Patient Focused Laboratory Medicine Group

Getting it right for the patient, are we good enough?

Meeting Report with Recommendations

February 2026

NHS Bedfordshire Hospitals NHS Foundation Trust

Birmingham Quality

Weqas

GIRFT GETTING IT RIGHT FIRST TIME

Contents

Abbreviations

ABHI	Association of British HealthTech Industries
APS	Analytical Performance Specifications
BDD	Blended Decision Diagnostic
BIVDA	The British In Vitro Diagnostics Association
CQP	Common Quality Practices
DM	Diabetes Mellitus
EQA	External Quality Assessment
GIRFT	Getting It Right First Time
IBMS	Institute of Biomedical Science
IQC	Internal Quality Control
LabMed	Association for Laboratory Medicine
MSC	Managed Service Contract
NDH	Non-Diabetic Hyperglycaemia
NHS	National Health Service
NHSE	NHS England
NICE	National Institute for Health and Care Excellence
NQI	National Quality Infrastructure
IVD	In Vitro Diagnostics
MHRA	Medicines and Healthcare products Regulatory Agency
PFLM	Patient Focused Laboratory Medicine Group
QMS	Quality Management System
RCPath	The Royal College of Pathologists
SNoW	Significant Non-Conforming Work
SoS	Secretary of State
TEa	Total Allowable Error

Report Writing Group

- Rachel Marrington, Consultant Clinical Scientist and Deputy Director Birmingham Quality (member of the UK NEQAS consortium), University Hospitals Birmingham NHS Foundation Trust
- Gareth Davies, Principal Clinical Scientist and Deputy Director Weqas, Cardiff and Vale University Health Board
- Danielle Freedman, Consultant Chemical Pathologist and Deputy Medical Director, Bedfordshire Hospitals NHS Foundation Trust
- David Housley, Consultant Clinical Scientist and Clinical Lead for Biochemistry and Immunology, Bedfordshire Hospitals NHS Foundation Trust
- Finlay MacKenzie, Consultant Clinical Scientist and Director Birmingham Quality (member of the UK NEQAS consortium), University Hospitals Birmingham NHS Foundation Trust
- Martin Myers, Consultant Clinical Scientist and GIRFT Pathology Co-Clinical Lead, NHS-England
- Annette Thomas, Consultant Clinical Scientist and Director Weqas, Cardiff and Vale University Health Board

Introduction

As part of the investigation into the cause and consequences of a positive bias in the HbA1c results using a particular method, NHSE requested that a full investigation was undertaken, involving NHS Getting it Right First Time (GIRFT), Dr Myers and Dr Rob Sherwin (Medical Director, East of England). This formal investigation is almost complete. In addition, GIRFT established an Expert Group of Laboratory Professionals to ensure that the lessons learnt were captured and to make recommendations to reduce the risk of this type of event occurring again. This Expert Group is the Patient Focussed Laboratory Medicine Group (PFLM Group), reporting to NHSE GIRFT. One of the tasks of the PFLM Group was to organise an open meeting with all relevant stakeholders to share the lessons learnt and to discuss their recommendations. This meeting report has been written jointly by the PFLM Group who believe that some aspects of Clinical Biochemistry diagnostic services require immediate development to ensure that this clinical service is more patient-focussed and to ensure that patient safety is a key foundation of service delivery, with the intention to improve the current status of clinical quality in UK laboratories providing a service to patients. The learning outcomes may be applicable to other disciplines within Laboratory Medicine.

This recent event, where a positive bias in a test in some laboratories resulted in over-diagnosis of disease, initiated a deep-dive into gathering evidence on the root cause, consequences and the Quality Infrastructure of the Service. The evidence showed that the issues identified could result in a further system failure for other tests. The PFLM group has gathered evidence and this report details recommendations to all Agencies involved and recommends that the professional societies — Association for Laboratory Medicine (LabMed), Institute of Biomedical Science (IBMS), Royal College of Pathologists (RCPath) — take leadership in developing and implementing our recommendations to ensure adoption by the wider laboratory medicine community.

