

Independent Review of the Quality Assurance Arrangements for Cervical Screening in Northern Ireland



This independent review was conducted by NHS England on the specific request of the Public Health Agency in Northern Ireland.

All statements in this report are made in good faith, based on the information available at the time.

Version history

Version	Date	Description
0.1	09 June 2025	Draft version sent to PHA team for factual accuracy checking
0.2	12 June 2025	Factual accuracy comments returned to NHSE
1.0	16 June 2025	Final version sent to PHA Authorised by Dr Harrison Carter, Director of Screening, NHSE

Background

This report was commissioned by Northern Ireland's Public Health Agency (PHA) for NHS England (NHSE) to provide a peer review of Quality Assurance (QA) arrangements and activities relating to laboratories within the NI Cervical Screening Programme.

This was in response to an independent review, commissioned by the Southern Health and Social Care Trust (SHSCT), and conducted by the Royal College of Pathologists (Consulting). The review was in response to concerns raised in July 2022 relating to screener performance in the cervical cytology laboratory of SHSCT. The review resulted in SHSCT announcing it was undertaking a precautionary review of the cervical screening results of over 17,000 women screened within the Trust between 2008-2021 as part of the Northern Ireland Cervical Screening Programme. The review is now complete, and two key reports have been published by the Trust and PHA.

Since its establishment in April 2009, the Public Health Agency has held responsibility for commissioning and quality assuring population screening programmes. This is in collaboration with key partner organisations including the NI Department of Health (DH), Business Services Organisation and Health and Social Care Trusts.

The QA function is underpinned by an organised structure of public health and professional leads, supported by programme managers, information and administrative staff. Given the PHA role in both commissioning and quality assuring the cervical screening programme in SHSCT, this review was commissioned to address 5 key objectives.

Objectives

- To review the extent and appropriateness of QA guidance and processes in place during the time period, and to identify any potential areas where processes could have been strengthened.
- To review the application of any guidance and processes in place
- To review if any deviations from standards in laboratories were identified and if so, if appropriate actions were taken.
- To consider whether the team in the PHA had sufficient capacity and capability to effectively provide the QA functions for cervical screening.
- To make recommendations for strengthening QA functions going forward

Reviewers

1. Philippa Pearmain, Consultant in Public Health, Senior Clinical Lead for the Cervical Screening Programme, NHS England, FFPH, MSc, BSc
2. Billie Moores, Consultant in Public Health, Deputy Director of Screening (Quality Assurance and Public Health), NHS England, FFPH, MPH, BSc

Approach

PHA submitted to the reviewing team a wide range of evidence from 2008 onwards. This included a selection of:

- QA visit reports, data reviews and follow up documents
- Email correspondence between PHA, trusts, DH
- Data reports for laboratories
- Descriptions of QA governance, staffing and documentation

On 13 and 14 March 2025, the reviewers conducted onsite meetings with:

- [REDACTED] – Deputy Director of Public Health & Public Health Consultant Lead, NI Cervical Screening Programme
- [REDACTED] – former Regional QA Laboratory Lead
- [REDACTED] – former Interim Assistant Director of Public Health for Screening and Professional Standards

During the onsite visit, additional data files specifically relating to anonymised individual screener performance at SHCST and minutes of laboratory QA group meetings were requested and received.

Due to annual leave commitments, Philippa Pearmain also had a telephone call with [REDACTED] [REDACTED] – former Public Health Consultant Lead, NI Cervical Screening Programme on 01 April 2025.

Limitations and context

It is recognised that reviewers assessing practice after a significant event have the benefit of knowing the outcome whilst they conduct the review. It is also difficult to look back over 17 years and understand the context and environment people were working in. This is where reliance on documentation becomes important, and like any newly developing service, this has improved over time. The reviewers have identified clear improvements over the last 2 years in the documentation reviewed.

The reviewers have taken the approach of considering what was reasonable at the time for a QA system to have in place. There are several factors, predominantly outside of the control of PHA, that impact on the effectiveness of QA systems and structures, and the findings of the review have taken these into consideration.

Firstly, the impact of the Covid-19 pandemic on both the operational delivery of screening programmes (and consequently the data reporting) and the pandemic response needed by qualified public health staff working in PHA at the time. This meant that data for 2020/21 had lower denominators than previous years – potentially making comparisons to previous years, and standards, more difficult. Additionally, PHA staff who had been providing leadership of QA were redeployed to support the Covid-19 response, resulting in a lack of continuity around ongoing concerns.

