

Scoping Inquiry into the CervicalCheck Screening Programme

Dr Gabriel Scally

**Supplementary Report
June 2019**

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Foreword

Dear Minister

In September 2018, when I presented my main report on the serious problems surrounding the cervical screening service in Ireland, I made it clear that there were matters in respect of the tendering, contracting and operation of laboratory services that I felt needed further exploration. You asked me to undertake further work in these areas, and in this supplementary report I document the following:

- The number of laboratories involved in CervicalCheck work was not six, as I was informed when I commenced the Scoping Inquiry in May 2018; nor was it 11, as I reported in the Scoping Inquiry Final Report in September 2018. The final total is in fact 16 (two in Ireland, two in the UK, and 12 in the US);
- The use of many of these laboratories for CervicalCheck screening was not approved in advance by the HSE/National Screening Service, as was required under the various contracts, nor was their use known to the HSE/National Screening Service;
- A laboratory used for CervicalCheck screening in Greater Manchester, UK, was *retrospectively* accredited for periods of time during which its existence was unknown to the Irish National Accreditation Board;
- Notwithstanding these concerns, we have not identified any evidence that the laboratory services used in the past, or those currently in use by CervicalCheck, have provided, or are providing, a service which does not meet acceptable standards in their country of operation;
- The two major accreditation standards applicable in different countries appear to be comparable and do not create any cause for concern in terms of the quality of laboratory services provided;
- The system in place in Ireland for responding to errors in screening is inadequate to the task.

In my many valuable conversations with women and families affected by the problems in CervicalCheck, laboratory services have been raised frequently as an issue about which they are concerned. I have taken those concerns into account in preparing this report and I include in this foreword a number of the many pertinent comments that they have made to me. The greatest concern is of course that we have a safe, efficient and effective screening service.

'I don't mind it if was 40 labs as long as they were adhering to the protocols and being checked'

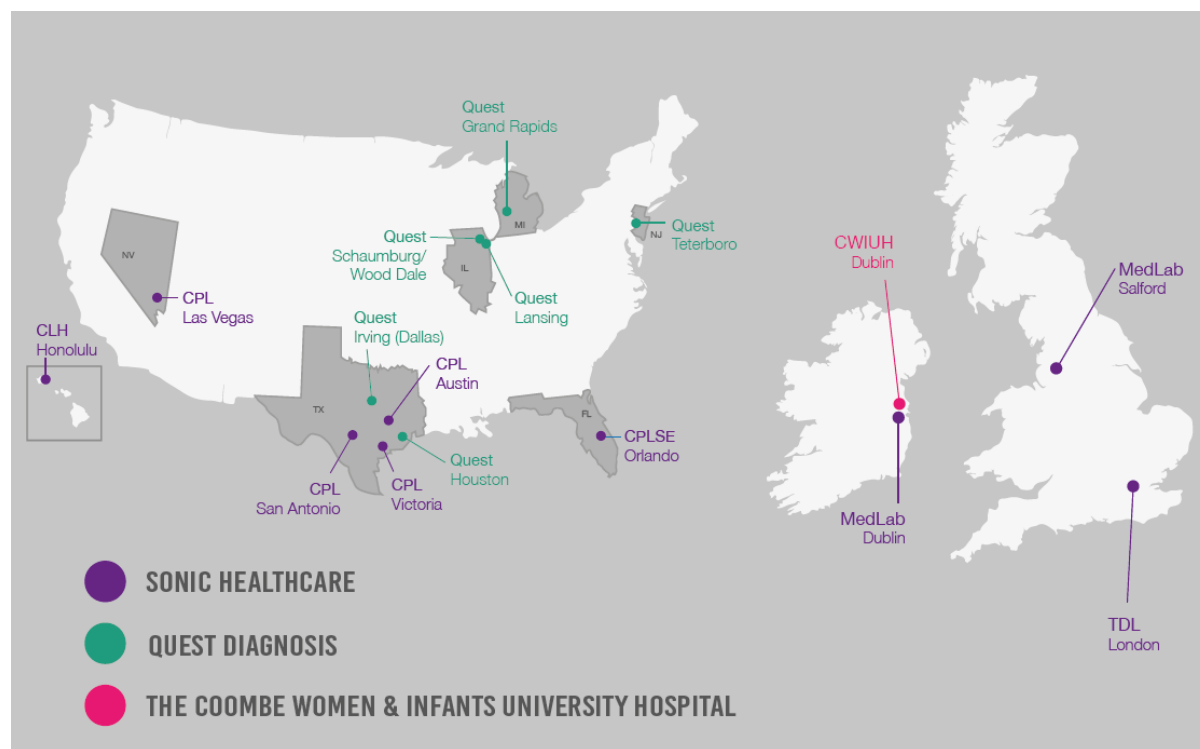
(One of the women affected)

The above quotation summarises a dominant concern for the women whose slides were being analysed. In that context, it should be noted that, despite the number of laboratories in use at various times, the Inquiry team did not, in the course of its work, uncover any

evidence to suggest deficiencies in screening quality at any laboratory. This view must, however, be understood in a context where many of the laboratories that have been involved in screening Irish slides either no longer exist or no longer perform cytology. Further, all but one laboratory had the appropriate accreditation at the time they were providing screening services to the HSE. The exception was a laboratory located at Salford in Greater Manchester, the circumstances of which are described in detail hereafter.

The science on which cervical screening is based, and upon which it has been dependent since its introduction, is cytology. The quality of this laboratory based activity is crucial to ensuring that a cervical screening programme is effective in detecting signs, sometimes very early signs, of cervical cancer. It therefore follows that the utmost attention should be given, by all involved, to ensuring laboratory services are efficiently and effectively provided.

In the early stages of the work of the Scoping Inquiry, which commenced in May 2018, I learnt that there were six laboratories that either were involved, or had been involved, in examining the slides of Irish women participating in CervicalCheck. By the time I was ready to deliver the main Scoping Inquiry report in September, this number had grown to 11. At the time of completing this supplementary report, the number of laboratories known to have been used has grown to 16. The locations of these 16 laboratories, which are widely distributed geographically, are illustrated below.



In addition to the laboratories listed in the September report, the Scoping Inquiry became aware, in January 2019, of Irish slides having been screened in four laboratories that are part of the Quest Diagnostics company. These laboratories are based in Grand Rapids, Michigan; Lansing, Illinois; Houston, Texas; and Irving (Dallas), Texas. The four laboratories were used to screen Irish slides at different points in the period from 2009 to 2010. The fifth

additional laboratory of which we have become aware, and the only one where screening of Irish slides continues to take place, is a small-scale ancillary facility to the MedLab Pathology laboratory in Dublin (owned by Sonic Healthcare) and is located in a section of another laboratory building in Salford, Greater Manchester, England. This ancillary laboratory facility has been in use since February 2016.

'Every time one of those bits of information about the labs comes out, it erodes trust further and makes you lose hope'

(One of the women affected)

It is profoundly disappointing that the Scoping Inquiry only learnt about the additional laboratories as a result of our extensive and intensive probing. There has been very limited evidence made available to the Scoping Inquiry to show that CervicalCheck was ever consulted actively and in writing about the potential or actual use of the 10 additional laboratories. There is evidence that the planned use of additional laboratories was raised during a meeting between one of the laboratory companies and CervicalCheck in 2009. Although no contemporary notes of that meeting are available, an email from CervicalCheck to the company in the following week made it very clear that bringing in additional laboratories, *'would introduce a level of risk that we are not willing to accept'*. An attachment to a document provided to CervicalCheck prior to that meeting reveals that two of the additional laboratories were already in use.

In respect of one of the laboratories, it has been suggested to the Scoping Inquiry that because, in the case of slides screened in the U.S., the laboratory where the slide was examined is named on the result notification, then CervicalCheck would have known that other laboratories were being used. However, at that time, the results went directly to the GP or other professional responsible for conducting the test, not to CervicalCheck.

It is entirely reasonable to have expected CervicalCheck's quality assurance activity to have prevented, or at least detected the use of additional laboratories. However, as was noted in the Final Report of Scoping Inquiry in September 2018, and repeated below, the quality assurance (QA) carried out by CervicalCheck was inadequate.

'The Scoping Inquiry believes that the early rounds of QA visits were limited in their governance, design and effectiveness. Opportunities were missed to develop the QA process, and the absence of a further QA visit to all reporting sites by 2017 has resulted in a failure to assure aspects of quality of provision.'

The revelation in this report of the use of further laboratories reaffirms and reinforces this opinion.

As stated later in the report, I find the circumstances surrounding the screening of Irish women's slides in Salford particularly surprising, and disturbing, in terms of the level of governance expected in a public health programme. The issues raised again emphasise the importance of creating effective quality assurance processes within the CervicalCheck programme.

The relative merits of the two different schemes by which the laboratories were accredited emerged as an important issue in the Final Report of the Scoping Inquiry in September 2018. **In summary, there are advantages to both schemes and, on the basis of the expert advice available to the Scoping Inquiry, the overall assessment is that there are no differences that might have a significant impact on the quality of the final reports on cytology.** This view should not, in any way, be taken to invalidate or repudiate decisions made by CervicalCheck to specify ISO accreditation in tender and contract documentation.

In this supplementary report I also look at the use of additional laboratories from the perspective of the tendering and contracting processes. It is my view, based on the documentation and expert opinion available to the Scoping Inquiry, that the tendering process appeared to move over time to place an increasing emphasis on price rather than quality. Similarly, and on the same basis, it is my view that the use of additional laboratories, without express authorisation, lay outside the bounds of the contracts and, in keeping with the view expressed at one point by NCSS, that the introduction of additional laboratories with no previous experience of CervicalCheck did introduce a potential risk.

The lack of transparency by the major private sector laboratory companies about the precise locations of their screening services provided to CervicalCheck, and therefore to Irish women, is entirely unsatisfactory. The reasons for requiring prior written permission to use additional laboratories were to ensure accreditation and quality of service, to enable CervicalCheck to monitor and gauge risks, and to maintain overall transparency within the screening programme. I understand that the companies wished to provide a laboratory service that met their contracted requirements on turnaround times for slides and also to avoid the financial penalties that accompanied failure to meet targets. But there can be no excuse for their failure to obtain written permission from CervicalCheck in advance of their use of additional laboratories to screen the slides of Irish women. In some cases, the companies hold that they informed CervicalCheck orally about additional laboratories being used, but, according to the information available to the Scoping Inquiry, there is no record anywhere, and no recall in CervicalCheck, of that having happened. In the one case where there is a written exchange about such additional laboratories being used, the response from NCSS was to advise that it was not prepared to take the risk of using other laboratories.

It is worth reiterating here that, on the basis of the information available to the Scoping Inquiry, the use of these additional laboratories did not in fact result in a reduction in the quality of the screening provided to Irish women and it is important to acknowledge this. Nonetheless, the failure to recognise the reasons (set out above) for the contractual provisions requiring prior written notification of any change in the location of the provision of this service remains a matter of concern.

Neither is it acceptable that the laboratories did not inform the Scoping Inquiry of all locations used at the first possible opportunity. This has served to impede and delay the work of the Scoping Inquiry at a time when, quite rightly, women and families affected want to know the full picture of where the slides of Irish women went.

