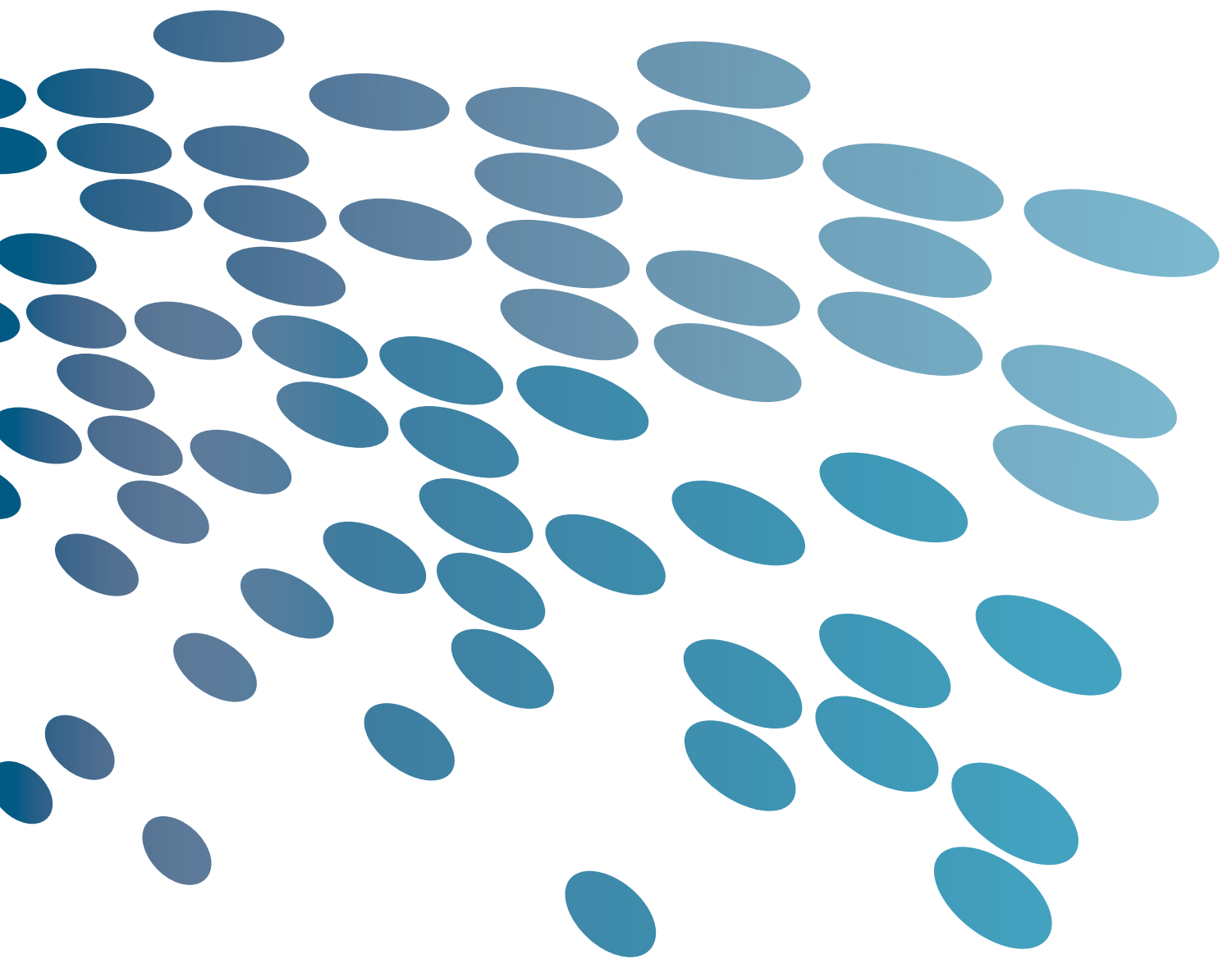


Pathology Quality Assurance Review



Chaired by Dr Ian Barnes

January 2014

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Chair's foreword

Dear Sir Bruce,

You asked me to chair a Review to assess the current quality assurance frameworks and governance mechanisms for pathology services at a national level, making recommendations as to how any issues I uncovered could be remedied.

This request in late 2012 followed an incident at Sherwood Forest Hospitals NHS Foundation Trust, subsequently one of the hospitals studied in your mortality review last year, where problems with quality assurance and an inadequate governance process was reported to have negatively impacted upon the care of a number of women with breast cancer.

Your ambition for quality assurance in pathology was to make it a benchmark against which other services could measure their own success.

As I have taken forward this Review, I have engaged extensively and am pleased to report that I have found your ambition to be shared across the system, from Ministers to pathology staff on the front line. I have also found consensus on areas for improvement which has allowed me to move beyond just making recommendations, to being in a position to set out an agreed system-wide way forward.

Pathology contributes to an overwhelming percentage of patient pathways, and only a service that supports the rest of the system to make the best possible decisions about treatment can be acceptable to patients. In the light of Robert Francis' *Report of the Mid-Staffordshire NHS Foundation Trust public inquiry*, this means a service with a relentless focus on improvement, which champions the patient as a user and operates in a reflective and open manner, so that it can improve not only its own performance, but share its learning to benefit the rest of the NHS. Pathology services should be reliable, robust and responsive, heeding your challenge to the NHS to "make quality our primary concern"¹.

In the course of this Review, the Review team and I have heard from a wide range of organisations and individuals, including a strong patient and public voice, laying out what is expected from pathology – a service which fundamentally informs clinical decisions about diagnosis and treatment – in terms of visibility, transparency, experience, communication, professionalism, reliability, safety, utility and contribution to the wider aims of NHS care.

I have heard that, for the most part, NHS pathology services compare favourably with the rest of Europe, and have multiple measures in place to ensure that the results they produce and the advice that they give is of high quality. The NHS in England boasts a dedicated and highly skilled workforce, good internal quality assessment and quality management systems, and mature external assurance of its pathology services that overall provides a safe, reliable and effective service.

¹ Review into the quality of care and treatment provided by 14 hospital trusts in England: overview report, July 2013

Chair's foreword

However, gaps exist. Elements of the system have become outdated. Quality must be scrutinised and made transparent, skills must be updated, and roles and responsibilities must be formalised. Steps must be taken to ensure that patients are truly safeguarded, and a culture developed where any errors that do occur are made in an environment primed to detect and correct them, seeking constantly to improve clinical and working practices through continuous learning, sharing and innovation.

It is important to note that, while the remit for the Review was for England, some of the changes suggested will impact upon the devolved administrations. We have therefore engaged with colleagues from Northern Ireland, Scotland and Wales, throughout the development of this report.

With the energy, appetite and shared aspirations for pathology quality assurance I have come across throughout this Review, it is my hope that this report and the agreed actions it sets out will speak to the service, empowering individuals and organisations, both at the centre and at the front lines, to work together to make its ambition a reality.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Ian Barnes', is displayed within a light grey rectangular box.

Dr Ian Barnes PhD, FRCPath
Chair, Pathology Quality Assurance Review

1. Introduction

- 1.1. Pathology lies at the heart of the NHS's work. NHS pathology services in England employ around 33,000 people in over 150 organisations responding to approximately 200 million requests a year, representing involvement in around 80% of patient interactions with the NHS.
- 1.2. The service routinely offers hundreds of different tests and investigations to requesting clinicians. Demand for tests has risen consistently as the NHS has understood the contribution that pathology can make to better outcomes and longer lives and patients and clinicians have consistently high levels of confidence in the service provided.
- 1.3. This confidence is not without foundation: the UK has been at the forefront of quality assurance in pathology for the past 50 years, leading the way on external quality assurance. The UK was, along with Holland, the first European country to introduce a laboratory accreditation scheme for pathology.
- 1.4. However, the current system relies almost entirely on professionalism and goodwill. It was set up to provide assurance to laboratories. It was not designed to provide public assurance to patients, nor to assist boards and commissioners in fulfilling their statutory duties.
- 1.5. Moreover, the current system is focused on minimal acceptable standards, and it does nothing to identify, incentivise or reward those who are striving for excellence. Nor, it must be said, does it provide much in the way of sanctions or support when laboratories do fall below an acceptable standard of performance.
- 1.6. We believe there is an appetite to improve and move towards aspirational practices at every level of the quality assurance system in pathology. Taken individually, the changes suggested in this report are modest and achievable. They simply make better use of the processes we already have in place. But taken together, these measures should ensure that pathology services are:
 - visible to patients
 - accountable to boards and commissioners
 - reliable, robust, and responsive
 - rewarded when they make improvements in quality, patient safety, and in the contribution they make to patient experience
 - held to account when they fail to offer the level of service patients expect

Why the Review?

- 1.7. The current pathology quality assurance framework lacks several key factors: transparency, integration, scrutiny, oversight and effective triggers for reward and sanction, without which we cannot say the best interests of patients and healthcare generally are truly being served.
 - 1.7.1. The broad assurance framework has a lack of key assurance indicators (KAIs) to evidence quality and safety of pathology services, and to

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enable effective contract management both within organisations and by commissioners.