Secondly, as rightly outlined in PHAs QA frameworks, Trust Chief Executives are accountable for the performance and quality of screening programmes delivered by their organisation. Effective quality assurance requires good relationships and engagement with providers, especially when reliant on providers to submit timely data returns, audits and

engage with QA processes. There is clear evidence that the relationship with [REDACTED] broke down, leading to a lack of engagement with PHA and quality assurance requirements [REDACTED].

Finally, there were significant staffing gaps, or temporary cover arrangements in place, in PHA from 2015 through to 2023, especially in the cervical programme. This impacted PHAs ability to ensure effective end to end QA processes, especially against a backdrop of significant programme changes. This is considered in more detail further in the report.

Findings

The findings, and associated recommendations, focus on improvement to the QA function going forward, not a detailed examination of past actions. As with any review, the reviewers have found room for improvement in some areas, as well as things which are done well. There are 6 main recommendations below. As the narrative to support the recommendations threads throughout the findings section, where applicable, there is a reference to a numbered recommendation.

Recommendations

Develop a QA improvement plan, encompassing the following recommendations:

1. Revise the overarching QA framework to ensure it covers the full range of QA activity and explicitly documents how commissioning issues are separated from QA issues.
2. Develop and implement detailed processes and procedures that underpin the QA framework including a review of language used and content documented in QA outputs. This will improve timeliness and consistency of approach across all programmes. Processes should include but not be limited to: - follow up of recommendations; monitoring of activity against standards (including trend data, time periods covered, RAG ratings and follow up of previous issues); QA visits and data reviews.
3. Introduce a post with responsibility to deliver the development of effective QA processes across all screening programmes.
4. Strengthen service specifications (or equivalent) to ensure participation and engagement with QA activities is compulsory.
5. Put in place professional QA advisor arrangements that ensure that a range of opinions are obtained to inform decision making and that there is clarity on the role of QA advisors with respect to direct engagement with providers
6. Publish guidance branded as NI QA so that it is clear what is expected of NI screening services.

Detailed findings

1: To review the extent and appropriateness of QA guidance and processes in place during the time period, and to identify any potential areas where processes could have been strengthened

1.1 QA structures

As with many health care systems, there has been several changes over the last 17 years, resulting in different organisations having responsibility for the commissioning and oversight of screening programmes. Since 2009 PHA has been responsible for the commissioning and QA of population-based screening programmes.

From the evidence reviewed, there is a clear review process of QA governance structures occurring in 2008, 2010, 2013, 2017 and 2023. In the later years there is evidence these were ratified through appropriate channels.

Documentation from 2008 demonstrates a cervical QA committee structure which has remained largely unchanged, although the Chair, membership and upward reporting structures have necessarily evolved.

The last update in 2023 brought the three cancer screening programmes together in one document, clearly outlining role, scope and function of the different QA committee structures.

1.2 Wider systems and escalation

Recognising the 2011 governance framework needed revising to strengthen governance arrangements, in 2019 PHA published a new population screening guidance- with a particular focus on escalation.

The revised guidance provides a clear framework for escalation, and expectations of what and how issues are escalated. The first level of escalation occurs when the consultant lead for the screening programme identifies issues or concerns, and these are discussed at the consultant group. Any issues or concerns that cannot be satisfactorily addressed through current programme arrangements, that impact on the safety or effectiveness of a screening programme, must be escalated to level two via the Assistant Director of Public Health to the trust management team. Where problems persist or are of a more serious nature, these are considered at the Screening Programme Board (SPB), with an option of serious quality issues being raised with the Strategic Planning and Performance Group within DH.

From the minutes of the first Screening Programme Board meeting in February 2020, it is not clear whether all relevant cervical screening issues were raised. Given the reviewers have not seen later minutes, the QA team should assure itself that all relevant issues have been raised appropriately and there is a clear process in place to capture issues that require escalation. (**recommendation 2**)

1.3 Cervical QA laboratory group

The NI CSP had a laboratory QA group led by a formally appointed QA lead for laboratories who was a senior biomedical scientist working in one of the 4 cervical screening laboratories within the NI CSP. The laboratory QA group was chaired by the QA lead and had

representatives from each of the 4 laboratories in the NI CSP along with PHA QA staff. From minutes supplied, the group discussed issues raised by the laboratories, shared learning from incidents, along with updates from the QA staff, reviewed new guidance published by the English CSP to determine if there were any areas that were not to be recommended for use in the NI CSP and developed alternative protocols for use in NI where deviations were agreed. The laboratory QA group reported to the overarching QA committee, chaired by the QA director where each QA lead for the programme professional areas attended to represent their area of the programme.

