viapath

pioneers in pathology

Viapath 2017 Quality Account

end-to-end pathology

Contents

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A message from Viapath's CEO **Dougie Dryburgh**

The quality theme for 2017 was 'Pioneers in Pathology'. It served to highlight the important role Viapath's scientists, clinicians and employees play in helping to push the boundaries of healthcare, using innovative approaches by developing new tests and techniques. Importantly, we strengthened Viapath's Executive team by appointing our first Chief Scientific Officer, Dr Dominic Harrington; Dominic brings fresh scientific and business insights to the table.

Viapath is a public-private sector multisite business, which provides a full range of core and specialist pathology services to a broad complement of complex healthcare organisations. 2017 saw a very positive step-change in business activities, resulting in double-digit growth, significant investment in equipment and training, and importantly, employee contributions recognised through our new employee incentive scheme.

This year's Quality Account demonstrates Viapath's commitment to openness and transparency, and continuous learning to help us to improve. Customers play an important role in helping to highlight improvement opportunities. In 2017, we had a number of complex issues to resolve which on occasion did, unfortunately, impact on patients and customers. However, our teams' focus, attention to detail, resolve to overcome and continuously learn, have strengthened both our skills and ability to make changes and improve services.

During 2017, Viapath continued its focus on developing unique offerings to customers, which led to the launch of 'Viapath Nutris' (pathology-to-patient) service in early 2018. By taking laboratory services directly to consumers, this signalled a significant step forward for the company, and we intend to extend this service in 2018.

The quality theme for 2018 is 'end-to-end pathology', which will see Viapath respond to the anticipated changes in NHS pathology networks, and focus on the Viapath growth strategy – direct to consumers. It will also see the appointment of two independent non-exec directors strengthening the Viapath board: we are pleased to welcome Sir Jonathan Michael and Dr Sneh Khemka, both of whom have a strong track record in entrepreneurial and commercial leadership as well as leading complex healthcare organisations.

Finally, I would like to thank all our employees and teams for their continued enthusiasm to continuously learn and provide a great service for patients and customers.

Dougie Dryburgh
Chief Executive Officer

"2017 saw a very positive step-change in business activities, resulting in double-digit growth, significant investment in equipment and training, and importantly, employee contributions recognised through our new employee incentive scheme."

Medical Director **Professor Jonathan Edgeworth's** Report

Viapath is now in its tenth year and this is our fourth annual Quality Account. Looking back one can see evidence of continuous improvement in how we deliver and develop our services, but it is still hard to know whether we are doing enough to keep pace with increasing demands and expectations of patients and clinicians, and the rapid pace of technological development. We get individual feedback from employees during appraisals; at an organisational level patients and other customers give compliments, feedback and make complaints; and there are incidents, sometimes serious, that make us stop and explore deeply to find out why and prevent recurrence. This all helps us to improve, and examples to illustrate all these things can be found in this Quality Account.

As Medical Director, I provide assurance to the Board that we are doing the best we can to provide safe, quality services across all hospital sites. I therefore pay particular attention to these events and have overseen improvements and new investment, where required. One of the most important aspects is how our staff respond, and, yes, on a daily basis it is clear they care about what we are doing, that they want to do better and that they are engaging and professional in sometimes quite difficult situations, working as teams to do the right thing. This applies equally to the everyday as much as the exceptional, such as when Guy's and St Thomas' hospitals – including our front-line laboratories – were locked down during terrorist incidents, or when our laboratories worked alongside Kings College Hospital clinical services as a main trauma receiving site.

2017 also saw Dr Jim Wade step down as Clinical Director on the King's College Hospital site, with Dr Malur Sudhanva stepping up. Sudhanva joins his other Clinical Director colleagues, Dr Fraser Mutch at Bedford Hospital and Dr Paul Cane at Guy's & St Thomas' Hospital. All our Clinical Directors bring wise counsel and a deep understanding from working many years in pathology, each predating Viapath. Their willingness, along with clinical leads in each specialty, to work alongside scientific and managerial leads across Viapath, also gives assurance that we will continue to move forward together.

Looking ahead, we increasingly recognise the need to work in partnership with clinical and academic colleagues across King's Health Partners, to transform patient pathways from the moment a sample is collected through to the intervention that has a positive impact on patient care and experience. This was evidenced by our contribution to the South London Genomics Medicine Centre bid. For 2018 our focus will include cancer pathways, controlling antimicrobial resistance and making pathology more accessible to patients with long-term conditions. We are working with ambition for tomorrow, whilst also keeping eyes firmly fixed on the needs of today. I hope you find our Quality Account interesting and look forward to hearing your feedback.

Professor Jonathan Edgeworth
Medical Director

"Looking ahead, we increasingly recognise the need to work in partnership with clinical and academic colleagues across King's Health Partners, to transform patient pathways from the moment a sample is collected through to the intervention that has a positive impact on patient care and experience."

Innovation & Scientific Progress – Dr Dominic Harrington

Throughout 2017 the Innovation Academy continued to promote innovation, quality and the professional development of our scientists. The seventh annual scientific symposium, which we hosted in December, provided an opportunity to share recent achievements and for us to explore the theme 'Threescore and Ten'. The theme was selected to highlight how science and technology can best serve the NHS as it prepares to celebrate the seventieth anniversary of its founding.

It is remarkable to think that life expectancy in the United Kingdom in 1948 was just 66 years for men and 71 years for women. Tuberculosis, polio and rickets were common afflictions – all of which favoured the overcrowded and unsanitary environments in which the poor lived. Seventy years on, life expectancy has increased to 79 and 83 years for men and women respectively. To help ensure that the NHS celebrates fourscore years, pathology providers must find innovative ways to support and promote the leading of healthier, not just longer lives.

To demonstrate Viapath's commitment to driving and celebrating innovation, we are proud to sponsor the national Advancing Healthcare Award for Innovation in Healthcare Science – having won the award in 2016. Our desire to speed up the identification and dissemination of healthcare innovations was further demonstrated in 2017 when Dr Rachel Carling, Consultant Clinical Scientist and Clinical Lead for Biochemical Sciences at Viapath, became an inaugural winner of the NHS England Knowledge Transfer Partnership Programme for Leaders in Healthcare Science. The programme has been designed to ensure ongoing future collaborations across industry, academia and research teams and position the NHS as a key contributor and committed partner to the development and testing of new technology to transform services, improve outcomes and reduce cost. As part of the programme Dr Carling collaborates with the National Measurement System – the government-funded body that maintains the UK measurement infrastructure – to investigate aspects of calibration and how it impacts on the national New Born Screening service.

Within Viapath, our 'Innovation Fund' and 'Scientific Learning and Development Fund' continued to make awards during 2017. These two funds have facilitated translational research and helped employees reach their full potential respectively. In recognition of the expertise of our scientists, we were delighted to hold Viapath's fourth annual 'Excellence in Pathology' award in December and congratulate our winner Charlotte Lee on her work on Skewed T Follicular Helper Cell Subsets in Common Variable Immunodeficiency – one of the most common, clinically significant primary immunodeficiencies.

In June 2017, I was delighted to be appointed as Viapath's first Chief Scientific Officer. This new role supports Viapath's commitment to innovation and scientific progress, and builds on the contributions that Professor Roy Sherwood and I had the privilege of making to the organisation as Scientific Directors from 2012. Our healthcare scientists now have representation at the highest level of management at Viapath. During 2018 we will continue to provide an environment where talent is nurtured, supported and ideas are brought to life; fundamentally, a place where the 'make it happen' attitude prevails.

Dr Dominic Harrington
Chief Scientific Officer

"To help ensure that the NHS celebrates fourscore years, pathology providers must find innovative ways to support and promote the leading of healthier, not just longer lives."

Caldicott Guardian

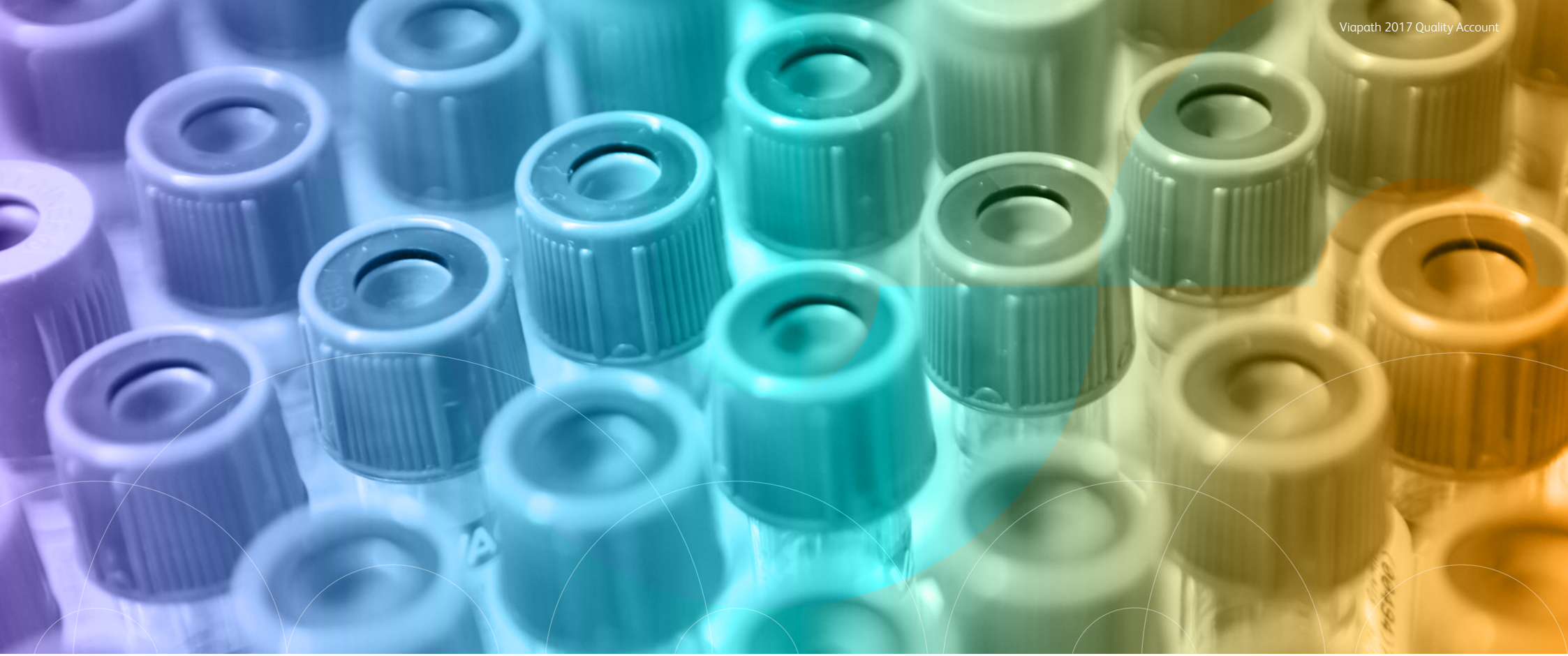
Dr Robert Hangartner retired last year after a long and respected career as a Consultant Histopathologist, former Viapath Clinical Director and our Caldicott Guardian. Robert had a deep understanding of the legal, regulatory and ethical framework supporting the safeguarding of Personally Identifiable Information (PII). Recognising the challenge in taking his place, I first appointed the Viapath Information Governance Manager, Jeremy Skinner, who worked alongside Robert for many years, to the position of Deputy Caldicott Guardian. Having now had numerous opportunities to consult the Caldicott Guardian Handbook as part of my duties, and having attended a second annual Caldicott Guardians conference, I can see at first hand how increasingly important it is that patients have confidence in how we protect their data when reviewing and transferring it. They know that pathology results must be available for their own care when they are seen in a particular hospital or GP surgery, but that data must also be available when they get care from different healthcare organisations. Viapath scientists and clinical colleagues also ask to see pathology results to help audit, review and improve services.

All these transfers require oversight from our information governance committee, and we ensure they conform to the common-law duty of confidentiality, legislation such as the Data Protection Act and the Caldicott principles. In essence, for pathology, the latter means that only the minimum necessary PII must be used or transferred for a justified healthcare purpose (beyond usual care), in a lawful and secure way, for an agreed purpose, and accessed only by identified trained individuals who are then responsible for its security. The final Caldicott principle is that the duty to share PII can be as important as the duty to protect patient confidentiality. As a pathology provider working with clinical teams needing to constantly improve services, we understand the need to respect both duties: it's often a judgement, being proportionate and striking a balance between individuals' confidentiality and wider considerations such as needing to improve services, protecting patients from future potential harm and acting in what we believe to be the patient's best interests. This is what makes the work of a Caldicott Guardian both complex and rewarding in equal measure.

Looking back on 2017, I am reminded that information governance and security extends beyond the conventional remit of a Caldicott Guardian. You may remember that for a few days in May 2017 the NHS was affected by a worldwide cyber attack (WannaCry ransomware) that locked NHS computers and demanded payment to regain access. It did not affect Viapath computers, but some of our NHS customers were affected and needed our support to ensure continuity of pathology services over a difficult weekend. The attack was stopped after a few days by emergency patches released by Microsoft that unblocked computers and prevented the spread to other computers.

Finally, most of you will be aware that new European Union General Data Protection Regulations (GDPR) replaced the UK Data Protection Act on 25 May 2018. GDPR is the most important change in data privacy regulation in 20 years and applies to every aspect of how an organisation controls and processes the personal data of everyone, be they employees, patients or customers. Approaching any new piece of legislation can feel daunting, but there are standard principles we can apply, and GDPR builds upon the principles of existing data protection legislation. We will review the new GDPR requirements with reference to our current information governance processes – particularly our data-holding assets and data transfers – continue to follow good practice, and recognise there will need to be increased transparency and communication about what we do. GDPR introduces new rules

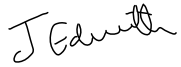
“Looking back on 2017, I am reminded that information governance and security extends beyond the conventional remit of a Caldicott Guardian.”



around retention and security of data, and gives patients and the public increased rights, including the right to rectification when personal data is inaccurate or incomplete and the right to erasure (right to be forgotten) under certain circumstances. However, these rights must all be considered in the context of personal data that it is necessary to retain in order to provide the best possible care for patients.

How this will affect pathology remains to be seen, and will likely become clearer particularly when we get requests from patients to do something about the data we hold, or from new case law that creates legal precedent. At the moment there are no experts in GDPR, only a lot of people and organisations going on the journey to interpret and implement the law in a timely and reasonable way.

One particular thing we can do is to ensure all our employees are made aware of progress implementing GDPR and undergo their annual Information Governance (IG) mandatory training so they understand the new requirements under GDPR and their individual responsibilities of protecting all confidential data. A new electronic interactive IG training tool was introduced in September 2017 to replace the old version and Viapath is tracking IG training compliance through the Viapath Information Governance Committee.



Professor Jonathan Edgeworth
Medical Director

Quality Director **Liz Adair**

2017 signalled a series of step changes in our patient-centred approach to governance, risk and quality and these are described in the following section.

In my report last year, I reflected on the national patient safety agenda gathering pace and Donald M Berwick's eloquent vision for patient safety, which was:

'A safer care system is conceived from the perspective of the patient, following their journey through different care settings irrespective of organisational boundaries. It is judged not by the prevalence of adverse incidents, but by the ability to proactively identify potential harm and risk before they harm patients.' [1](Donald M Berwick MD President Emeritus and Senior Fellow, Institute for Healthcare Improvement.)

Viapath has continued on its journey to keep patient safety at the centre of everything we do, in partnership with our customers, in order to respond and resolve issues before they impact on patients. The 'Incidents section' describes what the incident themes were and examples of what we have put in place to change practice or highlight early potential harm.

Regrettably, Viapath had more NHS Serious Incidents in 2017 than in previous years, which had an impact on services and patients. We have taken the opportunity from these events to 'deep dive' into the reasons why things go wrong, scrutinise processes and systems and work with NHS customers to resolve. It also signalled the need for review of our assurance processes.

Over summer 2017, I led a discovery exercise to examine how incidents are escalated, what processes and reporting mechanisms are in place and how our work needs to be aligned with NHS partners, with a particular focus on openness and lessons learnt. The Viapath Complex Incidents section describes the Viapath Complex Incident process and how we now put together a response team to investigate and tackle very complex problems. The Viapath Complex Incident process was launched in October 2017 and will continue to evolve in 2018.

An in-depth review of Viapath's Risk Management system was undertaken in late 2016, to ensure that it was easy to differentiate between what was a risk held by Viapath and what was the consequence on laboratory services of risks held by NHS partners. We issued the revised Risk Management process in February 2017, with local divisions managing their local Risk Registers. The process is being embedded at a local level and monitored through the Viapath Governance, Risk & Quality framework which you can learn more about in the 'Risk' section.

Finally, our laboratories made considerable progress throughout 2017, with their transition from CPA (Clinical Pathology Accreditation) to the international ISO 15189 standard for medical laboratories. You can read about our progress in the 'Accreditation & Regulations' section. I would like to acknowledge and thank all our employees for their hard work and dedication, which has resulted in accreditation success.

Liz Adair
Quality Director

"A safer care system is conceived from the perspective of the patient, following their journey through different care settings irrespective of organisational boundaries."

[1]Illingworth, J. Continuous Improvement of Patient Safety: The case for change in the NHS. The Health Foundation. November 2015

2017 Quality Performance Report

Accreditation & Regulation

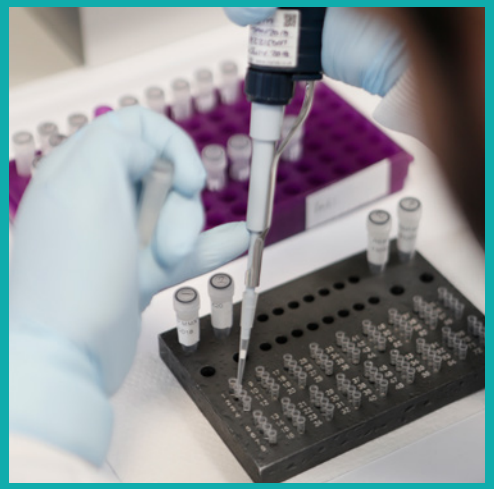
There are a number of external inspection, regulation and accreditation agencies that regularly visit Viapath sites. They include:

- **CQC** Care Quality Commission
- **MHRA** Medicines & Healthcare products Regulatory Agency
- **UKAS** United Kingdom Accreditation Service
- **HTA** Human Tissue Authority
- **PHE** Public Health England – Quality Assessment for Screening programmes
- **HSE** Health & Safety Executive

You can read more about them and the way they inspect healthcare organisations in the Viapath 2014 Quality Account in the 'Key Assurance and Regulatory Bodies' section. The Care Quality Commission did not visit any Viapath sites in 2017. However, you can access the reports from their last visits on the CQC website (http://www.cqc.org.uk/provider/1-126775137).

UKAS undertook 28 laboratory assessment visits in 2017, ranging from initial assessments, for the accreditation standard ISO 15189: 2012, to annual surveillance visits. Excellent progress has been made and Viapath will have received all its initial assessments visits by the UKAS deadline in 2018.

The infographic on the following page summarises progress.

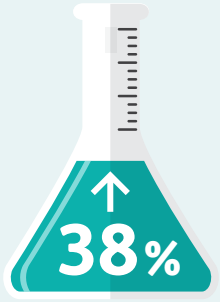


Viapath laboratory services site	Date CQC report issued
Bedford Hospital, Bedfordshire	16 January 2013
Guy's Hospital, London	11 April 2013
St Thomas' Hospital, London	11 April 2013
Kings College Hospital – Denmark Hill site, London	29 March 2013
Kings College Hospital – Princess Royal University Hospital site, Kent	Not inspected yet

Table 1: Summary table of CQC inspections to Viapath

Accreditation & Regulation Progress in 2017

10
laboratories
ISO 15189
accredited



Adverse incidents reported in 2017 encouraging a healthy reporting culture

Public Health England
One antenatal screening Quality Assurance assessment by Public England in 2017 at Bedford site

28 Visits
by UKAS in 2017

CareQuality Commission

No visits from the CQC in 2017

MHRA

Two inspections: PRUH and Bedford sites

HTA Human Tissue Authority

One visit to Denmark Hill site Histopathology service

Incidents

Viapath provides services for NHS-funded patients and therefore, each time there is an incident which may or has caused patient harm, we are required to report the incident using the NHS incident reporting system (mandated by the Health & Social Care Act 2012). Each of our sites has access to the electronic NHS reporting system and we work very closely with NHS patient safety teams to establish what happened and resolve.

In 2017 there was a 38% increase in adverse incidents reported across all our laboratories compared with 2016 (from 646 to 891). It can be hard to know whether an increase in incidents is an encouraging sign of a healthy reporting culture whereby employees report incidents which may impact on patients, services and employees to help improve, or whether it represents a reduction in service quality. To place our reporting in context, NHS Improvement reported that between October 2016 and September 2017, 1,895,834 incidents were reported in England. They have reported a year-on-year increase in incident reporting, actively encouraging a reporting culture in healthcare.

However, the occurrence of twelve NHS Serious Incidents over 2017 including one Never Event, is undoubtedly more significant and requires closer scrutiny. It prompted a Viapath-wide review of our whole approach to quality, safety, communication and engagement.

The NHS defines different types of incidents: Adverse, Serious and Never Events. The definitions are as follows:

Incidents

Adverse Incident (AI) is 'an unintended event or circumstance which adversely affects patients, visitors, employees, or has the potential to do so.'

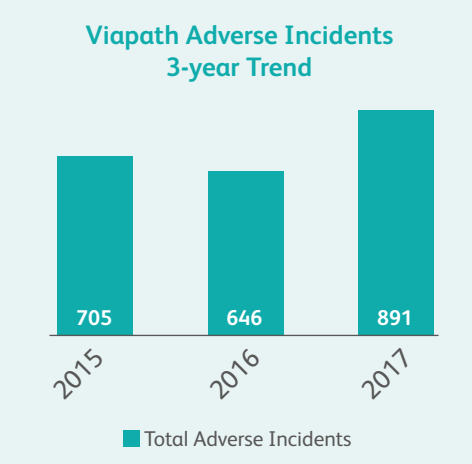
Never Event is 'a serious, largely preventable patient safety incident that should not occur if the available preventative measures have been implemented.'

Serious Incident (SI) is 'an adverse incident which has caused moderate to serious patient harm or death and/or is likely to cause major disruption to services, significant financial or asset loss or reputational damage.'

	2015	2016	2017
NHS reported Never Events/ Serious Incidents	2	1	12*
Adverse Incidents	705	646	891
Total incidents	707	647	900

Table 2: Summary of total NHS reported Never Events/ Serious Incidents and Viapath Adverse Incidents (*includes one Never Event)

> "Each of our sites has access to the electronic NHS reporting system and we work very closely with NHS patient safety teams to establish what happened and resolve."



Graph 1: Viapath Adverse Incidents 3-year Trend

Graph 2: NHS Reported Never Events / Serious incidents 3-Year Trend

Never Event

The Never Event in October 2017 involved a patient being transfused with a blood product (plasma), of the wrong blood group. This means that there was a risk of the patient reacting to the transfusion and causing them harm – not as high as if it had been whole blood, but still a risk. The reason this is a Never Event is because there are multiple checks in the laboratory and on the ward to ensure that each patient receives the correct blood product, and therefore the occurrence implies multiple errors along the pathway. The investigation identified a number of factors relating to laboratory processes and IT systems, which contributed to the incorrect blood product being transfused. Thankfully the patient did not have any obvious side effects.

A joint investigation was immediately carried out between Viapath and the hospital team and was presented to both Viapath and the hospital boards. The investigation report and resulting action plan are being overseen externally, both by the Clinical Commissioning Group and the MHRA.

Incident Review

We reviewed all these 12 Serious Incidents to identify whether there were commonalities that needed to be addressed, both within the department where they occurred and across the organisation. This included discussion at the bi-annual Viapath Governance, Risk & Quality Assurance Committee which includes members from the Viapath Executive, all the Medical Directors / Director of Governance from external NHS partners and Viapath's owners. We could not find any systemic reasons, with incidents mainly involving:

- IT system processes
- Human error
- Equipment failure

However the Never Event described above, in part involved a recognised IT risk due to the use of an old laboratory IT system. A £2 million investment, which will be completed next year, had already been prompted, but sadly the incident materialised before the investment project was completed.

The 'human error' Serious Incidents have prompted a 'human factors investigation' to understand what the drivers are. Human errors can be made for a range of reasons including environmental disturbance, failure to follow procedure or simply making a mistake.

The equipment failures, three in total, have prompted a lengthy discussion with manufacturers and we have sought external advice to identify the causes. This has also triggered a review of our procurement service arrangements and capital investment processes so that we have particular focus on equipment, which, if it fails, can destroy precious human samples.

So in conclusion, no evidence was found to suggest that there had been a systematic failure in operations or quality. However, we have requested further external advice and support and will take this opportunity to update all our quality processes – of which there will be a description in next year's Quality Account.

Viapath Complex Incidents

Some of the incident investigations raised questions about how quickly serious incidents are dealt with and communicated by Viapath. It can take some time to establish which patients are affected, especially if the scientists and pathologists have to review multiple patient data and contact the team looking after the patient to establish what harm, if any, has been caused. As a result, the Viapath Quality team undertook a discovery exercise in 2017 to clarify the incident management processes across Viapath. This took place at a laboratory level and explored how the Viapath processes link with NHS incident reporting. The hypothesis was that with multiple reporting routes and steps there may be an unintended delay in discussing the incident quickly with all parties.

The exercise identified variation in processes between laboratories, reflecting in part both the different requirements of host NHS Trusts and historical practice. It also identified a need to strengthen Viapath-wide responses and escalation processes, particularly with a focus on early rapid actions and communication with NHS partners.

In response to the findings, Viapath developed a simple process for identifying complex problems with the appropriate pace and rigour to satisfy reporting requirements and early engagement with NHS partners. The Viapath Complex Incident Response procedure was launched in October 2017, after consultation and advice from employees and NHS partners.

An incident meets the Viapath Complex Incident definition if it fulfils one or more of the following:

- It falls into the definition of a NHS red/Serious Incident reportable to external bodies
- It is not clear what the incident grading/definition is and urgent, further investigation is required to establish the facts
- The incident requires urgent investigation to establish any potential or actual patient harm
- The level of investigation required may potentially impact on day-to-day service levels and resources, for example undertaking a look-back exercise
- Moderate/high risk of reoccurrence because the cause is not yet known
- A Formal Notice has been issued to a laboratory by an External Quality Assessment scheme following a series of poor performance reports

When an Incident has occurred and fulfils the definition of a Viapath Complex Incident, it is escalated to the most senior scientific, managerial and clinical colleagues, and the senior leadership team (SLT), both at site and executive level. The site SLT then trigger the Complex Incident Response (CIR) team meeting within 48 hours of the incident being identified including engagement with NHS partner patient safety/assurance leads.

The purpose of the CIR is for all key stakeholders to jointly agree facts, actions, reporting, investigation methods, monitor progress and communications. This means that the Board and NHS partners can be assured that everyone is taking the problem very seriously and working quickly to resolve it, with patient safety at the centre. A Complex Incident poster and procedure was issued across the business to describe the process for escalating Complex Incidents, see figure 2.

“Viapath developed a simple process for identifying complex problems with the appropriate pace and rigour to satisfy reporting requirements and early engagement with NHS partners.”

Complex Incident Identified

An incident is complex if it fulfils one or more of the following:

- **Incident** falls into the definition of a NHS red/ serious incident reportable to external bodies including screening programme/EQA Formal Poor Performance Notice, or not clear & further investigation to establish facts required
- **Incident** has caused patient harm, or requires urgent investigation to establish any potential or actual harm
- **The level of investigation** required may potentially impact on day-to-day service levels and resources
- **Moderate / high risk** of reoccurrence because cause not yet known

Most Senior Local Managers alert site Clinical Director and General Manager/ Director of Operations who trigger CIR Team communication.

Within 48 hours of incident being identified CIR Team set up and meet

Membership

- **Executive Sponsors (Report to CEO)**
  COO
  Medical Director/ Caldicott Guardian (advises on governance/ patient safety)
- **Coordination & oversee investigation**
  Director of Operations/General Manager
  Site Clinical Director (advises on governance/patient safety)
  Admin support – minutes/meetings/ action log
- **Corporate Advisors**
  Head of Quality/ Quality Hub Coordinator
  Head of H&S*
  Deputy Director of IT*
  Head of Procurement*
  Head of Communications*
  NHS Clinical Expert
- **Local Team**
  NHS Partner representative (BHT, GSTT, DH, PRUH)
  SDM
  Clinical/Scientific Lead
  Quality Manager
  H&S Lead*
  Departmental Head/Manager*

Role

CIR Team's first meeting – Agenda + Actions (actions will be resolved as investigation progresses)

- Establish facts
- Terms of reference for investigation
- Lead investigator identified
- Duty of Candour requirements clarified
- Reporting and notification to external bodies (e.g. CQC, MHRA) agreed and who by
- Agree CCG/ NHS England reporting requirements & timelines with NHS Partner (e.g. SI/Screening Incident)
  – RCA
  – Timeline
  – Reporting deadlines
- Agree point of contact and communication with NHS Partner
- Identify external advice requirements e.g. clinical advice
- Agree action plan / SBAR
- Agree status of incident e.g. Red, Amber, SI, Unknown current status is xxx)
- Frequency of meetings / incident updates required
- Staff support requirements who are directly involved
- Support required outside of department/deployment of additional resources for time limited period – business continuity
- Other review (e.g. risk register)
- Chair to update Executive sponsor if not present/ CEO

Figure 2: Viapath Complex Incident Diagram (reviewing image quality)

Risk

Risk management

The Viapath Group board is responsible for ensuring that Viapath has effective systems for identifying and managing all clinical and organisational risks. The risk management and escalation process flows from bench-to-board and board-to-bench and is embedded in the Viapath Governance, Risk and Quality (GRQ) framework. Figure 3 below demonstrates the risk management structure at Viapath and how it provides the required assurance.

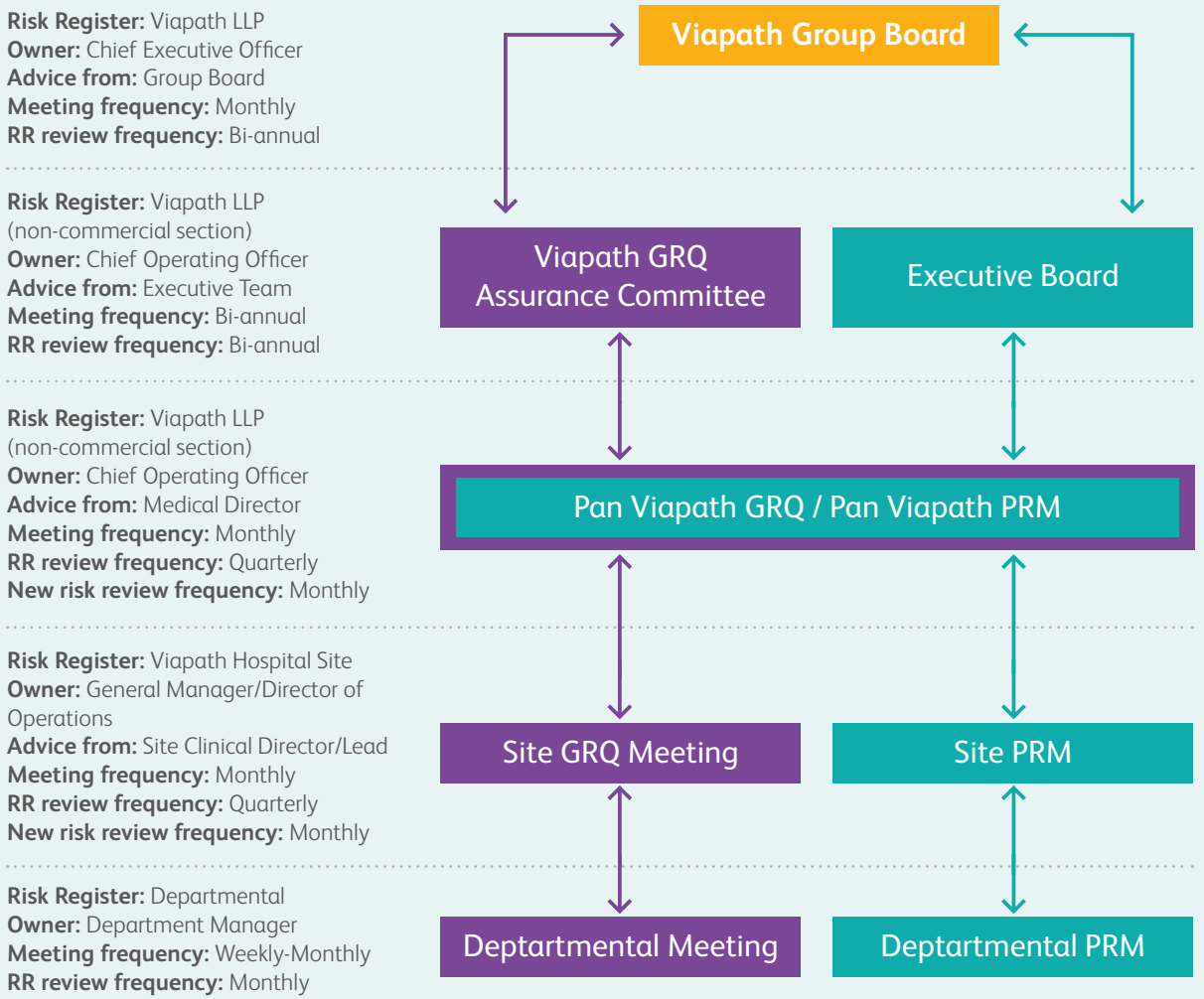
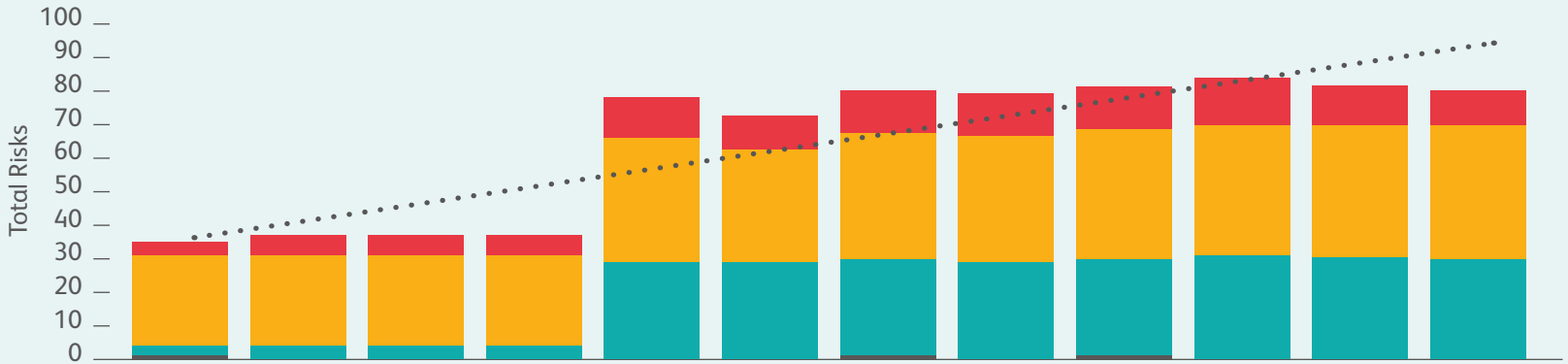


Figure 3: Viapath risk management structure and assurance. (Key: PRM – Performance Review Meeting; GRQ – Governance, Risk & Quality; RR – Risk Register)

Viapath Risks by Grading



	Jan 17	Feb 17	Mar 17	Apr 17	May 17	Jun 17	Jul 17	Aug 17	Sep 17	Oct 17	Nov 17	Dec 17
Red	3	5	5	5	10	9	11	11	13	13	10	10
Amber	29	30	30	30	39	29	36	39	39	39	40	40
Green	3	3	3	3	29	29	30	29	30	32	31	30
New red in last 30 days	1	0	0	0	0	0	1	0	1	0	0	0
Total	35	38	38	38	78	74	80	79	82	84	81	80

New Red in last 30 days Green Amber Red Risk Tr ends

Graph 3: Viapath risks by grading in 2017

Risk Register 2017

Risk management is important because it enables Viapath to improve quality and comply with the law. It supports a consistent process of identification, analysis, evaluation and control of actual and potential risks.

A risk is a chance of something happening that will have an adverse impact on the achievement of Viapath's priorities and the delivery of high quality patient care. Risks are contained in the Viapath risk register which is managed and reviewed at all levels of the business. A red rating is attributed for the highest risks and green for those where the risk of impact is low. Risks move off the register when mitigation (action to prevent or minimise reoccurrence) has been put in place.

The total number of risks per month represents the number of active risks contained in the risk register that month.

Over late 2016, Viapath reviewed its risk management processes and a new policy was rolled out in February 2017. Between February and August 2017 Viapath held meetings with its host NHS Trusts risk management teams to agree a process of transfer or closing risks from the NHS Trust risk register to Viapath.

This was a collaborative approach to ensure risks are jointly understood between both parties, the correct risk and impact are articulated on respective risk registers, and action plans are in place to mitigate/remove/accept the risk.

Graph 3 shows a spike in risks in May 2017 due to the risks from the Princess Royal University Hospital (PRUH) being added to the Viapath risk register. All risk registers were reviewed between the period of February to August 2017, which meant individual risks were reviewed – resulting in some being closed, some downgraded or upgraded and, in addition, some new risks added. However, from May 2017 green, amber and red risks remained fairly constant, although effort has been applied to mitigate or close a number of red risks.

“Between February and August 2017 Viapath held meetings with its host NHS Trusts risk management teams to agree a process of transfer or closing risks from the NHS Trust risk register to Viapath.”

Risk escalation and de-escalation

Risks can be identified through a variety of proactive measures (development of controls that avoid an incident from happening) or reactive measures (analysis of incidents data after they have occurred). When a risk is identified, a risk assessment is carried out which includes a description and details about the risk, assessment and evaluation, action planning, risk review, escalation or de-escalation, risk control and outcome. When a risk is escalated to the GRQ meetings, the risk assessment is reviewed and a decision is made to escalate or de-escalate. The five steps for risk escalation and de-escalation are displayed in figure 4.

The Viapath risk monitoring principles are:

- Risks are monitored through a consistent and integrated approach across Viapath, embracing clinical, non-clinical and corporate risks.
- All general risks are assessed using a consistent grading tool which is in line with that of our NHS partner Trusts.
- All general risks are recorded and maintained in a controlled local/departmental risk register which provides authorised access.
- Viapath maintains a hierarchy of risk registers, and risk is escalated or aggregated so it is managed at the appropriate organisational level.

Risk registers are formally reviewed at the appropriate management level at least quarterly. Risk information is recorded and controlled so that lessons can be learnt and recurrence prevented, with new Red risks being escalated to the Board.

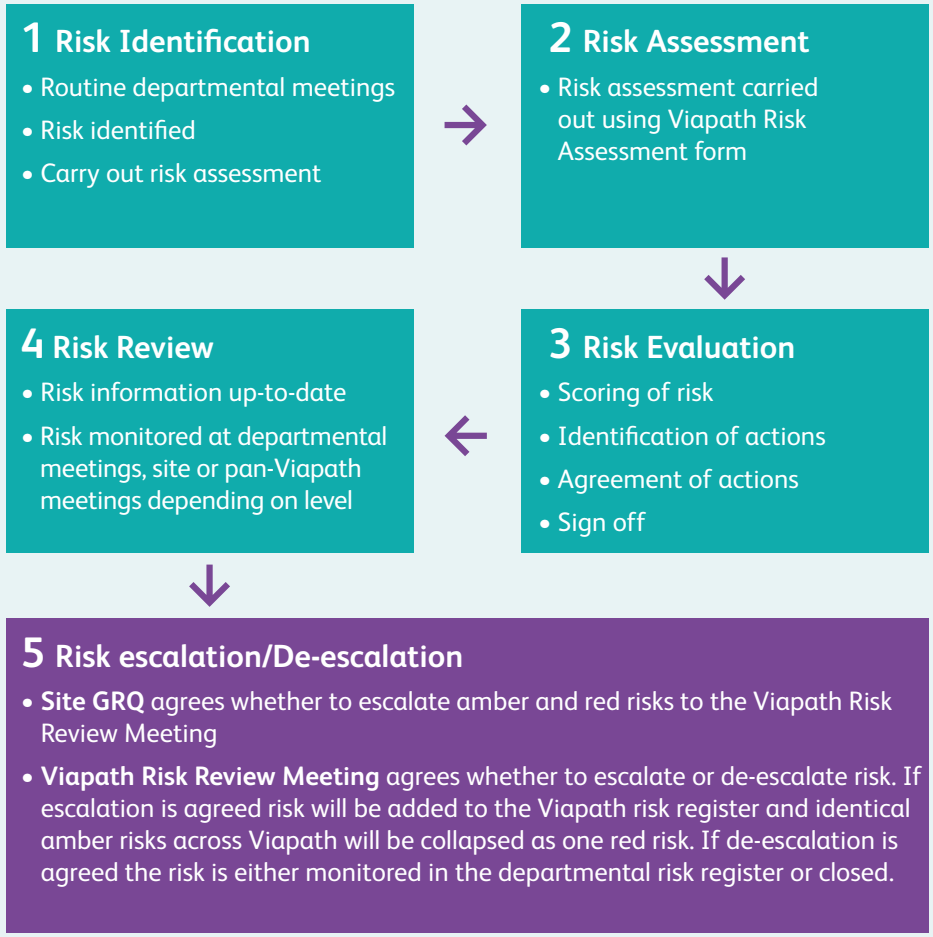


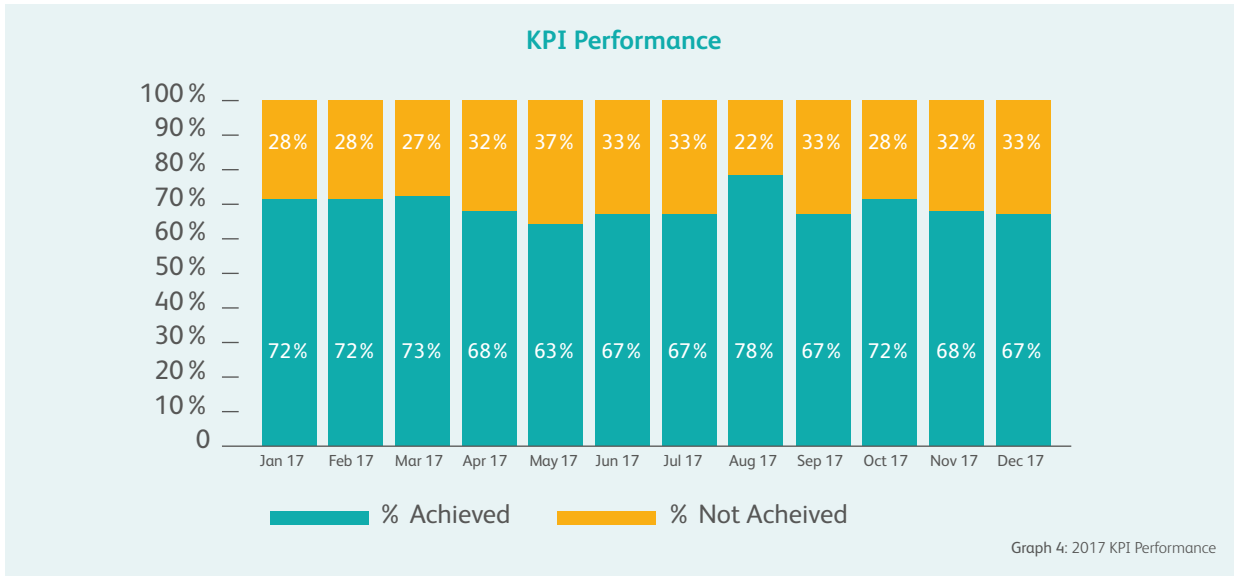
Figure 4: Viapath risk escalation and de-escalation procedure

Chief Operating Officer Progress **Richard Rolt**

Over 2017 our operational teams have risen to the challenge of the growing demand for our laboratory services, from across the healthcare system, and the pressure it places upon delivering against our key performance indicators (KPIs) and turnaround times (TATs). In fact, in 2017 the Viapath laboratories processed the highest volume of work ever undertaken, with a total of 33.1 million units of activity processed – a 6% increase on 2016. In October 2017, we also saw the highest ever single month for activity at 2.96 million units of activity delivered. In line with the increased demand for our tests and our focus on driving up quality across the business, there was a steady increase in total labour hours, an 11% increase compared to the previous year.

In December I finalised appointments that have strengthened our senior operational leadership team. Firstly, with the establishment of the new post of Director of Operations, focused on service performance, improvement and transformation; and secondly, with the appointments to three Divisional Operations Directors posts for Core Services, Reference Services and Support Services. I am delighted to report that all four posts were appointed by promotion of internal candidates – a great reflection of the experience, talent and opportunity that exists today within Viapath.

Across our business we aim to deliver against numerous laboratory KPIs that are reviewed within every service line each month to spot trends and develop action plans where the bar is not reached. We report on 60 of these KPIs to the most senior level of our organisation every month in order to manage the overall performance of our operation. Some of the KPIs have presented a number of challenges that needed to be overcome; we are both proactive and reactive in responding to these by adding resources or equipment capacity where needed, or by developing longer term service improvement plans for deeper issues. Our progress for 2017 is shown in Graph 4.



Graph 4: 2017 KPI Performance

In 2017 our productivity, which is measured by the total units of activity processed per hour, remained steady compared to previous years at 22.6. Employee sickness absence was below the business agreed target of 3.5% across all sites, with average sickness absence at 2.7% across 2017, a notable result.

2017 was a very successful year for ISO 15189 accreditations, with a total of eight accredited laboratories and a further nine recommendations for accreditation, pending clearance of non-conformities. During 2017, the laboratories faced a busy UKAS calendar with nine initial assessments and seven surveillance visits across Viapath.

2017 was a challenging year for incidents, with 12 Trust declared Serious Incidents (SIs) reported. Exceptional efforts by our operational teams, with support from both Quality and Clinical colleagues, have ensured a thorough and detailed investigation into all root causes. The increased trend in incidents prompted the creation and implementation of the Viapath Complex Incident Response procedure. Arising from our response to SIs there are many and varied action plans associated to lessons learnt that have been implemented across the organisation. For example, we have implemented increased controls around equipment that processes precious, irreplaceable patient samples and we have established innovative processes to ensure that our scientists can work uninterrupted on critical tasks in busy laboratory settings.

I look forward to continuing our commitment to scientific and clinical service excellence during 2018, with our patients at the heart of all we do.

Richard Rolt
Chief Operating Officer

“Across our business we aim to deliver against numerous laboratory KPIs that are reviewed within every service line each month to spot trends and develop action plans where the bar is not reached.”

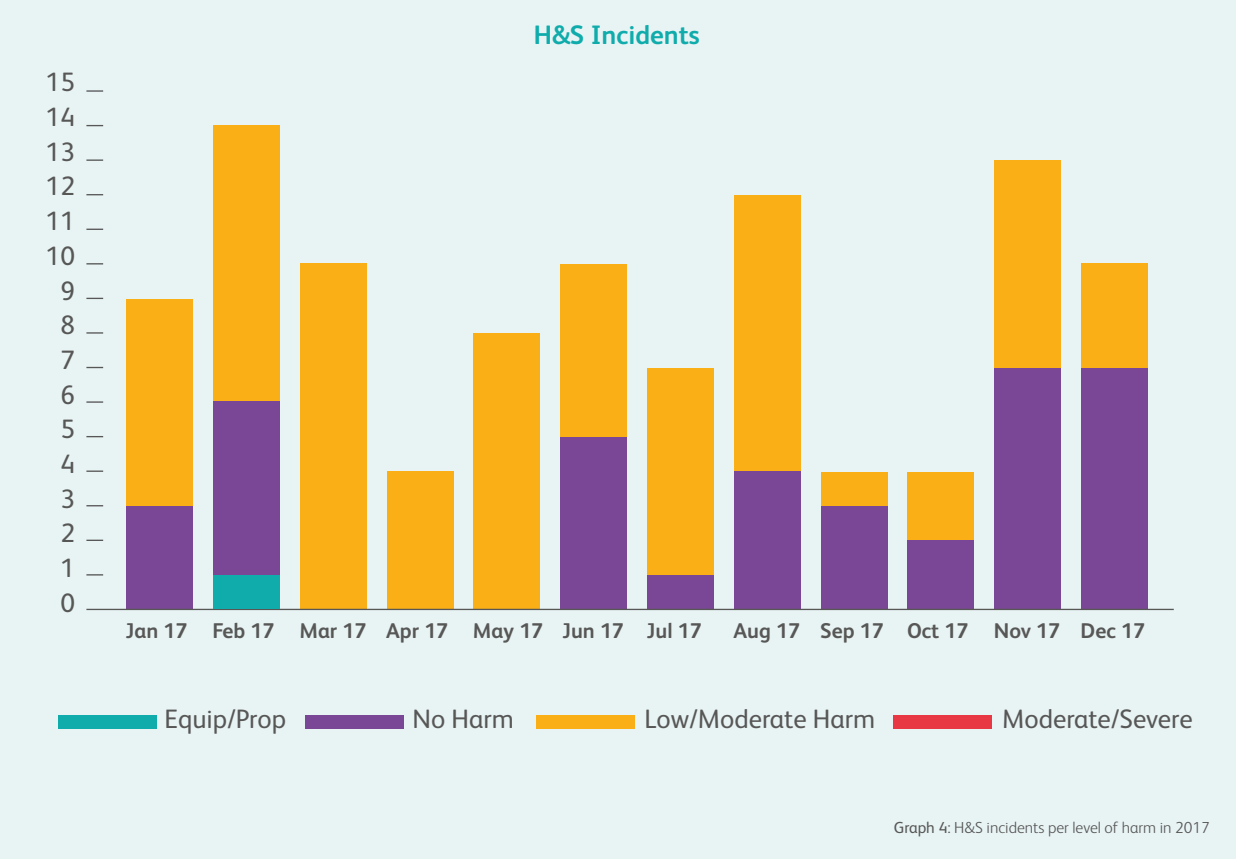
Health & Safety

Throughout 2017, we identified a growing trend in Health & Safety (H&S) incidents where the direct cause was non-compliance with personal protective equipment (PPE), such as eye goggles. In response to this trend, Viapath carried out an audit of all its laboratories and as a result purchased and implemented the use of positive pressure air hoods into everyday laboratory activities, such as disposal of formalin and large chemical spillage. This is particularly important where PPE is not an appropriate solution in the event of a spillage. A hood is also available on each site if required.

Due to the importance of wearing PPE, Viapath set an objective for 2017 to accomplish 100% PPE compliance and as a result, PPE-related incidents have decreased significantly with only six incidents reported in 2017 in comparison to 16 reported the year before, showing a 62% reduction overall.

Throughout 2017, another main focus was fire management, particularly fire risk assessment (FRA) which requires every department to have a plan with ways to effectively manage and minimise potential fire risks. Individuals across Viapath have received training, which will continue to develop throughout the coming year in order to support the structured fire management programme.

Viapath's commitment to training and supporting the H&S teams has been supported in 2017 by identifying the need for consistent, in-house first aid training. Individuals have been identified to become first aid trainers and therefore, once trained, can provide competent first aid training to as many individuals as required.



Graph 4: H&S incidents per level of harm in 2017

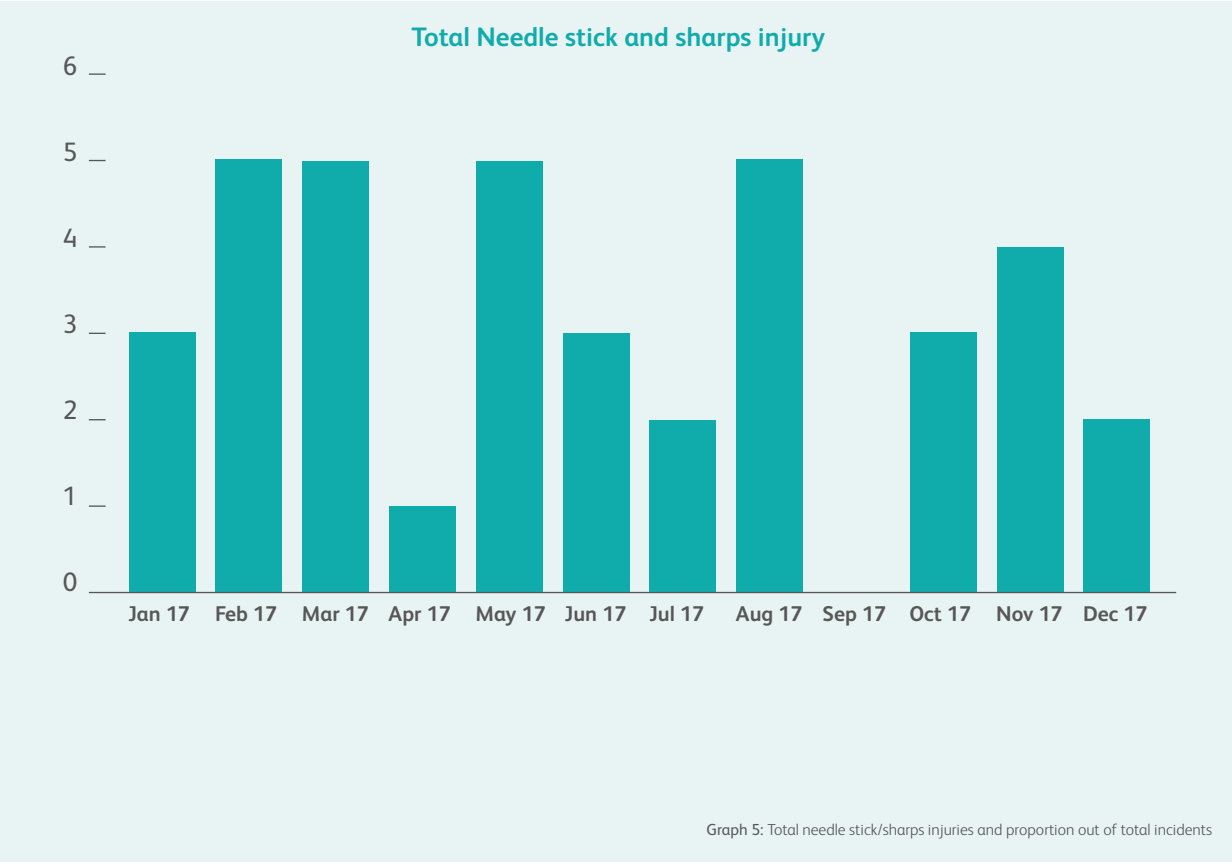
In 2017 there were 106 H&S-related incidents reported, a 12% decrease from the year before where 120 H&S incidents were reported. All H&S incidents reported in 2017 fell under the category of either no harm or low harm, with one incident occurring due to equipment damage. Overall, the H&S incidents trend is decreasing, but sharps injuries and exposure to hazardous substances continue to be the most commonly reported type of incident.

Health & Safety Needle Stick Incidents Trend

In 2017 Viapath reported 19 needle stick/sharps incidents, which accounted for 29% of the overall reported incidents in 2017, a 2% decrease from 2016.

2018 Health & Safety Objective

In 2018 Viapath will focus on the development of a Viapath's Health & Safety Management System – a formal management system is to be developed based on the new ISO standards 45001: Occupational health and safety management systems – Requirements. This will help Viapath manage health and safety and improve employee safety, reduce workplace risks and create better, safer working conditions.



Graph 5: Total needle stick/sharps injuries and proportion out of total incidents

Customers

GP Alerts

How do GPs raise quality concerns?

A GP practice or patient group can raise any quality concerns by raising a Quality Alert. GP Quality Alerts are not necessarily a complaint – but they are important because concerns can be raised quickly directly to our services and can also act as an early warning to clinical commissioning groups (CCGs) where there may be themes or services which require attention. There is a template for the alerts which the GP practice completes electronically.

What kinds of things do GPs raise Alerts about?

The simple answer is anything which causes the practice to have concerns about quality! In pathology this includes issues such as turnaround times, antibiotic prescribing, lost samples, delays in results reaching the GP and patients having delays in their treatment or having to have repeat samples as a result of delay.

What happened when a practice raised a Quality Alert about pathology?

King's College Hospital NHS Foundation Trust's (KCH) Primary Care Liaison Manager, Rebecca Barnes, receives all GP Quality Alerts. Becky works with both GP and the service to ensure that the GP Quality Alert is acted upon and feedback given. Becky's role covers a large geographical area for GPs in four London boroughs – Bexley, Bromley, Lambeth and Southwark.

Becky's primary care background and role as an assistant practice manager have proved to be very helpful when trying to resolve complicated concerns from a GP perspective.

Who does the Primary Care Liaison manager talk to in Viapath?

At the KCH Denmark Hill site, Becky usually speaks with Penny Mitchem, Viapath's senior Quality Manager, who assists with investigating the GP's concerns and response. At the KCH Princess Royal University Hospital (PRUH) site, Quality Manager Julie Jordan, coordinates the investigation and takes the lead in responding to the alert directly with the GP, keeping Becky updated.

Where are Viapath's responses to Quality Alerts discussed and how do we learn from them?

Each month the site Governance, Risk & Quality (GRQ) meetings reviews any GP Quality Alerts for pathology which have been raised that month; the responses are discussed and learning shared.

At the PRUH, Becky attends the monthly meetings Viapath has with KCH managers and Bromley CCG, which includes GP representatives. This group considers the responses from the PRUH to GP Quality Alerts and monitors them closely to ensure that matters are addressed and lessons learnt.

An alert can highlight issues that the CCG, Viapath and hospital services have to work together to resolve. A recent example was in endoscopy services where GPs were receiving results of the investigation direct from the laboratory. However, the report and advice from the doctor who undertook the procedure was sent separately. This caused a delay for the patient receiving advice from their GP.

The Quality Manager and Head of Quality went to meet the endoscopy Service Manager and discovered that the CCG could resolve the problem by commissioning endoscopy services differently and prevent the issue from reoccurring. When the problem was explained to the CCG, they hosted a workshop with all parties, which resulted in the commissioners changing their arrangements. GPs now receive laboratory results and clinical advice at the same time. The problem which had existed for several years has not reoccurred since the change.

Our work in partnership with hospital and CCG colleagues, with direct communication with GPs, makes for a closer working relationship and helps us to understand better what GPs need and the impact our service provision pathways have on them and their patients.

“Each month the site Governance, Risk & Quality (GRQ) meetings reviews any GP Quality Alerts for pathology which have been raised that month; the responses are discussed and learning shared.”

Customer Feedback

Accolade from GSTT & KCH hospitals

During the Westminster Bridge Major Incident on Wednesday 22 March 2017, the Viapath Blood Transfusion services based at St Thomas' and King's College hospitals, stepped into action and commenced our major incident plan, to support the hospitals deliver emergency care to injured patients. Teams have a well rehearsed incident response, to ensure that a large number of blood products are available for immediate use by clinicians, who are caring for multiple injuries. Clinicians, particularly in the Emergency Departments, Intensive Care Units and theatres work very closely with the laboratory team, to ensure that patients receive the correct blood product quickly.

Challenges arose especially around blood sample transportation by the courier service, but due to quick thinking from the Central Specimen Reception operations team working with the Viapath Logistics Manager, we were able to ensure couriers were directed to the correct place quickly. Our employees went the extra mile to ensure that the life saving blood products were delivered straight to the patient.

Compliments

King's College Hospital

Background: A baby with meconium aspiration syndrome, a medical condition affecting newborn infants where meconium (dark green substance forming the first faeces of a newborn infant) is present in their lungs during or before delivery, experienced pulmonary haemorrhage. The baby needed urgent blood and the Blood Transfusion Laboratory staff dispensed four units of blood for the baby and helped member of staff.

Compliment: "Matron and neonatologist were very eager to let you know that the assistance they received from the Blood Transfusion Laboratory was fantastic. They were also grateful for the assistance collecting the blood."

Paediatric Intensive Care Unit Team 13/02/2017

Princess Royal University Hospital

Compliment: Two acute medicine consultants e-mailed to thank the immunology team for rushing through a test, staying back late to do so. They said how very much it was appreciated and helped significantly in the management of this patient.

Acute Medicine Consultants 05/01/2017

Guy's & St Thomas' Hospital

Compliment: Specialist Women's Hospital thanked the biochemical and molecular departments for being "most helpful" for providing accurate and prompt galactosaemia carrier test results.

Specialist Women's Hospital 02/11/2017

Princess Royal University Hospital

Compliment: A specialist screening practitioner gave a compliment following an informative update on the actions taken following an incident. The practitioner stated: "I found the Cellular Pathology Department to be prompt, considerate and thorough".

Specialist Screening Practitioner 22/11/2017

"Matron and neonatologist were very eager to let you know that the assistance they received from the Blood Transfusion Laboratory was fantastic."

Complaints

Princess Royal University Hospital

Complaint: An eye clinic required an eye swab from a patient. However, when the laboratory received the sample the request form had requested a microscopy, culture and sensitivity test for virology and not an eye swab. This sample was therefore rejected by the laboratory.

Response: The laboratory and the eye clinic discussed the problem and as a result, Viapath revised the request form specifically to enable the eye clinic to make the correct request.

Eye Clinic 29/09/2017

Bedford Hospital

Complaint: A patient attended Viapath Central Specimen with a specimen for microbiology. This was sealed in the specimen bag but it was subsequently realised that the date and time the specimen was collected was not written on the bag. The patient asked Viapath for new bag, so that the information could be written on the specimen pot, but was informed this was not necessary. Later at the appointment with the consultant, the patient found out the specimen had been rejected due to not having a date and time of collection.

Response: An apology letter was sent to the patient. The procedure in central specimen reception was amended to reflect the correct process and all employees working in that department were trained on the new procedure.

Patient 08/05/2017

King's College Hospital & Guy's Hospital

Complaint: A referring hospital informed Viapath that they were unable to locate the results for a test they had previously referred.

Response: The root cause was investigated and as a result a booking in error was identified. The standard operating procedure has now been amended and the entire team received training on the new procedure. An apology letter was sent to the requesters.

Referral Hospitals 28/02/2017 & 27/06/2017

"I found the Cellular Pathology Department tobe prompt, considerate and thorough."

Our People Progress – Human Resources Director **Mary Fitzgerald**

2017 saw a particular focus on engaging with our people, reward and recognition, and developing the employee proposition.

At the start of 2017 we revamped our employee awards scheme and introduced three monthly ICE Awards – recognition for individuals or teams who have demonstrated particularly well Viapath's brand values of Innovation, Collaboration and Expertise. At the end of the year, employees' achievements were recognised at our first ever Viapath Heroes Awards ceremony. Attended by over a hundred employees, the event was a tremendous celebration of the hard work and dedication that goes into providing clinicians with the information they need to treat patients.

We also took many other opportunities to communicate with our people; through quarterly roadshows, the weekly publication of Our News, our monthly recognition newsletter, congratulatory emails from our CEO to award winners, and meetings with our senior leadership team.

In September, we started to share our vision for The Viapath Way – a simple and clear set of ambition statements describing 'the employee deal' at Viapath – what people can expect when they work here, and how they are expected to behave. Further work will continue this year to embed these ambitions into our organisation.

Achieving our financial target in 2017 meant that we were able to provide every employee with a £20 shopping voucher as a Christmas gift, and in January the Viapath Incentive Plan – our all employee bonus – paid out £500 to eligible employees. Not surprisingly, both of these initiatives were popular and well received.

We believe a unique selling point of working at Viapath is the learning and development opportunities available. 2017 saw us deliver more training internally than ever before, as well as creating the VIAcademy – our job-related development scheme through which we are able to utilise the funds we pay into the Government's Apprentice Levy that was introduced in April.

In February 2018, we conducted an all-employee survey and I am delighted the results demonstrate a significantly greater level of employee engagement when compared with a few years ago – evidence that the focus on 'Our People' and making Viapath a place where people can do great work for the benefit of patients, is showing positive results.

Mary Fitzgerald
Human Resources Director

"We believe a unique selling point of working at Viapath is the learning and development opportunities available."

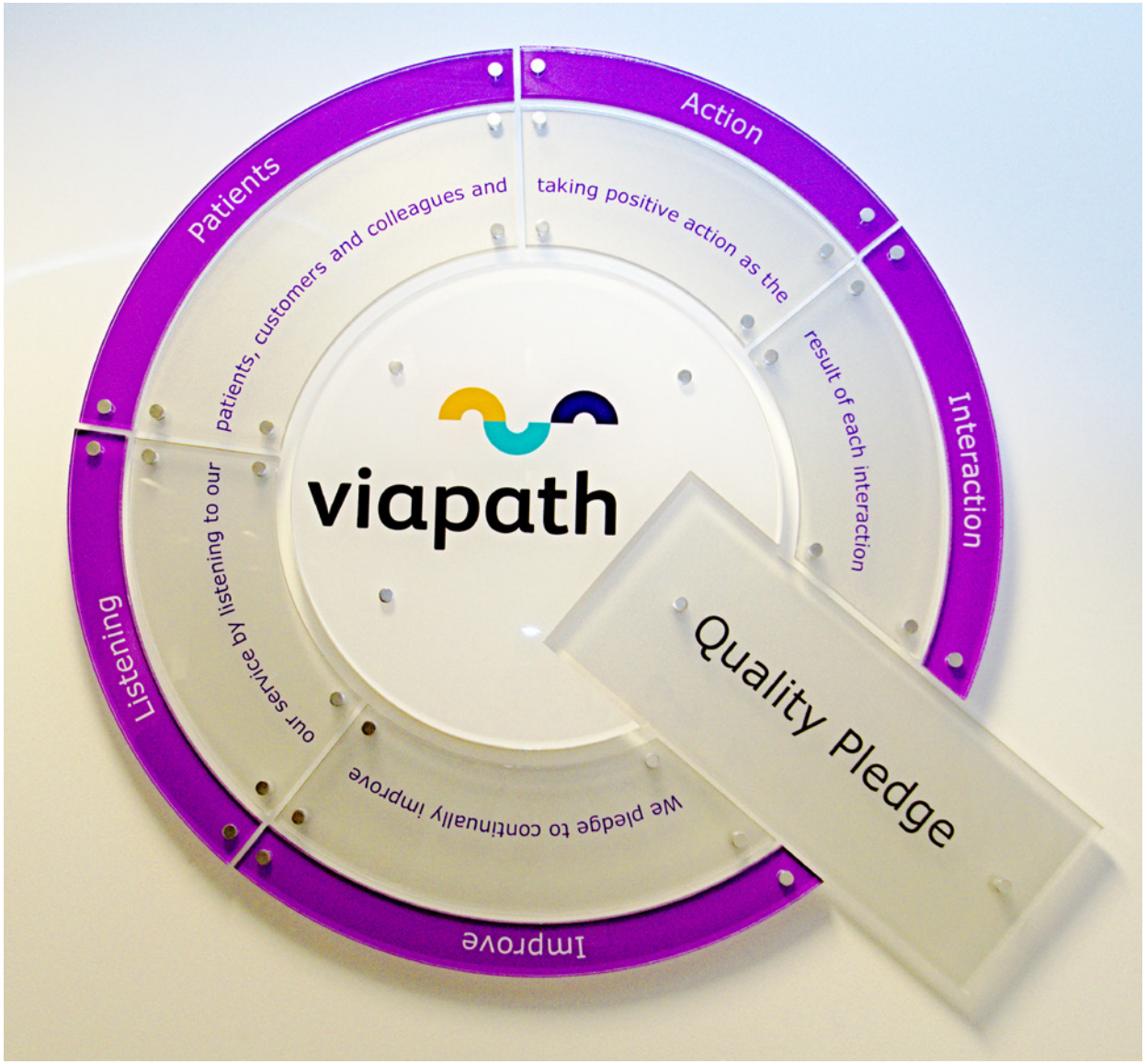
Future leaders in Innovation

World Quality Day

World Quality Day is celebrated around the world, and is designed to increase worldwide awareness of the important contribution that quality makes to our work.

2017 was the fourth year Viapath had participated in World Quality Day, with a cross-organisation challenge event organised by the Future Leaders in Innovation group. This has become a real high point in Viapath's annual event calendar. Its aim is to increase awareness of the importance of quality, encourage a real sense of team spirit and raise money for a charity that employees voted for. This year's chosen charity was Shelter. The event saw teams from around Viapath challenge each other in three different events; archery, monopoly and a pub quiz, all designed to test their knowledge, skill and ability to work as a team.

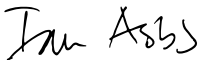
The day was every bit as fantastic as those before and it was great to see colleagues from across Viapath come together for a good cause, raising over one thousand pounds for Shelter. Here are some photos from the day.



Statements from NHS Partners

Statement from NHS partner - Guy's & St Thomas' NHS Foundation Trust

The Viapath Quality Account reflects on the breadth of pathology services that complement the Trust clinical services in aiming to provide the highest quality care to each patient at an individual level. The report recognises that an increase in reported incidents in Viapath has required further scrutiny to ensure there are no thematic or systematic issues that put patients at risk. Changes to the quality and governance processes have been welcomed and enabled enhanced collaboration between our organisations to protect patients from harm. The renewed focus on relationships and transparency has meant we are more effectively working together for the benefit of patients and staff.



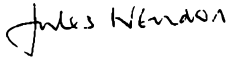
Dr Ian Abbs
Chief Medical Officer

NHS
Guy's and St Thomas'
NHS Foundation Trust

Statement from NHS partner - King's College Hospital NHS Foundation Trust

Reading this Quality Account and reflecting on the breadth of pathology services delivered every day, we recognise that Viapath shares with us the similar challenges and opportunities in delivering and developing NHS clinical services across a demanding agenda. We are pleased to highlight Viapath's response in supporting the ED services at our hospitals during the Major Incidents that occurred during 2017. However, Viapath also encountered a number of issues in 2017 with the reporting of Adverse Incidents rising by 38%. Whilst we accept that this rise may reflect an improved culture of reporting we will be working closely with Viapath during the coming year to ensure that the Complex Incident Response procedure delivers a step change in the way we evaluate the quality of services that are delivered by Viapath.

This Account provides an accurate perspective of the Quality agenda, reflecting discussions and reports we receive at our governance meetings throughout the year. We expect Viapath to retain this focus on continuous improvement and will keep sight of that on behalf of both our hospitals and commissioners. We are also pleased to see Sir Jonathan Michael and Dr Sneh Khemka join the Viapath Board, who will provide further advice and clinical assurance as Viapath increasingly deliver services further afield.



Professor Julia Wendon
Executive Medical Director

NHS
King's College Hospital
NHS Foundation Trust

viapath
pioneers in pathology

Acknowledgements

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