The aim of this report is to summarise findings from:

1. investigating a very significant event in 2024 (HbA1c) which exposed numerous gaps/deficiencies in the quality systems used by clinical biochemistry laboratories. (1, 2)
2. discussions from a webinar held in November 2025 where the PFLM group shared their concerns with a wider audience of professionals.

This report will be made available to laboratories via numerous mechanisms including via Birmingham Quality (a member of the UK NEQAS consortium) and Weqas EQA providers.

Background

In 2024, variation in the performance of a particular HbA1c assay resulted in the misdiagnosis of patients. This paper is written to be agnostic to the particular method involved and concentrates on wider lessons that would be relevant not only if another HbA1c incident were to recur, but more importantly that the lessons learned here would be transferable to any assay.

The HbA1c incident has been well publicised in the media, and, at time of writing, over 50,000 patients needed to be recalled for repeat testing, and many patients had their diagnosis changed. (1) However, during the investigation into this event, it became clear that the Clinical Quality Infrastructure for pathology laboratories requires review (3, 4), along with our escalations routes within the NHS:

- the way we work with the Regulators, such as the MHRA,
- the role of ISO 15189:2022 in the Accreditation of the Laboratory service for the patient,
- the contractual relationship with the In Vitro Diagnostic (IVD) manufacturers, including the Reasonably Foreseeable Misuse of the IVD and the post-market performance,
- how laboratories, EQA providers and suppliers work together to resolve issues.

The importance of such an infrastructure was first proposed in the Barnes Report into how diagnostic variation resulted in misdiagnosis of patients. (5) During our review into the recent event, it became clear that little of the Ian Barnes recommendations have been translated into practice, and we discovered further 'gaps' in the Pathology Quality Infrastructure. In the same way that Health and Safety is the responsibility of all staff, we would argue that Clinical Quality is the responsibility of all staff. To share the lessons learned from the more recent event, we decided that an open access, free of charge, webinar would be held to discuss the event and allow everyone to discuss the recommendations that we made. Over 1,000 people registered for the event! We had to suspend registrations, but we were encouraged that so many staff responded to our call for a discussion on a system-wide review of the Clinical Quality Infrastructure within Pathology. This meeting report outlines the themes that were presented and discussed and should be used as a *springboard* for system change.

Implications of Incorrect Results

Dr Freedman gave an excellent presentation on the impact of Getting it Wrong for the Patient. Pathology delivers a huge number of results each year — 1.12 billion tests according to GIRFT Pathology (6) — however, we must never forget the impact that a single wrong result can have on the patient; this includes personal and family stress, change in lifestyle and possible changes to insurance and medication. Every single result matters because every single result is on a patient. A wrong single result, which may be relatively cheap in terms of direct costs, almost certainly has an expensive effect on the NHS. This is especially true when a single 'number' is used in a pathway for diagnosis, further investigation or treatment. Patients are unnecessarily referred to follow on primary care and secondary care appointments, further expensive secondary care testing etc. which increases the workload and financial burden to the NHS. Pathology testing is not in its own financial silo; it is part of the economics of the patient pathway. It therefore makes little sense to apply financial and efficiency targets on Pathology in isolation, the result is a reduction in quality and increased expenditure in other parts of the Patient Pathway. There is a danger that the pursuit of cheaper Pathology may reduce the Clinical Quality of the service and result in increased cost to the wider NHS, as well as the unacceptable effects on patient safety and well-being. In addition to the many discussions with the Pathology Community regarding the cause and identification of the positive bias, further evidence was obtained from the National Diabetes Data Set on the impact to patients. The data clearly shows that laboratories using the affected IVD had a significant increase in the numbers of patients diagnosed with Diabetes Mellitus and Non-Diabetic Hyperglycamia during June to December 2024 compared to the national figures from laboratories using other IVDs. This Data has been sent to all affected Laboratories so that they are aware of the impact of the positive bias on the diagnoses in their locality.