Since the move to HPV primary testing in November 2023, membership and structure of the QA laboratory committee and the approach to appointing a professional QA chair will need to be revised as there is now only one cervical screening laboratory servicing the whole of NI. Due to this change and the conflict of interest it creates, PHA will need to access expert clinical laboratory advice independent of the regional laboratory provider. As cervical screening develops over the next 5 to 10 years, this is likely to become an issue across the UK, and PHA may wish to discuss developing a network approach to accessing specialist expertise with the rest of the UK nations. (**recommendation 5**)

1.4 Remit of PHA in screening programmes

As happens in some of the other parts of the UK, PHA both commissions the cervical screening programme providers and is responsible for undertaking a programme of quality assurance activities to independently assess quality of service. This can present a conflict of interest between commissioning and financial arrangements and implementing quality requirements. As part of the PHA's organisational restructuring a new Assistant Director of Commissioning post has been created, with proposals for additional commissioning staff. This will be helpful in terms of providing a greater separation between commissioning and QA going forward.

1.5 QA visit documentation and processes

QA framework documentation is in place, outlining the scope of QA consistently and appropriately, including a clear role in both collecting, reviewing, validation and disseminating data, together with monitoring and review of performance.

There is evidence of strengthened processes in terms of QA programme management since 2023, with processes such as a cervical change log being introduced. This is good practice. QA visit guidance documentation has been in place from 2009, when interim guidance for laboratories was first introduced. This evolved in 2013 to cover the cervical screening programme and was reviewed in 2016 and 2023. Whilst the documentation appropriately provides the purpose, scope and practicalities of a QA visit, it is not sufficiently detailed for providers to understand exactly what is being reviewed and evidence they will be asked for. Whilst this level of detail may exist, the reviewers have not seen it.

"The visit will include a review of examples of systems of work, policies and procedures, including arrangements for the audit of invasive cervical cancer. However, due to the limited timescale, it will not be possible for the QA team to fully review all systems of work, policies and procedures associated with an individual service." (2023 QA visit guidance)

It is helpful, as outlined above, for QA to be clear it is not reviewing everything. However, it is less clear if evidence requests/areas reviewed are applied consistently to all providers, or if each QA visit is bespoke. There is a more detailed list of nine areas of review in the QA visit guidance document. However, except for 'managerial arrangement', the other eight areas have the caveat 'Some or all of those topics will be covered in the assessment of performance'. It is unclear what criteria is used to determine if an area is reviewed or not. For transparency, the QA report should clarify what, if any, areas have not been addressed and why. This would mitigate the risk of false reassurance. (**recommendations 1 & 2**)

There are several areas that the QA team may wish to explicitly include in their areas for review, which are not currently documented. These are incident reporting, trust governance and risk and inequalities. From reading the QA visit reports submitted, it appears these areas are not explicitly reviewed, but given the importance of these, it is something PHA should consider including in the QA framework. In addition, the development of a QA framework that covers what will be reviewed, when, through what mechanism (such as QA data reviews, meetings, QA visits), and how services/individuals will be considered outliers will help support consistency of the overall QA approach. (**recommendations 1 & 2**)

There is lack of clarity and contradiction of timescales and expectations of follow-up action in the QA visit documentation. In various sections of the guidance, it is stated that the trust is expected to provide an action plan 4 months after the date of the QA visit; recommendations are expected to be actioned following the issuing of a draft report; and recommendations will be timed from the issuing of the final report. This risks inconsistency of approach and delays work to support improvement – especially considering the delays in issuing final QA reports (see section 2.2.1 (**recommendation 2**))

If the NI CSP continues to base its professional guidance on that of the NHS CSP in England, it will be important to put in place a communication mechanism to ensure that the up-to-date guidance is used and the NI CSP is aware when changes are made. (**recommendation 6**)

2: To review the application of any guidance and processes in place

2.1 Timeliness of reports

There are several timeframes in which QA should produce visit reports, as defined in QA visit documentation.

One is that immediate recommendations should be raised verbally at the feedback session and written up and sent to all lead professionals involved in the visit and the Trust Chief Executive within one week of the QA visit.

Two relate to the timeliness of the QA visit report – 6 weeks (normally) for the draft report and 12 weeks for the final report.

In relation to immediate recommendations, from the two examples provided as evidence, 1 immediate recommendation letter was sent at 7 days (2023), and another one at 14 days (2015). There is no evidence submitted to demonstrate compliance with the issuing of draft reports, but from the 5 final visit reports reviewed, only one was within the 12-week timeframe. The other 4 ranged from 6 months to 15 months post visit. Although it is not unreasonable to expect providers to start putting some improvements in place following both verbal feedback and receiving the draft visit report, a considerable gap between the visit and the final report risks issues not being addressed timely, and both losing momentum and credibility. Staffing pressures were clearly a factor in some of these delays (addressed later in the report), and there may be issues in agreeing a final report in some cases that the review team are unaware of.

2.2 Action plans and recommendations

The QA visit process documentation is appropriately clear that responsibility for acting on the findings from QA visits sits with the Trust Chief Executive. The QA team has documented its responsibility to continue to monitor the progress of the action plan against the timescales proposed, with a line of escalation to the Director of Public Health if the PHA Lead consultant is not satisfied with progress.

There is an expectation that a Trust action plan should be submitted to QA following the visit, within 4 months of the date of a visit. Whilst there is evidence that immediate recommendations are raised quickly after a visit, it is less clear whether action plans are submitted timely by Trusts, and if this is not forthcoming, whether it is consistently followed up by QA. The length of delay in issuing final reports may also be a factor affecting the follow up of recommendations.

The reviewers have seen evidence of follow up meetings with providers to discuss progress against the recommendations. These have tended to occur within 12 months of the visit, but not always. Given some of the non-immediate actions have timescales for completion of 3 months it is not clear how this is being monitored, or risk assessed. There is also evidence that sometimes feedback has been obtained from staff within trusts prior to the formal feedback of actions by the trust. Whilst this is positive in that earlier action is being taken, there appears to be a lack of consistency of approach.

Although there is QA visit guidance, the reviewers have not seen evidence of accompanying workplans, or standard operating procedures, detailing the action the QA function needs to take. Embedding these, alongside the overall framework, would improve the consistency of approach, enabling staff to better understand tasks and when to escalate if no progress. (**recommendation 2**)

2.3. Follow up of agreed actions

There is no documented process to ensure actions agreed by PHA, as part of either data review meetings, or committee meetings, are captured and progressed. There are numerous times within data review meetings where PHAs response is to discuss at the QA laboratory group but there is no evidence to suggest this has happened consistently. There was recognition at the 2022 QA laboratory meeting that an action log needed to be introduced to service the QA committee, which is good progress. (**recommendation 2**)

2.4 Engagement from Trusts

As commented earlier in the report, effective QA relies on constructive relationships with trusts, and it is necessary for trusts to be open about activity and share information proactively with QA. If a trust decides to withhold information from QA about any aspect of the screening programme or confirms that issues are satisfactory or resolved when they are not, QA cannot be held accountable for lack of action on something it was unaware of. In some ways, for laboratories, the risk of this happening is reduced, now that there is a single regional laboratory, but the questions remain about how to ensure engagement with QA is seen as mandatory and not optional.

There are several examples of trusts carrying out activities either out with cervical screening guidance and policy or commissioning external slide reviews and not informing QA. In these instances, the consultant lead for the programme has taken swift action to ensure trusts are aware of their obligations to follow guidance and keep QA informed of any activity which could impact on the quality of screening.

The cervical screening service specification for 2024 outlines that services should 'Demonstrate a commitment to monitor data and provide input into NICSP Quality Assurance activities on a regular basis'. PHA should strengthen this into a contractual requirement that services must engage timely and proactively with screening QA activities. (**recommendation 4**)

In 2021, PHA demonstrated the escalation of a lack of engagement from [REDACTED], by the QA laboratory lead writing to senior staff within the trusts. This eventually got resolved, and the annual data reviews completed, albeit considerably later than planned. As relationships were clearly strained between QA and [REDACTED], there is a risk that the assurances the trust gave around performance issues being resolved did not get the full scrutiny afforded if the relationship was satisfactory. Having clear processes in place for identifying and recording performance issues will mitigate this to some extent (**recommendation 2**).

