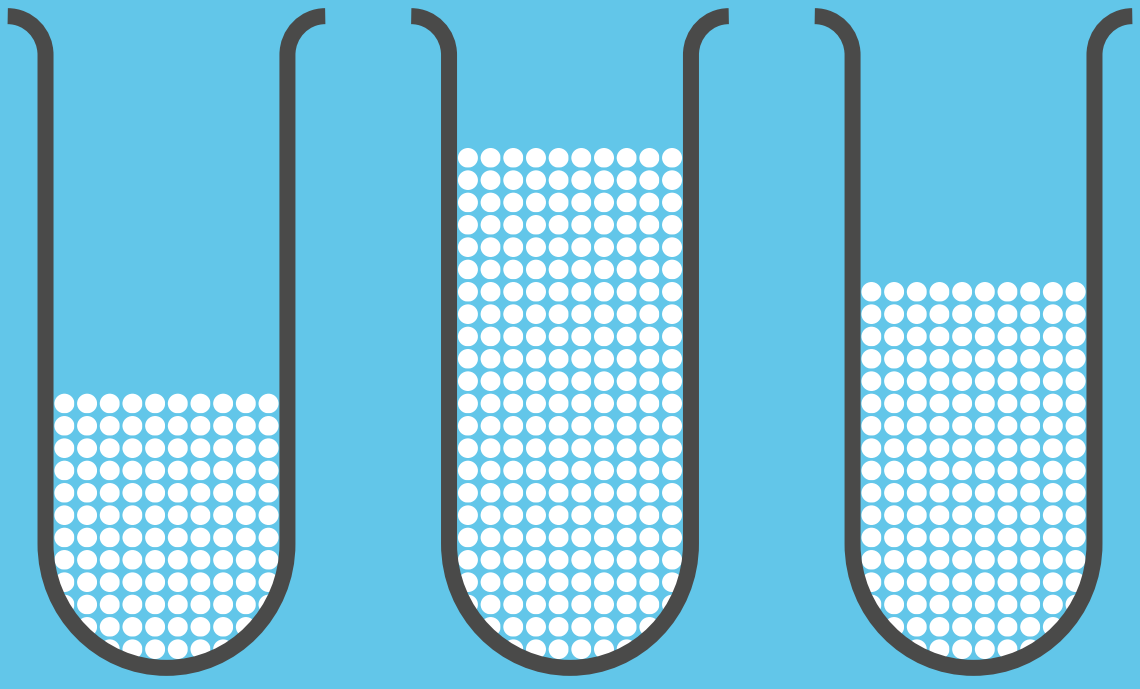
UK NEQAS
Compendium of Quality

International
Quality Expertise



UK NEQAS

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Foreword

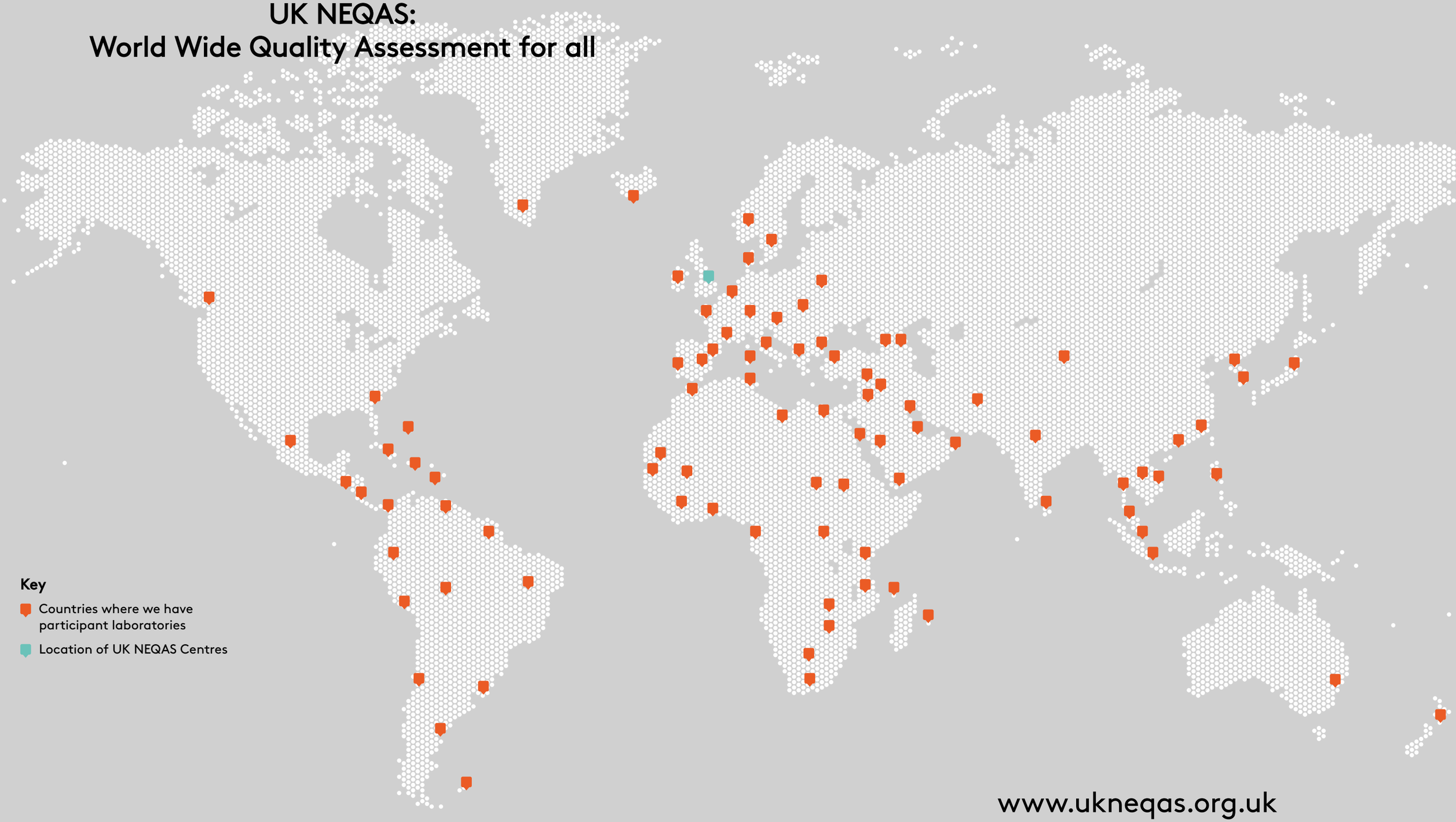
The NHS is in a period of rapid change and pathology has been undergoing its own transformation in response to innovative scientific and technical advances, increasing demand, and a relentless drive to improve efficiency and value for money. The primary concern, however, must be quality with a focus on continual improvement. Quality must be scrutinized and made transparent and a culture developed which seeks constantly to improve clinical and working practices through learning, sharing and innovation. Pathology has a dedicated and highly skilled workforce, good internal quality assessment and quality management systems, and mature external assurance of its services. There are high levels of confidence in the services provided. This confidence is not without foundation as the UK has been at the forefront of quality assurance in pathology for the past 50 years, and UK NEQAS has been leading the way on external assessment. However, elements of the assurance system have become outdated and, to this end, the findings of an Independent Review of Pathology Quality Assurance were published in January 2014 that recommended a set of actions to better align and strengthen the assurance framework.

The publication of the UK NEQAS Compendium of Quality could not have been more timely as the majority of the Review recommendations have an impact on EQA , and scheme providers have a pivotal role in the overall quality assurance framework. The Compendium illustrates the core activities of UK NEQAS, particularly in providing performance data for tests across the whole of pathology to diagnostic laboratories and industry, and for scrutiny of quality by UKAS, CQC, MHRA, provider governance systems and commissioners of services. This Compendium ably demonstrates that the activities of UK NEQAS are much broader than the technical accuracy and precision of results. It provides electronic learning facilities, meetings and websites to educate, train and develop the skills of the workforce in quality management and quality improvement methodology. It is at the forefront of the development of digital imaging techniques to provide educational packages for personal performance and development. Advances in new technology and processes (genomics, molecular pathology, POCT, digitisation, informatics) require a strengthened quality assurance framework and the Compendium provides examples of how new approaches to EQA are being developed.

Implementing the Review recommendations to ensure quality pathology services for the future will require a collective effort on the part of all parts of the assurance framework. The Compendium provides reassurance that UK NEQAS will be at the forefront of implementing the challenging recommendations.

Dr Ian Barnes PhD, FRCPath
Chair, Independent Review of Pathology Quality Assurance Board, NHS England

UK NEQAS:
World Wide Quality Assessment for all



Key

- Countries where we have participant laboratories
- Location of UK NEQAS Centres

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UK NEQAS Around the World

www.ukneqas.org.uk

1.
Increasing the impact of External Quality Assessment

1.1
Improving Patient Safety: Better screening for Clostridium difficile

The Challenge

Clostridium difficile infection (CDI) caused by antibiotic treatment is a major threat to hospitalised patients. We enabled laboratories to make an informed decision on the most appropriate testing algorithm for the detection of toxigenic C. difficile, in compliance with the Department of Health Guidance on the diagnosis and reporting of C. difficile.

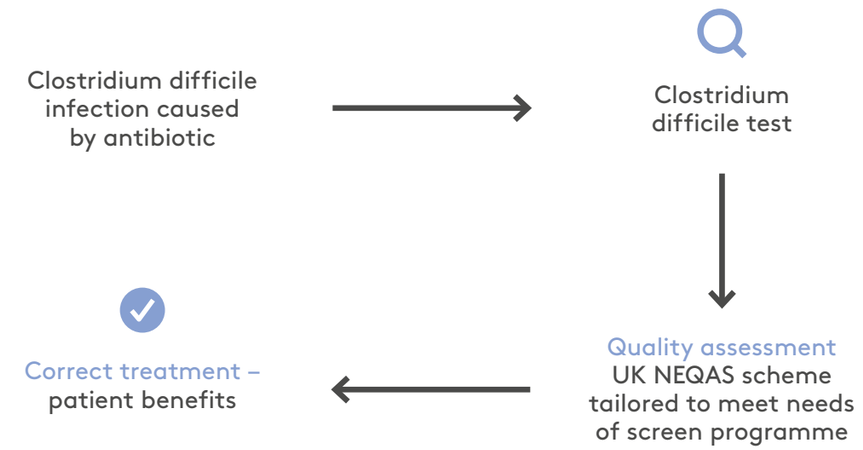
What UK NEQAS delivers

We tailored our scheme to determine the sensitivity of kits. EQA specimens positive and negative for toxigenic C. difficile were designed to challenge the clinically important aspects of performance of different technologies/methods used for detection of this pathogen.