RECOMMENDATION 1

Each laboratory should understand the consequences to the patient on the performance of all assays / investigations and understand the impact of out of tolerance results on patients.

Each laboratory needs to clearly explain and communicate consequences of the performance of all assays / investigations on the patient from recommendation 1 to clinicians and patients.

Note:

[1] For example, how does the method imprecision, lot-to-lot variation and bias impact patient management?

[2] The uncertainty associated with the test should be reported in such a way that both the clinician and patient can understand the consequence of that variation.

[3] When National Guidance (e.g. NICE) utilises specific thresholds, especially when those thresholds have a binary interpretation, laboratories need to inform clinicians of the potential impact of method related issues such as bias and imprecision on the application of that threshold. Where studies used by NICE as evidence base relate to assays different to the one in use, that should also be highlighted. The laboratory has an essential role in advising clinicians, not just on the impact, but how it maybe clinically mitigated.

[4] A resource such as LabTestsOnline UK should be used to support this. (7)

[5] See also Recommendation 3 relating to Analytical Performance Specifications.

The first webinar session was followed by Dr Myers who outlined a seven-point plan on improving the Clinical Quality Infrastructure of Pathology.

Many elements of the seven-point plan are being discussed with the stakeholders with translation in 2026.

1. Quality Infrastructure and Common Quality Practices. In our investigations it was clear that there was uncertainty and a lack of clarity of how performance concerns should be escalated. Recommendation 13 of the GIRFT Pathology National Report recommended the setting up of a National Oversight Group. (8) To date this has been partially fulfilled by the Royal College of Pathologists National Quality Assurance Advisory Panels and Quality Assurance Pathology Committee structure; however, as of 1st January 2026, these roles have been 'paused'. (2, 9) Quality must be the foundation of any Diagnostic Service and there is a requirement for a defined Quality Infra-structure for UK Pathology. We propose that a Quality Framework be set up to ensure clarity on Quality Failure escalation. A proposed example for England can be seen in Figure 1. There are different structures within each of the nations within the UK and each nation needs to address their own Quality Infrastructure. However, there needs to be a clear quality escalation pathway. In addition, there is too much unwarranted variation in the way Laboratories manage their Quality Performance. This needs to be addressed with the introduction of Common Quality Practices (CQP). CQPs need to be defined for the service to reduce this unwarranted variation. We would recommend that there is a mandate that there is a National Quality Infrastructure and associated Common Quality Practices.

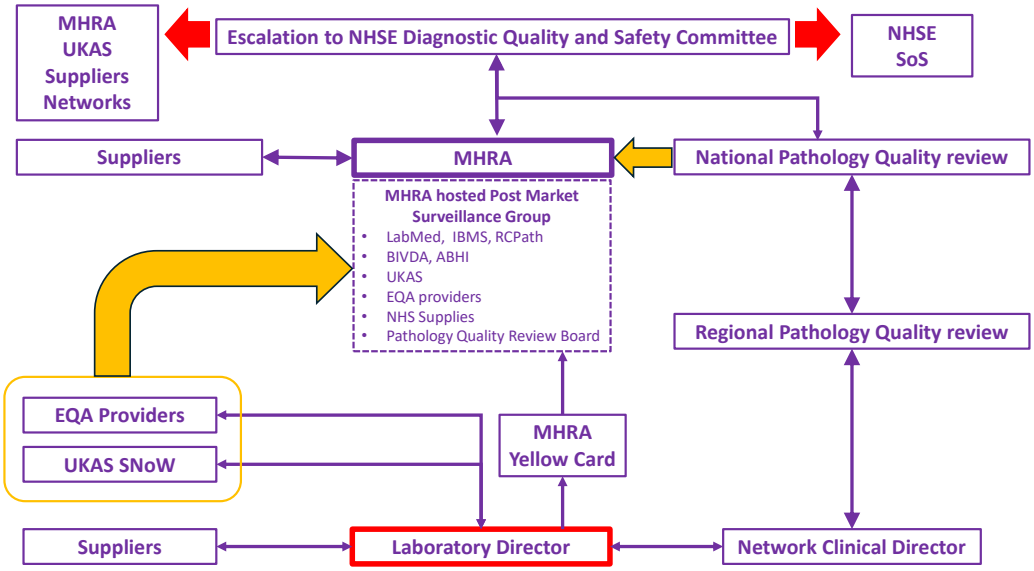

Figure 1. Proposed Quality Infrastructure for England to be adapted, where applicable, for all other nations in the UK