- 1.7.2. Pathology assurance and governance is not consistently embedded in provider governance and assurance frameworks.
 - 1.7.3. Pathology is unable to provide evidence to the Care Quality Commission (CQC)/Hospital Inspectorate of the overall quality of pathology services.
 - 1.7.4. Pathology needs to respond to changing and additional requirements from commissioners and the public for information and assurance around consistency of provision and reporting.
 - 1.7.5. The impact of new technology and processes (genomics, point of care testing (POCT), digitalisation, molecular techniques, informatics) on delivering pathology services, and the impact on a rapidly changing workforce, require a strengthened quality assurance framework.
 - 1.7.6. There is too much variation between pathology services, and a lack of harmonisation and standards, which is unacceptable to patients and users.
- 1.8. The current system was fit for the purpose for which it was designed, but it is not fit for the future, nor does it meet the emerging requirement for transparency and well-evidenced quality assurance. Therefore, the Review and the recommendations it makes will attempt to bring these features of the system into sharper focus, strengthening existing structures to ensure these gaps are filled.

Our approach

- 1.9. The work of the Review was broad, covering a great number of facets and levels of an already complex system. In order to best tackle this expansive area of investigation a secretariat and a Review Board was appointed (members listed at the back of this document), and the scope of work was divided into three tiered workstreams, each with an expert lead. These workstreams looked at:
- Professional development, ie individual responsibilities
 - Quality Assurance and Governance, ie provider and trust responsibilities
 - The NHS national system, ie the responsibilities of national organisations
- 1.10. In addition, Subject Matter Experts (SMEs), both individuals and agencies, contributed knowledge and expertise to undertake specific pieces of research and provide detailed information and analysis of some of the technical and specialist areas within the scope of the Review.
- 1.11. This included a survey of governance and culture with regards to pathology Quality Assurance (QA), an investigation into representative error reporting practice and attitudes, a large scale survey of aspects of roles and training for

1. Introduction

quality amongst pathology staff, a comprehensive stakeholder engagement and communications programme, and technical input on the progress with, and potential for, standardisation of pathology data. Industry colleagues provided their perspective on how manufacturers can work with services to improve quality and quality assurance, and a wide range of contributors from the profession, the professional bodies, the devolved administrations, the international community, statutory and third sector bodies and regulators have generously supported the Review with their time and expertise, allowing us to shape an holistic report that attempts to address as many stakeholders' interests as possible.

- 1.12. In studying the current systems of pathology quality assurance, the Review found much that was good. The professionalism, goodwill and commitment of the staff involved in the management of quality assurance schemes should be commended, as should the involvement of industry in the development and rapid diffusion of new technologies and process innovation. The professional bodies play a vital role in the existing assurance framework, and provide strong leadership for the service. The work of the Chief Scientific Officer (CSO) and team, with their recognition that the role of Healthcare Scientists is changing, has been visionary, and the efforts of the National Clinical Director (NCD) for Pathology and the Pathology Programmes at the Department of Health (DH) and NHS England have created a solid foundation of physical and human resources from which to build a pathology service that bears comparison to the best in the world.
- 1.13. During our Review, we asked pathology services how they assured themselves and their host organisations that their pathology service was safe, of high quality, and staffed by competent individuals. We received many submissions from organisations involved in the quality assurance of the service. We asked patients and commissioners what assurance they required, and what evidence of compliance they wanted. We also met with CQC and considered how the assessment of the quality of pathology services might best be incorporated into the CQC's new hospital inspection programme.
- 1.14. We have arrived at a view that the current systems of quality assurance in pathology are no longer able to meet the needs of modern healthcare, and the demand for greater transparency. Much of what is currently done is good and the structures and organisations necessary to carry out the changes proposed already exist. However, a redefinition of their scope and function is required, as well as a number of initiatives to enhance the use of data and information already collected. These themes form the basis of the recommendations of the Review.

2. Understanding the existing system: the current assurance framework

- 2.1. Meaningful assurance has three main requirements. There must be a clear understanding of what the service should be achieving (specification, standards), there must be clear evidence of how assurance is being achieved (key indicators, measurement), and there must be clear consequences if assurance is not provided (corrective action, sanctions).
- 2.2. The UK has been recognised internationally as being at the forefront of QA in pathology for decades, creating and running schemes that assure the quality of individuals, processes and systems. These include External Quality Assurance (EQA) schemes (used by pathology services as a tool to test the competence of individuals and the reliability of tests and methods), and a national laboratory accreditation scheme. The professional bodies including The Royal College of Pathologists (RCPATH), Institute of Biomedical Science (IBMS), Association for Clinical Biochemistry and Laboratory Medicine (ACB) have taken the lead in setting professional standards.
- 2.3. The framework that currently exists for governing, regulating and assuring the quality of pathology services comprises a variety of assurance measures at different levels of the system. This is illustrated in the diagram below:

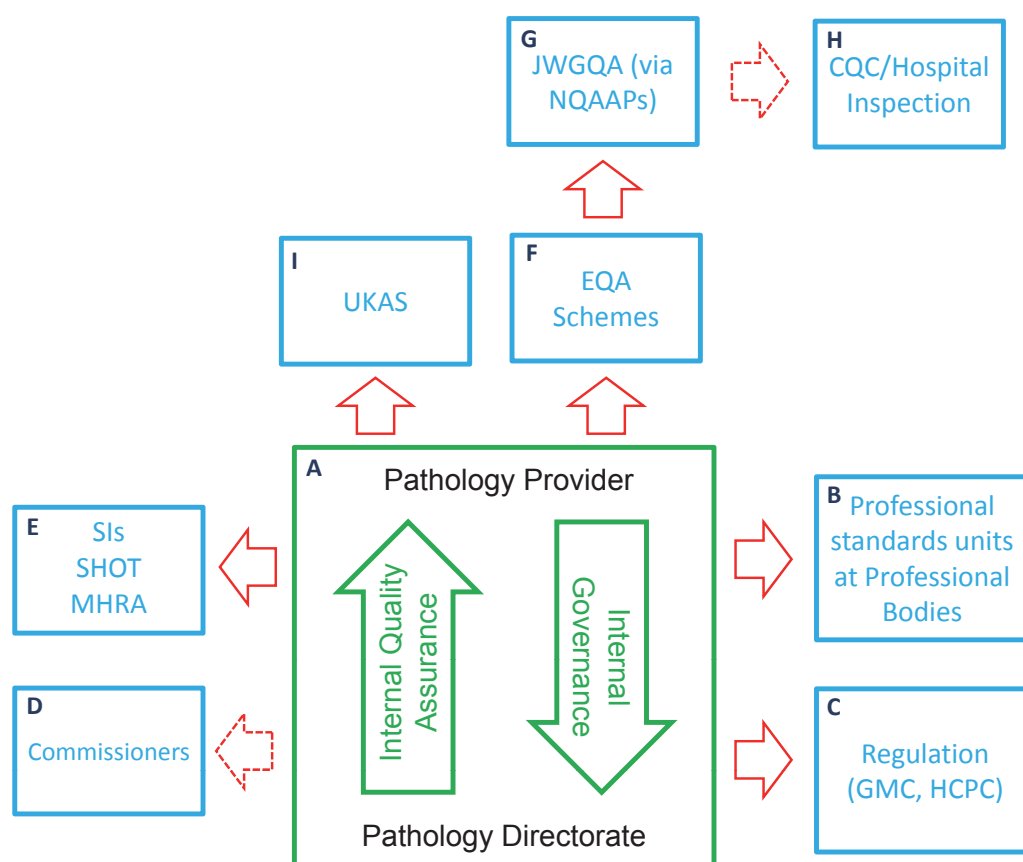


Fig 1: The above diagram gives a high-level view of the main roles of providers and laboratories, regulators, statutory bodies, commissioners, the accrediting body and professional organisations, in assuring the quality of pathology services. Activities shown in green are internal to laboratories and providers. Activities shown in blue are external processes of assurance. Red arrows indicate lines of reporting, and dashed arrows represent areas where this relationship exists in theory but is not extensively utilised. The nature of the relationships between the lettered boxes are indicated in the text below.