The benefits

We have provided reassurance of the accuracy of surveillance data for patients, health care providers and commissioners.

- The EQA scheme tailored its performance characteristics to monitor compliance with national recommendations. EQA specimens were designed and circulated containing toxigenic and non-toxigenic strains of C. difficile.
- We have enabled improved monitoring of compliance of laboratories with DH recommendations.
- We have enabled peer assessment and bench marking (UK and internationally) of the recommended testing algorithm through UK NEQAS.



1.2
UK NEQAS Network Reports – Complex Information, Clearly Presented

The Challenge

Laboratories working in networks and screening programmes with analysers at multiple sites are increasingly common. It is challenging to ensure that all the constituent parts are of equal quality, and difficult to spot problems in one site or analyser amongst many results from a large network. One patient may be tested in different parts of a network and the results need to be comparable.

We needed to provide a means to ensure that performance, all the components of a service can be monitored easily.

What UK NEQAS delivers

We had to summarise EQA reports across multisite laboratory departments to gain an overall picture of performance across their network.

We summarise the performance of all instruments for Network Co-ordinators with:

- Data from the last 6 months.
- Clear visual cues to facilitate interpretation.
- Coloured symbols reflecting the magnitude and direction of bias for individual specimens.
- 'Traffic lights' for performance over the last 6 months.

More detailed information is available to Network Co-ordinators, with access to individual site reports through the website.

The benefits

- Presentation of complex data in a simplified, easy to assimilate format with potentially important variances highlighted clearly.
- 'Penalty box' plots of bias against consistency-of-bias demonstrate at a glance whether patients' results will be the same across all analysers and sites.
- Method comparison data in relation to national target values across sites.
- Performance management of multiple instruments within a laboratory, or across a geographical area has been made more effective.
- Reduced likelihood of missing potential performance issues – these are highlighted clearly.
- Improved EQA for Screening Programmes e.g. UK Newborn Screening Programme.
- Network Reports facilitate accreditation compliance for multi-site departments.

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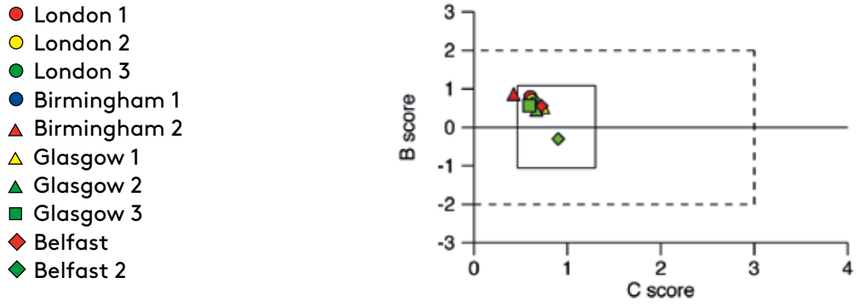
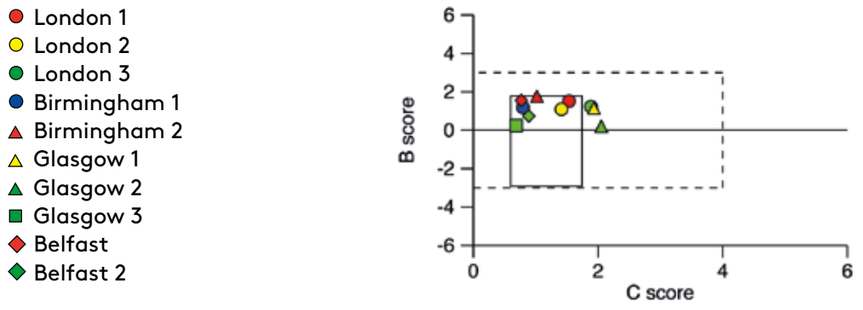
1.2 Network Report Penalty Box Plots - example data

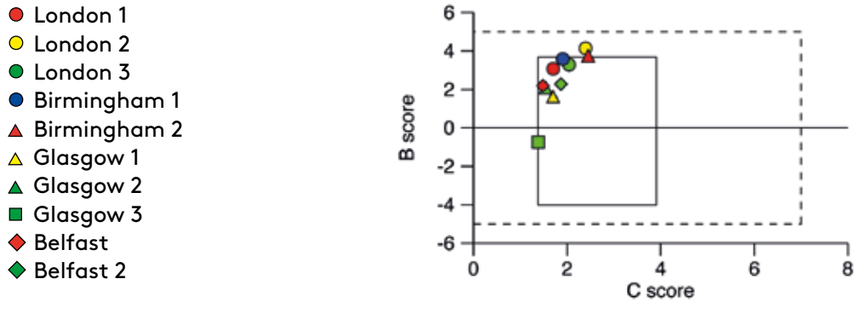
Sodium



Chloride



Glucose



1.3

Improving Corrective Actions: The UK NEQAS Root Cause Analysis Toolkit

The Challenge

Skills in root cause analysis, quality assurance and quality control are key to patient safety in internal and external quality assurance. UK NEQAS has a crucial role in maintaining these skills through the educational component of its schemes.

We needed to provide a way for laboratories to document best practice of corrective action for any issues raised in their scheme returns in a timely manner, despite increasing pressures on time and staffing.

What UK NEQAS delivers

We designed a root cause analysis form to stimulate and record corrective actions when early indications of potential problems were detected in the schemes.

This would enable a good laboratory to document its effective actions, and hopefully stimulate a laboratory to investigate properly. It can also be used to collate the evidence of good practice centrally for internal and external governance or dashboard reporting requirements.

The benefits

The incorporation of an educational event, triggered by potential quality issues to guide the investigation, record the corrective actions and perform a risk assessment that meets both internal and external governance needs.

This demonstrates:

- Good practice in quality control of both measurement and governance.

With one document a laboratory can provide dual purpose evidence of;

- A satisfactory approach to quality to the UK NEQAS provider.
- Data on EQA Corrective actions for their own Quality Management System.
- A personal and departmental record of CPD in root cause analysis.

Inadequate or erroneous root cause assessment can result in educational feedback.

Feedback from users has improved education and proficiency in quality assurance combined with the maintenance of skills in root cause analysis that is of use to both laboratories and UK NEQAS.

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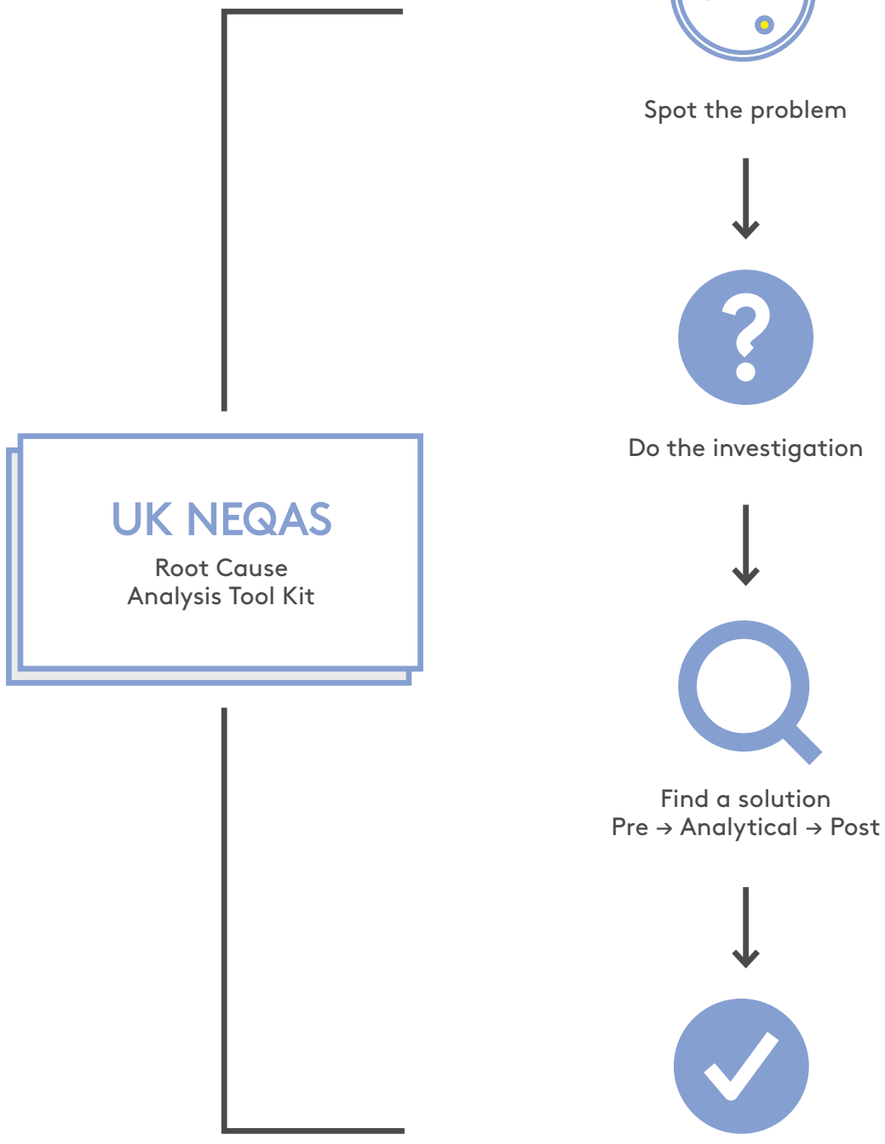

1.4

Experience and Expertise: Harmonising Performance Across Methods

The Challenge

UK NEQAS data showed that the measurement of the size of red blood cells (mean cell volumes, MCV) varied using different diluents. The UK NEQAS survey material is partially stabilised and does not react in exactly the same way as fresh blood in different instrument/ reagent combinations (non-commutability). This effect could be avoided by comparing similar (grouped) methods. This solution would often be considered if we could not solve the commutability problem. UK NEQAS Directors and Specialist Advisory Groups embedded in daily haematology service provision, knew that a similar, if less marked, difference appeared to be seen with patients' samples in the diagnostic laboratory community and decided to investigate.

What UK NEQAS delivers

- UK NEQAS alerted manufacturers and users to a potential issue.
- We worked with manufacturers to develop and trial a new calibration standard.
- We validated this in collaborating laboratories, under real-life conditions.

The benefits

UK NEQAS works closely with manufacturers to highlight and correct problems of significance to patients as early as possible.

But for the available clinical expertise, it would have been easy to attribute the observed differences to a "matrix" effect (an unusual property of the solution affecting the results) and to regroup the instruments into method groups for the purpose of performance assessment, which would degrade the utility and sensitivity of the scheme.

The differences in MCV using the UK NEQAS survey material were at a level that could influence the selection or interpretation of subsequent laboratory investigations, e.g. for haematinic assays. UK NEQAS therefore chose to investigate and correct the issue, because it had potential clinical consequences for patients. The outcome was a new calibration standard which corrected the problem.

Method related instrument grouping should only be considered when expert users, Steering Committees (and if necessary oversight bodies like NQAAP) are unable to resolve the issue in collaboration with the instrument manufacturers.

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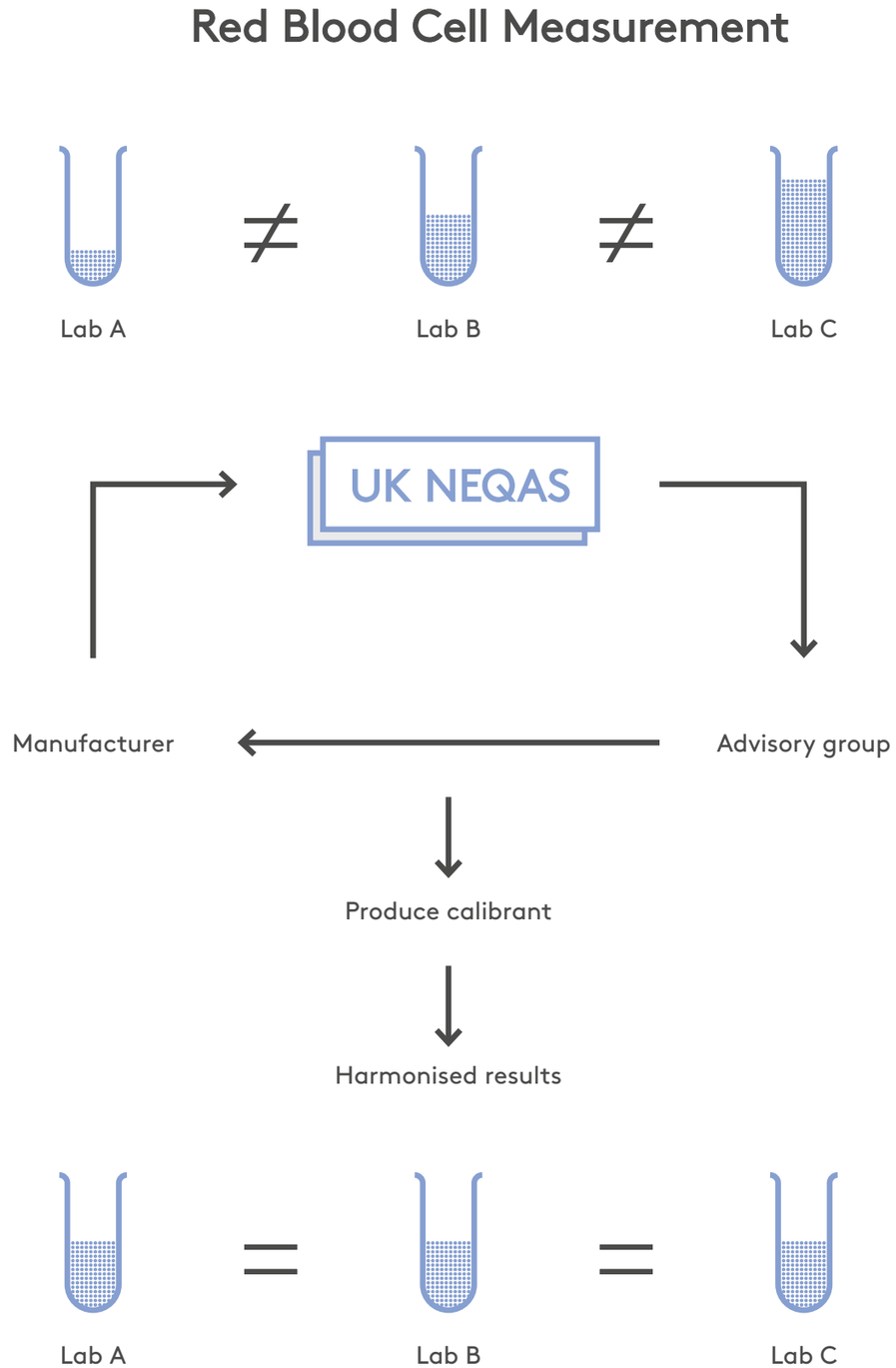

2.
Better National Screening Programmes

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Better National
Screening Programmes

2.1
Improving Governance and Transparency in Screening Programmes – NHS Sickle & Thalassaemia Programme

The Challenge

The NHS Sickle and Thalassaemia Programme oversees laboratories in England providing antenatal and neonatal screening for haemoglobinopathies. They needed early notification of any aspect of unsatisfactory performance by any of the laboratories within their commissioning remit, together with a regular update on the general 'state of the art' in performance.

What UK NEQAS delivers

- We supply the National Screening Programme's Independent Laboratory Performance Review Group (ILPRG) with a 6 monthly, anonymised performance report.
- We sought a transparency waiver from our participants to allow us to disclose their performance to the Programme Director.
- We proposed participation of the Haematology NQAAP (National Quality Assessment Advisory Panel) to the ILPRG.

We developed a confidential protocol, with input from the NQAAP and ILPRG, to improve early identification and support for laboratories with apparently unsatisfactory performance. This details the action taken by the Scheme Director, the advice from the NQAAP and the advice from the ILPRG.

The benefits

- Improved transparency for the benefit of patients, commissioners and participants. It allows removal of anonymity within the governance process but protection of confidentiality for the participant.
- It enables engagement and support at an earlier stage in the performance monitoring process.
- It ensures that advice is sought and shared across the governance process to improve outcomes.
- It improves and clarifies the process for acting on performance problems in a high profile area of public health.
- More responsive governance and better structured communications.

The early notification of performance issues to the ILPRG will allow them to make prompt intervention and offer assistance for performance problems within their remit; enabling review of historical results to identify any patient that may have been put at risk in the period during which performance was unsatisfactory in a manner analogous to that when an internal quality control incident occurs.

2.2

Tailored UK NEQAS Programme for Screening: Supporting the UK Bowel Cancer Screening Programme

The Challenge

Every two years, all UK men and women between 60 and 69 years are invited to participate in Bowel Cancer Screening. They apply small samples of stool to a Faecal Occult Blood (FOB) test card and return it to their local Bowel Cancer Screening Hub for analysis. When developed, the test card changes colour if haemoglobin is present.

We needed to design an EQA programme for all individual Screening Officers working in the 8 UK National Bowel Cancer Screening Hubs, that would meet the governance needs of the programme.

What UK NEQAS delivers

We produced an artificial faecal material into which we could add known amounts of human blood. We showed that it behaved in exactly the same way as human stool. Individual Screening Officers were supplied with FOB test cards pre-coated with the UK NEQAS survey material. We then designed a specific web-based reporting form and report format tailored to the needs of the screening services. As the Screening Officers are not from a laboratory medicine background, a report layout was developed to communicate performance in a simple but effective pictorial format.

The benefits

- We were now able to monitor within and between batch sensitivity of the guaiac testing cards to known amounts of blood.
- A simple web page was developed which allowed the Screening Officers to record the result for each of the 6 test windows on the cards as ‘positive’ or ‘negative’, exactly mimicking the real-life situation in their lab.
- The algorithm used by the Bowel Cancer Screening Programme to determine whether a patient requires further intervention is automatically applied to produce an outcome for the ‘patient’.
- Summary reports were developed to provide Hub Co-ordinators with an overview of both their individual Screening Officers’ performance, and how their Hub compared with national performance.

The Bowel Cancer Screening Programme undertakes thousands of FOB tests each year. In addition to the ‘positivity rate’ of each Screening Officer by the Hub Co-ordinator, the EQA programme gives independent data on the performance of individuals and Hubs throughout the UK for the assurance of commissioners and the public.

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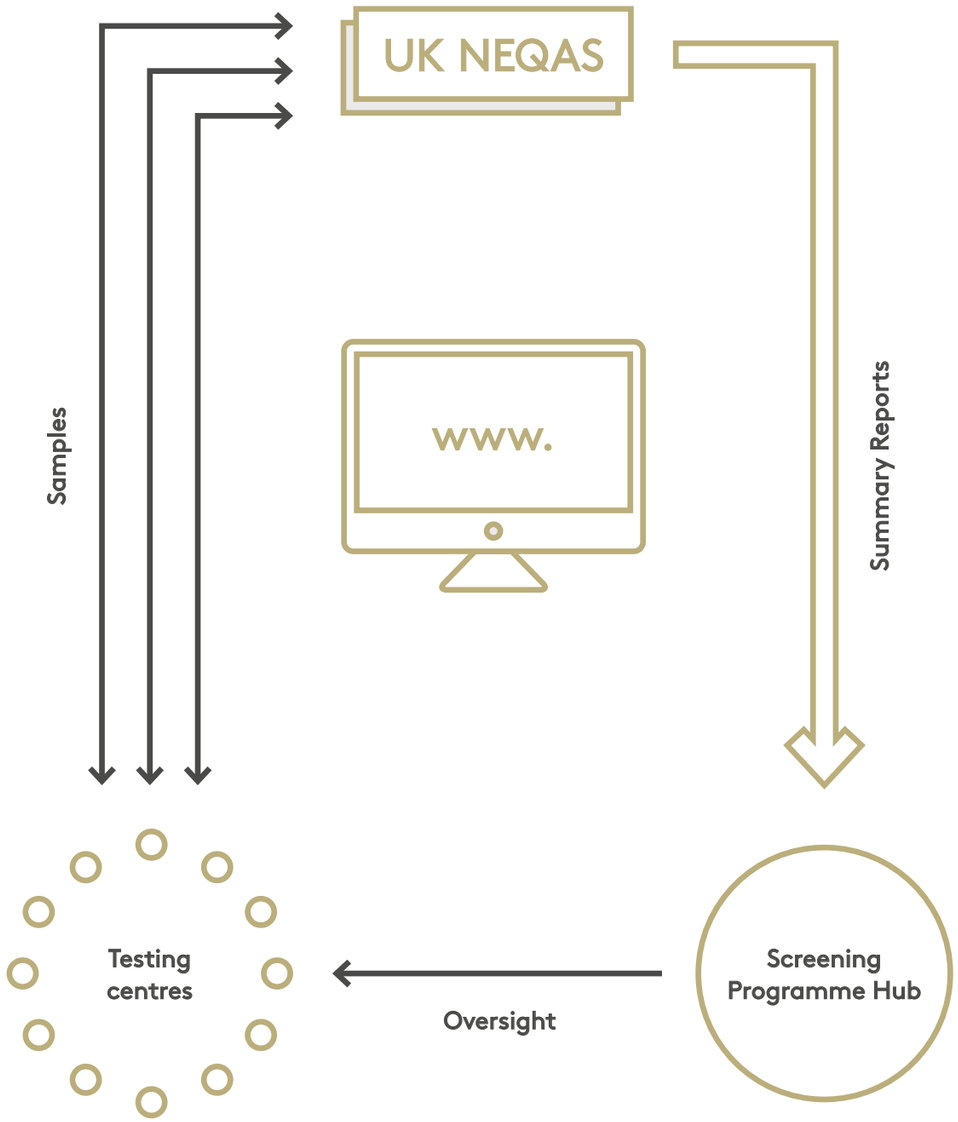
Better National
Screening Programmes



2.3
Improving European Surveillance of Antibiotic Resistance (AMR)

The Challenge

The European Centre for Disease Control (ECDC, Stockholm) collects epidemiological data from 31 countries (EU and EEA) on antibiotic resistance in bacteria (AMR). This requires assurance of the quality of AMR across Europe. Bacterial strains cross borders through travel, or during hospital transfers between countries. Monitoring spread of a new 'resistant' (to a few antibiotics) or 'highly resistant' (to nearly all antibiotics) infection is a major public health function worldwide. The EU community requires all laboratories to be competent to detect multiple resistance mechanisms, even where the level of resistance is normally low.

What UK NEQAS delivers

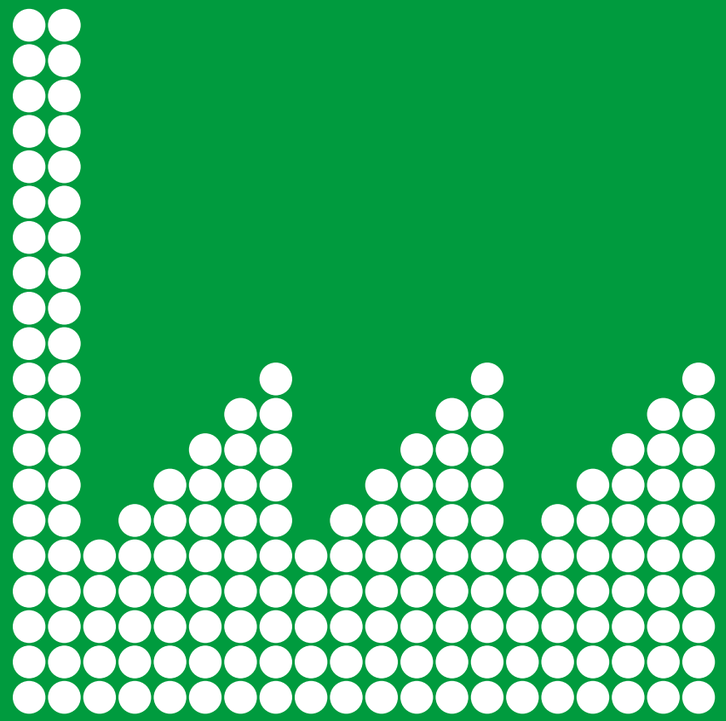
We had to cover the range of important infections in the UK and Europe. We developed UK NEQAS panels that include a range of infections from hospitals throughout European countries. We have to be alert to new imports and include isolates imported from outside the EU that are implicated in outbreaks within an EU country, including isolates of high importance such as multi-resistant bacteria carrying metallo-betalactamases (New Delhi NDMs).

The benefits

Each UK NEQAS distribution generates over 1000 results, which allows comparison of performance of different methods and adherence to recognised international guidelines for susceptibility testing. In addition to peer performance monitoring, participants and ECDC can assess and compare data at the national and international level thus providing a body of evidence on the quality of susceptibility testing.

- We provide key information to demonstrate that laboratories across Europe comply with the international guidelines on susceptibility testing for the benefit of their patients and public health bodies.
- We provide performance monitoring of both commercial (bought-in) and in-house (locally-made) methods.
- Peer assessment and bench marking (UK and Internationally).
- We provide data to monitor the accuracy and quality of surveillance data collected by ECDC.

3.
Education and Expertise: Interaction with Clinical Services and Diagnostics Industry



3.1
Interpretive EQA for Antibody Identification in Blood Transfusion – Matching Skills, Experience and the Needs of Patients

The Challenge

Laboratories may have limited panels for identification of red cell antibodies, beyond which they must refer clinical samples to Blood Service Red Cell Reference Laboratories for more complex cases.

We needed to allow participants to demonstrate that they were fully competent in selecting blood for safe transfusion. We previously accepted a report of 'would refer' to allow participants to report this situation without receiving a penalty. However, we removed this option, because it was hard to distinguish between lack of resource and an unwillingness to make a judgement on the day. Consequently participants were then penalised for being unable to identify an antibody mixture simply due to lack of resources rather than lack of knowledge or skill.

This required a new system which identifies participants whose interpretations are of concern, without penalising those who simply have insufficient panel cells to completely identify antibody mixtures or to exclude additional specificities. This required the utilisation of the clinical experience with UK NEQAS.

What UK NEQAS delivers

We allow participants to demonstrate their competence by submitting results by fax or email with an explanation of why they are unable to complete the identification.

Two expert UK NEQAS staff with clinical experience independently scrutinise each set of submitted panel sheets and mark the interpretation.

If we disagree with their interpretation, we provide clinically relevant educational feedback, citing the cells on the panel which would have allowed them to identify or exclude relevant antibodies; where appropriate referencing professional standards such as the British Committee for Standards in Haematology (BCSH) guidelines.

The benefits

This has allowed us to assess participants' interpretive skills in an interactive way so that we only identify those whose performance is of concern, and to provide personalised education to assist participants to understand how they have misinterpreted their results.

- Participants see this as a fairer and more useful method of assessment.
- Participants get educational feedback with distributions.
- This has allowed us to send more complex mixtures of antibodies, of clinical relevance, providing more effective EQA for larger laboratories and with consequent up-skilling of all laboratory participants.
- Smaller laboratories with fewer resources have benefited most and participate even if they refer all complex cases to a reference laboratory. The proportion of UK participants registered for antibody identification increased from 86% to 89% within 2 years.

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Education and Expertise: Interaction with
Clinical Services and Diagnostics Industry

3.2
Overcoming Commutability Issues to Allow Method Comparison: UK NEQAS for Lipid Investigations

The Challenge

Some schemes, such as the UK NEQAS for Lipid Investigations, requires large volumes of serum to provide 3-specimen distributions to over 400 participant laboratories monthly. Using a single donation from one individual is impossible. It is necessary to pool frozen serum donations together to provide enough material. Freeze-thawing cycles can also affect specimen behaviour with different methods so the material can lack full commutability. This makes assessment of method performance difficult, and prevents the use of a single target value for all participants.

We needed a way of circumventing this issue to re-assure manufacturers, laboratories and patients that this was not hiding important performance issues.

What UK NEQAS delivers

- We established a parallel sub-distribution with a subgroup of 180 UK participants, representing all major methods.
- We distribute 3 fresh single-donor serum specimens at quarterly intervals without freezing.
- These specimens are collected from volunteer patients with and without lipid disorders covering a range of relevant concentrations.
- Laboratories are asked to analyse immediately on receipt.

Method comparison performance data from these special distributions are included in the next main scheme report for the benefit of all users.

The benefits

We have been able to use limited quantities of freshly-collected serum to provide reliable assessments of method performance, and thereby overcome the unavoidable problem of potential lack of commutability in the specimens within the main scheme.

We are able to use the main scheme to assess laboratory performance despite technically having non-commutable specimens, and we use the special distributions with fresh serum specimens to assess method performance and provide this information to all participants. Similar experimental distributions are used widely in UK NEQAS schemes to provide the information necessary to improve performance and to determine if observed issues are related to commutability issues or method performance.

3.3
Ensuring Tests Meet the Needs of Patients and Health Services: MRSA Screening

The Challenge

Detection of resistant organisms is essential to monitor their spread and the effect of preventative actions in hospitals. In order to detect them, laboratories have to be able to grow the established strains reliably, as well as any emerging strains which may be different from the reference culture collection strains recommended for quality control of the media.

Manufacturers often design culture media that are evaluated using organisms circulating at the time of product development. Genotypic and phenotypic variants can emerge over time and manufacturers may only become aware when this is highlighted by a customer, or in scientific publications. UK NEQAS saw the need to maintain surveillance to assess the ability to grow and detect new strains and have the internal experience and expertise to be aware of new developments, as well as through interaction with participants.

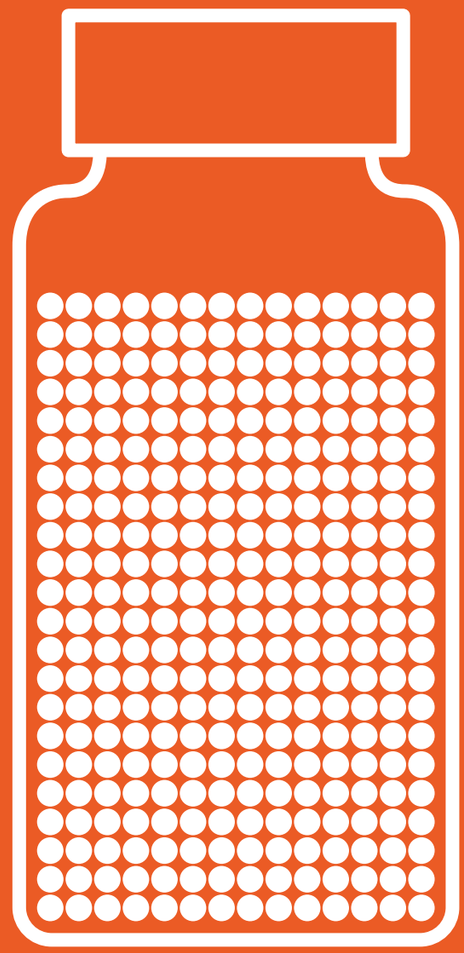
What UK NEQAS delivers

We design UK NEQAS panels that cover the range of MRSA strains selected from those currently circulating in community and hospital acquired infections, utilising our clinical knowledge and expertise and those of our advisory groups. These continually evolve to meet clinical need.

The benefits

- EQA can help with early detection of non-conformances in culture media related to bacterial strain.
- EQA can help with early detection of non-conformances in culture media due to failure of the media.
- EQA distributions can allow comparison of performance of different commercial products, thus providing evidence to detect and guide investigation and follow-up.
- We provide evidence to monitor compliance of laboratories with UK recommendations for detection of MRSA.
- We enable performance monitoring of commercial and in-house methods.
- UK NEQAS data can support peer assessment and bench marking (UK and internationally) of the recommended testing algorithm.
- UK NEQAS data can provide quality assurance of surveillance data collected as part of mandatory MRSA reporting in the UK.

4.
Production of new Reference Materials



4.1
A New Total IgE Reference Preparation to Replace WHO 75/502

The Challenge

The 1973 the World Health Organisation (WHO) IgE reference preparation has been depleted. UK NEQAS Immunology, Immunochemistry and Allergy worked in collaboration with NIBSC (National Institute for Biological Standards and Control) to ensure a timely replacement.

What UK NEQAS delivers

- We facilitated communication between NIBSC and users of the test to obtain material containing very high IgE levels, and supplied them with the information and consent pack.
- UK NEQAS also obtained and supplied material from single patient donors with appropriate consent.
- We participated in the evaluation of the candidate reference preparation.
- We collaborated in publicising the report and data analysis.

The benefits

- The successful and rapid replacement of an International Reference Preparation (IRP) by utilising the resources and contacts within UK NEQAS to assist.
- Total IgE measurement is performed relatively consistently, at least in part due to the availability of the WHO standard for 40 years. This is in contrast to the measurement of specific IgE to allergens, some of which remain heterologously calibrated against total IgE material and are not directly traceable to calibration against an international standard/reference material.

  The reference preparation is an important component for maintaining traceable calibration and is essential for future improvements in the comparability of measurement of IgE.
- A method has acknowledged and corrected a calibration drift since the production of the new IRP.

5.
The Future: Digital EQA

5.1

Digital Morphology: Maintaining Haematology Interpretive Skills Worldwide via the Internet.

The Challenge

Automation, coupled with changing skill mix and increased workload, has made the maintenance of blood film morphology skills amongst both scientific and clinical laboratory staff a challenge. These skills are needed in order to recognise variations in blood cell appearance that may be diagnostic of diseases. The potential impact on patient care of reduced training is considerable, since the majority of films examined in the UK nowadays are those with the most challenging features. In resource-limited countries, the knowledge and experience required to provide training may be lacking, although individuals may be exposed to greater numbers of samples and different disorders.

UK NEQAS needed to provide a scheme which could act as both a training resource and an interpretive CPD scheme to meet the needs of worldwide participants.

What UK NEQAS delivers

UK NEQAS collaborated with experts in blood and bone marrow morphology, digital imaging and virtual microscopy software to develop state-of-the-art virtual haematology slides and a clinically relevant knowledge base. Working in collaboration with participants we developed an educational package for continuing professional development. Collaboration with the World Health Organisation (WHO) provided peripheral blood and malaria galleries suitable for use in basic haematology education.

The benefits

- The development of digital imaging techniques for peripheral blood and bone marrow cells, able to mimic traditional microscopy with a similar level of detail and interactivity.
- The ability to demonstrate proficiency by scrutinising slides in real time, as in the laboratory.
- The ability to practise and learn anywhere, anytime.
- Utilization of large scale, stitched images as virtual slides rather than scanned whole slides, thus reducing the file size without compromising the educational content.
- Immediate expert educational feedback via an annotated version of the slide post-submission.
- The peripheral blood galleries are interactive and intuitive in operation, allowing the user to spend the time they need to achieve their educational aim in a non-directive manner.
- More than 2000 healthcare scientists in the UK have participated each year since its launch in 2008. It has consistently achieved more than 90% satisfaction from users regarding the quality of the cases and images presented.
- It is a cost effective means of delivering CPD, and is attractive to laboratory managers.

The effective impact of the galleries as an educational tool for use by the WHO was validated by a PhD research project.

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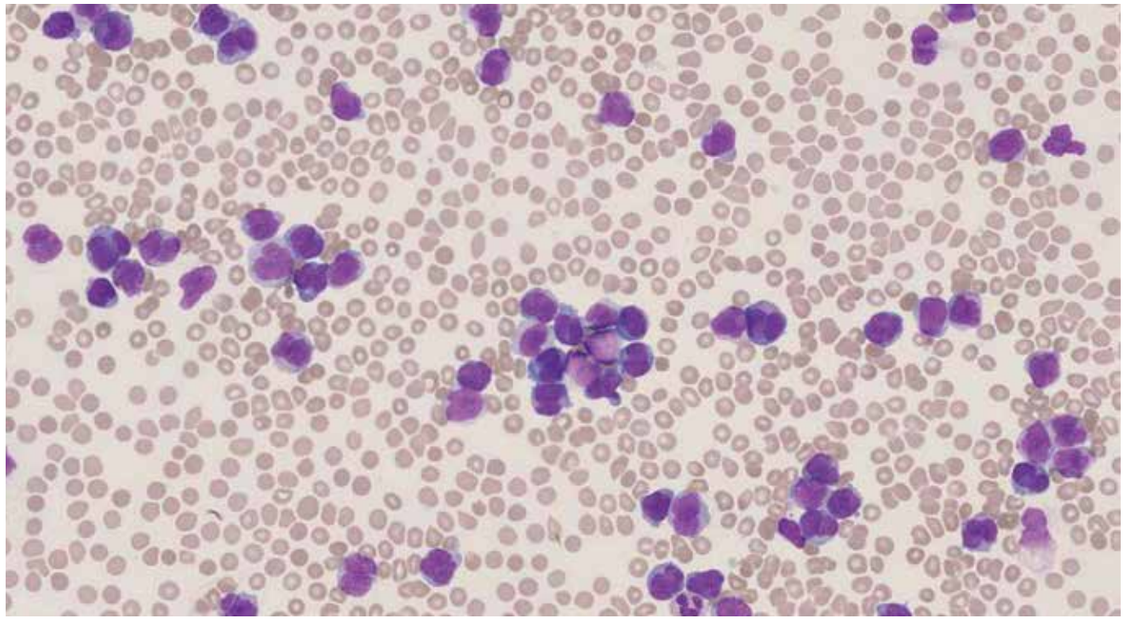
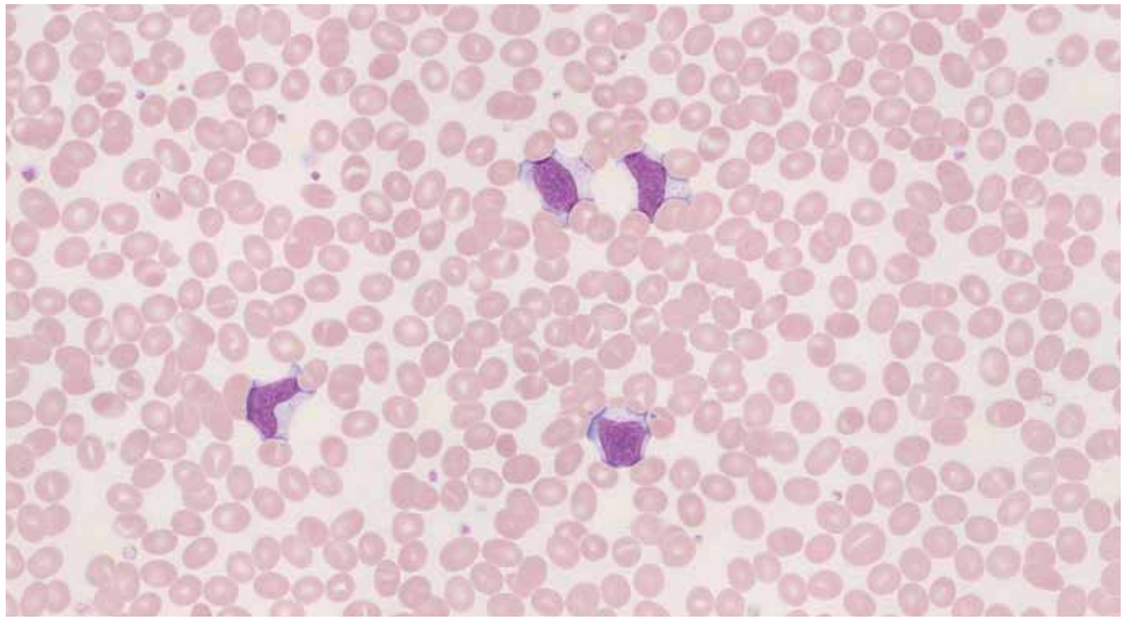
The Future: Digital EQA



Acute Promyelocytic Leukaemia: microgranular variant.



Atypical lymphocytes in Glandular Fever.

5.2

iEQA – An Innovative, Non-Directive Approach to Demonstrating Real-Time Proficiency (Continued Professional Development)

The Challenge

Time and resource for CPD is diminishing, in direct conflict with an increasing need to demonstrate life-long continuous quality improvement for patient safety. Electronic learning has the potential to fit with busy laboratory practice and can be delivered at home and work.

Electronic learning based around the common "Quiz:Read:Quiz" model may have restricted learning objectives, targeted at particular grades of staff, and cannot replicate real-time decision-making. As a result it may not assess proficiency nor allow exploration, reflection nor accommodate different learning styles.

UK NEQAS wanted to develop a system which could replicate a virtual hospital environment and fill these perceived gaps in CPD.

What UK NEQAS delivers

We designed a multidisciplinary system which complements existing E-learning, focusing on clinically relevant practical aspects of the patient pathway. It can be used as both a reflective training tool and personal proficiency assessment. It covers quality issues, interpretation, practical trouble-shooting and root cause analysis and more.

We wanted a non-directive bite sized approach that could replicate an ideal hospital environment and be usefully accessed by all grades of staff involved in the provision and use of diagnostic tests.

The benefits

- iEQA is convenient and cost-effective, reducing cost and time away for training days.
- iEQA covers internal and external quality issues and has a clear focus on quality issues.
- iEQA can link to sample distributions, extend the CPD content and present the complexity of real cases.
- iEQA encourages reflection on real-time performance against self, peers and experts at all grades of staff.
- iEQA provides and holds evidence for CPD portfolios and accreditation for use on demand.
- Participants can demonstrate incremental performance improvement or maintenance of proficiency.
- The iEQA 'Lab Manager' CPD and training review tool gives an overview of staff activity within the system.
- It is a one-stop-resource, with over 100 cases for proficiency evaluation, training and personal reflective learning. Participants can document this in a CPD portfolio friendly manner.
- User feedback indicates considerable satisfaction and feedback is used to improve the content.

The scheme functionality has been integrated successfully into the routine distributions of our Interferon Gamma Release assay scheme to increase the educational value of each distribution.

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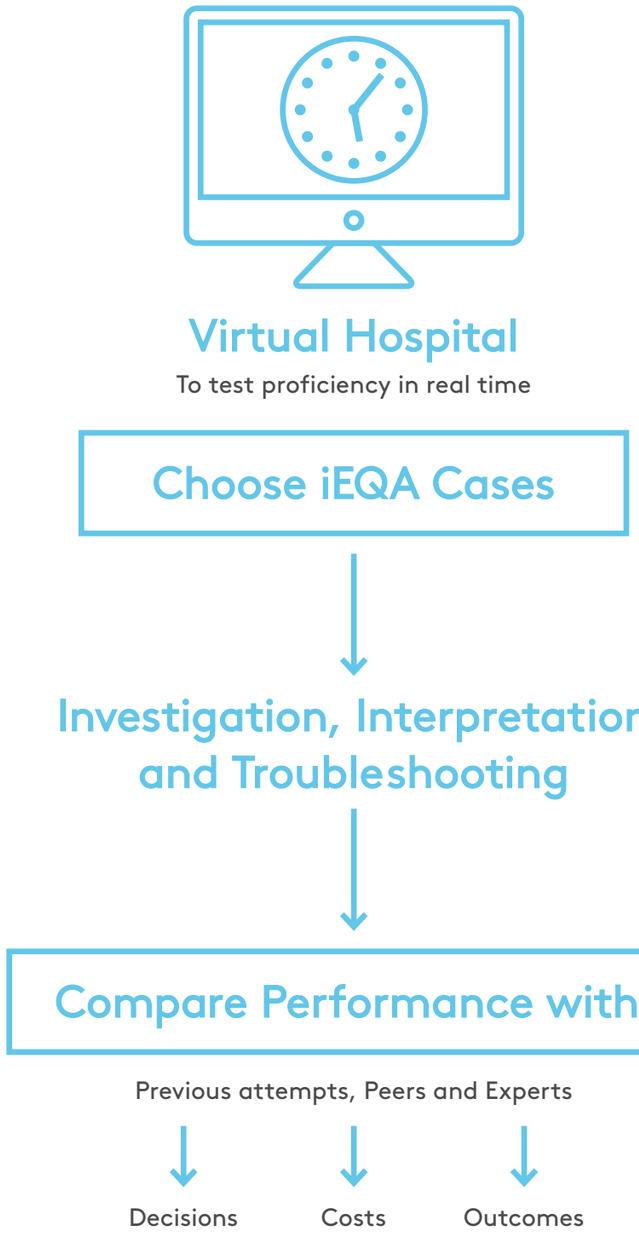
Compendium of Quality

The Future: Digital EQA



5.3

Improving Malaria Diagnosis using Web Based Digital Morphology Galleries in the UK and in Africa

The Challenge

The quality of interpretation of abnormalities in blood film slides and malaria diagnosis is dependent on skilled microscopists with appropriate training and experience, especially when determining the species of malaria. Microscopy training has become increasingly difficult with increased workloads and fewer staff. Laboratories worldwide may struggle to deliver this training, often due to a lack of experienced staff and resources. UK NEQAS needed to support basic blood morphology training for the benefit of patients.

What UK NEQAS delivers

UK NEQAS worked in collaboration with the World Health Organisation (WHO) and Manchester Metropolitan University to develop a virtual microscope with image galleries for use in training for red blood cell morphology and malaria diagnosis. The galleries replicate the variety and difficulty seen in routine practice, with both common and uncommon patterns. To assess the effectiveness of the training, 80 stitched images allow participants to practise malaria diagnosis and reflect on their performance and the learning outcomes.

The benefits

- A extensive gallery providing high quality images of individual cells is available.
- Covers both common and uncommon abnormalities.
- Virtual slides replicate a single microscope field for realistic practice.
- Multiple examples of each parasite/cell abnormality, replicating the range that can be seen in real life.
- Validated assessment of the effectiveness of the gallery has taken place as part of a PhD research project with improvements in diagnostic accuracy after the training.
- Interactive quizzes with CPD certification available when the pass mark is achieved.

UK NEQAS
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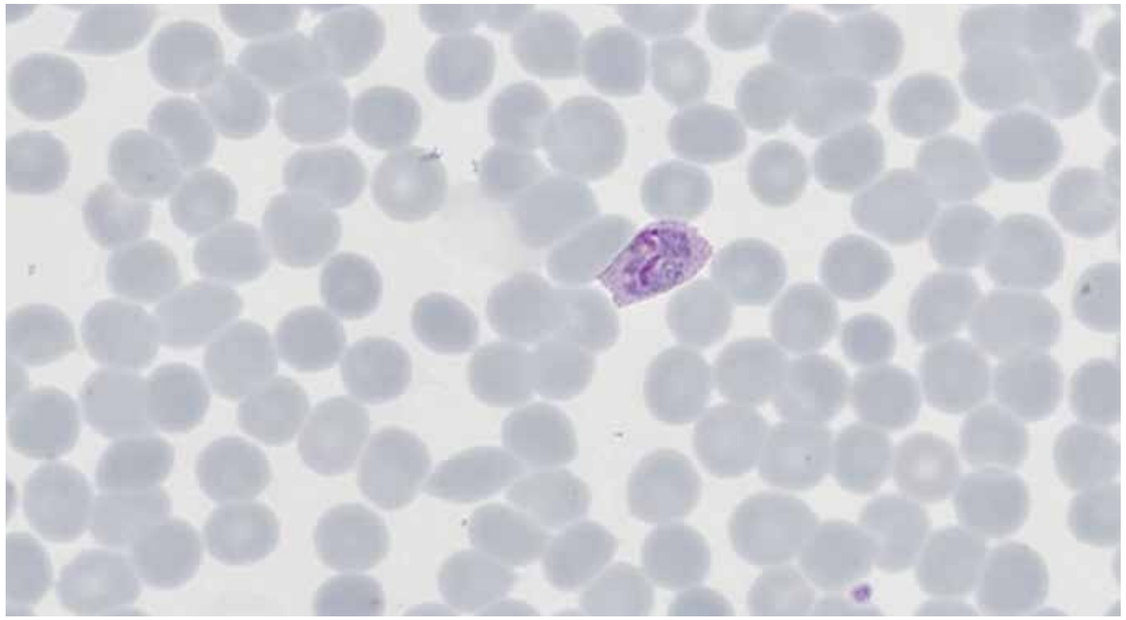
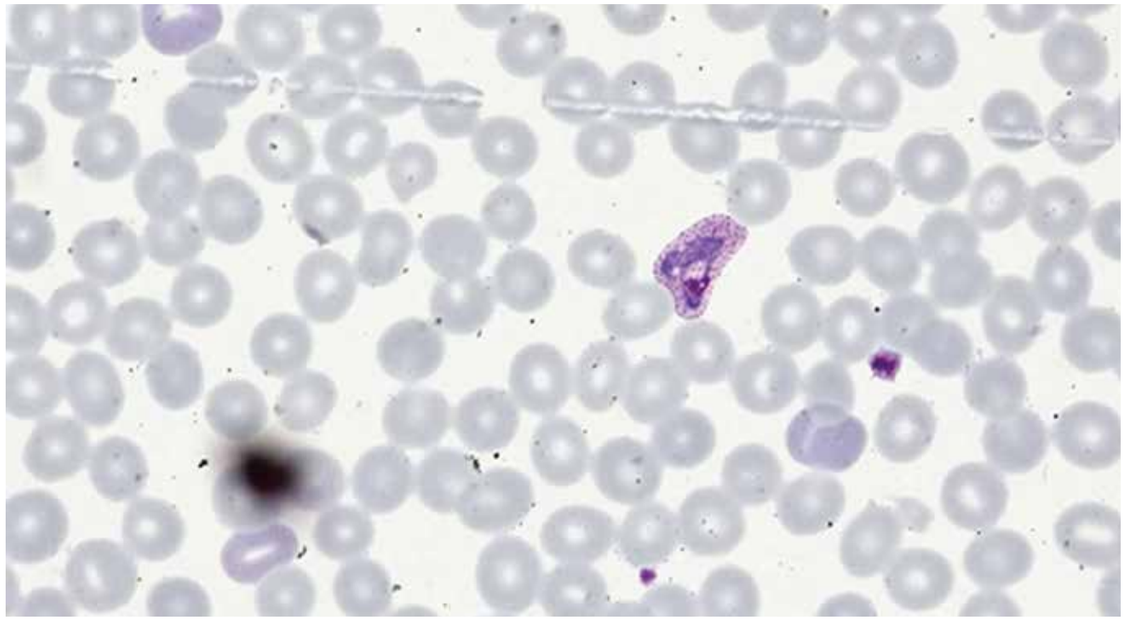
The Future: Digital EQA



Plasmodium ovale late trophozoite.



Plasmodium vivax trophozoite.

6.
EQA for Personalised Medicine and Companion Diagnostics

6.1
Personalised Medicine: EQA of Non-Standardised Quantitative Assays for HIV1 RNA

The Challenge

Monitoring levels of HIV using molecular biological techniques is a cornerstone of modern treatment. Decisions are made on the basis of the levels of virus genetic material present in the blood. Yet there remains a lack of standardisation between assays.

UK NEQAS needed to develop a sample stability and performance assessment mechanism suitable for all of the diverse assay methods (bDNA, PCR, RT-PCR, Isothermal and others).

What UK NEQAS delivers

We demonstrated that freeze dried plasma was a suitable, safe and stable sample type to distribute. We validated that measurement of the log difference in viral load between 2 specimens as a new approach to determining performance of the testing laboratories that is not influenced by the testing method.

The benefits

- The scheme mimics clinical practice in monitoring patients on anti-retroviral treatments, where decisions are made on the basis of changes in log copy numbers.
- Improvements in commercially available assays have occurred.
- Over time commercially available assays have replaced in-house methods.
- This performance monitoring approach can be applied in UK NEQAS schemes for other blood borne infections.

6.2
Personalised Medicine – EQA for Companion Diagnostics

The Challenge

Personalised medicine using targeted drugs in particular individuals has given many patients an effective new treatment choice for some cancers. Accurately detecting specific gene mutations within the tumour is pivotal for best clinical management of these patients. Proper External Quality Assessment (EQA) is essential to reduce variability and ensure the quality of this form of rapidly expanding molecular testing.

UK NEQAS developed an EQA scheme to provide a source of material with an appropriate range of mutations and an educational aspect to help improve the quality of the testing being performed.

What UK NEQAS delivers

Since 2008, four EQA schemes have been developed and delivered to assess the molecular testing in four tumour types:

- KRAS molecular testing in colorectal cancer
- EGFR molecular testing in non-small cell lung cancer
- Molecular testing in gastrointestinal stromal tumours
- BRAF molecular testing in melanoma (pilot).

The tumour samples are supplied with appropriate clinical case scenarios and participants are required to submit fully interpretative reports. They are assessed for genotyping accuracy, interpretation of the results and clerical accuracy of the report.

All reports are assessed anonymously by at least two assessors against peer ratified criteria. Full performance criteria (ratified by the National Quality Assurance Advisory Panel for Genetics) have been applied since 2010.

The benefits

- The standard of testing has been improved. A large reduction in genotyping errors has occurred since introduction of the EQA scheme. No UK laboratory now has ongoing persistence poor performance.
- This is the first UK NEQAS scheme in the field of molecular biology companion diagnostics for solid tumours.
- The samples are tailored to be handled using routine procedures in the same manner as patient samples.
- Educational feedback is routinely provided. The clinical interpretation of the genotyping result is assessed and educational guidance is given when interpretation is not appropriate or sub-optimal.
- Interpretation content has improved through scheme feedback to individual laboratories and the suggested minimal required information on molecular pathology testing report has been taken up by the majority of participating laboratories.
- The EQA scheme has been involved in promoting best practice through interaction with professional bodies and input into guidelines.

UK NEQAS
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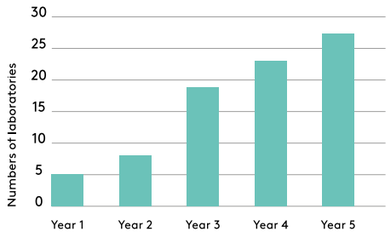
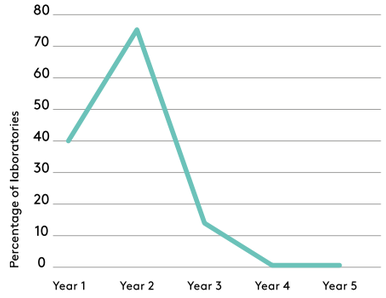
EQA for Personalised Medicine
and Companion Diagnostics

6.2 Molecular analysis of Gastro-intestinal stromal tumours EQA



Graphic displaying numbers of participants



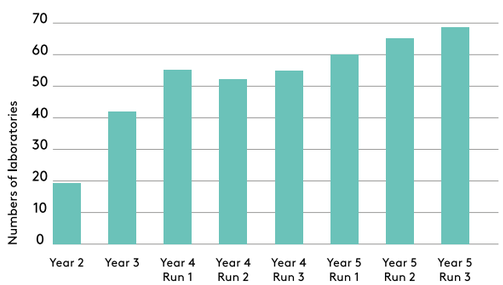
Graphic displaying percentage of laboratories with at least one genotyping error

Molecular analysis of EGFR in non-small cell lung cancer EQA

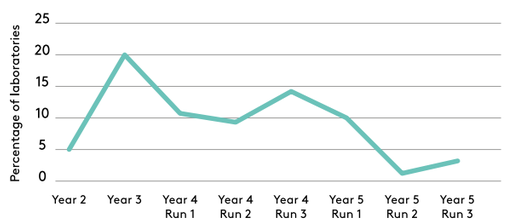
Graphic displaying numbers of participants

Graphic displaying percentage of laboratories with at least one genotyping error

Molecular analysis of KRAS in colorectal cancer EQA



Graphic displaying numbers of participants



Graphic displaying percentage of laboratories with at least one genotyping error

6.3

EQA for Personalised Medicine: Supporting the ABO Incompatible Renal Transplant Programme

The Challenge

ABO incompatible renal transplants (ABOi) are now possible due to antibody reduction by plasmapheresis or immunoadsorption and suppression of the immune response. The levels of anti-A and anti-B blood group antibodies assist transplant centres to decide:

- Who to recruit onto the programme
- When to transplant

There is no standard technique for measuring antibody levels. Assays can be subjective, lack precision and results vary between different techniques. There is no conclusive data on whether IgG or IgM antibodies are the most important marker, or on the correlation of pre-transplant levels with outcome of the graft.

What UK NEQAS delivers

The first challenge for UK NEQAS was to EQA the assay. We set up an EQA scheme to:

- Assess accuracy and precision in measurement.
- Develop a standard technique for measurement.
- Facilitate the production of reference materials for anti-A and anti-B.
- The second challenge was to work with the national and international transplant community from both the BTLP (Blood Transfusion Laboratory Practice) and H&I (Histocompatibility & Immunogenetics) schemes to collect and analyse data in order to demonstrate any correlation between titre and clinical outcome.
- We set up a pilot scheme for ABO titration. In collaboration with the NHS Blood & Transplant red cell reference laboratories we compared in-house technique with standard techniques based on the technology used by the majority of participants in-house.

We are in the process of developing reference preparations in collaboration with the National Institute for Biological Standards and Control.

The benefits

We set up a Specialist Advisory Group to include Renal Transplant Surgeons.

Close collaboration between the scheme, the laboratories and the transplant services has been essential to ensure clinically relevant outcomes, with the aim of improving the relationship between laboratory results and clinical outcome.

The pilot phase now established, we aim to establish:

- Greater standardisation of antibody measurement and the creation and use of reference preparations.
- The maximum level of antibody that allows safe acceptance into the ABOi transplant programme, so as not to exclude patients unnecessarily.
- The lower threshold antibody level which allows safe transplant without antibody mediated graft rejection and without subjecting the patient to excessive pre-transplant treatment.

UK NEQAS
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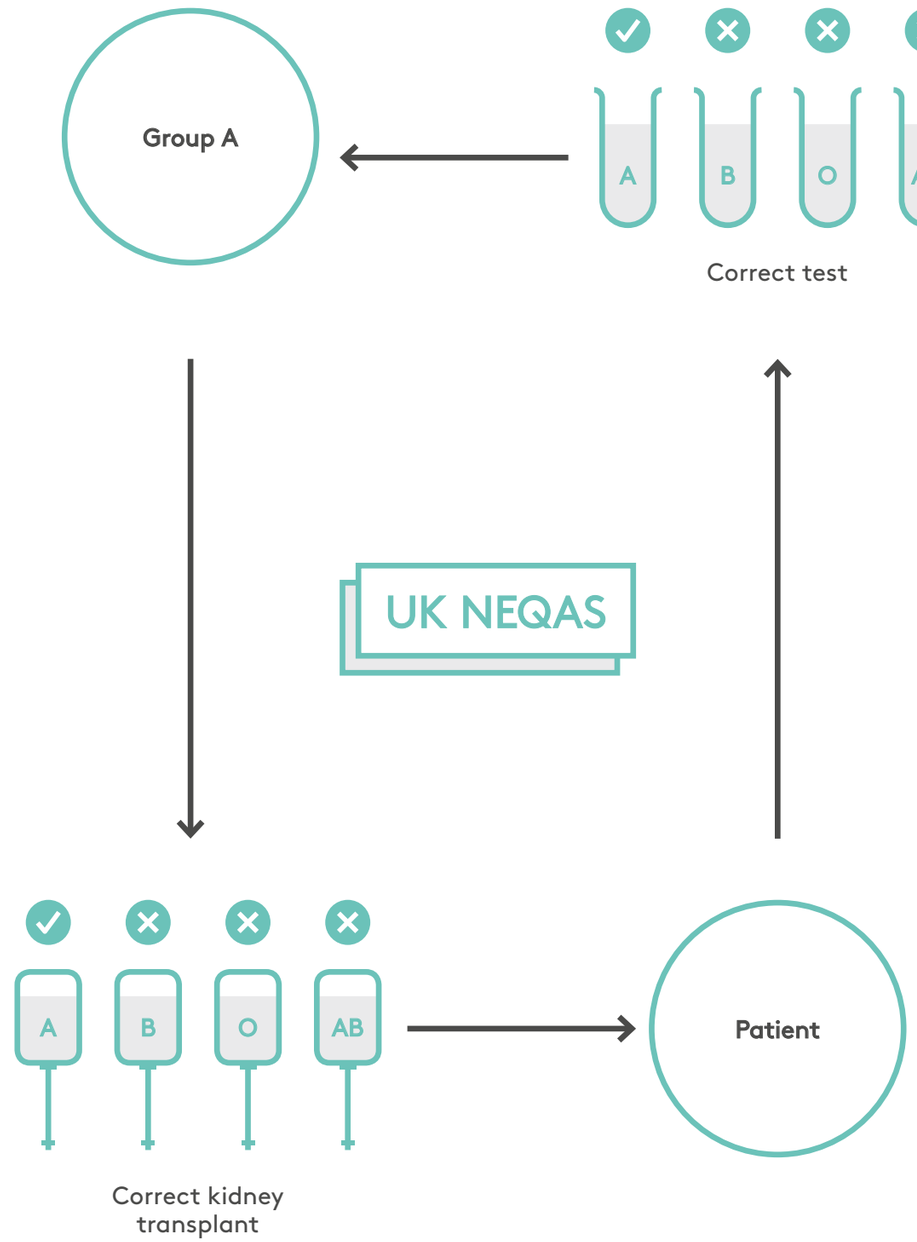
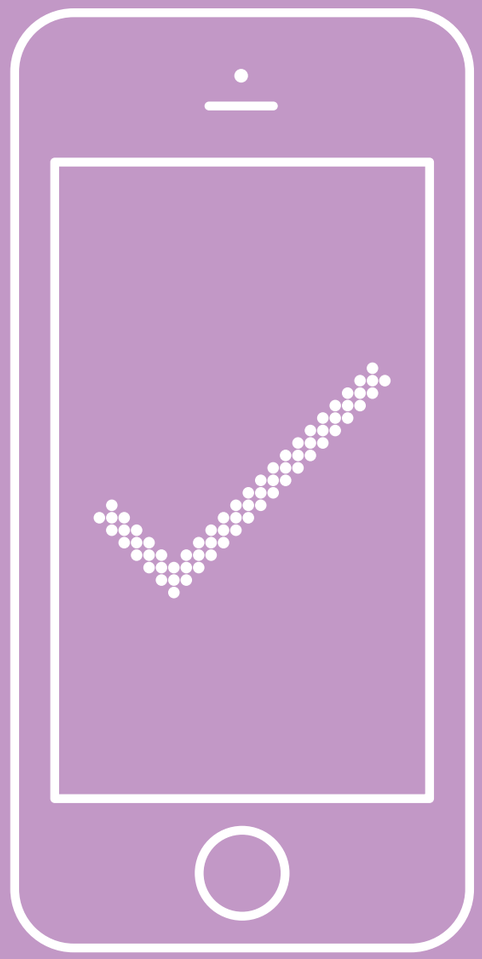
EQA for Personalised Medicine
and Companion Diagnostics



7.
Any Time, Any Place: Improving Near-Patient Testing



7.1
Supporting Near-Patient Testing for INR (blood clotting) Monitoring

The Challenge

Near-patient testing (NPT) or point-of-care testing (POCT) for INR (blood clotting) monitoring in patients taking warfarin is usually performed by non-scientific staff such as nurses, doctors and healthcare practitioners in outpatient clinics and general practice premises. These staff are not usually trained in laboratory quality control or assurance procedures and need support in the proper application of quality control procedures in the governance of testing. Although many have been given basic training in the operation of the device and the manufacturers internal control procedures, the application of independent external quality assurance is the best way to document proper governance and maintenance of testing standards for patient safety.