2. Analytical Performance Specifications (APS). There is uncertainty about what is acceptable performance. Whilst APSs have been discussed internationally for many decades, (10) translating this into common practice has not occurred effectively. To address the HBA1c issue, an APS of Total Error of 5% for Birmingham Quality and 6% for Weqas (reflecting the Scheme designs in use, but which identify the same out-of-consensus methods) has been introduced. These APSs includes bias and imprecision and show whether a laboratory performance and/or method performance does not meet the specification. If we do not define what is acceptable, how can we define what is not acceptable?

3. Clinical Decision Making (the problem with magic numbers). NICE produce clinical guidelines that are evidence-based and respected throughout the world. However, at times, there is too much reliance on 'magic numbers'. There is unwarranted variation in results due to bias and imprecision, both between manufacturers and between laboratories. The aspiration to have a single 'magic number' for decision making ignores these variations and patients with the same 'true result' could follow different pathways depending on where the sample was analysed. This must be acknowledged. In addition, even when the Laboratory Medicine Profession meets the defined APSs, there will still be Measurement Uncertainty, resulting in Clinical Diagnostic Uncertainty. It is therefore critical that in a patient pathway, the result of the test forms part of the pathway decision and not be totally relied upon to make a decision. A Blended Decision Diagnostic should incorporate the uncertainty of the result and the Patient symptoms. The diagnosis of DM and NDH is a good example where the laboratory test result alone cannot be used to make life-changing diagnoses, and there is a need to mitigate the diagnostic uncertainty.

4. ISO 15189:2022 Accreditation. (11) Pathology Accreditation under Clinical Pathology Accreditation (CPA) and since 2009 the United Kingdom Accreditation Service (UKAS), has improved Pathology Quality in the UK significantly over the last decades. The recent transition to ISO 15189:2022 by the majority, if not all, UK laboratories providing services to NHS patients shows the commitment of the UK laboratory to quality. Recently however, there has been a lot of focus on the Technical Quality Management System of the Laboratory. ISO 15189:2022 includes the pre- and post-examination phases. Assessment to this standard should be widened to fully embrace the pre- and the post-examination phases to include whether the result is fit for its intended use by the clinician. Accreditation needs to be Clinical as well as Technical.

5. MHRA Regulation. The MHRA is responsible for the regulation of IVDs, at launch and through post-market surveillance. Responsibility for adopting an IVD and Post-Market Surveillance sits primarily with the Laboratory Director. IVD usage has two regulatory elements: the introduction and post-market surveillance (MHRA) and the Placement and usage in the NHS (Laboratory Director). It is therefore critical that both parties understand their role and to ensure transparent communication. Under the Regulatory Framework, the MHRA have a yellow card system for communicating potential poor IVD performance. However, many laboratories do not use this system, which makes it very difficult for the MHRA to be made aware of, and respond to, issues of IVD Performance. In addition, Laboratory Directors need to be aware of their role in the Regulatory framework when they decide to use a device for patient investigations. Laboratory quality monitoring data (e.g., IQC, EQA, patient means, user complaints) must be fully accessible by any laboratory clinician in a leadership role, to allow that role to be undertaken robustly, and to allow the clinical impact of any issues to be fully assessed.