2. Understanding the existing system: the current assurance framework

- 2.4. The hierarchical framework comprises a number of separate, independent processes. Within the pathology provider organisation (shown in green on figure 1) there is a governance process for assuring both themselves and the executive management that the services being provided are safe and of high quality (box A). This should include regular reporting of KAls including error reporting, performance in external quality assurance programmes and internal quality control (IQC), accreditation status, and staff and technology issues.
- 2.5. IQC is the responsibility of the provider and is required for every test performed across all disciplines, providing assurance of the satisfactory performance of a test on a day-to-day basis. In the Welsh External Quality Assurance Scheme (WEQAS) audit of IQC in 2013², wide variability in IQC programmes in blood sciences across laboratories was revealed. Concern about the lack of appropriate IQC programmes in blood sciences has been expressed by diagnostic IVD (in vitro diagnostics) providers, and also about the increasing loss of skilled scientific staff with an understanding of quality control. IQC in microbiology and histopathology pose different and more challenging issues, since statistically based QA is not possible.
- 2.6. Medical and scientific staff in pathology are professionally regulated, statutorily or voluntarily, through their registration bodies, eg the General Medical Council (GMC) and Health and Care Professions Council (HCPC) (box C). Professional issues are also dealt with by the Professional Standards Unit (PSU) in the RCPATH, including revalidation of medical staff, and the Education and Professional Standards Committee at the IBMS (box B).
- 2.7. Best practice examples exist where the provider organisation has an identified board level director with responsibility for pathology governance. However, this is not widespread. Provider governance processes vary from organisation to organisation and, with a few exceptions, there is no visibility or transparency of performance outside the organisation. In addition, there is limited use of performance measures/key performance indicators.
- 2.8. In the commissioning framework, commissioners have a duty of care to ensure all commissioned services are safe and of agreed quality. There is little evidence of commissioners agreeing a detailed service specification for pathology and of contract monitoring against the specification where regular governance reports from the provider would be expected (box D). An example of regular governance reporting within the provider organisation and to commissioners is given at the end of this document.
- 2.9. There are a number of statutory error reporting requirements for providers of pathology services (box E), such as SHOT (Serious Hazards of Transfusion) in blood transfusion and Serious Incidents (SIs). The SHOT reports are reported nationally in regular reports. Analysis and actions in response to Serious Incidents (SIs) are the

²National Audit of IQC Practice in UK Biochemistry Laboratories, 2013

2. Understanding the existing system: the current assurance framework

responsibility of the provider organisation, but there is little visibility or transparency nationally. Pathology departments are required to report errors/unsatisfactory performance of reagents and devices to the Medicines and Healthcare products Regulatory Agency (MHRA) who have responsibility for working with the diagnostic industry to resolve problems. MHRA believe there is an under reporting of these issues. There is no national definition of an error within the laboratory, and there is wide variance in error reporting within pathology providers.

External Quality Assurance

- 2.10. The external assurance framework (shown in blue on figure 1) is based on two main systems, an EQA system and an accreditation process, run by the United Kingdom Accreditation Service (UKAS).
- 2.11. EQA schemes play an important role in the quality management and improvement processes of clinical laboratory services (box F). EQA scheme performance should be assessed in the laboratory in conjunction with appropriate IQC programmes and procedures.
- 2.12. EQA schemes are available for most of the tests available across all disciplines in pathology and they are provided by a number of different organisations. EQA schemes are technical and interpretative, the latter important in professional opinion, rather than quantitative based diagnosis, as in histopathology. EQA schemes mainly focus on the analytical process and method performance, but in recent years there are also schemes for assessing individual performance of clinical staff. The pre- and post-analytical phases (before a sample reaches the laboratory, and from the point at which the test result is reported, respectively) are mainly outside of the scope of the schemes. The schemes are funded by individual scheme subscription.
- 2.13. Typically, a specimen (or slide) is sent to a laboratory and the laboratory should treat the specimen as a patient sample and return a result to the scheme organiser. This result is then assessed and compared with the overall results obtained from all participants and national reference materials. A report is issued back to the laboratory indicating satisfactory/unsatisfactory performance. All reported data is anonymised. There is inconsistency in schemes: for example, the frequency of distribution of specimens is variable, typically monthly, but in some specialist/small schemes it may be only 1-3 times a year. This means that for some tests, detecting poor performance by EQA returns can be a lengthy process.
- 2.14. The definition of poor performance criteria may differ between EQA providers, and there are no internationally agreed performance standards or harmonised criteria across schemes. EQA schemes should be accredited by UKAS to ISO standard 17043 but this standard only requires scheme providers to define performance criteria and laboratories are able to choose the scheme in which they wish to participate. Some schemes appear to be more exacting in performance criteria than others. Participation in EQA schemes is voluntary, but is a requirement for UKAS accreditation.
- 2.15. EQA schemes are governed by discipline-specific expert panels, National Quality

2. Understanding the existing system: the current assurance framework

Assurance Advisory Panels (NQAAPs), which oversee the schemes and agree the functioning and performance criteria for each scheme. When a laboratory or individual performs poorly in EQA the provider works with them to improve performance, but if the laboratory fails to engage with the advice process or to resolve the performance issue the EQA scheme reports the laboratory to the relevant NQAAP. If this escalation fails the NQAAP refers the matter to the Joint Working Group for Quality Assessment (JWGQA) (box G).

- 2.16. The JWGQA is a multidisciplinary group within the RCPATH, which oversees performance in EQA schemes in the UK. It is comprised of discipline-specific professionals from the NQAAPs and has a chair appointed by the college. It oversees and supports the NQAAPs and will work with failing laboratories. It has no mandatory powers but will contact CEOs of provider organisations if they have a consistently poorly performing laboratory, and will report this to CQC (box H) and to UKAS.

Accreditation

- 2.17. UKAS has responsibility for two main accreditation processes, one for laboratories (ISO 15189) and the other for accrediting EQA schemes (ISO 17043).
- 2.18. The UK was one of the first European countries to introduce a pathology accreditation scheme (box I). In recent years, European countries have started to implement ISO 15189 as the accreditation standard. The UK is now adopting this and is in a transition from the previous standards to the new standards. The new standards recognise pre- and post-analytical responsibilities of a clinical laboratory, areas that are often not under the control of pathology.
- 2.19. Most European countries, like England, expect laboratories to meet an accreditation standard but this is not mandatory. There are exceptions (Germany and France) where it is required for regulatory/licensing requirements. Additionally in the USA, laboratories must meet standards defined in the Clinical Laboratory Improvement Act (CLIA). Many countries have no accreditation process.
- 2.20. Despite its non-mandatory status, accreditation is widely used, including by CQC, as a marker for quality of pathology services and there is an expectation in the system that laboratories should achieve this independent seal of approval.
- 2.21. Quality assessment and assurance in pathology services has mainly focused on achieving accreditation status and acceptable performance in EQA schemes. This should be regarded as achieving the minimum acceptable performance, and does not encourage continual improvement where services should be striving for the best achievable performance. The new ISO 15189 standard has increased emphasis on continuous improvement, which should help to address this issue.

Conclusion

- 2.22. Overall the quality assurance framework in pathology lacks several key factors without which we cannot say the best interests of the patient are being served: transparency, integration, key assurance indicators, oversight and effective triggers for sanction and reward.

3. The need for change

- 3.1. The NHS defines quality as care that is effective, safe and provides as positive an experience as possible for both patients and carers.
- 3.2. We believe that a high quality pathology service is founded upon reliability, robustness and responsiveness. Quality pathology services are reliable – given the right question, they will provide the right answer. They are robust because they are continually improving their processes in the light of experience. Finally, they are responsive because they are capable of adjusting to the varied and changing needs of patients and clinical users of all kinds, and embracing the rapidly changing technology to enhance patient services.

Clinical effectiveness

- 3.3. Pathology has an impact across the whole end-to-end patient pathway and requires a strong user/provider partnership. Improvement in clinical practice and healthcare leading to improved clinical outcomes and patient experience will not be achieved without high quality pathology services. Pathology is a clinical service and provides clinical advice as well as test results. The clinical effectiveness of pathology can be judged on its impact on clinical services and outcomes. It requires quality-assured pathology services and tests of proven clinical utility, which, if used optimally, improve patient management and clinical outcomes.
- 3.4. Pathology quality assurance processes have mainly focused on the analytical phase and until recently there has been little performance assessment of pre- and post-analytical phases. Accreditation has focused on internal processes in the laboratory, and not on the quality of what is produced as a clinical/testing service. There is a lack of measures for the clinical effectiveness of testing. However, the transition to the new international standard ISO 15189 against which laboratories will be accredited will require an increased focus on pre- and post-analytical assessment and clinical effectiveness.
- 3.5. The RCPATH has established a Clinical Effectiveness department and other professional bodies eg ACB have clinical committees. The production of guidelines, with a consistent and standardised approach to requesting, testing and reporting is a key function of these groups. Strong professional leadership will be required, with involvement in the evidence and evaluation of test effectiveness, guidance on demand optimisation, measurements of KAls, and audit of clinical effectiveness.
- 3.6. Examples of current good practice include the production of National Institute for Health and Care Excellence (NICE) accredited microbiology standardised investigations by the Standards Unit, Public Health England (PHE), and standards for transfusion produced by NHS Blood and Transplant (NHSBT). The Atlas of Variation³ (2013) has illustrated the variation in direct access pathology testing in primary care across England, due to local decisions and policies, and GP individual preference. Benchmarking has for many years provided data to show the variation in efficiency and productivity of pathology services.