3: To review if any deviations from standards in laboratories were identified and if so, appropriate actions were taken

3.1 Professional guidance

Professional guidance used in the NI CSP is primarily based on the guidance published by the NHS Cervical Screening Programme in England. This is reported to be a pragmatic approach due to the small size of the NI screening programme and associated quality assurance and programme infrastructure. New guidance or standards published by the English CSP are considered at the relevant NI professional QA group and recommendations on acceptance of all, or part, of the guidance are made. However, there is no publicly or easily available website that details how to interpret the NHSCSP guidance documents for use in NI. This creates risks that services are not clear what guidance applies to them, and that the approach of accepting the NHSCSP guidance or not (in full or part), as a strategic approach sets an impression for providers that implementing guidance is optional. Evidence from the laboratory QA group minutes shows that individual laboratories were practicing

differently even when the national guidance was clear and that some laboratories were choosing not to implement agreed national guidance. (**recommendation 6**)

3.2 Approach to review of data

The NI CSP reviews the performance of laboratories at QA visits and since 2012 annually at data reviews. Over time, this has evolved from a review of overall laboratory data to include the review of individual staff performance data as well.

From around 2008 onwards, laboratories were encouraged to implement the Cyres cervical cytology reporting software to make data reporting against standards easier and more consistent. The data definitions and therefore mapping of underlying laboratory data into this software were not clearly defined. Up until 2018/19, laboratory sensitivity data was being calculated using the final report instead of the rapid review opinion which meant that the data outputs would not be consistent with the measurement of the actual standard. It is not clear from the evidence seen that this was being fully considered when interpreting the data. There is evidence that the measurement was discussed with laboratories prior to, and following, the letter endorsed by the CMO sent in 2019 to all trusts mandating the use of the published English NHSCSP standards and associated definitions.

3.3 Annual data reviews

The reviewers looked at several QA data review meeting notes across the four laboratories within NI over the period of the review. It is clear from these meetings that each standard was discussed with the laboratory and issues were highlighted by the QA team with providers and an explanation expected. However, the notes are summarised to different levels of detail and there are no references about whether previous issues highlighted have been satisfactorily resolved in the following year's documentation, or that issues were followed up in between. There are several occasions where issues have been identified and documented, but a statement to the effect that no significant issues were identified was also included. Having a systematic, documented approach to data reviews would improve consistency and the accuracy of summaries. (**recommendation 2**)

3.4. Consistency and accuracy of reporting

Looking in detail at the Southern Trust laboratory as an example, as this was the trust that performance issues were raised and a rescreen took place.

There is evidence from QA visit reports in 2009, 2014 and 2019 and in annual data reviews, that there were various concerns about the performance of screening staff, data collection and the ways of working within the laboratory raised with the trust by the QA team. However, there are instances where the written documentation and/or outcome does not reflect the concern identified. For example, at the 2009 QA visit it is noted that ways of working in the laboratory with respect to rapid review may be impacting on the performance data, but at the same time, the QA report noted that there were robust arrangements for performance monitoring in place within the laboratory.

Similarly, at the 2014 visit, in relation to identifying concerns about additional reviews and staff performance monitoring, the report states “No significant issues of concern were noted. There is robust monitoring of screener and Consultant performance data using Cyres.” Subsequent evidence supplied by the trust in 2022 suggests that there was continuous underperformance against national standards by at least one member of screening staff throughout the period covering the 2009 and 2014 QA visits.

A final example is the 2015 data review, where there is evidence that the QA team raised concerns about staff performance against the sensitivity standards. However, the QA data review document for that meeting states “all staff met national standards”. In discussion with PHA as part of this QA review, it was stated that the outcome of the data reviews was intentionally brief. However, this means that the full depth of the discussion and the basis for any judgements being made is not captured.

The potential to record different things risks confusion on what the actual performance issues are and hinders the ability to act on it and follow it up. Having documented processes that ensure QA visit reports and data reviews are read as a single document, and issues and concerns are captured accurately will improve consistency, provide a robust audit trail and will reduce the risk of issues being overlooked. **(recommendation 2)**.

3.5 Engagement with the data review process

Following the QA visit in September 2019, the QA team attempted to engage the laboratory in further annual data reviews. This proved very challenging as there was a lack of engagement from [REDACTED], which the QA team escalated. A partial review of 2018/19 data was undertaken, followed a year later by a review which documented findings from 2018/19 and 2019/20 together. The decision to wait for [REDACTED] to complete the data review resulted in a delay of a year, in a laboratory where there were already concerns. In reviewing data processes, PHA should consider how to continue with data reviews when the [REDACTED] is unavailable. **(recommendations 2 & 5)**

3.6 Clarity, urgency and follow up of recommendations

At the 2019 QA visit, the QA team noted performance concerns about an individual screener and that all reasonable attempts to improve performance had been made by the trust without success. A recommendation was made that the trust considered removing the individual from screening duties. It is not clear how much emphasis was put on this potentially significant issue at the QA visit itself and the language of the recommendation in the QA visit report could have been stronger, given the potential implications of the underperformance **(recommendation 2)**.

At the follow up review meeting in May 2020, the trust stated that the individual was performing satisfactorily and no action would be taken. It is not clear whether this recommendation was considered closed based on this information, or that evidence of improvement was seen. It is not clear whether the definition of the data being used was discussed or considered a factor in interpreting the performance data. **(recommendation 2)**

3.3 Performance against standards summary

Overall, it is clear that the QA team appropriately raised issues related to staff performance against national standards, unusual ways of working and data collection and that various recommendations for improvement were given. However, there is a continuous theme of concern on these topics which is not visible in the documents reviewed which concentrate on individual issues that have arisen at the time of each review.

There is the potential that as everyone was aware the data were not being calculated consistently across all four laboratories prior to and immediately following the issuing of the 2019 CMO letter, this led to an assumption that performance outside standards was more likely to be a data collection issue than real underperformance and so assurances from laboratories that everything was satisfactory were more likely to be accepted. **(recommendation 2)**.

There is evidence that it was agreed at the laboratory QA group that trend data of two years should be included in data reviews as well as several other additions, as quality improvements to the process but it is not clear if these have been implemented yet. Regular assessment of trend data, alongside tracking and documenting actions taken in respect of previous issues, is an important part of the QA process so that improvement, or otherwise can be identified, and followed up as necessary **(recommendation 2)**.

There is clear evidence of application of learning and process improvement by the PHA team with the development of the 2021 “annual data review guidance” document. Auditing regularly against this document or developing key performance indicator approaches to measuring compliance with key elements of this document, such as timeliness of issuing reports, and follow up of key issues, would be helpful.

4: To consider whether the team in the PHA had sufficient capacity and capability to effectively provide the QA functions for cervical screening

4.1 Capacity

Historically there have been two posts (1x band 8A and 1x band 7) for the cervical screening programme, with the band 7 covering both breast and bowel cancer. Between May 2015 and late 2023, there have been times when neither post has had someone in place, or they have been covered by temporary staff. In July 2019, the band 7 post was disbanded, with new programme specific roles created – at which point a new band 7 post was established that was fully dedicated to cervical screening.

In addition, there has been a long-standing band 5 cervical information officer [REDACTED]. This has subsequently been replaced by a band 6 cervical information officer [REDACTED]. Several changes in clinical leadership within the programme, together with long term sickness in the team, and vacancies has led to considerable difficulties in continuity and consistent oversight.

There are examples where staffing shortages have resulted in work being delayed, such as the issuing of QA reports, or data reports being produced.

Developing an effective QA framework requires more staffing resource than is currently in the team, given there are significant programme changes/additional new screening programmes on the horizon (not just in cervical). In addition to developing resilience and cross-cover opportunities across teams, a post dedicated to developing a QA improvement plan, incorporating implementing the recommendations in this report is required. Without this, there is a risk of inconsistency and follow-up of issues and concerns. It could be a time-limited post to establish the necessary arrangements. Based on the reviewer's experience, the resource needed routinely to audit QA practice against an agreed framework on a systematic basis should not be underestimated and should be a core part of substantive job roles. **(recommendation 3)**

4.2 Capability

The PHA QA approach to securing professional and clinical advice involves appointing an appropriately qualified professional lead for each area of the screening programme. There is evidence of a formal appointment process and training being given. Evidence reviewed suggests that the QA Leads, at times, make formal contact with trusts rather than the mechanism being through the PHA staff. This potentially reduces the oversight PHA has in relation to these activities. PHA should decide whether the scope of professional leads includes responsibility for identifying and following up issues directly with individual trusts, or whether their role is to advise PHA on issues and suggested actions. If the latter, the role description should be strengthened to make the scope of the role clearer. **(recommendation 5)**

The minutes of the QA laboratory meeting show that there is a reliance on each QA Lead to determine policy in areas of inconsistency or conflict. As there is only one professional lead per area, their ability to canvass opinions and consult is limited to the providers who are reporting the inconsistency or conflict. There is also a risk that providers may feel they are being asked to change practice to that operated in the QA Lead's service rather than being based on evidence or professional consensus. It is good practice to be able to canvass a range of opinions to inform QA work and widening the pool of QA advisors, including from outside NI, would provide greater support to the QA service. A minimum of three professional opinions from a specific area would be the ideal. **(recommendation 5)**