6. Manufacturers. According to a 2023 market audit conducted by BIVDA the UK IVD market is approximately £1.2 billion. (12) Most of this is spent by the NHS. Under the MedTech code of Conduct, used by the *British In Vitro Diagnostics Association* (BIVDA), and the *Association of British HealthTech Industries* (ABHI) emphasis is put on the premarket and marketing element. At the Webinar it was proposed that the NHS and Manufacturers should work together to propose a post-market code of conduct to ensure that the NHS and the Manufacturers can work together to discuss issues without the need for escalation.

7. NHS Supplies. The NHS spends a lot of money on IVDs. It is proposed that when the other proposals are embedded, then NHS Supplies will have a better understanding on the Quality Infrastructure of IVDs to ensure that the public money is spent within a quality framework. NHS Supplies would need to ensure that IVD usage within the NHS sits within a contractual framework that not only includes procurement, but to ensure that the contractual framework includes use-case, adoption, post-market surveillance etc. The NHS must ensure a “lifetime” contractual framework exists to ensure continual quality.

RECOMMENDATION 2

Fully implement Recommendation 13 of the GIRFT Pathology Report. (8)

Note:

[1] Make better use of EQA information at national level.

[2] Since this meeting an NHSE Diagnostic Quality and Safety Committee has been set up as part of the escalation infrastructure for poor performance of tests.

RECOMMENDATION 3

PFLM have requested that the RCPath lead the review of APSs for clinical biochemistry analytes to determine the most appropriate model based on the Milan Paper for a UK based patient population. (13) This should be based on what is required for the clinical utility of that test rather than what is achievable by the majority.

The laboratory is responsible for implementing and monitoring their performance of the RCPath APS findings as part of the laboratory's QMS.

Note:

[1] APS is defined as a range of values around the target which is considered acceptable for the performance of that test. We suggest that Total Allowable Error (TEa) is used as the basis for APSs. We have set one up for HbA1c and APSs for other key tests will be introduced.

[2] See also recommendation 1.

RECOMMENDATION 4

LabMed to lead a review of criteria for the diagnosis of Diabetes Mellitus and Non-Diabetic Hyperglycaemia. PFLM recommend that the outcomes of this be taken to NICE for consideration in relevant NICE guidelines.

Note:

[1] All patient pathways involving diagnostic tests need to be cognisant of the bias and imprecision of the test.

RECOMMENDATION 5

ISO 15189:2022 accreditation should be focussed on risk management of the whole patient pathway involving clinical laboratories.

Note:

[1] ISO 15189:2022 includes both pre- and post-examination elements.

[2] Includes, but not limited to, assay / equipment selection, post-market vigilance and clinical guideline development / use etc.

[3] Laboratory Directors need to be aware of their obligation under Significant Non-conforming Work (SNoW).

RECOMMENDATION 6

PFLM have requested that:

(1) MHRA introduce formal process for post-market surveillance of IVDs.
(2) Laboratories need to increase usage of the MHRA yellow card system.

Note: None

RECOMMENDATION 7

NHS Supplies to have a greater awareness of the quality infrastructure of IVDs to ensure that public money is spent within a quality framework.

Note:

[1] To include procurement, contracts and contractual surveillance.

Role of the Laboratory

David Housley shared his experience on how Laboratories need to ensure that the Clinical Quality Management System can be introduced. A Technical Quality Management System may rely on Internal Quality Control (IQC) with certain limits — but we have seen huge unwarranted variation in how laboratories define their Technical Quality Management System, which could lead to a 'failure' in one laboratory, but a 'pass' in another. The Technical Quality Management System needs to reduce this variation, with possible national guidance. However, the Clinical Quality Management system needs to be patient and outcome focussed. For example, daily patient means, number of patients diagnosed with DM etc. Numerical results need to have a clinical QMS and not just a numerical QMS.

RECOMMENDATION 8

PFLM have requested that LabMed provide guidance/toolkits on quality processes available including, but not limited to IQC, patient means, ongoing verification, lot-to-lot variation, data extraction etc. (14)

Note: None

RECOMMENDATION 9

PFLM have recommended that LabMed provides further training and education of consultants/laboratory directors regarding their roles and responsibilities (clinical utilisation and legal) in relation to the regulatory and accreditation framework (IVDR/MDR and ISO 15189:2022) in general and post-market vigilance via the MHRA.