³Diagnosics: The NHS Atlas of Variation in Diagnostic Services, November 2013

3. The need for change

- 3.7. There is a need for a national approach by the professional bodies to produce agreed testing protocols which local laboratory services should implement to reduce this variation and promote more standardised testing for patients.
- 3.8. Laboratories can improve the quality of the whole diagnostics cycle by increasing engagement outside the laboratory. For example, KIMMS (Key Incident Monitoring and Management Systems) produced by the Royal College of Pathologists Australia provides a quality assurance service for the pre- and post-analytical phases.
- 3.9. There is a role for the laboratory to proactively reach out and educate users. As new tests are introduced, redundant tests should be removed. New diagnostic markers for specific diseases will require more engagement with multi-disciplinary teams managing patient pathways in both primary and secondary care settings. There is a need for a more proactive attitude to supporting and enabling POCT and digital solutions⁴. There is a lack of understanding by commissioners of the value of pathology and the opportunity for better utilisation of testing to impact on patient pathways. This can only be improved if the visibility of pathology and direct engagement of users and patients with pathology professionals is improved.
- 3.10. Pathology is a key player in the patient pathway, and will be critical in delivering wider improvements to NHS care, such as 7 day service provision. There are examples (see below) of improving clinical effectiveness and changing clinical pathways by implementing new approaches to pathology testing, though these tend to be local, rather than nationally implemented, and dissemination and uptake nationally is often poor.

Case study: Clinical Effectiveness

Derby Hospitals Foundation Trust – Improving breast cancer treatment choices by streamlining results from 15 to 1.91 days⁵

Initiatives come in all shapes and sizes. Derby's Histology initiative was relatively small; team orientated; had clear clinical leadership; had specific aims and was effective in achieving an improved diagnostic service to our clinical users and ultimately patients. The aim was to shorten the laboratory diagnostic pathway for specific cancer patients (Breast) by providing prognostic hormonal results for the pre-operative multi-disciplinary team (MDT). Patients under go biopsy of a suspected malignant breast lesion and are discussed at MDT 3-5 days later where clinical decisions are made regarding further treatment options such as surgery and chemotherapy. By having the hormonal status available patients will have the opportunity to participate in peri-operative clinical trials and will be better informed regarding their treatment options. The Histology laboratory team led by the lead Breast Histopathologist evaluated the current diagnostic pathway. Analysis of the data indicated an average turnaround time of 15 days for the availability of hormonal results. Each step of the laboratory process was reviewed and adjusted to eliminate unnecessary waits, enable smarter streamlined working practices and ensure full utilisation of the technology available in the laboratory, instigate new Quality Assurance steps for the pathway. Review of the pathway post change has seen significant improvements in the reporting times from 15 to 1.91 days. Meaning that the majority of patients now have their hormonal receptor results available for the Pre-Operative MDT. Having the ability, skills and knowledge to impact directly on patient care is rarely in our gift as a diagnostic service. Support Being encouraged and enabled to think differently with a clear vision and strong clinical leadership has enabled a change in process, in attitude and in service delivery for better patient care.

⁴Digital First: the delivery choice for England's population, 2014

⁵Shortlisted for Efficiency in Pathology Services Category, HSJ Efficiency Awards, September 2013

3. The need for change

Looking ahead: the changing nature of pathology in the NHS

- 3.11. The most significant technological innovation affecting pathology over the last several decades has been the introduction of automation into the laboratory, particularly in blood sciences, but increasingly in microbiology and histopathology. As in many other high-volume industries, instruments capable of performing repetitive actions at relatively high speeds have been developed to improve quality, consistency and efficiency. The results of tests on samples that previously took hours to process can now be reported in a matter of minutes.
- 3.12. In histopathology, technology where high-resolution digital images of slides provide a virtual three-dimensional image of samples for investigation is predicted to revolutionise workflow and reduce leadtimes of interpreted results.
- 3.13. New technology for blood culture analysis dramatically reduces the time taken for the isolation of organisms from positive blood cultures. This enables more rapid and focused antibiotic treatment to be given, resulting in better patient management, improved outcomes, and reduced lengths of stay in hospitals.
- 3.14. Advances in screening techniques, genetic testing and new technologies are often cited as key contributors to the predicted increases in longevity. Perhaps the most significant innovation is the development of genetics and molecular technologies into mainstream medicine, which will have substantial impact on the health of the population, clinical practice and the management of patients.
- 3.15. An understanding of how an individual's genes can inform decisions about appropriate therapy is likely to have major positive effects on patient outcomes. The use of companion diagnostics in personalised medicine, where pharmaceutical products will be supplied only to those patients who are shown to be likely to benefit from treatment, will avoid possible harm and inconvenience to patients.

The patient view

- 3.16. Diagnostic testing is important to patients. As well as playing a major role in diagnosis, it also underpins patient care and treatment. The ubiquitous nature of pathology in healthcare makes it crucial to understand what patients want from this service. Consequently, the Review undertook face-to-face 'challenge events' with lay groups and patients where we heard the following key messages:
- 3.17. Visibility: pathology services are 'hidden' from patients, accessed only through a gatekeeper (a GP or other clinician) and as such are not a visible part of the care pathway. Patients want to have the importance and function of the service pathology provides made clear to them and to understand the role it plays: what is being tested, what that test might find and what the result might mean. They want to have their own results clearly explained, and, if relevant, to have access to their previous results in order to monitor progress or change.

3. The need for change

- 3.18. Transparency: with improved visibility comes a requirement for transparency. Patients want services that have transparent quality assessment and assurance so that they can be confident that the service they are receiving is safe, effective and accurate. They want to be assured that the service that underpins the rest of their care is high quality, independently assured and well governed, with accessible evidence to support this.
- 3.19. Unacceptable variation: different parts of the country have different approaches to testing with variation in provision, methods, turnaround times and communication of results, all of which can have an impact on the patient pathway. Patients felt strongly that this variation is unacceptable and that more should be done to provide all patients and their requesting clinicians, irrespective of location, with the best possible access and quality of service from pathology in a more standardised and harmonised way.
- 3.20. Improving testing: pathology is a technology-driven discipline which gives it the capacity to evolve and improve rapidly by using innovative technologies. Patients understand this and want to be sure they are getting the best possible testing, on the most appropriate equipment, performed by staff whose training and knowledge is up to date, in a culture of continuous quality improvement.
- 3.21. Patient experience: the assessment a patient wants to make of the quality of pathology services is not just about the accuracy and timeliness of results. The quality of reporting, availability of advice and interpretation when required together with information about their local pathology services, are important parts of patient experience. High on the patient agenda was the phlebotomy service where they want sensitive, skilled, considerate staff taking blood in a compassionate way and in an accessible and comfortable setting. Patients want to be assured that as much care is put into ensuring the quality of these experiences as is put into ensuring the quality of a test result.

Conclusion

- 3.22. The framework for quality originally laid out by Lord Darzi references key building blocks for the establishment, measurement, and propagation of a quality system for healthcare. It looks to bring clarity to quality; measure quality; publish quality; reward quality; promote leadership for quality; innovate for quality; and safeguard quality.
- 3.23. When applied to pathology, we can see that many of these blocks are well served in the system. However, gaps do exist and there is a need for change if pathology is to continue to deliver clinically effective services, which meet the evolving needs of patients and clinicians, against the quality framework.
- 3.24. The Review recommends a set of actions that can be taken to better align and strengthen this framework for pathology services, which will require collective effort and collaboration at every level of the system.

4. The way forward

- 4.1. This section of the report sets out our findings, and the ways in which we propose the system should be strengthened. We summarise the key outcomes of the proposed changes, and then move from the frontline – people and their training – up the system through provider and trust responsibilities, to the role of commissioners, and onward to actions for the whole NHS.

Expected outcomes

- 4.2. We believe that implementation of our recommendations will better align and strengthen the quality framework for pathology services to the NHS. Pathology departments must put quality at the forefront of their practice, with strong leadership driving a culture of continuous quality improvement, seeing each sample as a patient and striving, organisationally and individually, to do all they can to ensure quality is as good as it can be for patients. In this way:-
- 4.2.1. Pathology departments will be able to send CQC an agreed set of KAls which will contribute to the assessment of the safety and quality of a provider organisation's pathology service.
 - 4.2.2. Commissioners will be in a position to manage their contracts with providers in a way that exercises their duty of care, maximises the impact of pathology and improves clinical services and patient outcomes.
 - 4.2.3. Chief Executives of provider organisations will be able to interrogate their own organisations to assure themselves that their pathology departments have appropriately trained staff, effective leadership and robust monitoring to protect and care for the populations they serve. They will also be able to evidence the quality of their service using key assurance indicators from both internal and external assurance programmes.
 - 4.2.4. Pathology will be in a better position to work with and support requesting clinicians to maximise the contribution that pathology can make to patient outcomes, enabling more informed requesting through effective communication between pathology specialties and clinicians.
 - 4.2.5. The IVD industry, working in partnership with pathology professionals and regulators, will be better able to ensure that the technology and reagents used in testing are suitable for clinical application, that adequate training is provided, and issues arising are dealt with in an open, transparent and constructive way.
 - 4.2.6. Patients and clinicians will have access to open and transparent details of how pathology services are quality assured and be in a position to better understand and engage with providers about patient needs and concerns, supporting the wider choice agenda.

4. The way forward

Training and development for quality

- 4.3. The foundation of a high quality pathology service is a well-trained, competent staff that actively seeks to ensure and improve quality through their everyday work and actions.
- 4.4. The pathology workforce is diverse, consisting of medically qualified pathologists, healthcare scientists and a small number of other healthcare professionals such as nurses. Healthcare scientists and the scientific support staff make up the majority (over 80%). Both medical and scientific staff lead NHS pathology services.
- 4.5. The workforce is expected to continually evaluate clinical practice and models of care, embrace new technologies and ways of working, and to innovate to improve patient care. It should also embrace research and development, including involvement in clinical trials.
- 4.6. The modernising scientific careers (MSC) programme is designed to provide a world-class workforce that delivers fit for purpose and innovative patient focused services based on both current and future health care delivery needs and on scientific and technological advances in each of the recognised scientific specialities. The programme seeks to educate and develop some of the brightest and best science graduates in the UK. Their specialist scientific knowledge, skills and the expertise required needs to be continually developed. Aspects of the programme are still developing; for example, the accredited scientific practice framework which will help to direct and inform those organisations responsible for Continuing Professional Development (CPD) requirements.
- 4.7. The RCPATH sets the education and training standards and develops and reviews the curricula for medical staff. It has also been actively involved in the development of the MSC higher specialist scientist training curricula in many pathology specialities which will introduce formalised and funded training.
- 4.8. Across both the medical and scientific workforce, with changing technologies, techniques and complexity, there is an increasing need to ensure there is a focus within education and training programmes on quality management systems and quality assurance to build the capacity and capability of individuals to assure the quality of the service. Such programmes need to be flexible and responsive to change in technologies or care delivery models.
- 4.9. The Review undertook a survey of training and CPD practices across the medical and scientific workforce in relation to quality. It found a high proportion of respondents reported a good understanding of quality management, quality assurance and quality improvement tools and techniques, but few reported undertaking formal training in many aspects of quality management. The number of respondents with formal quality qualifications was low and there appeared to be a lack of suitable programmes available. A review of guidance on CPD for medical and scientific staff across the pathology specialities revealed a lack of direct references to quality training, mainly limited to general language specifying the need to show that CPD contributes to the “quality of your work”.

4. The way forward

- 4.10. This led to the Review undertaking a study of the training content of both medical and scientific specialist curricula with respect to quality management and assurance. Across the different professions/grades and pathology specialties there was no consistency in approach or content. There is therefore a need to provide clarity on expectations and requirements for the different staff groups, roles and responsibilities.
- 4.11. Quality management, assurance and improvement should be a core module of training, common across professions and disciplines, with additional education and training as part of a recognised level qualification required for progression to leadership and management roles. Training in aspects of quality management, assurance and improvement, including developing understanding about the reporting of errors, should also become a significant component of CPD programmes.
- 4.12. In the new system, Health Education England (HEE) is responsible for the education, training and personal development of every member of staff within the health system. It is therefore within their remit to address many of the issues that currently exist in this area. The MSC programme has already taken steps to enhance the curricula for scientists across the career pathway in respect of quality management and quality assurance.

Recommendation

- 4.13. ***“A systematic approach should be taken to educating, training and developing the skills of the pathology workforce in quality management systems and quality improvement methodology, in ways appropriate to professional group, role and grade. This process should be led by HEE.”***
- 4.14. ***“HEE should work with the professional bodies and regulators to ensure that quality management and assurance can be recognised as an essential requirement in CPD, and in individual appraisal requirements.”***

Implementation

Training the future workforce

- 4.15. HEE will require relevant professional bodies and programmes to introduce specific modules in quality management, assurance and improvement within education and training programmes for the medical and scientific workforce. Integral to this will be the development of fit-for-purpose curricula and formalised assessment processes which will require close working with the MSC programme, the Pathology Leadership Programme, and the representative professional bodies. Linkage and embedding within regulatory and revalidation arrangements will be critical.

4. The way forward

- 4.16. A high level certification programme in quality management systems should be developed by HEE working in partnership with representative professional bodies for senior managers and directors of pathology services, which could have broader applicability across the senior healthcare workforce who have similar responsibilities.

Guidance to provider organisations

- 4.17. The CSO and the NCD for Pathology, working together with NHS employers and, where appropriate, representative professional bodies should explore how guidance could be provided to Human Resources directors on quality improvement and assurance activities and training requirements being discussed and documented as part of annual appraisals for both scientific and medical staff. This would need to embrace any changes in technology and techniques including IVD devices and informatics.
- 4.18. Every accredited pathology service should work towards having at least one member of staff with a high-level quality management systems qualification.

Upskilling the existing workforce

- 4.19. The quality management and assurance modules developed for the future workforce should form the basis of CPD for the current workforce. Given the current skill and expertise gap HEE, working with Local Education and Training Boards (LETBs), should explore and consider a systematic and cost effective approach to upskilling the existing medical and scientific workforce, recognising existing programmes of quality and leadership.

Creating academic excellence in quality management

- 4.20. There is a real opportunity to create academic excellence in quality management, assurance and systems in the pathology disciplines. As the service adapts in response to changing needs, technologies and techniques, a multiprofessional approach to research and development and creating the evidence base for best practice and outcomes in quality assurance and management needs to be taken. Pathology leaders in both the medical and scientific workforces must encourage the development of this research capacity and capability as part of applied health research programmes and fellowships. The CSO and other national clinical leaders in pathology, working with funding bodies, should explore specific and targeted fellowships and other capacity building opportunities to further this ambition, including for example being embedded in the work of Academic Health Science Networks (AHSNs).

Commissioning

- 4.21. Commissioners of pathology services should recognise the need for competent and appropriately trained staff in quality management systems, and adopt meaningful indicators of quality assurance competence into locally agreed contracts.

4. The way forward

The role of industry

- 4.22. Technologies, instruments, reagents and techniques used in pathology services are becoming increasingly complex and sophisticated. What could have been considered 'leading edge' a decade ago may no longer be relevant today. The IVD industry should develop sufficient capacity and materials to work in partnership with provider organisations to ensure that sufficient training of NHS pathology staff working with their products is routinely available, to ensure that safe processes and protocols are understood and consistently applied. This should be taken forward as a joint initiative between the IVD industry, providers and professional bodies.

4. The way forward

The External Quality Assurance (EQA) Framework

- 4.23. Professional bodies representing all specialties and regulated professionals within pathology set and maintain professional standards and assess an individual's competence to practice. The RCPATH Joint Working Group for Quality Assessment (JWGQA) co-ordinates and oversees the standards and performance of EQA schemes for all schemes regardless of provider, for both laboratory and individual participation.
- 4.24. As part of their work, the JWGQA receives data and information from EQA providers via specialty specific National Quality Assessment Advisory Panels (NQAAPs). In cases of poor performance the JWGQA has developed protocols for improvement. If performance does not improve the JWGQA can ultimately escalate the matter to CQC.
- 4.25. Poor performance and participants' responses to investigations are kept anonymous, in part to foster a culture of learning in a non-critical environment. However, the NHS of today is keen to promote openness and transparency and expects to publish data and information describing performance wherever possible.
- 4.26. The Review believes that an expanded JWGQA is ideally placed to act as an agent of change for quality assurance in pathology. Led by the RCPATH, the professional bodies are in the position to define scheme standards for both individuals and providers of pathology services, and to advise on appropriateness of performance data for publication. The JWGQA can call on the expertise of the professional bodies to support continual development of EQA schemes, setting revised standards for EQA programmes that reflect the challenges of the modern NHS.

Recommendation

- 4.27. ***"The membership, role and function of the JWGQA should be revised and expanded. It should set consistent standards and performance criteria for all schemes across pathology and work with UKAS to ensure their implementation in the scheme accreditation process. The JWGQA should advise on publication of performance data. The National Medical Director has confirmed that he will ask the RCPATH to lead this work."***
- 4.28. ***"Further consideration must be given to the ways in which individual performance can be assessed, monitored and competence-assured. The National Medical Director will ask the professional bodies, led by RCPATH, to review these issues and report back within twelve months on their findings."***

4. The way forward

Implementation

Establishing consistency across EQA schemes

- 4.29. The JWGQA should harmonise the activities of different NQAAPs by undertaking work to refresh and set consistent standards for EQA schemes, and work with UKAS to enhance their application of ISO 17043 for accrediting schemes. It should support NQAAPs to develop EQA schemes for emerging pathology specialities, and establish and publish protocols for managing poor performance. It should also be expected to define and report consistent poor performance to CQC and the Chief Inspector of Hospitals.

The expanded JWGQA

- 4.30. Membership of the JWGQA should remain professionally led, but be expanded to include, at least, UKAS, CQC, MHRA, NHS England and patient representative groups.
- 4.31. The expanded JWGQA should work with EQA scheme providers to agree changes to allow for the publication of attributable EQA data.

Individual performance

- 4.32. The professional bodies, led by RCPATH, should develop methodologies for assessing the performance of individuals in EQA schemes that will give a fair and accurate picture of their competence to practice.
- 4.33. All practicing individuals responsible for reporting pathology results and providing clinical advice should be registered with current EQA individual assessment schemes and demonstrate regular participation as defined by the JWGQA. They should achieve appropriate levels of performance as determined by the professional bodies. Performance in individual schemes should be discussed and noted at annual appraisal.
- 4.34. Where opportunities or a need to improve are identified, additional remedial training should be required, or practice in the area of concern should be stopped until appropriate retraining has been undertaken and revalidation achieved. This process should be noted formally as part of governance procedures, with support from the employing organisation.
- 4.35. EQA schemes are designed to assess and improve individual performance and employing organisations should ensure that resources are made available to support participation and remedial action if required.
- 4.36. Provider organisations and professional bodies should ensure that individuals understand that EQA schemes are designed to assess and improve individual performance, and that attempts at collusion are considered matters of professional probity.

4. The way forward

Governance

- 4.37. NHS organisations are accountable for the safety and quality of the services they provide. Good governance requires pathology services to integrate their quality management systems with those of their NHS host organisation, reporting on relevant measures that provide board members and management with assurance that patient safety, clinical risks and quality are being managed effectively.
- 4.38. The Review saw evidence and examples of integrated governance systems, and searched for guidance about best practice, as well as appropriate measures (KAIs) of quality. We also commissioned a short qualitative survey that included an established, validated measure of safety culture⁶.
- 4.39. We saw examples of pathology services that regularly informed their boards about quality performance and errors. We received good examples of transparency and publication of KAIs, and heard about two consolidated pathology services whose Governance Boards included the Chief Executives of the acute trusts they served.
- 4.40. We also met with the Care Quality Commission (CQC) to understand the emerging approach to hospital inspection from the perspective of pathology services.
- 4.41. The new acute hospital inspection model is utilising a mixture of intelligent monitoring, announced and unannounced inspections to get to the heart of service quality. CQC will assess whether the service is safe, effective, caring, responsive to people's needs, and well-led. Through this approach, they will have a richer and broader understanding of the quality provided. It will also allow for comment on new areas around leadership and governance.
- 4.42. It is clear that all services, including pathology, should look critically at themselves through the lens of the hospital inspection model. For pathology, as a cross cutting service, whether CQC is looking at Surgery, Outpatients, A&E or any other area, there are circumstances which could trigger a need to look at a particular pathology department. Therefore, a well governed, well quality assured pathology service will operate with this inspection model in mind.
- 4.43. Outstanding pathology departments will support outstanding organisations. Equally, inadequate pathology services, or those requiring improvement, will inevitably impact upon a provider's ability to achieve the best rating for the organisation overall.

⁶ *Safer Clinical Systems* University of Warwick 2009

4. The way forward

Recommendation

- 4.44. ***“The quality and governance systems of pathology providers must be integrated with trust governance and quality structures. This should include the measurement of appropriate quality assurance indicators and the identification of an accountable board member within the organisation. CQC and the Chief Inspector of Hospitals have indicated that robust information on the quality of pathology services could contribute to the overall assessment of quality under the new hospital inspection model.”***

Implementation

Good governance of pathology services

- 4.45. Pathology services should publish regular reports about their quality performance to their host organisation, commissioners and other interested parties. This should include their current status of accreditation, results of EQA scheme participation, and KAls.
- 4.46. Provider organisations referring samples for testing to third-party services should ensure they meet the same required quality standards as in-house provision.

Key Assurance Indicators

- 4.47. NHS England should work with the Inspector for Hospitals, the professional bodies, and representatives of acute trusts and commissioning organisations to develop a set of appropriate KAls in support of good governance. Patient groups should be encouraged to contribute to this work.

4. The way forward

Error reporting and the sharing of learning

- 4.48. The Review accepts that some errors in pathology, as in the rest of healthcare, are likely to occur due to the fallibility of individuals and the systems and environment within which they work. Errors in pathology services fall into three domains: pre-analytical, intra-analytical and post-analytical. Pre-analytical errors occur before the patient sample is received in the laboratory for processing. Intra-analytical errors occur within the 'walls' of the laboratory. Post-analytical errors occur in the transmission of results to, or interpretation by, requesting clinicians.
- 4.49. As technologies and working practices improve, and lessons learnt are disseminated widely, reported errors in all three domains should over time reduce, but to date there is no evidence of this. Because of pathology's prevalence throughout systems of healthcare, errors in diagnosis can have an effect on the treatment of patients, and/or cause actual harm. Where errors are associated with specific IVD devices or equipment it will be necessary to involve MHRA.
- 4.50. The Review feels that high levels of error reporting in an organisation that exhibits low overall rates of harm is a good indicator of a quality service, and is aware of a number of systems for the collation of data and reporting of errors. We commissioned a survey to understand the current state of error reporting. This exposed inconsistent definition of errors and reporting between systems, and few efforts to share lessons learnt beyond the individual pathology services or networks involved.
- 4.51. NHS Blood and Transplant use a Serious Hazards of Transfusion (SHOT) reporting system to identify areas where laboratory and clinical practice need to be improved and to make appropriate recommendations for changes that will improve outcomes for patients. The Review team were struck by the robustness of error definition and consistency of reporting.
- 4.52. All providers of pathology services should have local risk management systems such as Datix for the recording and management of incidents and errors locally. All of those local risk management systems should regularly upload their incident reports to the National Reporting and Learning System (NRLS). NRLS has an associated set of definitions and processes⁷, and directly facilitates the sharing of important lessons from incidents, particularly those that lead to serious harm.

Recommendation

- 4.53. ***"Existing guidance on the standardisation and transparent reporting of errors from pathology services must be rigorously followed, including the reporting of all incidents that could have, or did lead to patient harm, to the NRLS. Pathology services should be encouraged to share information and data about clinical risks, 'lessons learnt' and good practice, in order to contribute to education and quality improvements nationally. The Trust Development Agency (TDA) and Monitor/CQC should encourage trusts to improve their adherence to existing guidance."***

⁷ NPSA (2010) *National Framework for Reporting and Learning from Serious Incidents Requiring Investigation* updated by NHS Commission Board Serious Incident Framework (March 2013)

4. The way forward

Implementation

Reinforcing the message

- 4.54. NHS England should seek confirmation from the professional bodies through RCPATH and representatives of acute trusts and commissioning organisations to confirm that existing standards for classification of errors and reporting thresholds are appropriate.
- 4.55. CQC and UKAS should seek evidence of appropriate error reporting and root cause analysis during inspection and accreditation visits.
- 4.56. NHS England should look at how it might provide regular reports to the NHS of trends and errors in pathology.

Commissioning as a lever

- 4.57. NHS commissioners should require their provider of pathology services to report regularly about the overall number and type of errors and incidents occurring. This report should include observations about trends, root cause analysis, and the progress of any remedial action required as well as the sharing of lessons learnt.

Disseminating lessons learnt

- 4.58. The professional bodies should work collaboratively with UKAS to share information on error reports. This information should be consolidated and anonymised in order to facilitate lesson-learning.
- 4.59. Where important patient safety issues need to be highlighted and acted upon, a patient safety alert based on evidence from the NRLS and elsewhere should be issued, whose implementation can then be monitored by commissioners and regulators.

4. The way forward

Informatics and standardisation

- 4.60. During the Review, patient representatives explained that they assumed that the results of tests they received would be consistent, irrespective of the laboratory that had undertaken them. They also told us that they would like to receive some results of their test results directly, predominately by electronic means.
- 4.61. We listened to these expectations, and set out to understand the associated constraints. We learnt of a need to ensure that the naming of laboratory tests, and their units of measurement and reference ranges are of a consistent format wherever the tests are undertaken, ie that information exchange needs to be standardised. The National Pathology Programme has been working with RCPATH and the Health and Social Care Information Centre (HSCIC) to develop a National Laboratory Medicine Catalogue (NLMC) that will fulfil these requirements.
- 4.62. The transformation of pathology requesting and reporting required will need considerable input from the UK Terminology Centre working with system suppliers. Without the transformation described, we believe that pathology services will be unable to conform to patient desires, or provide meaningful data and information in support of clinical needs, disease surveillance and research purposes. These developments will help align pathology services with the clinical users of pathology services, the suppliers of pathology informatics and both clinical and technical governance processes.
- 4.63. For patients to have confidence about the consistency of their results, laboratory processes must also be harmonised, especially as patients start to gain access to their personal health records that may contain reports from different pathology services. There are also safety implications when data from different sources using different methods and reference ranges are combined in clinical networks and large primary care electronic storage systems.
- 4.64. One example of standardisation of data sets to improve clinical care is that Public Health England (PHE) is working with the RCPATH to ensure that microbiological analyses are consistent for samples and the detection of organisms. Alongside this, the RCPATH provide reference cancer data templates in order that consistently formatted data is available electronically for both clinical use and for cancer registries.
- 4.65. In addition, data from EQA schemes together with population-level data collected from pathology reports sent to GPs could provide a meaningful source of information for triangulation of laboratory method comparison and creation of more sophisticated reference ranges for key analytes.

Recommendation

- 4.66. ***“The continued development of the NLMC to ensure consistency of data and information across the NHS in England should remain a priority. Ministers and NHS England have confirmed that this task, undertaken by***

4. The way forward

HSCIC, with support from professional bodies and others, must continue at scale and pace. The professional bodies, the IVD manufacturers and others should work towards minimising the differences between analytical processes, requesting and reporting.”

Implementation

Setting direction from the centre

- 4.67. NHS England should continue to set the strategic direction and provide leadership for the development of informatics in both quality improvement and assurance. The NLMC is the key to providing consistent meaning to pathology data, and so the support of the newly created Professional Records Standards Board (PRSB) should be obtained.
- 4.68. HSCIC should engage with suppliers of systems to require the NLMC and other informatics developments to be embedded in future clinical and laboratory management information systems.

Professional leadership

- 4.69. The governance of the NLMC should be led by the RCPATH, supported by the PRSB, and be accountable to NHS England.

The role of commissioning

- 4.70. Commissioners should be encouraged to request that their chosen supplier of pathology services uses the NLMC.

4. The way forward

Accreditation

- 4.71. The main purpose of pathology laboratory accreditation is to assure the quality of the service being provided. Achieving accreditation requires conformance to a set of nationally agreed standards, demonstrating adequate processes to assure users of the service that it is safe, and of consistent quality. It is a tool to demonstrate the competence of medical laboratories and ensure the delivery of timely, accurate and reliable results.
- 4.72. The United Kingdom Accreditation Service (UKAS) is moving to accredit pathology services against internationally recognised standards: ISO 15189. Specialist scientific and clinical assessors, with expertise in the relevant discipline of practice, conduct a thorough evaluation of all factors in the laboratory service that affect the production of test data and outcomes. It is widely recognised that such visits can only provide a snapshot of quality on the date of assessment.
- 4.73. UKAS is intending to expand the laboratory accreditation criteria to include recognised performance and assurance indicators to create an additional aspirational standard, as well as the existing minimum performance qualification.
- 4.74. To be an accredited pathology service, organisations must demonstrate appropriate participation in EQA schemes. The Review understands that there are many providers of EQA schemes that assess the competence of individuals and departments. We have learnt that different EQA providers assess to different criteria.
- 4.75. The Review has also sought evidence to indicate if there is a minimum level of activity that allows for individual and service competence to be maintained in low volume specialist testing. For example, the National Screening service has issued guidance for cervical screening that specifies a minimum number of tests for staff and the service to remain assured.

Recommendation

- 4.76. ***“In order that patients and clinicians can rely on accreditation status as shorthand for a quality assured service, the accreditation of pathology services must be updated showing clearly which laboratories are meeting minimum requirements, and which are excelling to provide first-rate service quality. UKAS has agreed to undertake this work.”***

Implementation

Agreed actions by UKAS

- 4.77. UKAS is able to undertake additional, unannounced ‘spot checks’ as part of their accreditation of pathology services, focussing on the quality of the output of the

4. The way forward

service rather than conformance to processes – an innovation to compare with international best practice.

- 4.78. UKAS is currently working with the RCPATH, IBMS and ACB piloting the assessment of joint key assurance indicators.
- 4.79. UKAS has also agreed to work with the expanded JWGQA to reduce the current variation of standards assessed by providers of EQA services and to work with EQA scheme providers to agree changes to allow for the publication of attributable provider EQA data.
- 4.80. UKAS should work with the professional bodies and JWGQA to facilitate an assessment of the minimum number of specimens per annum required to quality assure an individual test.

4. The way forward

Commissioning

- 4.81. Commissioners have a statutory duty to monitor the quality of services that they commission. The commissioning of pathology services – Primary Care, Point of Care, Specialist or part of an Acute services ‘block’ contract – is, in principle, no different from the commissioning of any other clinical service.
- 4.82. The NHS England Patient Safety Team oversees the National Reporting and Learning System (NRLS), and in 2012⁸, over 20 thousand reports were submitted describing incidents that occurred in laboratories. Additionally, the *NHS Atlas of Variation in Diagnostic Services*⁹ contains data describing the effect on the population of commissioning of pathology services.
- 4.83. The Review heard some good examples of service specifications and contract management and reporting, although we also found many examples where commissioners were unaware of the quality of the pathology service for which they were responsible.
- 4.84. We also heard about inconsistent commissioning of POCT in the community despite the MHRA publishing guidelines¹⁰ for commissioning POCT.
- 4.85. We understand that work is underway by NICE to develop a Quality Standard (QS) for all of diagnostics. We expect that the new standard and the associated supporting statements will define clearly the elements of a high quality pathology service.
- 4.86. The Review sought to identify other sources of data and information that commissioners could use. The Department of Health has published a Pathology Services Commissioning Toolkit (PSCT).

Recommendation

- 4.87. ***“In order to support commissioners in the next planning round, the PSCT should be updated. The National Clinical Director (NCD) for Pathology, with the NCD for Diagnostics and the Chief Scientific Officer, will lead this project, working in conjunction with local commissioners and professional bodies. When the NICE QS is published, it should be included in the PSCT. Commissioners should follow the MHRA guidelines when commissioning POCT.”***

⁸Patient safety incidents reported to the National Reporting and Learning System (NRLS) in 2012 as occurring in ‘laboratories’, extracted by the NHS England Patient Safety team on 15th May 2013

⁹*Diagnostics: The NHS Atlas of Variation in Diagnostic Services*, November 2013

¹⁰*Management and use of IVD point of care test devices*, December 2013

4. The way forward

Implementation

The role of NHS England

- 4.88. NHS England should continue to work with NICE to develop a diagnostics QS with supporting statements and pathology specific implementation guidance. It should also update the PSCT.

The role of commissioners

- 4.89. Commissioners should seek and monitor data and information about the quality of the pathology services they are responsible for, including for POCT.

4. The way forward

Oversight

- 4.90. Many bodies have a role in the assurance of pathology quality: NHS England, CQC, MHRA, NHS trusts and Foundation Trusts, commissioners of pathology, and UKAS.
- 4.91. The system is complex and there is a need to ensure that the activity of these bodies is better aligned to achieve the right outcomes. There should be a specific function that maintains a view of the national picture, and has remit to advise and steer developments to the QA agenda at the highest levels.
- 4.92. This group should provide advice on the progress of quality improvement in pathology and provide assurance that the recommendations in this report are being implemented, and that a robust culture of quality improvement is emerging.
- 4.93. This model utilises and strengthens existing structures, lending greater weight to the JWQA, and provides a tool for scrutiny from appropriate audiences, with the power of intervention through existing Quality Surveillance Groups (QSGs), and sanction remaining with CQC.

Recommendation

- 4.94. ***“A high level, system-wide Oversight Group should be created with responsibility for steering the improvements in quality assurance frameworks and governance mechanisms outlined in this report. NHS England has confirmed that it will facilitate this group.”***
- 4.95. ***“The Oversight Group should also develop a Pathology Quality Assurance Dashboard, which draws transparent and meaningful information from existing data sources to provide a national picture of quality improvement across England, to enable trend analysis and the identification of opportunities for development of the system.”***

Implementation

Reinforcing oversight at the centre

- 4.96. NHS England should host and provide secretariat to the Oversight Group, assembling appropriate representation from DH, regulators, professional bodies, provider organisations, lay representatives and commissioners to meet the aims of the Group.
- 4.97. The Group should work together with subject matter experts to help define what a useful data set for the dashboard might look like, consulting with the service to ensure this does not represent an unnecessary additional burden of work, and that the set will be useful to service providers as a tool for scrutiny and improvement.

4. The way forward

Provider Responsibilities

- 4.98. Providers should make themselves available to contribute to the thinking of the Oversight Group as the model for the dashboard is created, and prepare themselves to provide the necessary transparent data to feed into it.

The role of commissioners

- 4.99. Commissioners, via Commissioning Support Units (CSUs) and Clinical Commissioning Groups (CCGs), should engage with the Oversight Group during the development of the dashboard, utilising it as a tool to inform commissioning decisions at a local level.

Case Study

Commissioning

In 2010, the Kent and Medway Pathology Network (KMPN) were undertaking a review of pathology service provision. During the review it became clear that although it was generally acknowledged that most clinicians felt the quality and safety of pathology services was good, it was impossible to evidence, or indeed provide assurance to patients, users and commissioners, that this was the case. In addition, service users were experiencing a significant variation across local acute trusts in terms of what and how the service was provided.

Despite extensive research by the KMPN team, very few, if any, examples of existing methods of providing this assurance could be found within the NHS. Although UKAS accreditation was seen by some as a proxy for good quality, it was considered by many that it did not provide the detailed surety that day-to-day service provision could be met; nor could it be used to monitor the service on a regular basis against the needs of its users; nor provide the necessary governance for providers and commissioners.

After a number of discussions with interested bodies, KMPN along with the local commissioners and providers agreed that the most appropriate way to provide the assurances required by all parties, would be by introducing a detailed service specification, which could be included as part of the main acute service contract. It was also agreed that a method of reporting and monitoring against that specification on a regular basis should be designed and implemented.

Utilising the expertise of pathology staff across Kent and Medway, recognised evidence-based best practice and quality standards which should be provided by a pathology service, were identified. A detailed service specification was written and subsequently agreed by all local organisations. The purpose of this specification was to:

- Define the service, quality, remit and reporting arrangements for the delivery of pathology across Kent and Medway;
- Commission pathology as an end-to-end clinical service across Kent and Medway;
- Ensure that the provision of pathology services was consistent and effective by achieving an agreed set of core standards, key performance indicators and reporting arrangements;
- Ensure best value and improved efficiency of services through standardisation; and
- Set a framework for monitoring the effectiveness of pathology services against the delivery of defined key performance indicators.

As part of the service monitoring framework, each provider was required to report to commissioners, on a monthly or quarterly basis, depending upon the item, a series of key performance criteria, which were then recorded, monitored and RAG (Red-Amber-Green) rated. These reports and compliance against the service specification are then discussed by the commissioners with the provider, who then jointly agree any remedial actions deemed necessary.

Since its implementation in 2011, it has been acknowledged by all parties in Kent and Medway that the specification and the monitoring of the end-to-end provision of the service has delivered evidenced assurance to providers, users, clinicians and commissioners that pathology services are meeting the quality and safety needs of them all.

Case Study

Kent and Medway - KPI Dashboard - 2013/ 2014

		Apr-13	May-13	Jun-13	Jul-13	Aug-13	Sep-13	Oct-13	Nov-13	Dec-13
NHS Number Compliance - 98%										
Trust		99.2%	99.2%	99.2%	98.8%	98.3%	97.5%	98.0%	97.9%	97.8%
Trust	Complaints	2	4	2	4	3	2	4	1	2
	SIRIs	0	0	1	0	2	0	0	1	0
Number of FOA Poor Performance Letters received										
Trust		0	0	1	0	2	0	0	1	0
Timeliness of responding to requests for clinical advice - 90%										
Trust		97.0%	97.0%	100.0%	100.0%	100.0%	100.0%	97.0%	100.0%	100.0%
Availability of clinical advice at MDMs - 90%										
Trust		97.0%	100.0%	98.0%	95.0%	98.0%	97.0%	100.0%	99.5%	100.0%
SNOMED or SNOMED-CT coding of Histopathology cases - 95%										
Trust		100.0%	99.9%	99.8%	99.7%	99.8%	99.8%	96.0%	95.0%	97.5%
Documentation of Histopathology second opinions - 90%										
Trust		99.8%	100.0%	99.8%	100.0%	100.0%	100.0%	99.0%	100.0%	100.0%
Consultant Appraisal - 100%										
Trust		83.0%	83.0%	83.0%	83.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Clinical Scientific Staff Appraisal - 100%										
Trust		72.0%	77.0%	93.0%	95.0%	95.0%	95.5%	97.0%	98.0%	98.0%
Continuing Professional Development - 100%										
Trust		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Histopathology Reporting of Cancer Resections using a template or pro forma - 80%										
Trust		92.0%	91.0%	92.0%	86.0%	87.0%	100.0%	84.0%	90.0%	88.0%
Average Turnaround Time (All baskets) - 95%										
Trust		93.8%	96.5%	96.5%	95.7%	97.1%	96.6%	96.9%	96.5%	96.4%
A&E Blood Sciences Turnaround Times - 85%										
Trust	Renal	73.0%	75.0%	86.0%	89.0%	92.0%	81.0%	84.0%	82.0%	91.0%
	Liver	75.0%	77.0%	86.0%	90.0%	93.0%	81.0%	85.0%	83.0%	92.0%
	FBC	88.0%	85.0%	84.0%	100.0%	84.0%	79.0%	98.0%	97.0%	98.0%
Critical Results Communication - 90%										
Trust		97.9%	97.4%	96.3%	96.3%	97.9%	96.0%	97.6%	96.8%	97.6%
Histopathology Diagnostic Biopsy Turnaround Times - 80%										
Trust		65.0%	49.0%	27.0%	32.0%	30.0%	37.0%	43.0%	39.0%	42.0%
Overall Histopathology Reporting Turnaround Times - 80%										
Trust		64.0%	51.0%	25.0%	32.0%	33.0%	35.0%	39.0%	41.0%	44.0%
Routine Antenatal Screening Tests for Hep B, HIV, Syphilis and Rubella Susceptibility - 90%										
Trust		83.0%	100.0%	100.0%	97.0%	98.0%	88.0%	100.0%	100.0%	99.0%
Late Presentation Antenatal Screening Tests - 97%										
Trust		95.0%	100.0%	91.0%	88.0%	94.0%	100.0%	83.0%	100.0%	91.0%
Teaching, Training, Supervision and Succession Planning - no less than 15% and not to exceed 30%										
Trust			36.0%							

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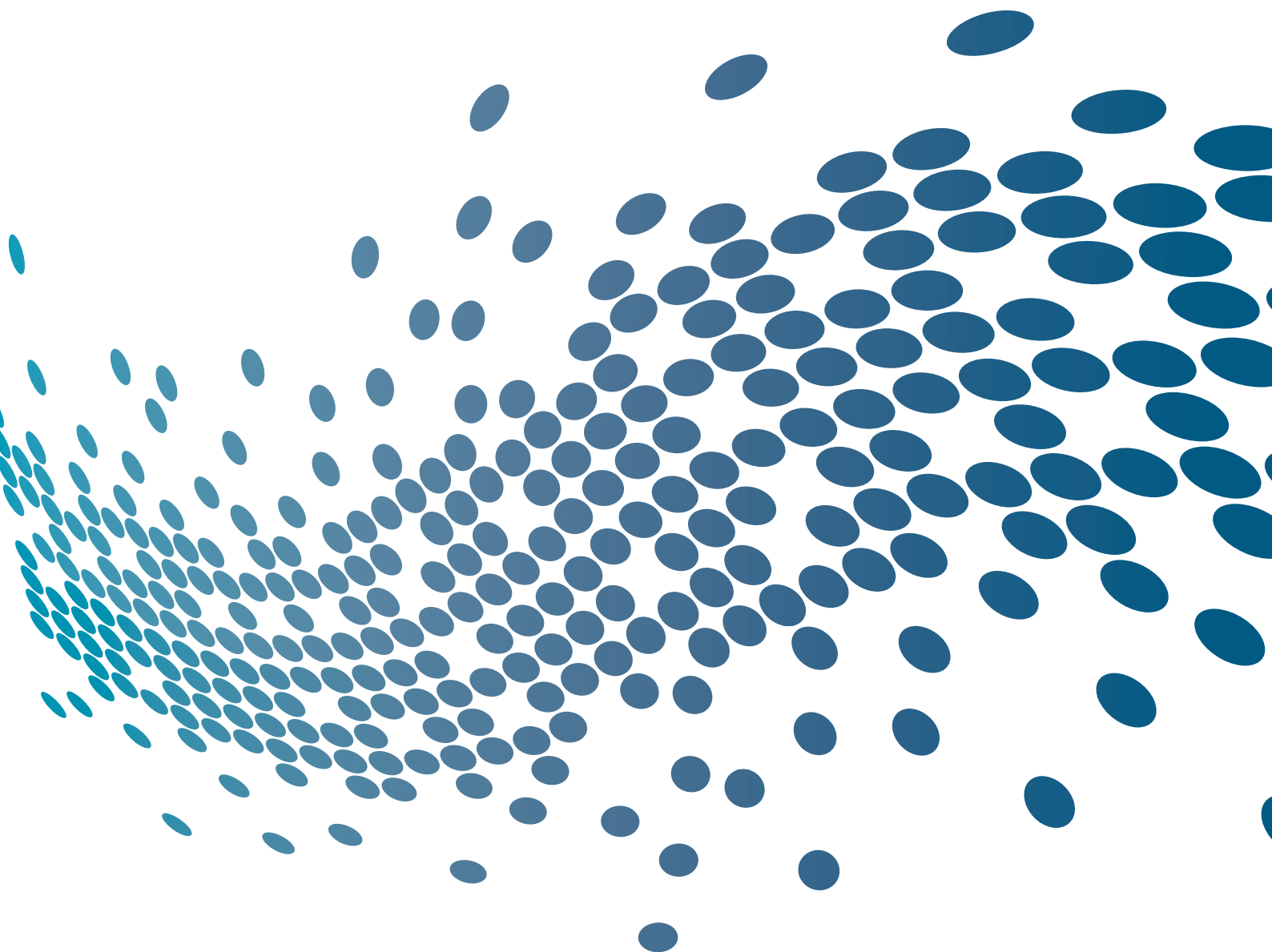
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