I know, only too well, that this supplementary report on aspects of tendering, contracting, provision and accreditation of laboratory services to CervicalCheck will both help to reassure Irish women in terms of the high standard of the laboratory work undertaken, but also make unsettling reading due to the failure to implement, perhaps even to recognise, important governance and transparency measures in the past. It is a shame that new and unwelcome information is being made public at this late stage.

'The only way we can ever fix anything, is by highlighting the failures of the past and fixing them'
(One of the women affected)

In my main report, published in September 2018, I made 50 recommendations which were aimed at restoring public confidence in, as well as renewing, the cervical screening programme for Irish women. Those recommendations were comprehensive and remain valid. I see no pressing need to add substantially to the list of recommendations as a result of what is contained in this report, but I do make two further recommendations (see section titled Recommendations) that I now believe to be necessary.

The supplementary investigations carried out by the Scoping Inquiry in respect of laboratory services have, for the most part, concerned laboratories that carried out CervicalCheck work some years ago. **On the basis of the information available to the Scoping Inquiry, we have not identified any evidence that the laboratory services used in the past, or those currently in use by CervicalCheck, have provided, or are providing, a service which does not meet acceptable standards in their country. Further, the differing accreditation standards applicable in different countries appear to the Inquiry to be comparable and do not create any cause for concern in terms of the quality of laboratory services provided.**

As was noted in the Final Report of this Inquiry, it remains impossible to reliably compare clinical effectiveness between providers. The detailed examination of slides being carried out for the Department of Health by the Royal College of Obstetrics and Gynaecology may provide further insights in due course.

In recent weeks, much public attention has been paid to the future of screening programmes in Ireland. The great benefit obtained by screening should not be put at risk because of the absence of satisfactory mechanisms for responding to the thankfully rare occasions when, through error, harm results. In my view, there is a crying need for a change of approach and I address this briefly in this report.

I am pleased to have been asked to continue reviewing the implementation of my recommendations. There has been substantial and important progress in implementation. Indicators of good progress include the appointment of patient advocates to the reconstituted Board of the HSE and of public health medicine and pathology professionals to key positions in the screening services. Whilst there is, of course, more to be done, the rate of implementation and the steps taken so far, particularly by the HSE, have impressed me. It

is, of course, too early in the change process to make a judgement on the overall improved effectiveness of the screening system.

In the Final Report published in September 2018, I suggested that the women and relatives affected should play a prominent role in oversight of the change process. I am very pleased that they are represented on the CervicalCheck Steering Committee of the Department of Health. It is very clear that in the process of developing policies, plans, and initiatives in the health field, the earlier patient advocates are involved, the higher the likelihood of success.

I would, again, like to thank all the members of the Scoping Inquiry team. Their skill, commitment and tenacity have been well deployed in getting to the facts laid out in this and the previous reports.

Yours sincerely,

Gabriel Scally

Important Notice

When reading this supplementary report, it is important to bear the following in mind:

- 1. This is a Scoping Inquiry and not a Commission of Investigation.**
- 2. This supplementary report should be read in conjunction with the Final Report of the Scoping Inquiry, which was published in September 2018.**
- 3. Information on which any conclusions or views are based is confined of necessity to the information that was furnished to the Scoping Inquiry. It has not been possible to offer each person or body who is named or referred to in the report an opportunity to comment on the report, or to canvass and represent views of all parties on every issue therein or on opinions expressed by other parties who met with the Scoping Inquiry. Those who were given a preview of the preliminary analysis and permitted to make submissions on the conclusions reached in this report, insofar as it might affect them directly, include the following bodies: Quest Diagnostics Incorporated, Sonic Healthcare, the Health Service Executive, and the Irish National Accreditation Board.**

The Inquiry team is grateful to each such body for reverting to the team within the strict timeline adopted, of necessity, by the Scoping Inquiry.

- 4. All views expressed within the report are subject to the caveat that persons or bodies affected have not been given the opportunity to cross-examine or test the sources of information made available to the Scoping Inquiry, and the information, and hence the conclusions and views expressed as a result of the information, must therefore be treated with a certain degree of caution.**

Glossary

Organisations

CervicalCheck	The national cervical cancer screening programme
CWUIH	Coombe Women & Infants University Hospital
HIQA	Health Information and Quality Authority
HSE	Health Service Executive
INAB	Irish National Accreditation Board
ISCCP	Irish Society for Colposcopy and Cervical Pathology
NCCP	National Cancer Control Programme
NCRI	National Cancer Registry Ireland
NCSS ¹	National Cancer Screening Service
NCSSB ¹	National Cancer Screening Services Board
NOCA	National Office of Clinical Audit
NSS ¹	National Screening Service
RCOG	Royal College of Obstetricians and Gynaecologists
SCA	State Claims Agency

Medical Terms

Asymptomatic	Where a disease is present but the patient has no symptoms
CIN	Cervical intra-epithelial neoplasia
Colposcopy	A detailed examination of the cervix using a colposcope
Cytology	The microscopic examination of cells
Cytopathology	The diagnostic technique that examines cells to determine the cause or nature of the disease
False negative	Samples where the test is originally reported as negative but on review abnormal cells are found
False positive	Samples where the test is reported as abnormal but the disease is not present
Histology	The study of the microscopic structure of tissues
HPV	Human papillomavirus, which can cause cervical and other cancers
Interval cancer	A cancer that is diagnosed clinically in the interval between screening tests

¹ The organisation now known as the National Screening Service (NSS) has previously been called the National Cancer Screening Services Board (NCSSB) and the National Cancer Screening Service (NCSS) at different times since its establishment, as set out in more detail in Section 5. Throughout this document, references may variously be made to the different names of this entity depending on the period of time being referred to within the text in question.

TBS	The Bethesda System: a system of classification of cervical cytology abnormalities
TIS	ThinPrep Imaging System – a computer assisted microscopy system for identifying abnormal cells on cervical cytology slides
True negative	Samples which genuinely have no abnormal cells on them, despite the presence of disease
True positive	Samples where genuine disease is detected

Other Terminology

FL	State of Florida, USA
Framework contract	A procurement process whereby a number of suppliers compete for inclusion in a restricted list, whose members will then be invited to tender for specific contracts via ‘mini-competitions’
GA	State of Georgia, USA
HI	State of Hawaii, USA
IL	State of Illinois, USA
ISO 15189	International standard in respect of quality and competence requirements particular to medical laboratories
ISO 9001	International standard in respect of quality management systems
KPIs	Key Performance Indicators
MI	State of Michigan, USA
MoU	Memorandum of Understanding
NHS	National Health Service (Britain)
NJ	State of New Jersey, USA
NV	State of Nevada, USA
NY	State of New York, USA
PA	State of Pennsylvania, USA
PQQ	Pre-Qualification Questionnaire
QA	Quality Assurance
RFP	Request for Proposals
SOP	Standard Operating Procedure
TX	State of Texas, USA

1 Introduction

1.1 Terms of Reference

Further to the issues reported on by the Scoping Inquiry, I was requested by the Minister for Health to:

- A. Examine further the facts and details of:
 - i) The additional laboratories involved in CervicalCheck work which came to light during the work of the Scoping Inquiry – their nature, ownership, extent of activity, quality and accreditation arrangements, governance structures, and other relevant matters;
 - ii) The circumstances which led to these laboratories undertaking work for CervicalCheck;
 - iii) The extent to which CervicalCheck / the NSS / the HSE were aware of, and approved, workload being transferred to other sites;
 - iv) The effectiveness and operation of procurement and contracting of laboratory-based cervical cytology services;
 - v) The use of Schedule 13 of the 2010 contract under the heading ‘Storage and Disaster Recovery Plan’;
 - vi) The respective and comparative merits and limitations of the standards achieved by each of the laboratories, and whether there is equivalence between the standards reached and ISO 15189;
 - vii) The intent and understanding of parties to the laboratory contracts in respect of ISO 15189.
- B. Incorporate further relevant elements if identified during the course of the supplementary analysis.
- C. Consider the implications of the above issues for quality and safety.
- D. Report to the Minister for Health on the matters above and making recommendations to address the issues arising.

1.2 Purpose of This Report

The purpose of this report is to provide supplementary information on issues surrounding the provision of laboratory services to CervicalCheck.

2 Arrangements for the Supplementary Work

2.1 Advisors

2.1.1 Overview

In order to undertake the Inquiry, a number of advisors have been appointed to assist in the work programme and to carry out specific tasks relating to their professional expertise. A brief outline of their role and declarations of interest is provided here. Further information is available on the Inquiry website.

2.1.2 *Dr Karin Denton*

Dr Denton provided advice, as requested, on screening quality assurance. Dr Denton is a Consultant Cytopathologist at North Bristol NHS Trust and has had substantial involvement in the quality assurance of cervical screening programmes at a senior level in England.

2.1.3 *Mr Allan Wilson*

Mr Wilson provided a comparison of accreditation schemes for laboratories used by the CervicalCheck Screening Programme. Mr Wilson is Lead Biomedical Scientist in Cellular Pathology, Monklands Hospital, Scotland and has substantial experience in cytology and accreditation.

2.1.4 *Ms Mary Rose Gearty, S.C. and Ms Emer Woodfull, B.L.*

Ms Gearty and **Ms Woodfull** provided invaluable legal and practical advice at the outset and throughout this Scoping Inquiry as to its remit, its priorities, and the powers and limitations of my role. They have been influential in shaping my approach to this work. Both have extensive legal experience but in particular in the field of investigative and quasi-judicial tasks and the relevant principles of law which apply to such work.

2.2 Support to the Inquiry

2.2.1 *Crowe*

Crowe is a professional advisory firm based in Dublin and part of the Crowe global network. They are providing logistical, project management, investigative and analytical support to this Inquiry. Crowe are providing office and meeting space together with administrative support for the Inquiry.

3 Screening Programmes and Error

The Final Report of the Scoping Inquiry explained some of the key aspects of screening programmes. Given current discussion about the future of screening programmes, it is worth noting some of the distinctive features of screening programmes that differentiate them from the usual clinical care situation where an individual patient seeks care for an ailment.

Firstly, they are universal programmes with clear protocols and are aimed at detecting the very early markers of disease in people who have no symptoms. The ideal is to reach 100% of the target population with the programme. **Secondly**, it is aimed at tackling a specific disease for which there is a viable screening test. **Thirdly**, the state, via its agencies, makes the decisions about how the programme should be run and reaches out to the public with the offer of screening. **Fourthly**, these programmes can cause some harm as well as provide great benefits to individuals, so the more the benefit outweighs the harm the more successful the programme will be. **Fifthly**, screening programmes are generally managed, quality assured and evaluated to a much higher degree than normal clinical services – in order to ensure benefit for the individual is maximised and harm minimised.

The issue of how frequently cervical screening should occur has been raised, with many references to annual cervical screening in the U.S. The U.S. did at one time have a general approach of annual cervical smears, but that was before the introduction of organised screening programmes. The official U.S. policy is now, and has been for some time, for cervical screening to be carried out at a three-year or five-year interval. This is not to do with the introduction of HPV vaccination, as has been erroneously stated, but because of the harm resulting from annual smears. This approach has been clearly stated by the U.S. Preventive Services Task Force, most recently in August 2018.

‘Screening more frequently than every 3 years with cytology alone confers little additional benefit, with a large increase in harms, including additional procedures and assessment and treatment of transient lesions. Treatment of lesions that would otherwise resolve on their own is harmful because it can lead to procedures with unwanted adverse effects, including the potential for cervical incompetence and preterm labor during pregnancy.’²

This statement illustrates a key difference between screening and the normal pattern of individual clinical care. In screening a balance must always be struck between the population benefit and the population harm as well as, of course, taking into account the most effective use of healthcare resources.

Avoiding screening too often, in order to avoid harm, is accompanied by considerable effort devoted to making the screening test, when it is carried out, as good as

² *Final Recommendation Statement: Cervical Cancer: Screening.* U.S. Preventive Services Task Force. August 2018.

possible. As explained in the Final Report, false negatives (i.e. the reporting of a slide as clear even though cancer or pre-cancerous changes are present) can occur in a number of ways. One of these is due to human error. Because judgement about the presence of changes in the cells on a slide may, in a very few cases, be erroneous, an important safeguard in cervical screening in Ireland and Britain (and in the contracts placed by CervicalCheck in the U.S.) is that the slides are always screened not by one, but by two screeners before they can be reported as normal. Errors by an individual are rare, but having the same slide looked at twice reduces the chances of a false negative in the presence of cancerous or precancerous changes hugely. This double reading of Irish screening slides, including those screened in the U.S., is in contrast to the general U.S. practice where 90% of slides are examined by a single screener.

The double-reading of slides gives not just an opportunity to avoid providing the woman involved with a falsely reassuring result, it also means that the professionals doing the screening can have their performance reviewed on a regular basis for quality improvement purposes.

However, as we know only too well, screening errors do happen and how they are responded to is extremely important. As I pointed out at the very beginning of this Scoping Inquiry and emphasised in my Final Report, people who are affected by clinical errors, in screening or in general health services, wish for three things to happen. The outcomes that people want are:

- To be told what happened and why (the truth);
- For someone who was involved to say they are sorry, and mean it;
- To be assured that this won't happen again to anyone else.

If this can be achieved, many people are satisfied and they are less likely to take legal action.³ The difficulty in screening cases is to provide assurance that it won't happen again. When millions of slides are being examined and human judgements made, it is inevitable that errors will occur. What can and must be done is to reduce the rate of errors by improving quality assurance processes and seeking to reduce the opportunities for human error. For example, the introduction of HPV testing as the routine screening test will reduce the opportunity for human error substantially.

Unfortunately, the system in place in Ireland for responding to error is inadequate to the task. As a result of the recommendations of the Final Report of the Scoping Inquiry, open disclosure, carried out in an appropriate way, is much more likely to happen. But, in my view, much more is needed. I have written previously about the absence of grace and compassion in this whole area. In its place, we leave people with two options: either to forgo being satisfied on the three key issues listed above, or to take legal action.

³ Vincent, C., Phillips, A. and Young, M., 1994. Why do people sue doctors? A study of patients and relatives taking legal action. *The Lancet*, 343(8913), pp.1609-1613.

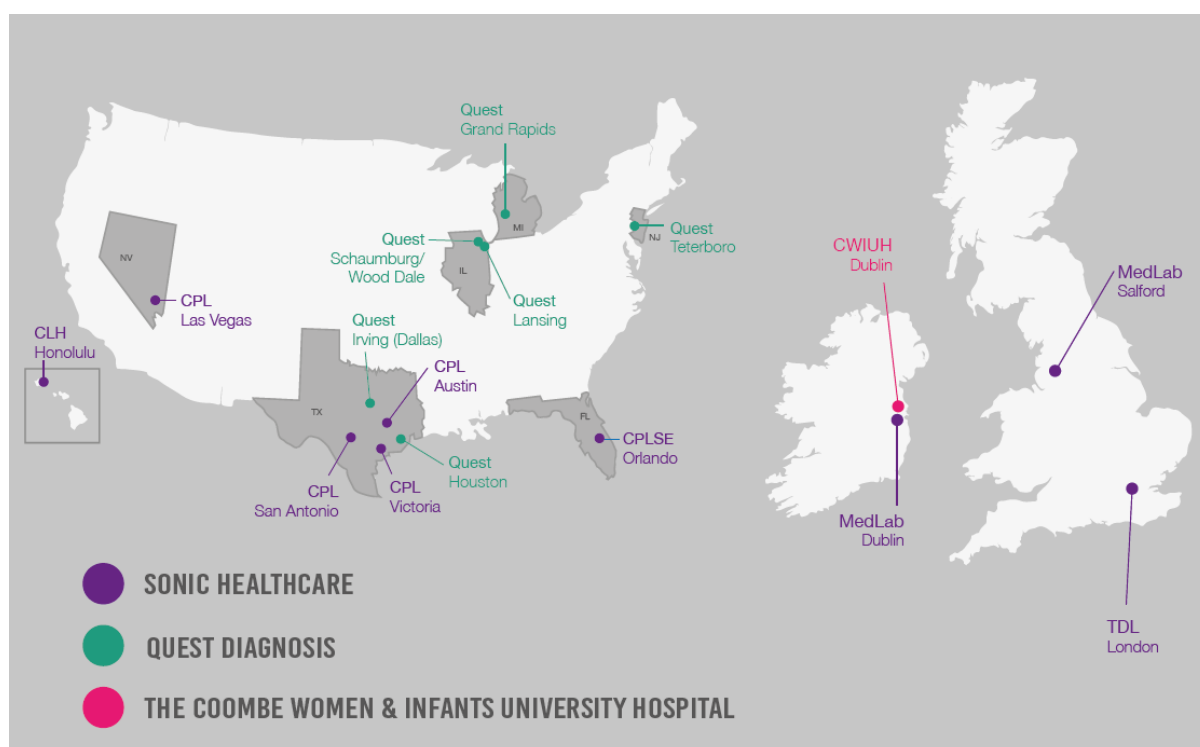
The legal processes currently in place are deeply unsatisfactory. They convert error into injustice, and then convert that injustice into financial remedy. The process is traumatic and filled with uncertainty for the person at the centre of the legal action and for their family. Access to legal action can require the person involved to commit, what is for many, a significant financial sum before legal action can be initiated formally. This is certainly the case for many of the women and relatives involved in the CervicalCheck controversy who are expected to pay, via their solicitors, for external professional opinions before the solicitors will consider taking the case further. It is commendable that, for cases that they judge will be successful, solicitors and barristers will take on case on a 'no win – no fee' basis. However, the initial costs constitute a major barrier for some of the women and families concerned. It is clear from talking to many women and families concerned, that their principal goal is simply to find out the truth of what happened to them and to their slides.

Established legal processes clearly fail to meet the needs as expressed in the three key outcomes listed above. Public health programmes, such as screening and immunisation are, in my professional view, entirely suitable for the introduction of a No-Fault Compensation Scheme. This is particularly so when combined with systems of dialogue and restorative practices so that compensation comes with listening, hearing, grace and compassion – and the real hope that what happened in the past shall not happen again in the future. The goal is that an attack/defence dynamic is replaced with a discourse in which all are involved. I would suggest that this approach might not only enable people who have experienced adverse effects from avoidable error in the screening process to gain the assistance they need and the outcomes they desire. It might also pave the way for the adoption of such approaches across the rest of the spectrum of medical care.

4 Laboratories

4.1 Background to this Section

Prior to the establishment of a national cervical screening programme in 2008, 14 laboratories around Ireland were involved in providing cytology services. The number of samples tested annually in these laboratories varied. As part of the establishment of the national cervical screening programme, laboratory services were tendered for. Since 2008, the laboratories illustrated below have been involved in the provision of screening services.



At the outset of the Scoping Inquiry in May 2018, it was believed that six laboratories had been used since 2008. By the time of my Final Report in September 2018, this number had increased to 11. The supplementary work has identified a further five laboratories that have been used to screen Irish slides. This brings the total number of laboratories to 16. The location and operations of these laboratories is outlined in the following sections.

4.2 Overview

The Final Report of the Scoping Inquiry published in September 2018 included a detailed account of the involvement of various laboratories in the provision of cytology screening services as part of the CervicalCheck programme. This included the services provided by the following laboratory companies, which were engaged to undertake the testing of samples:

- Quest Diagnostics Incorporated with headquarters in Secaucus, New Jersey, USA;
- Sonic Healthcare, a global healthcare company with headquarters in Sydney, Australia, which owns laboratories including:
 - Clinical Pathology Laboratories (CPL) of Austin, Texas, USA;
 - MedLab Pathology Ltd (MLP) of Sandyford, Dublin, Ireland;
 - The Doctors Laboratory (TDL) of London, UK;
- Coombe Women & Infants University Hospital, Dublin.

The September 2018 report highlighted a number of concerns regarding a further five laboratories in the U.S. that had been used by Sonic Healthcare as part of the CervicalCheck contract held by CPL between 2010 and 2013, each of which required further investigation as part of supplementary work requested by the Minister.

During the work of the Scoping Inquiry, and after the publication of the report in September 2018, the Inquiry received information from a number of sources that suggested that one or more of the contracted laboratory companies had sent CervicalCheck slides to other (unidentified) laboratories in Mexico or India. The Oireachtas Joint Committee on Health debate in relation to CervicalCheck, which was held on 10 October 2018, included mention from one Dáil Deputy of speculation that CervicalCheck screening was being performed in Mexico⁴. Separately, an article in the *Irish Medical Independent* in November 2018 asked whether ‘cervical smears from Ireland went to the Quest lab in Mexico’⁵.

It should be noted that, although the Scoping Inquiry had been in receipt of rumours regarding the use of laboratories in Mexico at a very early stage, the September 2018 Scoping Inquiry report did not make any reference to Mexico, as these matters were unsubstantiated and required further investigation. Any speculation regarding Mexico did not come from any member of the Scoping Inquiry team.

While some of the rumours regarding the use of laboratories in Mexico and India to perform CervicalCheck screening were of a general nature (many of them circulating within the UK pathology community), the Scoping Inquiry received some very specific information regarding the alleged use of one or more laboratories in Mexico by Quest. (Quest operates two laboratories in Mexico, one in Mexico City and the other in Ciudad Juarez.).

Accordingly, as part of the supplementary terms of reference agreed with the Minister for Health, the Scoping Inquiry has focused on the following matters:

- Was there any use made of laboratories in Mexico, India or other overseas locations?

⁴ Deputy Alan Kelly, cited in the Oireachtas record at: https://www.oireachtas.ie/en/debates/debate/joint_committee_on_health/2018-10-10/3/

⁵ Dr Christine O'Malley, *Irish Medical Independent*, 26 November 2018, “The time for restraint is nowover”

- What was, or is, the position with regard to the use of laboratories for screening work which were not included in the original CervicalCheck contracts?
- What issues arise for CervicalCheck and for the laboratory companies as a result of the use of laboratories which were not included in the original contracts?

The findings of the Inquiry team in relation to each of the laboratory parent companies are presented in the following paragraphs.

4.3 Quest Diagnostics Incorporated

4.3.1 Accreditation and Quality Systems

Before embarking on a description and analysis of the different laboratories used by Quest Diagnostics at various times, it is important to acknowledge that Quest has provided the Scoping Inquiry with detailed information to show that **all of the laboratories involved in CervicalCheck work have, or had, their own CAP and CLIA accreditation.**

In addition, each laboratory must comply with Quest's national, corporate Standard Operating Procedures (SOPs). Quest has stated that *'although the Medical Director of each laboratory had ultimate responsibility with respect to quality and adherence to applicable SOPs, local QA personnel at each laboratory as well as personnel in Schaumburg who were managing the CervicalCheck work also had QA oversight responsibility and verified that CervicalCheck rules, such as work load limits and double screening rules were followed.'*⁶ **There is no evidence available to the Scoping Inquiry that these laboratories were unaccredited or lacking in quality systems.** However, the involvement of at least some of those laboratories does not appear to have been known to the NCSS, they were not listed in the schedule of approved laboratories within the contract, and the NCSS had no opportunity to monitor their accreditation, quality assurance or governance arrangements.

4.3.2 Mexico, India, or Other Overseas Locations

Quest Diagnostics Incorporated, headquartered in Secaucus, NJ, is a large global business operating laboratories, patient service centres, offices and other facilities in the U.S., Puerto Rico, Mexico, India and Ireland. Employing over 20,000 phlebotomists, paramedics, nurses and other health and wellness professionals, it generated net revenues of \$7.7 billion in 2017.

The original understanding of the Inquiry Team was that Quest's screening work under the CervicalCheck contract was performed only at its laboratories in Teterboro, NJ, and Schaumburg/Wood Dale, IL, both of which were permitted under the contract

⁶ Letter dated 5th February 2019 from Quest to the Scoping Inquiry

signed with the National Cancer Screening Service in 2008.⁷ (The Schaumburg/Wood Dale laboratory stopped screening work for CervicalCheck in October 2010.)

Members of the Scoping Inquiry team visited the Quest laboratory in Teterboro in late July 2018 and met with a number of senior executives from Quest. The visit was pursuant to a request to all of the laboratory service providers working with CervicalCheck, which stated that *'the purpose of these visits will be for the Scoping Inquiry team to get a first-hand view of the laboratories which have been involved in undertaking work for CervicalCheck, to understand how their operational processes work (or worked), and to meet key representatives of the laboratories to take their perspective on the issues within the terms of reference for the Scoping Inquiry.'*

During the July 2018 visit to Teterboro, the Scoping Inquiry team was advised by Quest that all cytology screening which that company had undertaken for CervicalCheck was performed in Teterboro, with some historical activity having been undertaken in Schaumburg/Wood Dale. No mention was made by Quest regarding the use of any other laboratory facilities for CervicalCheck work. It did not appear at that stage that there was any evidence to substantiate the vague rumours relating to the use of laboratories in India and Mexico, which indeed were not specific to Quest.

Following publication of the Scoping Inquiry report in September 2018, further information was provided to the Scoping Inquiry team which was specific to Quest and which referred directly to laboratories in Mexico. Accordingly, a follow-up meeting was held with senior representatives of Quest in Secaucus, NJ in late January 2019, in order to probe these matters in more detail.

Quest has strongly denied the suggestion that laboratories in Mexico or India were used to undertake cytology screening as part of the CervicalCheck contract. With specific regard to the unsubstantiated information which the Scoping Inquiry received regarding Mexico, Quest has stated categorically that its two laboratories in Mexico do not provide cytology services and have never done so. Furthermore, the unsubstantiated allegation that a Quest employee from Ireland was regularly travelling to Mexico on business in 2008/09 is strongly refuted by Quest, which has stated that no person matching the description provided to the Scoping Inquiry was employed by Quest during this or any subsequent period.

Having considered all of the facts at my disposal, I accept Quest's assurances that no work in relation to CervicalCheck was undertaken in Mexico or India. (It may be that the rumours regarding Mexico were in some way connected to the separate contract held between the National Cancer Screening Service and CPL of Austin, TX, a matter upon which I comment below.)

⁷ We understand that the laboratory is based in Schaumburg, Illinois, approximately 7 miles from the Quest corporate office in Wood Dale, Illinois, and that the location Wood Dale is mentioned in some documentation when in fact Schaumburg is the correct reference. In other Quest documentation, the laboratory is stated as being in Chicago. Schaumburg and Wood Dale are north-western suburbs of Chicago. The three names appear to be used interchangeably.

4.3.3 Other Laboratories Used but Not Named in Original CervicalCheck Contracts

A face-to-face meeting of members of the Scoping Inquiry team with Quest on 29 January 2019, and subsequent correspondence in the days following that meeting, involved the disclosure by Quest that four additional laboratories owned and operated by Quest had also been involved in undertaking cytology screening work as part of the CervicalCheck contract. No mention had been made of these four laboratories, or their involvement in CervicalCheck, when the Scoping Inquiry team visited Quest in July 2018.

These four laboratories, and the approximate activity volumes involved, were as follows:

Laboratories not named in the contract and/or not disclosed to the Inquiry in July 2018	Number of Slides	Time Period
Grand Rapids, Michigan ⁸	17,660	April-November 2009
Lansing, Illinois	1,772	November-December 2009
	1,927	February-July 2010
Houston, Texas	2,289	May-June 2009
Irving (Dallas), Texas ⁹	917	May-June 2009
Total	24,565	
Total slides read by Quest	1,424,506	2008 - 2017
Slides read in laboratories not named in the contract and/or disclosed to Inquiry in July 2018 as a percentage of all slides read by Quest	1.7%	

Table 4.3.3a: Quest laboratories by CervicalCheck workload and time period used

Quest advised the Scoping Inquiry that these slides had been received by its laboratory in Schaumburg/Wood Dale and had then been sent to the other four sites for screening due to capacity issues within Schaumburg/Wood Dale at the time. Specifically, there had been a significant spike in demand for CervicalCheck screening in Ireland as a result of the publicity surrounding the March 2009 death from metastatic cervical cancer of Jade Goody. In order to deal with this increased demand and avoid the development of a significant backlog, Quest opted to involve the other four laboratories in CervicalCheck screening work. The majority of this activity was undertaken during an eight-month period between April and November 2009, but several thousand additional slides were screened by the laboratory in Lansing, IL between then and July 2010, by which point the demand for CervicalCheck screening had stabilised.

⁸ This laboratory is also referred to as Wyoming, as it is located in Wyoming, a suburb of Grand Rapids, Michigan. This is not to be confused with the state of Wyoming, which is approximately 1,400 miles west of Michigan. Some newspaper coverage appears to have confused the two places.

⁹ Irving (Dallas), Texas was named as a Secondary Laboratory in the 2008 Quest contract but not specifically approved for use. The contract is not clear as to whether a named Secondary Laboratory could be used without prior written notification and approval.

The involvement of these four laboratories was not disclosed to the Scoping Inquiry until the 29 January 2019 meeting, and this information was provided following a direct question from the Scoping Inquiry team regarding whether any other U.S. laboratories had been involved in CervicalCheck screening work. Almost a month before the meeting with Quest, the Scoping Inquiry advised Quest in writing¹⁰ that it needed *'to be absolutely satisfied that all CervicalCheck work undertaken by Quest was performed in Teterboro or in Wooddale (both of which locations were approved by CervicalCheck / the National Screening Service), and that no other Quest laboratories were engaged in CervicalCheck work.'*

The use of the laboratory in Grand Rapids came to public attention on 30 January 2019, in a legal case being taken against the HSE, Quest and MedLab. A consultant cytopathologist gave evidence that he had examined a slide of the 2009 cervical test sample, and that the slide had originally been screened by Quest Diagnostics in its laboratory at Grand Rapids, MI. The location of the laboratory performing the screening was indicated on the screening report sent back to the woman's doctor.

(U.S. regulations require that all laboratory reports include the name and address of the performing laboratory, its U.S. license number and the name of the Medical Director. Laboratory reports seen by the Scoping Inquiry show that Quest has complied with this regulation and that all reports from sites that conducted screening of slides for CervicalCheck identified the performing site.)

The inclusion of the laboratory location on the pathology reports does not mean, however, that the NCSS was necessarily aware of the use of Grand Rapids (or any other laboratory not included in the CervicalCheck contract), as these reports were intended for the patient and her doctor, and were not copied to the NCSS at the time.

Whether the NCSS was fully aware of the involvement of all four sites remains unclear and is a matter at issue between the parties. To date, the documentation provided has been insufficient to allow me to make a definitive decision on this issue. This comment applies to material provided by the HSE and by Quest. Quest has advised the Scoping Inquiry that many of the people involved in managing and overseeing CervicalCheck work at the time are either no longer working for the company, or (in the case of one senior clinician) are deceased. Most, but not all, of the senior Quest personnel currently involved in managing the delivery of CervicalCheck work did not hold those responsibilities in 2008 to 2010, and in some cases worked for other companies at that time. Nonetheless, it is disappointing that not one of the bodies involved retains complete records dating from a time period within the last decade.

An email dated 22 May 2009, from a senior Quest executive to an official in the NCSS, makes reference to the surge in demand following the death of Jade Goody, and an attachment to that email makes specific reference to laboratories at Grand

¹⁰ Email dated 3 January 2019 from the Scoping Inquiry to Quest Diagnostics, Inc.

Rapids and at Irving (Dallas), TX. The Irving (Dallas) laboratory was named as a Secondary Laboratory in the two-year contract agreed in 2008 between Quest Diagnostics and the NSS, but the Scoping Inquiry was not aware that it had been in use. This laboratory is referred to as 'Dallas' throughout the documentation received, including in this email. The relevant part of the email reads as follows:

NCSS Testing Status 05/20/09

Background:

The Quest Diagnostics Chicago testing network prepared for 1250 per day based on the NCSS tender. Chicago sequestered testing capacity for up to 385 patients per day with the tender. Chicago has averaged 700 Patients per day in 2009 (967 per day in April with help of Grand Rapids).

Current State:

Capacity - Chicago = 600 patients per day, Grand Rapids = 200 Patients per day (800 total per day with voluntary overtime)

Patients referred to Chicago exceed daily testing capacity available.

Grand Rapids has indicated they are withdrawing testing capacity and we are pursuing Dallas to replace capacity to remain at 800 patients per day.

The Quest document also refers to the proposed continuation of CervicalCheck activity in Grand Rapids:

- If Grand Rapids can continue to participate at a rate of 100 patients per day, this will further improve capacity and performance.

Thus it appears that reference was made, in a document attached to an email sent to the NCSS in May 2009, to a laboratory in Grand Rapids which had processed tests in April 2009 and was at that time processing '200 Patients per day,' and that Quest was pursuing 'Dallas' to replace capacity when Grand Rapids ceased processing. There is no record of prior written notification in relation to the use of the laboratories by Quest. It is reasonable to conclude that the past and then current use of the Grand Rapids laboratory and the intended future use of the Irving (Dallas) laboratory during 2009 was brought to the attention of the NCSS as set out in the above document, but whether this was the first such communication or not, it is now impossible to say. An email from Quest in June 2009 attaches a Laboratory Response Times Report from 1 January 2009 to April 2009 and it only refers to use of laboratories in Schaumburg/Wood Dale and Teterboro. Further documentation provided to the Scoping Inquiry includes Laboratory Response Times Reports for the periods 1 April 2009 to 1 July 2009 and from 1 July 2009 to 1 October 2009; both reports, again, only refer to use of laboratories in Schaumburg/Wood Dale and Teterboro. The Inquiry has not had sight of any such similar reports for the critical periods in question, namely November – December 2009 (Lansing) and February/April/May – July 2010 (Lansing). The use of the Houston and Lansing laboratories does not appear to have featured in any of the documentation which the Scoping Inquiry has examined.

However, senior staff employed at the NCSS at the time have stated to the Scoping Inquiry that they have no recollection of any of the four sites being involved in CervicalCheck screening work, and that their only recollection was of involvement by the Quest laboratories in Teterboro and Schaumburg/Wood Dale.

No record could be found showing that the NCSS Board had agreed to the use of laboratories other than Teterboro and Schaumburg/Wood Dale; the only relevant reference in the available documentation was to the planned use of the Irving (Dallas) laboratory, which was a named Secondary Laboratory in the 2008 Quest contract. Under the 2008 contract, Quest was required to obtain written approval from the NCSS Board in advance of undertaking any such activity in Grand Rapids/Wyoming, Lansing, and Houston. In relation to the use of the laboratory in Irving (Dallas), the contract is not clear as to whether a named Secondary Laboratory could be used without prior written notification and approval. In any event, when its planned use, in the specific context of an unexpected surge of work, was brought to the attention of CervicalCheck in 2009, the NCSS expressly indicated its disapproval of such use in any future surge, along with the other additional laboratories identified in accompanying correspondence from Quest.

Furthermore, the then-CEO of the NCSS has informed the Scoping Inquiry that his clear recollection is that no such permission was granted, and that the NCSS was deeply uneasy about the prospect of CervicalCheck work being distributed across a wide network.

It seems that the NCSS did not expressly approve the use, as appears to be required by contract, of any Quest laboratories other than the approved locations at Teterboro and Schaumburg/Wood Dale. While the laboratory in Irving (Dallas) was named as a Secondary Laboratory in the 2008 contract, there is no evidence available to the Inquiry that it was ever approved for use by the NCSS.

Although there is an absence of definitive documentation in relation to the use of additional laboratories, it would appear that a notification by Quest of its intention to use additional laboratories for CervicalCheck work was rejected or, at the very least, there was a warning that such use should not be repeated. Available records read as follows:

- 22 May 2009: email from Quest to the NCSS refers to the increases in demand for screening following the death of Jade Goody, and states that Quest will use *'a wider laboratory network utilising the following Quest Diagnostics sites; Auburn Hills, Michigan, Dallas, Texas, Syosset, New York, and Horsham, Pennsylvania'* which *'will address peaks and valleys in the Ireland cytology volume'*.
- 3 June 2009: email from the NCSS to Quest states *'We have reviewed the plan which includes disbursing slides to additional labs within Quest Diagnostic if there were to be another surge similar to the one experienced during April and May 2009. We would not be supportive of this aspect of the plan. Bringing in*

additional labs that have not had previous experience with aspects of CervicalCheck (admin, smear takers, colposcopy) would introduce a level of risk that we are not willing to accept. We recommend that you have a plan in place that uses the two existing labs to handle any future surges.'

- Notwithstanding the attitude of the NCSS towards future disbursing of slides across other Quest laboratories, the language in the above email suggests that the NCSS was aware that another laboratory in Grand Rapids was used during the April-May 2009 surge, albeit after the fact, although this is disputed by Quest and is a matter at issue between the parties. This usage does not appear to have been approved in writing.
- 26 June 2009: letter from Quest to the NCSS refers to the spike in activity volumes and states that '*Quest Diagnostics ability to utilize it's (sic) laboratory network provided the means to contain the TAT¹¹ from reverting back to unacceptable standards as experienced from previous service providers.*' The letter goes on to state that '*volumes have begun to stabilise*' and that Quest '*will continue to work with our two main laboratories in Chicago and Teterboro...In the event of a force majeure (sic) or unnatural unforeseen spike in volume. We will notify the NCSS of our desire to utilize other Quest labs in our network. This action will insure (sic) adherence to the NCSS and be transparent to the GP's/Smear takers.*'
- The 26 June 2009 letter from Quest also makes it clear that these laboratories had been used and had 'provided' (past tense) the capacity for Quest to control its turnaround times. Furthermore, Quest undertook to work with its two main laboratories in Schaumburg/Wood Dale and Teterboro and, in the event of a spike in volume, to notify the NCSS if Quest wished to use other Quest labs in their network.

Therefore, based on the information/documentation available to the Inquiry, it seems clear that:

- In 2009, Quest listed a number of additional laboratories that it intended to use for testing and in appended documentation referred to two other laboratories, one that it had used and one that it intended to use.
- The NCSS replied that it would not be supportive of this approach.
- Quest replied that it would continue to use its two main laboratories (as named in the 2008 contract) and that it would notify the NCSS of its desire to utilise other Quest laboratories in its network if there was a future surge in demand. The Scoping Inquiry has not seen any response to this last letter.
- In addition to using its main laboratories, Quest used other laboratories up until July 2010. It is not clear if Quest considered this to be part of the same 'surge', but it appears to be in contravention of the express concern set out by the NCSS in the email dated 3 June 2009, that referred to 'any future surges'. It is noted, however, that an email from Quest to the NCSS dated the 26 June 2009

11 Turnaround time

indicated that the then surge was in hand, that '*volumes have now begun to stabilize and TATs have improved...*', with the then TAT '*holding at 95% of the samples being reported within 17 days*'.

- There is no evidence of written approval in relation to the use of these other laboratories, as appears to be required by the terms of the contract between the parties.

Quest advised the Scoping Inquiry that measures were taken to ensure that the work in additional laboratories was monitored by personnel in the named laboratory.

4.3.4 Analysis

At one level, it is understandable that Quest wanted to distribute CervicalCheck cytology screening to a number of its laboratories within the U.S., given the significant spike in demand which occurred following the death of Jade Goody and Quest's desire to keep its turnaround times within manageable proportions. However, for Quest to do so without the explicit prior agreement of the NCSS, and to continue to do so despite advice from the NCSS that it did not support the use of other laboratories, meant that the NCSS had no means of assessing the accreditation, quality standards, governance or other critical features regarding the suitability of these laboratories to undertake CervicalCheck work.

While I am now satisfied that there is no evidence that these laboratories were unaccredited or lacking in quality systems, at that time the NCSS could not have effectively ensured this. The May/June correspondence, outlined above, suggests that the NCSS may have understood that such work had ceased, whereas we now know that it continued in two separate laboratories about which the NCSS had no information. While Quest may have considered that the NCSS had acquiesced in such use, the ambiguous nature of the correspondence is an unfortunate instance of miscommunication and the exchange above ends in apparent acknowledgment by Quest that in order to abide by its contract and to be transparent, it was required to notify the NCSS if it had to use additional laboratories.

The most benign interpretation of these events is that neither party appears to have understood, or articulated, the importance of the role of the NCSS in monitoring the quality and safety of the laboratories and the importance of documenting how and where the work was being done, how it was monitored, and by whom.

The NCSS appears not to have known that Quest had commenced the use of these laboratories in April 2009, although the past use of the Grand Rapids and the proposed future use of Irving (Dallas) are referenced in a document attached to an email sent to the NCSS on 22 May 2009.

It is disappointing that it took Quest more than six months (from the time of the Scoping Inquiry's first engagement with the company) to disclose the involvement of these four laboratories, despite the specific assurances which the Scoping Inquiry

team had sought, and against the backdrop of the considerable public concern that arose in September 2018 when the main Scoping Inquiry report identified the use of a range of other U.S. laboratories by CPL.

It does appear, however, that the transfer of CervicalCheck work to other Quest laboratories was only for a relatively limited period in order to meet a one-off spike in demand, and involved fewer than 25,000 slides out of more than 1.5 million screened by Quest. From mid-2010 onwards, all of the CervicalCheck cytology screening undertaken by Quest was done exclusively at its major laboratory in Teterboro, NJ. As stated in the September 2018 report of the Scoping Inquiry and on the basis of the evidence supplied to the Scoping Inquiry, **I am satisfied with the quality management processes in place at the Quest laboratory in Teterboro, and I know of no reason related to quality why the existing contract for laboratory services at this location should not continue.**

4.4 Clinical Pathology Laboratories (CPL) of Austin, Texas, USA

4.4.1 Background

Clinical Pathology Laboratories (CPL) is part of the Sonic group of companies headquartered in Sydney, Australia. The Sonic companies employ around 34,000 people, and in the full year ending 30th of June 2018 Sonic reported a statutory net profit of A\$476 million (equivalent to €300m) on revenues of A\$5.54 billion (€3.49bn).

The Final Report of the Scoping Inquiry published in September 2018 highlighted a number of questions regarding a further five laboratories in the U.S. that had been used by Sonic Healthcare during certain periods of the group's contracts with CervicalCheck, specifically between 2010 and 2013, and which required further investigation as part of this supplementary work requested by the Minister. The parties to the two-year 2010 contract were Sonic Healthcare (Ireland) Ltd and the National Screening Service Board, with the named laboratory as Clinical Pathology Laboratories [CPL] of Austin, TX. The parties to the two-year 2012 contract were MedLab Pathology Limited [MLP] with two named laboratories, these being CPL in Austin, TX and MedLab Pathology in Sandyford, Dublin.

4.4.2 Original Understanding of CPL's Involvement in CervicalCheck

At the commencement of the Scoping Inquiry, it was understood that CPL had used one laboratory for CervicalCheck screening work during the period 2010-13: its major facility in Austin, TX. During a visit to Austin by the Scoping Inquiry team in July 2018, CPL disclosed that a substantial proportion of this work had in fact been transferred to a smaller laboratory in San Antonio, TX, around 80 miles from Austin. The existence of this laboratory and its involvement in CervicalCheck work does not appear to have been disclosed to the National Cancer Screening Service (NCSS), nor did it feature in a Quality Assurance (QA) visit made to Austin in 2011 on behalf of CervicalCheck/NCSS.

Further questions were posed to CPL in July 2018 as to whether any other sites had been engaged in CervicalCheck work, and the following response was received from CPL:

CPL Main in Austin, TX performed the majority of CervicalCheck primary and secondary screenings with CPL auxiliary sites in San Antonio, Texas, Victoria, Texas and Las Vegas, Nevada acting as primary screening sites. With a small surge at program establishment in 2010, a limited number of accessions were distributed in accordance with Schedule 13 of the initial CervicalCheck contract to two Sonic Healthcare USA (SHUSA) affiliated laboratories, Honolulu, Hawaii and Orlando, Florida for primary screening with secondary review and authorization at CPL Main.¹²

Subsequent to the disclosure by CPL of the involvement of the additional laboratories, further correspondence was received by the Scoping Inquiry from the CEO of Sonic Healthcare, stating the following:

CPL participated in the CervicalCheck program from 2010-2013 during which, a total of 326,260 CervicalCheck cases were reported. Within this same period, CPL reported more than 2.5 million cases unrelated to CervicalCheck. The breakdown by year of service for the Irish cases is indicated below.

	2010	2011	2012	2013
<i>Irish Case Volume:</i>	61,866	163,530	95,233	5,631

These cases were reported within the CPL network of CLIA and CAP accredited cytology laboratories including CPL Austin, CPL San Antonio, CPL Victoria and CPL Las Vegas. All these laboratories are an integral part of CPL and are operated under a single medical, operational and quality management structure and all contributed to the overall screening capacity that CPL was required to maintain under the terms of the CervicalCheck program. As these laboratories are all part of CPL's integrated regional laboratory network, we believe that the utilization of all of these cytology screening sites was appropriate under the contract. While these are geographically separate facilities, they are all part of the networked CPL laboratory group.

During the first year of service, when CervicalCheck workload was progressively being transferred to CPL, fluctuations in slide volumes arriving in the laboratory occurred. Due to logistical issues relating the transportation of slides from Ireland to the US and processing by US Customs short term critical capacity pressures occurred. To meet contractual obligations relating to turn around time, CPL needed to urgently and temporarily increase screening capacity. This was achieved by utilizing excess capacity in two other US-based Sonic Healthcare laboratories – CPLSE in Orlando, Florida

¹² Document supplied by CPL on 10th August 2018 to the Scoping Inquiry

and Clinical Laboratories of Hawaii (CLH) in Honolulu. In total, 300 cases were screened at CPLSE and 250 at CLH in 2010. Together, these cases represented less than 1% of the total 61,866 CervicalCheck cases screened by CPL in 2010. Please note that only the initial primary screen was performed at these laboratories while secondary screening and pathologist review continued to be performed at CPL Austin and CPL San Antonio.

It is important to emphasize that all CPL and Sonic Healthcare US laboratories that performed screening services were fully accredited and of the highest quality, and all screening services were performed in accordance with the HSS quality criteria. The temporary use of non-CPL laboratories was an action that was taken as an exigency measure to maintain turn-around times required for optimal patient care.

In our assessment of the CervicalCheck contract, rebalancing workload to other non-CPL Sonic Healthcare laboratories within the US was contemplated by the contract as a necessity to meet service needs and our ethical obligation to provide screening as timely as possible. We acknowledge that we should have notified the CervicalCheck program of the screening at other SHUSA laboratories. If we did in fact fail to make this notification we apologize however, 8 years after the fact and as a result of the subsequent departure of key personnel, we are unable to identify documents to confirm whether or not this notification occurred.

In summary, an insignificant number CervicalCheck cases were reviewed in non-CPL laboratories during 2010 in order to address an acute capacity deficit related to surges in workload arriving in the laboratory due to logistical issues. All screening was performed to the highest quality standards by highly qualified and experienced cytologists working in fully accredited, Sonic owned laboratories and under the supervision of key CPL medical and scientific personnel. We believe that the use of non-CPL laboratories was contemplated under the terms of the contract in acute circumstances in order to meet contractual obligations and duty of care.¹³

4.4.3 Further Enquiries

This additional information from Sonic Healthcare raised a number of questions which necessitated a further visit to Texas in October 2018 by the Scoping Inquiry team, and involved a series of supplementary questions being posed to CPL, which were as follows:

- What is/was the nature of the two additional 'CPL auxiliary sites' in Victoria, Texas and Las Vegas, Nevada? Do they still exist or, like the site in San Antonio, Texas, have they been discontinued? What other work goes on there? What is their scale and size?

¹³ Letter dated 24th August 2018 from Dr Colin Goldschmidt, CEO, Sonic Healthcare, to Dr Gabriel Scally

- What is/was the nature of the ‘two Sonic Healthcare USA (SHUSA) affiliated laboratories’ in Honolulu, Hawaii and Orlando, Florida? What does ‘affiliated’ mean? Are these laboratories part of Sonic or are they independently owned?
- What was the volume of CervicalCheck tests performed in each of the US laboratories owned by Sonic Healthcare, over the lifetime of the programme?
- What was the compliance of each Sonic laboratory with quality and regulatory standards?
- What were the reporting and governance arrangements in place for each of these laboratories?
- What were the data recording and accounting arrangements in place with regard to the work performed by all relevant CPL labs for CervicalCheck? (We would like to get an understanding of the processes in place in this regard.)
- What were the circumstances which led to work being transferred from Austin to other sites?
- Did CPL inform CervicalCheck of workload being transferred to other sites? Were such transfers approved?

As part of the preparation for the October 2018 visit to CPL, the Scoping Inquiry established that the laboratory in Orlando was no longer operational, having been closed in 2017. It had already been disclosed by CPL that the laboratory in San Antonio had also been closed. Given the very small number of CervicalCheck slides which were screened in Honolulu, it was felt that a visit to that facility was probably unwarranted. Accordingly, the October 2018 visit included further discussions with senior CPL executives and clinicians in Austin, and a site visit to the laboratory in Victoria, TX (a city of approximately 60,000 people located 120 miles south of Austin). During the visit to Austin, the Scoping Inquiry team also met with a cytotechnologist who had previously been based in the Las Vegas facility and had undertaken much of the Irish work routed through that laboratory, and who subsequently transferred to Austin.

4.4.4 Result of enquiries

A central element of the supplementary enquiries with CPL concerned the number of CervicalCheck cases which had been screened at its various laboratories within the U.S. During the July 2018 visit to Austin and subsequent discussions with CPL, it was stated by CPL that ‘separate tracking of CervicalCheck screening productivity as a proportion of total productivity is not available’ – in effect, detailed workload figures specifically related to CervicalCheck could not be provided as CPL did not retain sufficiently detailed records by primary screening location. CPL has advised the Inquiry that detailed workload data was collected. However, this was reported in an aggregated fashion (i.e. not location-specific) to MLP and the NCSS at the time the work was done. By 2018, CPL no longer retained the detailed location-specific information in relation to CervicalCheck activity.

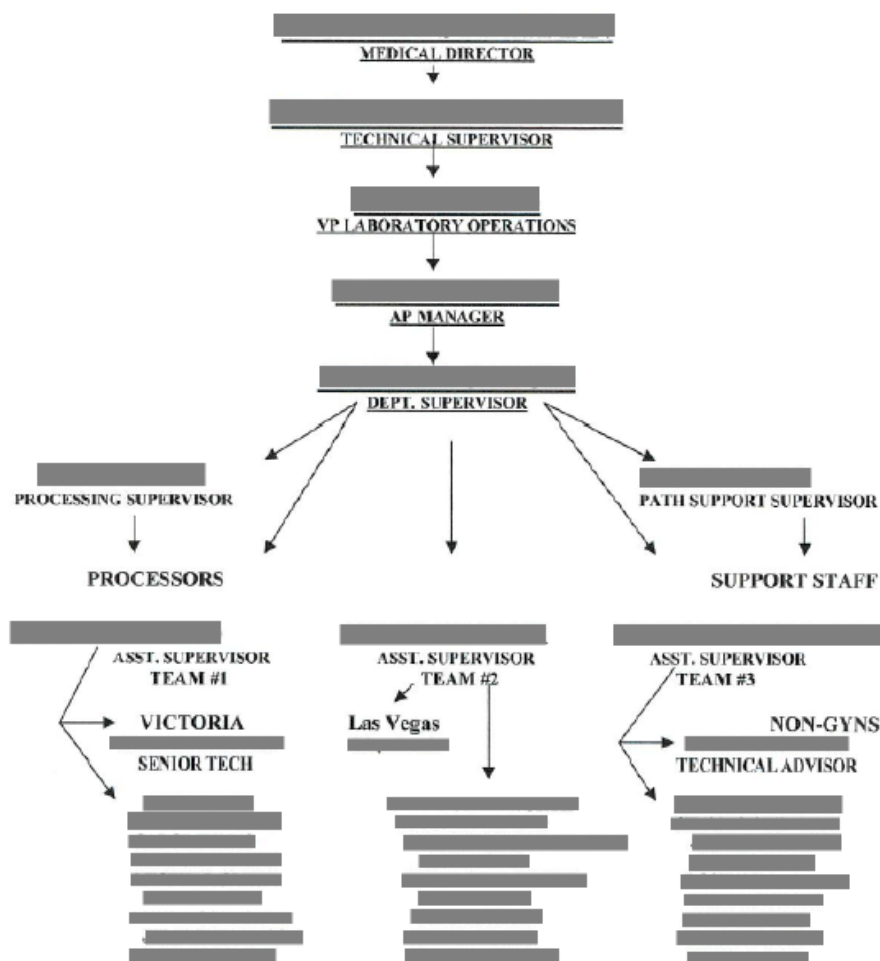
This matter was discussed with CPL during the October 2018 meeting. Following data extraction and rendering of CPL’s cytology archives to a format suitable for detailed retrospective analysis in November 2018, the figures below (Table 4.4.4a) were provided by CPL to the Scoping Inquiry.

Primary Screening Location	Case Volume (number)	Case Volume (%)
Austin	192,722	59.06%
San Antonio	118,009	36.16%
Las Vegas	12,695	3.89%
Victoria	1,732	0.53%
Hawaii (December 2010 distribution)	542	0.17%
Florida (December 2010 distribution)	615	0.19%
TOTAL	326,315	100.0%

Table 4.4.4a: CPL CervicalCheck workload by laboratory site

The image below is an extract from the tender of CPL, dated 1 February 2010, which illustrates CPL’s organisational chart for its cytology services, and lists both Victoria and Las Vegas (but not San Antonio, Honolulu or Orlando):

CYTOLOGY ORGANIZATIONAL CHART



4.4.5 Analysis

The Inquiry team found no evidence that any of these laboratories were unaccredited or lacking in quality systems. However, the involvement of at least some of these laboratories does not appear to have been known to the NCSS, they were not named within the contract, and the NCSS had no ability to monitor their accreditation, quality assurance or governance arrangements at the relevant times.

Sonic Healthcare and its U.S. subsidiary CPL appear to have taken a very flexible attitude towards the servicing of the CervicalCheck contract. Whereas the original understanding of the NCSS was that one laboratory (Austin) would be used for cytology screening and reporting under the CervicalCheck 2010 contract, in fact a total of six laboratories in four states were used by CPL.

The basis for the use of the other five laboratories appears to have been a combination of a 'temporary pilot program to meet turnaround time obligations'¹⁴ (in the case of Honolulu and Orlando) and an interpretation by CPL of Schedule 13 of the 2010 contract with the NCSS Board which allowed workload to be transferred to other Sonic sites, under the heading 'Storage and Disaster Recovery Plan'. CPL's interpretation of the contract, generally, remains that it was entitled to transfer CervicalCheck screening work across its network, under the governance and quality control of the main laboratory in Austin.

This appears to have been done without informing the NCSS. Senior staff in the NCSS at the time who were involved very closely in the CPL contract – including in the tender process, in the ongoing engagement with CPL when the contract went live, and in the quality assurance visit made to Austin in 2011 – have informed the Scoping Inquiry that they had no knowledge of the involvement of the five laboratories in San Antonio, Victoria, Orlando, Las Vegas or Honolulu. Detailed searches of all relevant HSE / NCSS documentation, including emails, reveal no mention of these laboratories in any correspondence or other documents, whether hard copy or electronic. CPL has also stated that 'we cannot identify additional documents to show notice to the program that we redistributed Pap tests to additional sites for primary screening.'¹⁵

The only document which mentions any of these laboratories is the listing of the names 'Victoria' and 'Las Vegas' in an illustration to support CPL's tender document, with no apparent explanation as to what these names represented. Unsurprisingly, given the oblique nature of their mention, the NCSS does not appear to have interpreted the inclusion of these two names in a chart in CPL's tender as a formal statement of CPL's intention to route CervicalCheck screening to these locations.

I find aspects of this situation troubling, albeit that CPL's involvement in the CervicalCheck programme ended six years ago. CPL has placed considerable emphasis on its governance arrangements for CervicalCheck work, which entailed that all cytology quality assurance activities were coordinated at the Austin laboratory, with four of the six sites providing only primary screening services (i.e. secondary review and authorisation taking place in Austin). However, a number of features give cause for concern:

- The distances between these laboratories were often considerable: Honolulu is 3,700 miles from Austin, and Las Vegas is 1,270 miles from Austin. It is also notable that there is a five-hour time difference between Honolulu and Austin. Notwithstanding modern communication methods such as emails, electronic document transfer and video-conferencing, operating a seamless service with such physical degrees of separation would have been very challenging, particularly in terms of the benefits which accrue from professional and clinical colleagues working together, sharing experience and discussing unusual or interesting cases.

¹⁴ Presentation by CPL, "Sally Commission Visit," October 23, 2018

¹⁵ Presentation by CPL, "Sally Commission Visit," October 23, 2018.

- Several of the laboratories used by CPL appear either to have been relatively small operations (e.g. San Antonio), or to have had a very small cytology component within a general pathology laboratory environment (e.g. Victoria, Las Vegas). These appear to have been somewhat unusual arrangements and pose questions about effective governance and quality assurance, particularly when the resource involved appears to have been a single-handed cytotechnologist working far away from the main CPL cytopathology laboratory.
- Two of the laboratories used by CPL within the CervicalCheck contract were part of separate Sonic Healthcare USA subsidiary firms – the Orlando laboratory (under CPL South-East) and the facility in Honolulu (under CLH Hawaii). While all three firms were part of Sonic Healthcare USA, the involvement of two separate companies – each with its own corporate and clinical governance structures – is likely to have further clouded the arrangements for effective quality assurance, governance and accountability. What the NCSS originally thought it was getting was a single laboratory (Austin) delivering CervicalCheck cytology screening, with a single chain of corporate responsibility and governance. What it actually got, unknowingly, was six laboratories across four States, with three separate, ‘federated’ companies delivering the service.

As noted above, the evidence provided to the Scoping Inquiry by CPL makes it clear that each of these laboratories was accredited, had quality systems in place, and was operating in compliance with the relevant regulatory requirements applying in the U.S. at the time.

4.5 MedLab Pathology Ltd

4.5.1 Background

In October 2018, the Scoping Inquiry was informed by the HSE that, during recent negotiations, MedLab had mentioned that it was carrying out screening under its own auspices in Salford, Greater Manchester, England. The Scoping Inquiry had been unaware of this.

MedLab Pathology (MLP), an Irish company based in Dublin, is part of the Sonic group of companies. As previously described in the main report of the Scoping Inquiry, it has a formal relationship with another Sonic company, The Doctors Laboratory (TDL), which was established in 1987 and is a large, private sector supplier of laboratory services in the UK.

TDL was engaged to provide additional screening capacity for MedLab. TDL has done so by examining Irish slides in its laboratory in London, with the approval of NCSS. However, it is a company which has widely dispersed facilities undertaking laboratory work elsewhere, including a location in Salford Quays, Greater Manchester. This TDL Manchester laboratory analyses a wide range of medical tests but not cytology.

According to information provided to the Scoping Inquiry, a longstanding member of the screening staff (a laboratory scientist) working in MedLab in Dublin approached their managers to say that they were relocating to Greater Manchester in January 2016 for personal reasons. They asked if they could continue to work for MedLab. An arrangement was made between MedLab and TDL that resulted in a dedicated screening facility being set up in the Salford laboratory and screening commenced in February 2016. This screening facility was set up specifically and exclusively for the purpose of reviewing CervicalCheck slides from Ireland. A second MedLab screener was subsequently recruited at the cytoscreener grade and commenced work in November 2016, again working exclusively on CervicalCheck slides.

Subsequent to the employment of the two staff based in the room in Salford, MedLab undertook a formal recruitment process for locum cytoscreeners to undertake locum screening sessions on CervicalCheck slides at both their Dublin and Salford facilities. Two cytoscreeners, both working in the NHS in Scotland, were recruited and undertook sessional work in Dublin and Salford, in addition to their NHS work in Scotland.

The Scoping Inquiry has been informed by MedLab that the existence of the Salford facility was mentioned at operational meetings with CervicalCheck and that CervicalCheck was fully aware of the arrangement. However, the staff of CervicalCheck and senior HSE management have no recollection or record of the matter being discussed, or even mentioned at meetings. Neither MedLab or CervicalCheck has been able to locate any written information being given to CervicalCheck about the existence of the Salford ancillary laboratory.

4.5.2 The service

The two permanent members of staff are the sole occupants of a room in the TDL building in Salford. The professional advice available to the Scoping Inquiry confirms that this room meets the physical requirements for screening. Both members of staff have their own desk and microscope, with computers which are connected to the main IT system in Dublin. Local TDL management staff in Greater Manchester are responsible for overseeing issues such as health and safety which relate to the building, but for all professional aspects of their work the two staff are line-managed by staff in Dublin. This includes Continuing Professional Development activities, multi-headed microscope sessions and training feedback.

Slides for screening and rapid review arrive in Salford by courier. The Scoping Inquiry understands that all slides are fully traceable through packing, transport and receipting procedures and are reconciled at every stage. Screening results are entered directly onto the IT system and the system allows queries between screeners to be made in real-time for prompt feedback. No preparation of material or HPV testing takes place on site in Greater Manchester.

The members of MedLab staff based full-time in Salford have carried out a significant volume of work over the time that they have been working there (see data in Table 4.5.2a).

	Primary Screens	Rapid Reviews	Total
2016	11,959	8,619	20,578
2017	23,195	17,783	40,978
2018	18,780	11,223	30,003
Total	53,934	37,625	
Overall Total			91,559

Table 4.5.2a: Screens carried out in the Salford laboratory – 2016 to November 2018

The two locums are also line-managed from Dublin. In addition to their laboratory work carried out in the NHS in Scotland, the locums have attended the office in Salford, Greater Manchester, where there is a third desk and microscope available. They have also carried out screening sessions in the Dublin MedLab facility. The two locums ensure their CPD and annual update requirements are met. Copies of NHS External Quality Assessment results and NHS update training are kept on record at MedLab in training folders. They undertake six-hour sessions of work in Salford and Dublin during which they primary screen 50 cases and rapid review 50 cases. They work at weekends and during annual leave from their other posts, and, according to information from MedLab, ensure that they do not exceed the maximum allowed daily or weekly hours spent screening, as laid down by NHS Scotland.

All four staff have their outcomes recorded on the system based in MedLab in Dublin and were identified to us by their confidential screener numbers. This data forms part of the data already reviewed as part of the earlier MedLab visit during the earlier part of the Scoping Inquiry's work.

4.5.3 Accreditation

MedLab in Dublin is accredited by the Irish National Accreditation Board (INAB) as a 'Medical Testing Laboratory' conforming to ISO 15189. INAB is part of the Health and Safety Authority and is the national body with responsibility for the accreditation of laboratories.

The Scoping Inquiry submitted a question to INAB as to whether the cytology work carried out in Salford has ever been covered by INAB accreditation, and if it is currently covered by INAB accreditation. In response INAB informed the Scoping Inquiry that:¹⁶

¹⁶ Document supplied to Scoping Inquiry by INAB on 13th February 2019.

INAB: MedLab's past and current accreditation extends to all accredited activity undertaken within scope of accreditation by MedLab employees, included within the scope of the accreditation assessment, including the cytology work carried out in Manchester.

The Scoping Inquiry has explored the issue of accreditation in some detail with both MedLab and INAB. From the information supplied, it appears that when screening started in the Salford laboratory at the beginning of 2016, with a single laboratory scientist, INAB was not formally notified or its approval sought.

The existence of the laboratory in Salford (referred to as Manchester) was first mentioned by MedLab in email correspondence with INAB in November 2016 in connection with the employment of a second employee, a cytoscreener, to work there. The communication was not to seek approval from INAB for the establishment of a laboratory in Salford which had, at that point, already been in operation for more than nine months. It was rather a query concerning the employment of a cytoscreener, a new category of staff, to be based in that laboratory, and asked about the documentation that was to be supplied to the Board in 2017. Mention of the operation of the laboratory, sometimes described as 'TDL Manchester cervical cytology', also appears in documents supplied by MedLab to INAB as part of the accreditation processes focused on the facility in Sandyford.

In relation to the accreditation of Dublin-based MedLab Pathology Ltd, INAB has informed the Scoping Inquiry that, in respect of the accreditation assessments carried out in 2016, 2017 and 2018, it was not evident to the assessors, either from documentation submitted by MedLab in advance of the visits, nor from the visits themselves, that the Salford screening facility was operational. Indeed, according to information supplied to the Scoping Inquiry by INAB, documentation submitted by MedLab in advance of the 2018 visit by the accreditation assessors stated that:¹⁷

“MLP prepares analyses and authorises 100% of the cytology smears at the Dublin facility, with Medlab Pathology's sister Sonic Healthcare laboratory in the UK as a contingency laboratory for this service.”

MedLab has informed the Scoping Inquiry that this statement in the 2018 documentation was erroneous and described its inclusion as unfortunate.

INAB has confirmed to the Scoping Inquiry that no visits had been undertaken by its assessors to the Salford laboratory prior to a very recent visit, on 17 April 2019. The Scoping Inquiry has explored with INAB whether it was able to accredit a laboratory in another country and it confirmed (see text below) that there was a possible arrangement that could extend accreditation to an operation in another jurisdiction.

In a very small number of cases, if an Irish organisation decided to set up a branch office in the UK, then that could fall under the remit of INAB accreditation. This information would be clearly documented on the INAB published scope for that laboratory.

¹⁷ Email from Manager, INAB, Health and Safety Authority to Scoping Inquiry, 12 February 2019.

According to the Schedule of Accreditation dated 23 October 2018 on the INAB website, only one location, in Sandyford Business Park, Dublin D18 is listed as a site at which accredited services are delivered by MedLab and, at that time, there was no mention of a laboratory in Salford, or indeed Manchester, in the Scope of Accreditation.¹⁸

Sites from which accredited services are delivered		
(the detail of the accredited services delivered at each site are on the Scope of Accreditation)		
	Name	Address
1	Head Office	Unit 3 Sandyford Business Centre, Sandyford Business Park, Dublin, D18

The Inquiry understands that MedLab very recently underwent a Cytology Specific accreditation audit by INAB, which visited the Salford laboratory on 17 April and the Sandyford laboratory on 18 April 2019. INAB recommended the accreditation of MedLab in Cytopathology, specifically including the operation of the Salford site.

4.5.4 Governance

The service in Salford, but referred to as Manchester, is shown on the management chart for MedLab. It is clearly considered by senior managers at MedLab to be a fully integrated part of its service, even though delivered on another site, and indeed in another country.

The clinical lead within MedLab for the cervical cytology service is a consultant cytopathologist based in Dublin who is responsible for all clinical governance. This consultant cytopathologist is registered with the Irish Medical Council and not with the General Medical Council (GMC) in the UK. MedLab maintains that there is no requirement for the clinical lead to register with the GMC. MedLab also indicates that any abnormal test result reported by a screener in Salford which requires consultant involvement is read and reported in Ireland. However, the clinical governance of professional staff working in one country by professional staff working in another country is an unusual occurrence.

4.5.5 Analysis

It is unsatisfactory that the Scoping Inquiry only learned of the Salford screening location in October 2018. There is legitimate public concern about the issue of the screening slides from Ireland being examined in laboratories not listed in any correspondence or documentation passing between the private companies involved and CervicalCheck. The publication of the Scoping Inquiry’s main report in

¹⁸ <https://www.inab.ie/FileUpload/Medical-Testing/Medlab-Pathology-Ltd-296MT.pdf> (accessed 6th April 2019)

September 2018 should have alerted all providers of laboratory services to the necessity of disclosing information on the operation of all sites currently or previously involved in the reading of slides from CervicalCheck.

The MedLab ancillary laboratory in Salford is an extremely small operation, it is also unusual and poses questions about effective governance and quality assurance arrangements. It is clearly providing important extra capacity to the MedLab operation and the Scoping Inquiry is fully aware of the importance of reducing the current backlog of slides. It is also reassuring that the performance data for the Salford-based screeners was included in the information reviewed by the Scoping Inquiry team during their visit to Sandyford in mid-2018 when the conclusion was reached that there was no reason, on quality grounds, why the existing contracts for laboratory services should not continue.

On the basis of the initial statement provided to the Scoping Inquiry quoted above, it is clear that INAB considered that the cytology screening carried out in the Salford ancillary laboratory was automatically included in MedLab's accreditation. I find this both surprising and disturbing, particularly given that INAB does not appear to have been conscious that this facility was operational. MedLab did mention the existence of the 'Manchester' laboratory in email correspondence with INAB in November 2016, but it was not referred to in any written correspondence with NCSS or CervicalCheck. The Salford laboratory does not appear to have been considered actively by the accreditation assessors in 2016, 2017 or 2018. However, MedLab has provided the inquiry with material which indicates that INAB considered materials which mentioned the existence of the 'Manchester' laboratory, including an internal audit report, training files and risk analysis. If accreditation systems are to be relied upon as one of the planks of safe laboratory services, it is important that the operation of those services is thorough, expert and credible. The accreditation must also be specific about the facilities so accredited. It is stretching credibility that a laboratory facility can reasonably be accredited retrospectively for periods of time during which its existence was unknown to the accrediting body.

I am aware that HSE has taken the existence of the Salford laboratory seriously and that it has been subject to a quality assurance visit by HSE staff. I am also aware that there is an overall shortage of screening capacity at the present time. The continuation of the Salford facility is clearly an operational matter and one on which HSE should reach a firm view. However, I am of the view that such remote working by a single, or a very small number of, health professionals should be avoided. The days of single-handed healthcare professionals are gone.

4.6 Recommendations

1. Future CervicalCheck contracts for the provision of cytology and other laboratory services should contain even more explicit provisions to ensure that no contracted cytology or other laboratory activity should be carried out anywhere other than in the precise locations, and by the precise company, identified in the written contract, without prior written permission from CervicalCheck.
2. The quality assurance (QA) process developed and operated by CervicalCheck must be based on a consistent and thorough approach to the quality of the laboratory services being provided to the cervical screening programme. This QA system must be designed and operated irrespective of the physical location of laboratories and the possession of external accreditation by the laboratory should not be viewed as in any way replacing or diminishing the need for QA processes.

5 Laboratory Accreditation Schemes

5.1 Overview

As part of the process of quality control of laboratory services, the individual laboratories are usually subject to an external inspection process devised and administered by an independent and expert body. The terms of reference of the scoping inquiry indicated that it should consider accreditation and the issue was considered in the Final Report published in September 2018.¹⁹

The laboratories used by CervicalCheck in Ireland, the UK, and the United States of America were required to have accreditation. Although the tender documentation specified International Organization for Standardization (ISO) accreditation, it was apparent that not all the laboratories possessed it. Some laboratories relied upon the College of American Pathologists (CAP) accreditation. The Final Report of the Scoping Inquiry stated that:

'The Scoping Inquiry will investigate accreditation requirements and considerations further and undertake a comparative analysis of their application in the extended number of laboratories of which the Scoping Inquiry is now aware. These issues will be dealt with in the supplementary report.'²⁰

The issue of accreditation has indeed been considered further and, in particular, expert opinion sought on the strengths and weaknesses of the two major accreditation schemes.

5.2 What is pathology?

The work carried out by pathologists is concerned with the detection of changes in body tissues and fluids that are associated with the presence or causation of disease. It is, in the main, led by senior medically qualified personnel and is mostly carried out in laboratory settings. It is an area of medicine that often operates at the interface of science and medical practice. The work of pathologists is often supported by a significant number of skilled laboratory scientists and technical staff. It also frequently involves complex machinery and processes.

The field of pathology on which cervical screening is largely based is cytopathology. Cytopathology is concerned with the examination of cells or tissue fragments, and the identification of abnormalities.

¹⁹ Final Report of the Scoping Inquiry into the CervicalCheck Screening Programme, September 2018, pg 61

²⁰ Ibid. pg 61

5.3 What is laboratory accreditation?

In order to provide assurance of the quality of the work carried out in pathology laboratories, a number of external standards frameworks have been developed. Laboratories are expected to operate within the parameters laid down by these frameworks and compliance is assessed by means of external inspection. There are a number of different organisations providing external accreditation services, and use of these various and distinct accreditation organisations varies from country to country.

5.4 Comparison of the accreditation schemes used by laboratories examining cervical cytology samples from CervicalCheck

The CAP scheme is delivered by the College of American Pathologists, which has developed an extensive library of generic and discipline-specific checklists reviewed annually, and available to both the inspectors and the laboratories. The ISO standard is a generic set of internationally agreed standards applied to all medical laboratory disciplines. The national accreditation bodies, such as the United Kingdom Accreditation Service (UKAS), assess medical laboratories against the ISO standard. The current standards were introduced in 2012 and are currently under review.

5.5 Common approaches

Both the CAP scheme and accreditation to the ISO 15189 standard have a very similar approach to core areas of pathology services such as equipment, the laboratory environment, competency assessment and management of personnel. The inspectors for the CAP schemes are drawn from a group of experienced laboratory professionals and although the ISO standard does not mandate who assesses laboratories, it is usual (e.g. in the UK) for assessors to be drawn from a similar group.

5.6 Main differences between the two schemes

- The CAP scheme checklists are reviewed annually and can therefore incorporate changes in technology and staffing. The ISO standard was introduced in 2012 and, although under review, no date has been announced for the release of the new version.
- The ISO 15189 standard takes a more holistic and focussed approach to the quality management system, with an emphasis on management reviews, internal audit and continual improvement²¹. However, the standard is generic and provides no specific laboratory discipline requirements, including with respect to cytology and pathology.

²¹ International Organization for Standardization. ISO 9001:2008: Quality Management Systems—Requirements. Geneva, Switzerland: International Organization for Standardization; 2008.

- An advantage of the CAP scheme is the use of the detailed technical checklists that are specific to each section of the laboratory and are used by inspectors and laboratory staff.
- The CAP scheme follow-up visits are unannounced. The ISO standard does not indicate how assessment visits are planned, but in practice most organisations (e.g. UKAS in the UK) provide the accreditation service through pre-arranged assessment visits.
- The ISO standard endorses the role of the Quality Manager to provide a focus for delivery of the quality management system. No comparable role exists in the CAP standards.
- Some of the clauses in the ISO standard are difficult to apply to those laboratory disciplines, such as cytology, that rely on interpretation of structure. Many of the clauses are more relevant to blood sciences than to cytology.
- CAP provides specific guidance on cytology issues such as qualifications, workload limits, quality control and the use of semi-automated screening devices. No specific guidance on these issues exists in the ISO standard.
- The operational application of the ISO 15189 standard by national accreditation bodies may vary across international borders. The CAP standard is applied across the USA, standardised by the checklist approach.
- A more detailed side by side comparison is provided in Appendix 2.

5.7 Analysis

In general terms the standards are very similar. The main difference from a cervical cytology perspective is in the application of the standard. The CAP standard provides specific professional guidance on key areas of cytology and is more adaptable than the ISO standard due to the annual review of the checklists. There is a case that there would be benefit obtained by taking advantage of both a standards and a guideline approach in the accreditation of laboratory standards.²² But dual accreditation by both CAP and ISO is not commonplace.

Based on assessment of both schemes and how they are applied to cervical cytology, it is the view of the Scoping Inquiry, on the basis of the information that has been supplied to us, that there are no overall differences that may impact significantly on the quality of the final reports on cytology. Providing laboratories meet the standards of either scheme and comply with national professional guidance, it is generally immaterial if the laboratory is accredited by the CAP scheme or accredited to the ISO 15189 standard. However, this considered view does not, in any way, invalidate or repudiate decisions made by CervicalCheck to specify ISO accreditation in tender or contract documentation.

²² AbdelWareth, Laila O., et al. "Fast track to accreditation: an implementation review of College of American Pathologists and International Organization for Standardization 15189 accreditation." *Archives of pathology & laboratory medicine* 142.9 (2018): 1047-1053.

6 Procurement of Laboratory Services

6.1 Overview

As outlined in the Final Report of the Scoping Inquiry, the NCSS commenced public procurement for the provision of cervical cytology laboratory (Liquid-Based Cytology – ThinPrep™) screening services in 2007. Since then there have been three separate public procurement processes. The last of these in 2012 involved the creation of a four-year multi-supplier framework. This framework has been utilised for the appointment of cervical cytology laboratory screening services since then. From 2008 the following providers have been engaged to deliver services:

- Quest Diagnostics, Inc. of Secaucus, New Jersey, USA;
- A number of laboratories owned by Sonic Healthcare, a global company whose headquarters are in Sydney, