Summary Report on Issues Related to Northern Ireland Cervical Screening Programme (NICSP)

Professor Sir Frank Atherton

April 2026

1. Background

In late 2021, following the arrival of new clinical leadership for pathology and laboratory services in the Southern Health and Social Care Trust (SHSCT), an issue with performance of screening staff employed to deliver on the Trust's responsibilities within the Northern Ireland Cervical Screening Programme (NICSP) was identified. A report was prepared for the Trust's senior management team outlining a problem with screening performance potentially stretching back some years. In response to the issue the SHSCT and Public Health Agency (PHA) commissioned a number of reports in an attempt to assess the extent of any failures in delivery of the cervical screening programme, the possible impacts, and potential remedies. The aim of this summary report is to draw together findings of these disparate investigations, to summarise apparent failures in the NICSP and to outline what should be done to ensure the future safety and effectiveness of the service.

Although this summary report has been commissioned primarily as a desk review of the commissioned reports, I have taken the opportunity to discuss the issues which they raise with the current clinical and managerial leaders of the organisations responsible for policy, oversight and delivery of the NICSP. I have also been approached by a small number of women and families who have been failed by the programme and by the patient interest group known as "Ladies with Letters". I am grateful for my discussions with all these people.

The terms of reference for this work can be seen at appendix 1.

2. Consideration of Commissioned Reports

2.1 RCPATH Consulting Report (18.05.2023)

A team from the consulting arm of the Royal College of Pathologists (RCPATH) was tasked with an initial assessment of the situation with the specific purpose of making a risk assessment as to whether women whose slides had been screened by reporters who were deemed to be underperforming had a higher risk of false negative reports and thereby missed opportunities to treat any pre-cancerous changes. Noting that the PHA had (in August 2022) raised a concern about the quality of SHSCT performance data including the way in which screener sensitivity data was calculated, the RCPATH review was also expected to consider whether screener performance data and departmental performance management processes were appropriate.

The review identified a number of programmatic shortcomings including;

- A disproportionately high workload for screeners who were suspected of underperformance
- A heavy reliance on overtime as a consequence of lack of sufficient screeners in the programme
- Multiple screeners failing to meet national quality standards
- Inadequate management of potential screener underperformance
- Deviations between the SHSCT screening programme performance management and nationally recognised systems (specifically the adoption of a lower action target for all grade sensitivities)
- A failure of the SHSCT lab to meet the expected number of slide reviews compared with UK standards
- An unexplained reduction in the rate of high-grade anomalies between the years 2012/13 (1.6%) and 2021/22 (0.51%)
- A quality assurance system which was not systematically applied

While the review was unable to quantify the number of women who may have been at increased risk of having received a false negative result, it concluded that there was likely to be a significant number. The report made a number of recommendations but, based to some degree on questions of capacity in the national and broader UK programmes, it did not recommend a look-back clinical or slide review.

I have been asked to comment on the adequacy of the information requested, received, and considered by the RCPATH team in consideration of potential failings in the NISCSP. The RCPATH review was entirely based on document reviews and did not involve detailed discussions with individuals or groups who were responsible for delivering, managing, and assuring the quality of the systems in place. This may be regarded as a limitation in the commissioning of the report which would have benefitted from an investigative approach including such interactions. It is, however, clear that the RCPATH team did receive and consider a large number of documents as detailed in section 5 of their report. I have seen nothing to suggest that any requested data or documents were withheld.

Although the report noted and commented on variations (derogations) between the NICSP expectations and performance management standards/expectations within SHSCT, it did not address the issue of data comparability which had been identified by the PHA. Prior to finalisation of the RCPATH report a draft copy was circulated to allow for receipt of factual corrections. Some, but not all of the submitted comments appear to have been taken into account in the final report. However, the issue of data comparability was not addressed. RCPATH was asked to comment on the issue of

quality of data which had been raised by the PHA and the impact of the approach used by SHSCT on sensitivity calculations (specifically asking whether the method of calculation of sensitivity used could have overestimated or underestimated sensitivity). RCPATH did not address this question in the final report and it appears that neither PHA nor SHSCT took further action to follow up with the team other than logging the responses in internal documentation. It is not clear whether the RCPATH team was aware of programme variations between the screening pathway used in SHSCT trust and the nationally defined approach.

2.2 SHSCT Cervical Cytology Review - Activity and Outcomes Report (CCR 11.12.2024)

In response to the programme concerns which had been enhanced by the RCPATH report two further pieces of work were commissioned jointly by SHSCT and PHA. The first of these, the Cervical Cytology Review (CCR), reported the findings of a lookback exercise which was conducted in spite of the RCPATH conclusion that such an exercise would not be feasible due to capacity constraints across the UK cervical screening laboratories. The move towards primary Human Papillomavirus (HPV) testing in the Northern Ireland (NI) programme liberated screener capacity and facilitated a major re-screening exercise at NI laboratories outside SHSCT. The case review consisted of a look-back exercise on the slides of 17,425 women who had initially received a negative report on slides which had been first screened by one of 4 screeners who had been identified in the RCPATH report as having underperformed.

The methodology of the lookback exercise appears robust with a well-designed, implemented, and documented structure. A decision to undertake a review of this nature should not be, and was not, undertaken lightly as it inevitably raises levels of concern and anxiety in women and families whose slides are subject to re-examination. Although the CCR report details the efforts which were made to engage affected women in the review and to deal with issues sensitively and empathetically, it is clear from subsequent commentary and endorsed by my discussions that this was not entirely achieved.

The CCR recognised the challenges of inconsistent inter-observer assessments (whereby pathology staff can differ in their interpretation of slides particularly when abnormalities are rare, minor, or not clear cut) and ascertainment bias (where the knowledge that a slide is part of a look-back exercise can influence the interpretation). It found high rates (96%) of concordance between the original slide assessment and no cases of missed cervical cancer were identified through slide review or call forward smear tests.

In short, this well-designed look-back process exceeds the expectations laid out in the recommendations of the RCPATH review and gives reassurance that large numbers of false negative smear results have not slipped through the screening programme.

2.3 Cervical Cancers in the Southern Health and Social Care Trust Area (11.12.2024)

The second piece of work to be commissioned in light of the RCPATH report drew on cancer audit and registry data to look at the incidence of cervical cancer during the same period as that covered by the CCR (2009-2023) and make comparisons between rates in SHSCT area and those in other parts of NI

and England. This review found no statistical differences in cervical cancer incidence, stage of diagnosis, or mortality rate. It identified a number of cases (12) which would have met criteria for inclusion in the CCR and noted that all these cases had been reviewed as part of the Audit of Invasive Cervical Cancer with cases identified as having an "unsatisfactory" audit finding being subject to detailed SAI review.

This epidemiological work also provides a degree of reassurance that the overall programme was meeting its design aim of reducing cancer incidence and mortality but it should be recognised that only an egregious programmatic failure would lead to changes to the overall picture of cervical cancer in NI.

2.4 Independent expert opinion on findings of the Cervical Screening Review relating to the cervical cytology laboratory in the Southern Health Social Care Trust. (20.3.2025)

The PHA and SHSCT commissioned external experts to provide an assessment of these two previous reports (the CCR and the Epidemiological assessment). The Epidemiological work was assessed by a Consultant in Public Health Medicine while the CCR was reviewed by a Consultant Biomedical Scientist. The two external opinions were conducted separately with little overlap although the authors state that they met to discuss their respective sections and share findings.

The epidemiological review endorsed the reassuring finding that there is no clear epidemiological signal suggestive of a significant variation in the profile of cervical cancers between the SHSCT area and NI as a whole.

The external assessment of the CCR found the process to be robust and logical. It acknowledged the issue of ascertainment bias as a common finding in any review of slides during invasive cancer audits. The appointed expert identified a discordance between the finding of the RCPATH report (that screeners had not reached the required standards for a number of consecutive years) and the sensitivity results from the CCR. It noted that the process in the SHSCT laboratory was for two full screens to be undertaken on slides instead of the normal process which consists of an initial full screen followed by a much briefer rapid review. The reviewer postulated that it would be reasonable to expect that this process of undertaking two full screens would identify more false negatives and therefore would reduce the perceived sensitivity of the person undertaking the initial screen. Furthermore, he noted that the method of calculating screener sensitivity used in SHSCT was different from that used in other UK laboratories with the risk that this could also have resulted in an under-estimation of sensitivity levels for the screeners.

2.5 Independent Review of the Quality Assurance Arrangements for Cervical Screening in Northern Ireland (NHS England 16.6.2025)

External reviewers who were senior clinical leads in cervical cytology programme in NHS England were asked to provide a peer assessment of the current and historical functioning of the quality assurance (QA) system relating to the laboratory services within the NICSP. Although a main focus of this review was on future improvements to the QA function, it did also shed light on areas of significant past weaknesses.

The report highlights a relationship breakdown between staff working in the SHSCT laboratory ecosystem and the PHA leading to a lack of engagement between the two organisations. It also flagged the lack of specialist QA staff in the PHA between 2015 and 2023. Some other issues which were identified as requiring further attention were the timeliness of final QA report delivery, delays in the production of SHSCT action plans, and the lack of a clear process to document and follow up the improvements recommended by the QA visits. Although detail was not specified, the report noted several examples of Trusts operating out-with national cervical cytology guidance.

It further noted that while the NICSP generally operated within the guidance published by the English Cervical Screening Programme (NHSCSP) there was no clearly documented process or central repository of information which would allow providers to understand the relevance (or otherwise) of NHSCSP guidance to the NI programme. A lack of clarity over which elements of guidance were mandatory and which were optional had resulted in some variations in practice between laboratories. Section 3.2 of the report gives an example of this variation in practice whereby SHSCT laboratory sensitivity data were calculated (up to 2018/19) based on final report rather than rapid review opinion thereby making data outputs inconsistent with the measurement of the defined performance standards. Although this data inconsistency had been identified in the 2009 QA visit the report from that time simply noted that there were robust arrangements in the laboratory for performance management – a conclusion which appears contradictory. The report cites similarly inconsistent findings between the identification of concerns over staff performance and outcome reports in a further QA visit in 2014 and a data review in 2015. These clearly represent missed opportunities to correct problems and inconsistencies that had been identified in the cervical cytology programme.

In summary, the overall picture painted by this report is one of QA visits and data reviews identifying potential data comparability concerns and potential underperformance among screening staff but not following up either the data definition issues which could be a contributory factor or the management actions which were expected to follow from the recommendations on screener management. Insufficient capacity and inadequately developed processes in the QA system together with poor relationships between SHSCT and PHA contributed to these failures. SHSCT should have identified and better managed the poor relationships between their staff and the PHA and should have exercised greater urgency and diligence in delivering change against the recommendations in QA reports. The PHA should have been more pro-active in following up actions which stemmed from issues and recommendations in QA reports.

2.6 Summary Learning Report (November 2025)

This report consolidates the findings of 12 Serious Adverse Incident (SAI) reports which were conducted for patients who had been identified with cervical cancer between 2018 and 2024 and whose audit findings were classified as “inadequate”.

I have been asked to comment on the appropriateness and independence of the review panel. The report was produced by a team led by an external independent chair who is a retired senior nurse/manager with clinical and managerial experience in the UK and Canada. She has previously worked for a number of Trusts in Northern Ireland and also acted as interim Chief Executive for the PHA during the Covid-19 pandemic (approximately March 2020 to Sept 2021). The skills of the other members were in cervical cytology systems and in the conduct of serious adverse incidents (SAIs). The skill mix of the panel appears to be appropriate. Although it would perhaps have been ideal for the chair of the review team to have had no previous connections with any of the organisations under

scrutiny, the level of independence appears to be consistent with the anticipated arrangements for conducting SAIs in NI and the report reads as unbiased by previous professional affiliations.

The report summarises a slide review looking at 29 slides relating to previous screenings undertaken on behalf of the 12 women. It was noted that most of the cases of cancer (8/12) were adenocarcinomas and acknowledged that the cytology findings in these cases can prove difficult to interpret. Limitations due to ascertainment bias were again acknowledged and observer variation was seen with 5 of the slides for which the reviewers disagreed on their findings. The results of slide review are not very clearly laid out in the report but the discordance rate (between primary screen and SAI review) appears to be 14/19 slides.

The report concurred with the RCPATH findings that there had been persistent under-performance by a number of screeners but it is not clear whether this conclusion was made de novo from primary data or was taken as an assumption from the RCPATH analysis. Screener workload, working methods, and excessive use of overtime were identified as potential contributory factors in poor performance. It also recognised the issue of data non-comparability due to the inclusion of a full second screen (as recognised at the 2014 QA visit) and the confusion over whether screening sensitivity should be determined against rapid review or final report (it is notable that the authors report that the PHA directed laboratories in NI to calculate sensitivity according to rapid review). The report concluded that screeners who were under-performing were not properly managed but the extent to which these data issues may have skewed screener sensitivity was not discussed.

3. Discussion and Issues Identified

3.1 Screening Policy and Pathway

Northern Ireland has a relatively small population for which it delivers screening services. It receives advice from the UK National Screening Committee and it generally adopts screening policy and guidance produced by the NHS Cervical Screening Programme for England (NHSCSP). Some areas of deviation from English guidelines are inevitable given the size of the population served. For example, standards on the number of cervical cytology slides processed annually through laboratories were (and remain) unachievable and so this standard has not been adopted in NI. However, as noted in the peer review of the QA system, there has been a tendency in NI for individual trusts to make local decisions on the elements of policy and guidance which they adopt and to make changes to the management of cervical screening pathway.

SHSCT made a number of variations in the cervical screening pathway delivery and performance management. These are well documented in the various commissioned reports and include:

- The adoption of “action levels” which were lower than nationally sanctioned sensitivity targets
- The inclusion of non-standard steps in slide processing – specifically the replacement of the rapid review with a second full screen

These deviations from national expectations were undoubtably made with the best intent (for example the second full screen might be seen as identifying more women at risk of cancer) but they produced unintended consequences. In the case of the “action level” variation, screener performance was not as closely monitored as it should have been while the adoption of a second full screen altered the calculation of screener sensitivity data and undermined the performance management process.

The way in which the laboratory service itself was able to make these changes represents a clear governance and risk management failure in the Trust. There should have been a clearly defined process for making any programme alteration. Programme variations should have been proposed by clinical management, properly risk assessed in conjunction with the PHA, approved by the trust Senior Management Team, and reported through the Trust risk management system so that the Board had adequate oversight and assurance. None of this appears to have happened and it is a particularly significant failing for variations in process to have been made without consultation or technical input from the PHA which should have been engaged as soon as they were proposed.

3.2 Data Management and Interpretation

In my discussions with the various agencies and individuals involved in the cervical cytology programme in NI I encountered considerable confusion over an issue related to the technical management of data. This lack of clarity appears to extend to the NHS Cervical Screening Programme. The issue of contention relates to the way in which sensitivity calculations are made. Two approaches can be used; the initial screen result can be compared to either the rapid review finding or to the final report which is issued. The choice of denominator matters because the latter approach will result in a lower sensitivity than the former.

- Laboratory management in SHSCT is adamant that the final report is consistently used as the denominator

- The report entitled "Northern Ireland CSP - Cervical cytology primary screener sensitivity data 2008-2023" was prepared by the PHA and submitted to the Health Committee on 17 July 2025 and states that the sensitivity calculations are made against rapid review (although the tabular calculation mentions final review).
- English Guidance (CSP-S04) mirrors this internal inconsistency. While the descriptive text references rapid review, the associated tabular data formats utilize final review as the metric for sensitivity.
- In an effort to understand practice in other screening programmes SHSCT staff reached out to two providers (one in England and the other in Scotland) with both reporting the use of final review as the appropriate denominator.
- As previously noted, the independent review of the QA arrangements for cervical cytology in NI (Section 3.2) reported that SHSCT lab sensitivity data were calculated using final report instead of rapid review up to 2018/19 implying that the standard should be rapid review (and also implying that there may have been a change in process from final report to rapid review after that year).

In summary there appears to be a critical technical discrepancy in how cervical screening sensitivity is measured and reported across different jurisdictions and guidelines. This "ambivalence" in measurement standards—specifically whether sensitivity is calculated against rapid review or final review—has created significant uncertainty in evaluating individual screener performance. This is an issue which the PHA should further explore and clarify with colleagues in NHSCSP.

3.3 Management Failures

A consistent theme running through the various commissioned reports and recognised in my discussions is the lack of adequate management and governance oversight of the complicated and inter-related elements of the cervical screening programme.

SHSCT was responsible for operational delivery of a safe, effective cervical cytology screening process but it failed in this duty at a number of levels;

- The delayed transition from a cervical cancer screening service based on cervical cytology to primary HPV testing resulted in a fragile service which struggled to recruit and maintain screening staff. The risks that this posed to the screening population were not adequately documented or mitigated in the SHSCT risk management system.
- For a considerable period, the laboratory was understaffed, screeners were insufficient in number, and screeners were allowed/encouraged to perform significant amounts of overtime in order to alleviate backlogs in the screening system.
- At service delivery level an issue with screener performance was being identified but the limited steps taken to correct this were inadequate and not sufficiently monitored.
- At operational management level the laboratory leadership team was making decisions about screening service delivery which were inadequately considered and not properly discussed with either the PHA or SHSCT senior management.
- Internal quality controls in the laboratory were insufficiently developed; the setting of "action targets" on sensitivity data distracted attention from the need for more urgent inquiry and action related to potential issues of screener performance
- SHSCT senior management did not have processes in place which would have identified the risk in altering screening pathways or in under-performance of primary screeners.

- SHSCT Board was lacking in governance process which would have identified these levels of failure so allowing them to remain unchecked. There was inadequate Board oversight of the functioning of the cervical screening programme.

PHA was responsible for commissioning the delivery of cervical cytology programme by the NI Trusts and for quality assurance. There were a number of failures in its responsibilities;

- Although QA visits identified issues related to both data management and potential screener performance as early as 2009, the actions taken to explore and correct these issues were delayed or absent.
- PHA was aware of inconsistencies in data management but did not resolve the confusion over technical aspects such as the calculation of sensitivity data. The organisation should have been more proactive in addressing this issue; possibly by liaising more closely with programmes in the other UK nations to resolve this (seemingly ongoing) problem.
- PHA did not follow up robustly with SHSCT on actions which had been either recommended in QA visits or agreed in Trust management action plans.

Neither PHA nor SHSCT appear to have identified or taken appropriate action to address the issue of inter-personal relationship breakdowns which impinged on the QA process and hampered its effectiveness.

Department of Health is responsible for setting policy for the cervical NICSP and ensuring that resources are available to the various organisations so that they can deliver their designated functions.

- The 2009 reorganisation of the health system in NI created the PHA and the Strategic Planning and Performance Group (SPPG) with a consequent separation of commissioning and public health expertise which impacted on programmatic oversight. Although PHA held the commissioning function for screening services, expertise in commissioning migrated to SPPG leaving PHA with insufficient capacity to deliver on its assigned functions. It also led to a potential conflict of interest for the organisation as its responsibility for financial oversight could be seen to be at odds with the need to implement recommendations arising from QA visits.

3.4 Discrepancy between Reports (Underperformance vs Data Inconsistency)

A striking feature of the set of commissioned reports is the inconsistency in findings and conclusions. The RCPATH report concludes that a significant number of women may have been harmed as a consequence of screener underperformance leading to an increase of falsely negative smear results. The CCR report provides a reassuring picture as it did not find a major difference between the original slide results and the results obtained through slide review. In particular there were no cases of missed cervical cancer which were identified. The epidemiological picture which shows no difference between the SHSCT area and the rest of NI is similarly reassuring although this would not be a very sensitive way of identifying any problem arising from programme delivery. The expert review on these latter two documents raises the issue of data comparability and suggests that that the original RCPATH report may have exaggerated or over-estimated any underperformance issues. It is notable in this regard that, despite a clear steer to look at data inconsistency issues in both the initial brief and in feedback on its first draft, the RCPATH report makes no mention of data comparability as a possible

contributor to perceived underperformance. Finally, the SAI summary audit repeats the finding of the RCPATH report by reporting screener underperformance. However, this conclusion appears to have been drawn from the RCPATH report itself rather than arising from primary investigation or conclusions drawn from the independent audit process.

3.5 Limitations within Screening Programmes

Screening programmes such as the NICSP are not diagnostic programmes. Inherent in their design is an understanding that they will not detect all cases of a disease or all conditions which will lead to disease in the future. The generally accepted sensitivity of cytology based cervical cancer screening programmes is 70-80% which means that the programme will fail to detect around a quarter of the screened women who will go on to develop cancer. These false negatives in the programme can arise from poor sampling technique, slide preparation and storage, technical difficulties in interpreting the slides, difficulties in identifying changes due to unusual forms of cancer (for example adenocarcinomas), and errors by reporting staff. Additionally, inter-reporter inconsistency in smear interpretation is commonly recognised whereby two or more experienced staff can review the same slide and come to different conclusions as to whether it is normal.

This difference between a screening programme and diagnostic testing comes into starkest relief when considering individual false negative reports such as those identified through the audit of women who have developed cervical cancer. In these cases, it is impossible to distinguish between a false negative which may have arisen from the inherent design limitations of the screening programme and one which could have resulted from screener underperformance. A specific case of cancer cannot be attributed to the failure of a particular screening outcome. All that can be concluded is that the likelihood of a false negative result has been increased by the fact that programme sensitivity has been reduced. I am not aware of any way in which this increased likelihood can be quantified and it is clear that the RCPATH team were equally unable to address this issue. The best that can be said in the present case is that the reassurance provided by the CCR makes it less likely that any increased risk was a large one.

4. Conclusions

4.1 What problems have been identified?

Available data (as reviewed in the RCPATH report) were judged to show significant underperformance of a number of primary screeners over several years. The data on which this assessment was made are flawed; the method of sensitivity calculations was inconsistent and the SHSCT laboratory had made changes to the cervical screening pathway. Both of these factors could have artificially lowered the sensitivity data for the primary screeners and the SHSCT laboratory as a whole. It is impossible to say whether this data inconsistency accounts for the whole of the perceived underperformance. The RCPATH report did not take account of data inconsistency despite requests to do so.

The RCPATH report concluded that a significant number of women were likely to have had negative screening results on tests which would have been identified as abnormal in other UK screening laboratories). Despite the RCPATH report expressed scepticism about the ability to deliver a review of previous cytology results, SHSCT together with the PHA did design and conduct such an exercise (the CCR) together with an analysis of the epidemiology of cervical cancer in NI. The results of these two reports have been externally reviewed and judged to give a fair assurance that widespread harm did not result.

The Summary Learning Report on SAIs identified a number of instances where slides which were initially reported as normal showed abnormalities on follow up review. Such findings reflect the inherent parameters of a screening programme and could be expected in any audit of cervical cancer cases. If the data consistency issue is put to one side and the RCPATH report is taken at face value as showing underperformance it would still be impossible for any individually discordant result to be attributed to either underperformance or the underlying false negative rate which is built into the programme parameters.

On the basis of these reports it is impossible to say either that harm has occurred to some women or that there has been no harm to any. However, the work undertaken by the SHSCT and PHA to look back at previous slides makes it unlikely that large numbers of women have been adversely affected and come to harm.

4.2 Where does responsibility for any failings lie?

There have been clear management and governance failings within SHSCT and the PHA as outlined in the previous section (see section 3.3). A difficult question remains as to individual as opposed to corporate responsibility and accountability. It is important to document that in none of my discussions or any of the commissioned reports was there any indication of malign intent…no individual or organisation set out to deliberately cause harm or to provide a poor service.

Any underperformance by the screeners within the SHSCT should have been properly identified and corrected. That this did not happen is a recurrent theme in the documents I have reviewed and in the discussions with programme managers and leaders. Some sanctions are already in place; I understand that individual screeners who are deemed to have underperformed have been removed from the programme and either left the NHS service or been reassigned to other duties. However, within the context of a screening programme I believe that it would be inappropriate to seek further sanction against individual screeners. Although the SAI process identified screeners whose misreading of slides may have contributed to delays in women receiving prompt investigation or treatment, I also note that it found cases where consultant pathologists had incorrectly downgraded positive slide results

which primary screeners had reported as abnormal. Furthermore, there were cases where the use of reflex (triage) HPV testing on some slides identified as having “borderline” abnormalities led to false reassurance with the affected women being returned to the routine recall system. The use of reflex HPV testing in this way was consistent with NI and NHSCSP policy and practice extant at the time.

The finding of discordant results (false negatives) is not unique to NI or to SHSCT. Any cervical cancer programme in the UK or globally would be subject to this; it is an inherent feature of screening programmes that false negative results will occur and some of these will be attributable to human error. The SAI process is neither intended nor designed as a way of apportioning blame or individual accountability; it is a process through which lessons can be learned so that the screening process and outcome can be improved.

The failures of different layers of management are clearly laid out in the various commissioned reports and are summarised in the issues section of this report. As with many NHS and governmental organisations there has been a high level of turnover of management staff and board membership in the time since concerns about the cervical screening service delivery first surfaced.

4.3 Have failings been addressed and is the future programme safe?

The move which has been made to primary HPV testing for cervical cancer programme in NI obviates much but not all risk from the system. The cytology element of the service is now concentrated on one site in the Belfast Health and Social Care Trust. It will be important that the reconfigured service is adequately staffed and that it adheres closely to expected standards in both internal quality control and external quality assurance. With regards to the internal quality standards (including the contested practice and definitions on sensitivity measurement and reporting) it will be important for the PHA to clarify the expectations – this may require further discussion with NHSCSP. For the purpose of quality assurance of the laboratory aspects of the NICSP there is now a one-on-one relationship between the PHA and the Belfast Health and Social Care Trust. This potentially limits learning across the programme as there will be no comparators within NI. Unless NI decides at some future point to contract out the QA function to another part of the UK it is advisable to seek external input to QA visits and data reviews. I understand that colleagues in Scotland have been approached in this regard but arrangements should be clearly formalised and approved through the Cervical Screening Oversight and Assurance Group (CSOAG).

As with any complex health system there will remain the possibility of problems arising in non-laboratory aspects of the NICSP such as procurement, primary smear taking, transport of specimens etc. For effective future governance there is a need for close collaboration between SPPG and PHA to ensure that all elements of the programme are properly monitored, that issues are identified and addressed at an early stage. If not already addressed, I would recommend the production of a joint annual report on the delivery of the NICSP with effective oversight/reporting through both the Belfast Trust Board and the CSOAG.

4.4 Considerations regarding a Possible Statutory Inquiry

I have been asked to comment on whether a statutory public inquiry might provide additional significant assessment to the findings that have been made (as described in the commissioned reports and summarised in this paper), to questions of responsibility, and to the future safety of the programme.

In my discussions with impacted women and their partners I heard a very clear message that, in their opinion, a public inquiry is required to assign accountability and to ensure that individuals and

organisations are obliged to give truthful account of actions/failures. I understand these concerns as reflecting a desire for both closure and certainty. I also heard anxieties (largely from officials) that a public inquiry would be time consuming, risk re-traumatisation, further delay resolution, involve significant expense, and potentially fail to deliver any greater clarity on the nature and extent of programme failures which are documented in the commissioned reports and summarised here.

I believe that it is highly unlikely that a statutory inquiry would be able to make further progress on unravelling the technical aspects of the programme failure which I have summarised. The inconsistencies in both programme delivery and data management which are described in the commissioned reports militate against any further clarity being shed on the questions of the degree to which the cervical screening programme may have failed women or on the quantification of any impact.

A statutory inquiry would, by its nature, give a greater degree of assurance on matters related to full disclosure and truthfulness of testimony by individuals and organisations. All I can say on this matter is that the authors of the commissioned reports appear to have received all the documents and data which they requested and that I did not encounter any reluctance to provide information or explanation during my inquiries (although I recognise that my discussions were with current rather than former incumbents of key leadership roles).

With regard to the role of a statutory inquiry in assigning accountability, it should be clear from this summary report that there have been significant failures in management and governance by the organisations which were responsible for delivery and oversight of the cervical screening programme. These failures have been recognised by those organisations and the challenge for them is to ensure that the many recommendations which have been made in the individual commissioned reports are implemented without delay. The production of a consolidated action plan is helpful in this regard and delivery against this should be closely monitored through the SPPG and the CSOAG. A statutory inquiry might attempt to assign accountability against individuals either in the front-line delivery or management of cervical screening services. In my view this would be inappropriate as to do so would encounter the difficulty outlined above of distinguishing between the inherent features of a screening programme (which, even when operating under optimal circumstances, will never be able to identify all cases of future disease) and a diagnostic programme (which is expected to give a more definitive conclusion).

4.5 Governance and Oversight Issues

Separately from my terms of reference I have been asked to reflect on the governance arrangements for the NICSP (and potentially for cancer screening programmes more generally). A number of issues have surfaced during my consideration of the issues in the NICSP which may have relevance to this question and which merit consideration by the organisations responsible for programme policy, implementation, and monitoring.

- The relationship between laboratory quality control (QC) and external quality assurance (QA) is not clearly defined. It should be specified that the former is the responsibility of the delivery organisation (generally the Health and Social Care Trusts in NI) while the PHA discharges the QA function. If this clarity had been achieved it would have been apparent to all parties that SHSCT was responsible for performance monitoring and management of screening staff while the PHA remit was focussed on the performance of the system (including laboratory performance) as a whole.

- The accountability and performance management of senior clinical staff also need to be properly formalised. Consultant pathology staff are employed by SHSCT but it is not clear whether the oversight of their performance (with regard to the cervical screening programme) is managed through the Trust or the PHA.
- PHA is responsible for both the commissioning and the quality assurance of the screening programmes. An alternative might be for these two very distinct functions to be more formally separated. SPPG is responsible for commissioning the bulk of health and social care services in NI and consideration could be given as to whether it would be a more appropriate body to deliver this function with regard to screening programmes.
- The DOH led CSOAG which was created in response to the need for a stronger management response to the recent concerns in the NICSP appears to have functioned well. However, it may be more appropriate in future for DOH to establish a central structure such as a Screening Board to provide high level oversight across all the cancer screening programmes which currently operate in NI. Such a body could devolve operational oversight and assurance of the individual programmes jointly to PHA and SPPG.

APPENDIX 1

Terms of Reference

As a result of concerns raised in July 2022, the Southern Health and Social Care Trust (SHSCT) commissioned the Royal College of Pathologists to undertake an independent assessment of its cervical screening services from 1 January 2008 to October 2021. The RC Path report was published in October 2023. As a consequence of the RC Path report, a precautionary review of 17,425 women, known as the Cervical Cytology Review (CCR), was undertaken and two factual reports were published in December 2024.

An independent expert opinion on the findings of the Cervical Cytology Review was then commissioned to assess if the intended objectives of the CCR were met. The SHSCT also undertook a Serious Adverse Incident (SAI) learning review of the cases of twelve women, who developed cervical cancer and where the audit of their cases found significant issues or areas for further review or investigation. To help support learning and additional analysis of the wider cervical screening system, the Public Health Agency commissioned NHS England to undertake a Peer Review of their Quality Assurance arrangements and activities relating to laboratories within the NI Cervical Screening Programme.

The above reports were published in November 2025 and the Health Minister agreed to the appointment of an independent expert to conduct a review of all the work completed to date and advise if there are any gaps or areas that need to be explored further. This will primarily be a desk review of existing documentation with some additional information obtained during meetings with relevant individuals/organisations.

<u>Objectives</u>

The Independent Expert will review all of the work undertaken in relation to cervical cytology services in the SHSCT during the period 2008 to 2021 (a list of reports and information published to date is at Appendix 1), and will provide an opinion to Minister as to whether sufficient clarity has been obtained regarding the following:

1. To assess whether collectively the information and data answer the key questions that would be addressed by a Statutory Public Inquiry i.e.
    I. What findings have been identified?
    II. What led to any findings and where does responsibility lie? And
    III. Are the reports received to date and changes made to the cervical screening programme adequate to prevent this happening again.

2. To look at the questions submitted by RC Path and consider if the information provided by the SHSCT, and other HSC organisations as relevant, was adequate.

3. In the context of the Level 3 SAI Learning Review (involving 12 patients / service users) commissioned by SHSCT, consider the appropriateness of the review panel engaged to undertake this learning review with particular reference to the independence of the chair and panel members.

4. To liaise with and bear in mind the concerns of the group Ladies with Letters and others affected by failures in the SHSCT cytology service

5. To advise Minister whether/if a statutory public inquiry may provide additional significant assessment to the questions noted at para 1 above.

Methodology

6. This will be a matter for the Independent Expert to determine. The Independent Expert may request additional and further information as he deems necessary to complete his work.

7. The Independent Expert may make recommendations for further actions / improvements, including a statutory public inquiry, if it is deemed that these are required.

Timescale

8. The Independent Expert Opinion will be completed by April 2026.

Appendix 2

Acronyms and Abbreviations

CCR	Cervical Cytology Review
CSOAG	Cervical Screening Oversight and Assurance Group
DoH	Department of Health
HPV	Human Papillomavirus
NI	Northern Ireland
NHSCSP	NHS Cervical Screening Programme
NICSP	Northern Ireland Cervical Screening Programme
PHA	Public Health Agency
QA	Quality Assurance
RCPATH	Royal College of Pathologists
SHSCT	Southern Health and Social Care Trust
SPPG	Strategic Planning and Performance Group