above) the police did not appreciate the significance of the 10.6% of samples statistic. The Options Paper does contain the findings (whether rightly or wrongly generated), and thus the data were accessible for the decision process. However, based on communications internally at QHFSS, discussions with staff, and the documents provided, QHFSS management appears to be focused more so on turnaround times and cost for the laboratory compared with obtaining results and the potential benefit to Queensland (in a cost/benefit analysis based on tangible and intangible costs). Indeed, in the final information in the Options Paper the focus for considering continuing or discontinuing processing of low quantity samples was the 1.45% (a database upload metric) figure and there was no mention of the overall 10.6% figure. Cost and turnaround times should not be dismissed as unimportant; they do factor into the operational aspect of the laboratory. But the laboratory seems more focused on these considerations than the cost/benefit of obtaining usable information and whether or not a 10.6% value is worth pursuing concentration of all samples (or a good portion of samples) that fall in the low quantity range. Lastly, the laboratory did not seem to address the difference in success percentage between its 2015 and 2018 (lower success in 2018 study) assessments. It would have been informative to determine if the difference was statistically significant and if the process was different due to various factors (for its own process improvement).

Question 4

22. How, if at all, would you improve the methodology?

Response to Question 4

23. It is difficult to suggest improvements because the details on selection of samples, what is determined as usable and successful, the testing of the validity of the data mining process itself, to name a few things are not described sufficiently to render an opinion whether what was done was adequate for the task. Obviously defining these aspects would be requisite. An improvement that would have been beneficial is more engagement and response to those with requisite scientific and operational knowledge. During the review of the Project #184 report, the comments that overwhelmingly were addressed by management were cosmetic in nature. There seems to be little or no documentation showing that substantive comments were considered. Two staff (see sources e and f in paragraph 2 above) provided

technical comments that do not seem to be addressed or there is no documentation to explain why their comments were not addressed (yet there is an excel file on the mostly cosmetic edits). Bringing in some of the laboratory operational scientists at the design stage could have strengthened the design of the study. Additionally, consultation with stakeholders would have helped define what is a success or usable result as well as what success rate would be cost beneficial to the Queensland community.

Questions 5

24. Should anyone else in addition to the QPS have been consulted about the Options Paper?

Response to Question 5

25. The police are the primary customer, under the current system; indeed, they provide the funding for the laboratory and are responsible for investigations. So, the police should be consulted. But as stated above the determination of success and value includes more than just the police. Some discussion with the legal community would have been advisable; the legal community also makes use of the DNA results to litigate cases (see paragraph 33 below). The testing/no-testing decision does have consequences for each side of the adversarial system. If one thinks in terms of a systems approach, the few cases that identify a perpetrator, who for example is a serial rapist, could reduce the number of future victims, if identified early on. That reduction could result in savings in medical costs, adjudication costs, loss of productivity costs, to name a few, as well as provide safety and security of the community. Thus, one could envision discussions with other parties can add value to the decision process. But at a minimum, the legal community could have been engaged.

Question 6

26. Do you think the concerns raised by the FSS scientists during feedback process of Project 184 were valid or appropriate? Why/Why not?

Response to Question 6

27. QHFSS management sought input from its staff. Therefore, all feedback was important. However, feedback could be informative or uninformative from either the perspective of management or the staff or both. In the siloed workflow system at QHFSS (based on communication with anonymized staff) the feedback could better inform the management (which might have been addressed better during project design) and also better inform staff on issues. There were examples of feedback provided from two staff scientists – one for KDR and one from AJR. The comments are contained within edited versions of the draft report of Project #184 and appear to be helpful and constructive in understanding and strengthening the data analyses. For example, KDR points out that reworked samples may be due to a number of contributors assessment and not post concentration work; that the data for the 1.45% may be more relevant for volume crime than violent crime; the consideration of how many samples yielded likelihood ratios as opposed to focusing on

database uploads; presentation of data on quantitative ranges and database hit values; and extrapolation to volume crime without interpretation rules. AJR poses a very fundamental issue in that she raises points on defining what value is and for whom and what. AJR also suggests that the report should be specific regarding what is considered success; DNA intelligence should be defined; also, the number of contributors issue; and potential bias of risk focusing on the laboratory's interests. These comments appear to be reasonable and consistent with the assessment herein; they are appropriate and should have been given consideration.

Question 7

28. Do you think the concerns raised by the staff were adequately addressed or incorporated into the Options Paper?

Response to Question 7

29. Their comments do have value. They overwhelmingly do not appear to have made it into the report. There is no documentation provided that indicates discussion or justification for not including their comments.

Question 8

30. Definition of 'Fail and 'Success' in Options Paper – Explain whether the above is a suitable categorisation from:
    a. A forensic science perspective
    b. An investigative policing perspective

Response to Question 8

31. At first glance the criteria may seem reasonable. But they are too superficial and do not address what is considered useful especially for low level and/or low-quality level profiles. The example above in response to Question #3 points to the intricacies that can arise in each case both from scientific and investigative perspectives. As pointed out by staff scientists' comments (see Question 6 Response), defining the categories would have been beneficial. Likely, under the broad definition of usable, the set of samples would increase from what was considered by QHFSS. However, the actual outcome is difficult to predict because the details on the categories are not defined well in Report #184.

Question 9

32. Is an NCIDD upload relevant to how informative a sample is? If so, why and how?

Response to Question 9

33. For a DNA profile to be uploaded to the Database it must meet minimal criteria (which is the amount of genetic information in a DNA profile attributed to a single source). Thus, in one perspective profiles uploaded tend to contain quite useful genetic data and thus are directly associated with being informative. From another perspective samples with less

genetic data or too complex to upload to a Database still can be informative. Informativeness is related to the specific case, the questions that need to be addressed, etc. DNA can assist in eliminating a suspect, proving *corpus delicti*, providing corroborative evidence to support a confession, linking a crime scene and suspect/victim, proving an essential element(s) of a crime, affirming or disproving an alibi, encouraging an individual to make a confession, building cases against defendants, to name a few values. Thus, uploads are not the only way DNA can be informative and the value depends on the case circumstances.

Question 10

34. What other factors may be relevant to determining whether a DNA sample is informative within the context of a police investigation?

Response to Question 10

35. See answer to Question #9.

Question 11

36. What is the significance of a sample providing a 'cold-link' or a 'future link'?

Response to Question 11

37. From a laboratory operation perspective neither is particularly different in significance. The laboratory's responsibility is to generate DNA profiles and, if suitable, upload them to the Database. If there is a reference sample (for example, from a convicted offender) in the Database, a hit may be obtained. If not, the profile remains in the Database to potentially yield a hit if the donor's reference profile is placed into the Database at a subsequent time. From a functionality of the Database perspective, the number of associations made are important for assessing the value of the Database.

Question 12

38. Do you agree that the 1.45% figure was "the pertinent value" for the QPS to assess if the auto-microcon process should be performed? Why/Why not?

Response to Question 12

39. The 1.45% figure has value to inform on the quality of DNA information and the functionality of the Database to serve as an investigative tool. But, as indicated above, in itself, it is not the sole indication for the assessment of value. Indeed, given all the ways that DNA can assist in investigations and the nuances on a case-by-case basis, the 10.6% figure would seem more pertinent.

Question 13

40. Is the ability to compare a DNA profile with a reference sample informative for the QPS or the criminal justice system? If so, why and how? Include reference to both identifying the likelihood of contribution or excluding contribution.

Response to Question 13

41. DNA typing has been a boon to forensic science. It is used primarily (in the context of this Inquiry) for human identification. With sufficient quantity and quality, a DNA sample can associate an unknown sample to a very few individuals, if not only one, as well as help determine kinship relationships for identifying human remains and missing persons. That same power of potential individualization also makes DNA typing very effective for excluding individuals wrongly associated with forensic biological evidence. Because of enhanced sensitivity of detection minute and even trace samples may yield useful genetic information for identity purposes. Lastly, just about any tissue in the human body can be used to obtain a genetic profile. Thus, DNA is one of the most powerful human identification tools available to the criminal justice system. For human identification to occur through a DNA association, the profile from evidence (or human remains) must be compared to a reference DNA profile from a known donor(s). Thus, the ability to compare a DNA profile to a reference sample is requisite for the majority of human identity testing applications (note: there are some intelligence DNA testing systems that can predict eye, hair, and/or skin color of the donor of biological evidence; but the majority of DNA testing requires a reference sample for comparison). The comparison can be an inclusion or an exclusion. Both are important to the criminal justice system for the reasons described above in response to Question #9.

Question 14

42. In your view, was the statistic (10.6%) measuring criteria a "pertinent value" for QPS's interests? Why? Was it more or less important than the 1.45% figure?

Response to Question 14

43. see response to Question #12.

Question 15

44. Would the option presented in the Options Paper give the best chance of obtaining a useable DNA profile for every sample delivered to the laboratory?

Response to Question 15

45. In fairness two options were provided in the Options Paper:

1. Continue with 'auto-microcon' process for Priority 2 (Major Crime) casework; or,

2. Cease the 'auto-microcon' process for Priority 2 (Major Crime) casework and report the exhibit result of 'DNA insufficient for further processing' based on Quantification result.

    a. Priority 1 samples could proceed with the 'auto-microcon' process. If a DNA concentration rework is required, the Microcon® process can be ordered manually by the scientist.

46. Option 1 would give a better chance of obtaining a usable DNA profile simply because more samples would be processed. Option 2 was the one selected by the Police.

Question 16

47. If not, are there other considerations which could justify the approach in the Options Paper? What considerations are those?

Response to Question 16

48. Again, both options were provided. But the question seems to be focused on the selection of option 2. Success and value to the greater system might justify option 2. If it were deemed that the cost in time, labor and resources for the number of samples (in this situation 10.6% which may be an underestimated figure) processed outweighed the benefits to the overall system, then option 2 could be supported. In contrast, if the opposite were concluded, then option 1 would be better supported. If, however, option 1 was supported and there were insufficient funds available to meet the casework demand, then reduced testing might become necessary or shifting of current funding allocation undertaken.

Question 17

49. Is there reference to any of those considerations in the paper? Were those considerations explained adequately in your view?

Response to Question 17

50. No for both questions.

Question 18

51. Is the balance struck by the option in the Options Paper one you would consider to constitute international best practice?

Response to Question 18

52. This issue may not be relevant to international best practice. It seems to be what is best practice from quality service and operational business perspectives. Instead of balance, perhaps best informed is a better consideration. Since, as explained in the immediate previous few responses, there were considerations not fully undertaken and comments from internal staff not adequately addressed by QHFSS administration; the process may not have been one that was fully informing for both QHFSS and the police. A consequence of not being well informed is that pertinent questions may not be asked, missing data are not appreciated, bias can negatively affect proffered solutions, and decision making is hampered.

Question 19

53. What other options could have been explored regarding workflow?

Response to Question 19

54. This question in part is difficult to address as I am not familiar sufficiently with the current QHFSS workflow to offer options per se. It has become apparent that the current system, however, is quite siloed, which may not be the best suited for casework operations. It is conceivable that moving to another system may be more costly but should be evaluated to create a more communicative and interactive system. An obvious option to explore, which has been intimated above, could be to perform a cost/benefit analysis on the benefits of concentrating all low quantity samples or taking option 2. The analysis could possibly support an increased budget to process the samples. Alternatively, an assessment into the increased success rate with the requested samples by the police and subsequently confirmed by QHFSS could provide insight. There may be a bias in the samples selected that impacts the success rate, and if there are indicators for those samples, an informed triage could be implemented improving the overall efficiency of the process.

Question 20

55. Was the work done in Project 163 and Project 184 sufficient to make any determination of a threshold below which stochastic effects were identified?

Response to Question 20

56. Stochastic effects occur in every DNA analysis performed by QHFSS (and for that matter any laboratory worldwide). As the amount of input DNA for analysis decreases the stochastic effects become greater. Laboratories historically have used an input amount as an initial decision process to proceed or not. The amount designated by QHFSS (i.e., 0.132 ng) is similar to other historical thresholds. The determination of a threshold by QHFSS was not performed in either project. The QHFSS threshold was determined in other studies (which were not provided). Regardless, with increased sensitivity of detection and advanced computational tools in the laboratory plus the consideration of how DNA may be informative, the threshold should be re-visited.

Question 21

57. Is the threshold of 0.0088ng/µL too low or too high?

Response to Question 21

58. This question can only be answered through a proper validation study using the tools available today. Publications on the sensitivity studies of current DNA analysis kits overwhelmingly show good success for single source samples around a total of ~0.050-0.063 ng, which is less than 0.132 ng. However, testing needs to be performed in the laboratory to determine what the value should be.

Question 22

59. What would you consider to be an appropriate threshold at which to cease processing a sample?

Response to Question 22

60. Thresholds are lines in the sand. Wherever the line is drawn, there are consequences that scientists need to understand. If the threshold is too high, then good DNA data may be lost. If the threshold is too low, then noise may be misinterpreted as DNA and stochastic effects may become unmanageable. Thus, a balance between these two consequences is struck (favoring one or the other consequence) or at least there should an understanding of which one may impact more so if a higher or lower threshold is selected. The threshold to consider is that value at which obtaining useful information (once defined) is a low probability (again determined on what is a desired success rate). The rates could be different depending on the case priority or sample type or other criteria relevant to be considered useful.

Question 23

61. Is it appropriate to have a hard quantitation threshold to determine whether samples are further processed? Why/Why not?

Response to Question 23

62. From a laboratory operational perspective having a defined threshold is important. It allows for more uniformity among scientists, allows for common ground for trouble shooting, reduces protocol drift, and allows for outside reviewers to understand what was performed by the laboratory. While such thresholds are in place, some discretion is allowed in many laboratories (often with proper discussion and/or approval and always with documentation). With additional information made available during the quantitation assay the "hard" threshold might be modified on a case-by-case basis. It is conceivable that a sample with a quantitation value below a hard threshold but shows no indication of degradation may yield usable data. Also, if there is a low-level male contributor in a sample with a large amount of female DNA, such as might be obtained from a fingernail scraping from a female victim, then Y chromosome marker testing might be considered a better option than standard testing. With Y chromosome marker testing the "hard threshold" may be lower for the male component (for technical reasons not necessary to be explained herein). Of course, these options should be assessed before implementation.

Question 24

63. What considerations, in addition to quantitation value, are relevant to determining whether a sample would benefit from further testing?

Response to Question 24

64. See response in Question #23. Additionally, sample testing could be based on the particular sample as well as priority and severity of the case.

Question 25

65. What contextual information may be required when assessing whether a sample would benefit from further testing?

Response to Question 25

66. Context would not determine if a sample would benefit from testing. Context, however, may impact whether a sample should be tested, regardless of the quantity and quantity indicators. As stated above, sample testing could be based on the particular sample, as well as priority and severity of the case.

Question 26

67. What information could be lost if a sample is not fully processed?

Response to Question 26

68. For those samples that if processed would yield useful genetic data, information would be lost. As stated in response to Question #9 informativeness is related to the specific case, the questions that need to be addressed, etc. DNA can assist in eliminating a suspect, proving *corpus delicti*, providing corroborative evidence to support a confession, linking a crime scene and suspect/victim, proving an essential element(s) of a crime, affirming or disproving an alibi, encouraging an individual to make a confession, building cases against defendants, to name a few values. Which one or ones that would apply is case dependent. Regardless, the DNA information that supports these areas would not be available for those samples that were not processed but would yield useful genetic data.

Question 27

69. Should the quantitation threshold of 0.0088ng/µL have been revisited following the introduction of the 3500xL? Why/why not?

Response to Question 27

70. It is unknown to me whether this assessment was performed by QHFSS. It may have been done, and the documents were not provided. Regardless, changes in instrumentation and methodology should undergo validation or verification (the process dependent on whether the change is material or substantive to the process). If in the hands of QHFSS the new instrument version is demonstrated to be more sensitive than the current system in the

operation, then testing the impact of the increased sensitivity would be warranted. It may allow for a lower input of DNA; it may increase observing greater degree of stochastic effects; it may reduce the amount of missing data in low level samples; it may reduce the minimum DNA detection threshold; and so on compared with the current system. If there was no change in sensitivity of detection in the hands of QHFSS, then there would seem to be less need to revisit the threshold because of a new version instrument.

Question 28

71. Identify any limitations of the Update Paper, and the underlying internal report 'Assessment of the ability to obtain DNA profiles when further work is requested on samples with low-level Quantification values'.

Response to Question 28

72. The concerns are similar to those stated above for the other Projects and thus do not need to go into further detail herein. Briefly, it is not defined what 'suitable for comparison purposes' means, whether the data mining process was tested for validity, if other biases in sampling or analyses impacted the results and if these results are representative of the actual work in the laboratory (or at least mentioning the limitations of the study). It has not been determined why there are differences in the percentage success in the three analyses, but they can be in part due to sampling, different search parameters, changes in the way analysts are interpreting data, a bias in ascertainment in the selection of samples for concentration, bias by analysts to scrutinize more so these requested samples, to name a few. The information could improve laboratory practices. QHFSS again emphasizes the stochastic effects with the 0.132 ng threshold. QHFSS states (on page 2, second paragraph under observations):

> The value of 0.0088ng/µL is based on assessment of the data (and equates to 132 picograms). Validation studies conducted within the laboratory has shown that stochastic effects become apparent from DNA templates below 0.132 ng (132 picograms) making interpretation of the resultant DNA profile more complex.

73. It is important to note that being more complex does not equate to being non-informative. As stated above validation studies reported in the scientific literature (for example see Ludeman et al, Developmental validation of GlobalFiler™ PCR amplification kit: a 6-dye multiplex assay designed for amplification of casework samples, International Journal of Legal Medicine (2019) 132(6): 1555–1573; and Ensenberger et al. Developmental validation of the PowerPlex1 21 System. Forens. Sci. Genet (2014) 9:169-178) and have obtained good results with less than 0.132 ng input.

74. In the Update Paper QHFSS offers an option (page 3, 3c):

> c) Priority 3 samples that fall into the quantitation range of either 0.001ng/µL to 0.0088 ng/µL or 0.001ng/µL to the newly determined value will be amplified without a concentration step.

75. While volume crime is not afforded the same consideration as violent crime, this option is not based on the laboratory's findings or opinions. If the laboratory opines that samples with quantitation values in this range have a low success (which low is not defined), then processing without amplification would seem to be costly and a waste of time. If the success is reasonably high (again which still needs to be defined), then the laboratory should definitely redefine its DNA input value to a lower threshold. Lastly, data in the U.S. have shown that a large portion of individuals associated through a database search with evidence derived from a violent crime have a criminal history of committing lesser crimes (personal communication, Virginia Department of Forensic Science). If the same holds for Australia, then working Priority 3 case samples and obtaining the best quality data may be another cost/benefit consideration.

Question 29

76. Identify any problems or concerns you have regarding
    a. The data that were selected for inclusion in the Update Paper and underlying internal report; and
    b. How those data were presented and interpreted.

Response to Question 29

77. The issues are the same for selection as for the other Projects and are addressed in Question #28. Not being present during the meeting between QHFSS and the police, I cannot opine on presentation and understanding. However, the statements by Ewen Taylor and Dale Frieberg indicate that the police accepted the 1.45% figure as the valid one for their decision process. other than what was mentioned in response to Question #28, there does seem to be more options to weigh and the intention of a follow up meeting to foster a "collaborative decision" which were good indications of a positive working relationship.

Question 30

78. How, if at all, would you improve the Update paper?

Response to Question 30

79. This question has been addressed in responses to the other projects and Question #28. They hold here as well.

Question 31

80. Outline any other concerns regarding the Options Paper and/or Update Paper not addressed by the above.

Response to Question 31

81. A large contributing factor to the limitations of these studies may be the siloed nature of the laboratory which does not appear to foster communication and taking advantage of the intellectual capacity of the staff. Adding to the limitations could be that management may not be adequately trained or experienced in experimental design, statistics, or relevant issues seen at the bench or by reporting scientists.

82. Concluding Remarks: After reviewing various materials for this assessment and other tasks and having discussions with some staff and the police there are some concerns about root causes related to the laboratory system. As with all issues (retroactively or proactively) it is important to determine the root cause(s) and corrective action(s) to improve the system. While a deeper dive is needed to address the root cause(s) than is possible solely from the documents provided by the COMMISSION and discussions with some QHFSS staff and police, some areas should be considered for improvement to improve communication within and without the laboratory, develop better workflows and reduce the chances of performing improper validation studies and thus implementing potentially problematic methodologies. These issues identified are preliminary and could be topics for an audit of the laboratory system for a comprehensive assessment. As indicated above, the siloed approach at QHFSS does not support communication and good quality. A system that engages all relevant parties and involves them beyond their sole designated functions would be more empowering and take full advantage of the intellectual capacity of the staff. Additionally, there appears to be a disconnect of the role of QHFSS and the stakeholders and end users. Clearly, the police are customers. After all, the police pay for the QHFSS services and use the results to support their investigations. That relationship, however, may favor throughput by QHFSS over quality and should be re-evaluated. There also are other stakeholders that are impacted by the results and findings reported who may have good input on what "value" means and assist in better cost/benefit analyses. These other entities include the prosecution, the defense, the accused, the victims, families, the public, and government services, to name a few. More engagement with stakeholders would be beneficial to effect better services. As part of an improvement process, training of laboratory management should be undertaken to develop effective management practices, reconsideration of the laboratory workflow to engage staff, and implementation of an effective quality system. Lastly, there are indications that the laboratory culture may not be one of a just culture. Management and staff should be trained in this very important part of maintaining a quality program.

The findings contained in this report are based on the information available to Bruce Budowle as of the date of the report. If additional information becomes available these findings may be subject to revision.

This report was completed on 19 September 2022 and describes the opinions and conclusions of the undersigned.

Bruce Budowle