What UK NEQAS delivers

- We introduced independent External Quality Assurance to around 3600 NPT/POCT sites across the UK to support better testing for INR.
- UK NEQAS provides NPT/POCT-specific targeted educational meeting at venues around the UK to allow convenient access to training.

We monitor, support and educate these non-laboratory trained users in the maintenance of quality in diagnostics and interpretation for the benefit of patient safety.

The benefits

We have raised awareness of the need for a QC process in NPT/POCT to ensure reliable, accurate results.

- Many of these NPT/POCT centres have now introduced QC as part of the INR monitoring process.
- We provide education material and reports targeted to the needs of the participants.
- We are available to participants for personalised support and assistance with problems in performance of their tests.

7.2

UK NEQAS Network Reports services: Supporting Near-Patient Testing for Urine Analysis

The Challenge

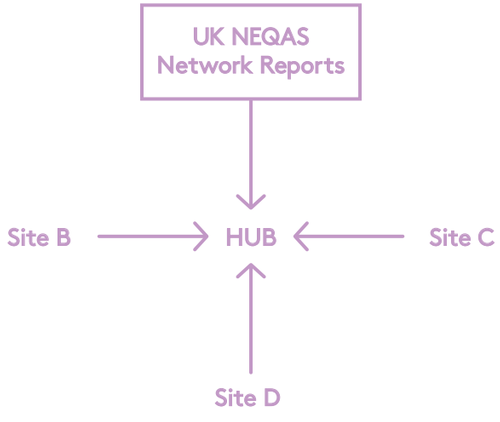
Increasingly, diagnostic tests are done on the hospital ward or in the GP surgery. This is called Near patient (NPT) or Point-of-care testing (POCT). NPT is often overseen by Network Co-ordinators both within hospitals and in the community. Communication and training is a challenge, and visiting multiple sites regularly becomes impossible. The testers often lack training in quality control and assurance and may fail to see the importance of regularly participating in the EQA programme.

What UK NEQAS delivers

UK NEQAS devised web-based programmes for urine dipstick testing and NHS Health Checks that can be used by testers of any level of experience. Specimens are sent via the hub (Co-ordinator) or direct to spokes (testing sites) as required and returns are made through a secure results & reports web service. Simplified network reports are provided, visually summarising the performance across the network with visual cues to highlight need for action, together with access to reports for individual sites. Importantly, Co-ordinators can also see which of their sites are failing to engage with EQA before the distribution closes, to allow reminders and encouragement.

The benefits

- We have provided tools for NPT management suitable for all types of staff, with or without laboratory experience.
- We present complex data in a simplified, easy to assimilate format.
- We provide resource effective tools for NPT Co-ordinators enabling easier remote monitoring of compliance and performance, improving productivity and efficiency.
- Network Reports also facilitate accreditation compliance.
- Proof of concept and excellent feedback from users has validated the approach.
- Performance management for NPT has been made simpler and more effective, reducing the need for Co-ordinator resource.
- Governance and compliance has been simplified while improving efficiency.
- Development of similar NPT schemes for other UK NEQAS schemes is in progress.



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Any Time, Any Place:
Improving Near-patient testing

7.2 UK NEQAS for Urine Dipsticks

Specimen: 95A (You use: Siemens Multistix 10SG)

Your result

Leucocytes	neg	
Nitrite	neg	
Urobilinogen	normal	3.2 umol/L
Protein	neg	
pH		7.5
non-haem Blood*		
haem Blood*	++	80 Ery/uL
Specific Gravity		1.015
Ketones	neg	
Bilirubin	neg	
Glucose	neg	

Consensus response

Leucocytes	neg	
Nitrite	neg	
Urobilinogen	normal	3.2 umol/L
Protein	neg	
pH		7.5
haem Blood*	+++	200 Ery/uL
Specific Gravity		1.015
Ketones	neg	
Bilirubin	neg	
Glucose	neg	

On this specimen you were...

	VLo	Lo	Spot on	Hi	VHi
Leucocytes			◆		Spot on
Nitrite			◆		Spot on
Urobilinogen			◆		Spot on
Protein			◆		Spot on
pH			◆		Spot on
haem Blood*		◀	◇		Low
Specific Gravity			◆		Spot on
Ketones			◆		Spot on
Bilirubin			◆		Spot on
Glucose			◆		Spot on

Specimen: 95B (You use: Siemens Multistix 10SG)

Your result

Leucocytes	+	70 Leu/uL
Nitrite	positive	
Urobilinogen	normal	3.2 umol/L
Protein	+	0.3 g/L
pH		8.5
non-haem Blood*		
haem Blood*	trace	10 Ery/uL
Specific Gravity		1.015
Ketones	neg	
Bilirubin	neg	
Glucose	+	14 mmol/L

Consensus response

Leucocytes	+	70 Leu/uL
Nitrite	positive	
Urobilinogen	normal	3.2 umol/L
Protein	trace	
pH		8.0
non-haem Blood*	neg	
Specific Gravity		1.015
Ketones	neg	
Bilirubin	neg	
Glucose	+	14 mmol/L

On this specimen you were...

	VLo	Lo	Spot on	Hi	VHi
Leucocytes			◆		Spot on
Nitrite			◆		Spot on
Urobilinogen			◆		Spot on
Protein			◇	▶	High
pH			◇	▶	High
non-haem Blood*			◇	▶	High
Specific Gravity			◆		Spot on
Ketones			◆		Spot on
Bilirubin			◆		Spot on
Glucose			◆		Spot on

Recent Performance

This time:

Leucocytes	Spot on for 95A, Spot on for 95B
Nitrite	Spot on for 95A, Spot on for 95B
Urobilinogen	Spot on for 95A, Spot on for 95B
Protein	Spot on for 95A, High for 95B
pH	Spot on for 95A, High for 95B
non-haem Blood*	High for 95B
haem Blood*	Low for 95A
Specific Gravity	Spot on for 95A, Spot on for 95B
Ketones	Spot on for 95A, Spot on for 95B
Bilirubin	Spot on for 95A, Spot on for 95B
Glucose	Spot on for 95A, Spot on for 95B

Recent trend:

Leucocytes	Good and remains consistent
Nitrite	Good and remains consistent
Urobilinogen	Good and remains consistent
Protein	OK, but has deteriorated
pH	OK, but has deteriorated
non-haem Blood*	Currently OK
haem Blood*	Currently OK
Specific Gravity	OK and has improved
Ketones	Good and remains consistent
Bilirubin	Good and remains consistent
Glucose	Good and remains consistent

	Good	OK	Poor	
Leucocytes	●	○	○	Good
Nitrite	●	○	○	Good
Urobilinogen	●	○	○	Good
Protein	○	●	○	OK
pH	○	●	○	OK
non-haem Blood*	○	●	○	OK
haem Blood*	○	●	○	OK
Specific Gravity	○	●	○	OK
Ketones	●	○	○	Good
Bilirubin	●	○	○	Good
Glucose	●	○	○	Good

In Summary

Note: The colours on the web data entry page and on the reports are for guidance only: always use the colour chart provided with the strips by the manufacturer.

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7.3

Maintaining Skills in Near-Patient Testers: Metro-POCT: an Innovative Training Facility supported by UK NEQAS

The Challenge

Near Patient Testing (NPT) or point-of-care testing (POCT) is a test done at any site outside a central laboratory, where the patient is being seen. This gives immediate access to results and quicker clinical management decisions. However the nurses, doctors and healthcare practitioners running the NPT/POCT analyses need to be well trained and competent in performing NPT/POCT to ensure patient safety.

Central laboratories invest a lot of resource and training to ensure accurate results, and it is essential that NPT/POCT results are similarly robust.

The NPT/POCT process includes all the steps from blood sampling, then testing through to reporting results. In some instances, interpretations and clinical decisions are made by the tester e.g. anticoagulant prescribing after an INR which also require assessment.

What UK NEQAS delivers

The Metro-POCT project worked with all stakeholders to gain an understanding of how NPT/POCT is currently performed. Using questionnaires and focus groups UK NEQAS have learned what users want and expect from ideal NPT/POCT, and what training they need. We developed bespoke training to meet these needs and supported Metro-POCT in their novel training programme development.

Additionally, we supported the development of a 'Clinical Skills Suite' and 'Problem Based Learning' facility within Manchester Metropolitan University, specifically designed to meet the needs of NPT/POCT providers.

The benefits

- Direct delivery of bespoke training to NPT/POCT practitioners by expert pathology personnel.
- Development of a purpose-built facility using NPT/POCT-specific training media developed in conjunction with POCT users.
- Providing a library of NPT/POCT specific E-Learning resources through Manchester Metropolitan University that can be accessed readily at any time through smartphones and tablets.
- Specific training and refresher training material utilising electronic programmes including Smartphone Apps, enabling flexible training in any environment.
- End-to-End training to cover the training needs of NPT/POCT users through the whole process; from blood sampling to result reporting.
- The project will support enhanced service through NPT/POCT pilot sites set up within the primary care community of Greater Manchester to train and assess community healthcare staff and improve the training materials created.
- Surveys of practitioner and patient needs and attitudes towards NPT/POCT are underway to assist in future developments.
- The information generated will help shape UK NEQAS NPT/POCT Services across the organisation.

Who are UK NEQAS?

UK NEQAS is an independent, not-for-profit consortium of external quality assessment schemes based in the UK but providing services to diagnostic laboratories, assay manufacturers and near-patient testing schemes world-wide.

We have over 40 years' experience in delivering schemes to monitor the performance of diagnostic assays. Our current repertoire encompasses all forms of diagnostics, from Reproductive Science to Molecular Genetics. We cover both large volume routine analytes and specialist diagnostics and are continually increasing our repertoire to cover new tests.

We have close links with diagnostic laboratories and many of our Directors/Organisers are also actively involved in providing clinical diagnostic services to patients, basing all our advice and activity in the realities of current diagnostic practice. This gives us an insight into the requirements for patient safety, best practice and the needs of laboratories and near-patient analysis. We work closely with manufacturers to help them deliver the best diagnostics possible.

UK NEQAS is about more than monitoring technical accuracy and precision of results. We use our expertise and experience to educate and assist our participants through scheme distributions, electronic learning facilities, meetings and websites. We focus on clinically relevant issues of importance to good patient care. In this we are supported by advice from scientific and clinical experts through our Steering Groups and the National Quality Assessment Advisory Panels (NQAAPs) within the UK. This added value is becoming increasingly important to maintain quality in diagnostics and to develop the skills of the diagnostic workforce.

This brochure is a selection of some of the activities of UK NEQAS in recent years. If you want to see more examples and delve deeper into the details, please visit our website where you will find a link to these and more examples.

We hope you have found this informtion on our activities useful, for more information and to explore our services go to www.ukneqas.org.uk

Contact us at office@ukneqas.org.uk