Note:

[1] Suggest a Laboratory Director masterclass or equivalent.

External Quality Assessment

Evidence! Finlay MacKenzie (Birmingham Quality, a member of the UK NEQAS Consortium) and Annette Thomas (Weqas) both presented on how the newly agreed APS for HbA1c are now embedded into their respective EQA schemes for HbA1c. It is important to note that this is not the case for all EQA providers. Laboratories and Manufacturers can now transparently see the performance of the laboratory and the methods against the APS. This will allow action to be undertaken by both the Manufacturer and the Laboratory on improvements to the method being used and decisions on what method options are available. These results have already initiated a debate on whether there should be different APSs for HbA1c Methods for Diagnosis and Monitoring. Evidence is suggesting that the use-case (diagnosis or monitoring) of a method should be clearly defined and compared with the APS for each use-case. This will result in system change, but must be delivered in a transparent manner, such as having separate codes for HbA1c for each use case.

It should be noted that the UK is well served by high quality EQA and that although we can learn and improve on our systems, there is not any other stand-out provider we are aware of that would have picked up issues earlier, nor be running with tighter APSs than even those we historically used.

Discussion

As the day was intended to embrace the Pathology Community, one hour was set aside for a Question-and-Answer session to address the issues and concerns of the Pathology staff and other stakeholders. This was a very informative and active session, with discussions on the lessons learnt, the proposed way forward and many other elements where systems vary throughout the country. One key area of debate centred around contracting responsibilities. For example, many laboratories have contracts with a Managed Service Contract (MSC) Provider, who is often a Primary Provider, but the Managed Service includes third party IVD manufacturers. Under the MSC, the NHS has undertaken a contract to use a method that is fit for purpose. If the Method is not fit for purpose, then the MSC is contractually obliged to provide a method that is fit for purpose, and that can be at any time during the contract with either the Primary or Third Party.

RECOMMENDATION 10

PFLM recommends that there should be a corporate member group and establish a post-market code of conduct within BIVDA and ABHI to ensure continued use of an IVD.

Note: None

Conclusion

We have known for a long time that due to lack of Common Quality Practices, lack of Analytical Performance Specifications and lack of a National Quality Infrastructure there is a high risk that the unwarranted variation in service delivery is a risk to patient Safety, and we need to move forward in a coherent way with collaboration from all the relevant stakeholders. This episode should act as a *springboard* to ensure that the lessons learned will be translated into routine practice to ensure a focus on patient-focused Pathology.

We are aware that the IBMS has commissioned a new independent review, by Lord Carter of Coles and we would recommend that our proposals on a National Quality Infrastructure (NQI), the adoptions of APSs and Common Quality Practices (CQP) should contribute to the future strategy of Pathology Services.

Pathology has gone through multiple change strategies over the past 15 years. Laboratory services should ensure that the clinical impact and outcomes are central to all major decisions (e.g. equipment procurement, service reconfiguration), and this is reflected in key documents within the technical and clinical QMSs such that clinical rationale for change is as transparent and auditable as the operational and financial case for change. Therefore, we would strongly recommend that the ten-recommendations in this report are taken into consideration by the relevant professional bodies and laboratory directors by end of 2027.

We advise that these recommendations should be applied to all laboratories who provide a clinical service to NHS patients. There is a significant risk to patient safety and to the reputation of the professional bodies in addition to laboratories if actions are not taken.

We as a profession need to remember that the clinician makes a decision about the patient based on the patient's test result. It's never just about the laboratory, it is always about the patient.

Table of Recommendations

1	**Each laboratory should understand the consequences to the patient on the performance of all assays / investigations and understand the impact of out of tolerance results on patients. Each laboratory needs to clearly explain and communicate consequences of the performance of all assays / investigations on the patient from recommendation 1 to clinicians and patients**. *Note:* *[1] For example, how does the method imprecision, lot-to-lot variation and bias impact patient management?* *[2] The uncertainty associated with the test should be reported in such a way that both the clinician and patient can understand the consequence of that variation*. *[3] When National Guidance (e.g. NICE) utilises specific thresholds, especially when those thresholds have a binary interpretation, laboratories need to inform clinicians of the potential impact of method related issues such as bias and imprecision on the application of that threshold. Where studies used by NICE as evidence base relate to assays different to the one in use, that should also be highlighted. The laboratory has an essential role in advising clinicians, not just on the impact, but how it maybe clinically mitigated.* *[4] A resource such as LabTestsOnline UK should be used to support this. (7)* *[5] See also Recommendation 3 relating to Analytical Performance Specifications*.
2	**Fully implement Recommendation 13 of the GIRFT Pathology Report. (8)** *Note:* *[1] Make better use of EQA information at national level.* *[2] Since this meeting an NHSE Diagnostic Quality and Safety Committee has been set up as part of the escalation infrastructure for poor performance of tests.*
3	**PFLM have requested that the RCPath lead the review of APSs for clinical biochemistry analytes to determine the most appropriate model based on the Milan Paper for a UK based patient population. (13) This should be based on what is required for the clinical utility of that test rather than what is achievable by the majority.** **The laboratory is responsible for implementing and monitoring their performance of the RCPath APS findings as part of the laboratory's QMS.** *Note:* *[1] APS is defined as a range of values around the target which is considered acceptable for the performance of that test. We suggest that Total Allowable Error (TEa) is used as the basis for APSs. We have set one up for HbA1c and APSs for other key tests will be introduced.* *[2] See also recommendation 1*.

4	**LabMed to lead a review of criteria for the diagnosis of Diabetes Mellitus and Non-Diabetic Hyperglycaemia. PFLM recommend that the outcomes of this be taken to NICE for consideration in relevant NICE guidelines.** *Note:* *[1] All patient pathways involving diagnostic tests need to be cognisant of the bias and imprecision of the test.*
5	**ISO 15189:2022 accreditation should be focussed on risk management of the whole patient pathway involving clinical laboratories.** *Note:* *[1] ISO 15189:2022 includes both pre- and post-examination elements.* *[2] Includes, but not limited to, assay / equipment selection, post-market vigilance and clinical guideline development / use etc.* *[3] Laboratory Directors need to be aware of their obligation under Significant Non-conforming Work (SNoW).*
6	**PFLM have requested that:** **(1) MHRA introduce formal process for post-market surveillance of IVDs.** **(2) Laboratories need to increase usage of the MHRA yellow card system.** *Note: None*
7	**NHS Supplies to have a greater awareness of the quality infrastructure of IVDs to ensure that public money is spent within a quality framework.** *Note:* *[1] To include procurement, contracts and contractual surveillance.*
8	**PFLM have requested that LabMed provide guidance/toolkits on quality processes available including, but not limited to IQC, patient means, ongoing verification, lot-to-lot variation, data extraction etc. (14)** *Note: None*
9	**PFLM have recommended that LabMed provides further training and education of consultants/laboratory directors regarding their roles and responsibilities (clinical utilisation and legal) in relation to the regulatory and accreditation framework (IVDR/MDR and ISO 15189:2022) in general and post-market vigilance via the MHRA.** *Note:* *[1] Suggest a Laboratory Director masterclass or equivalent.*
10	**PFLM recommends that there should be a corporate member group and establish a post-market code of conduct within BIVDA and ABHI to ensure continued use of an IVD.** *Note: None*

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Acknowledgements

We would like to thank everyone who has contributed to this report, in particular delegates at the webinar for their comments which have helped in the development of the recommendations within this report. There were over a hundred questions submitted prior to the Webinar and the groundswell of positivity that we received in feedback after the webinar was truly incredible.

Data and Copyright Acknowledgments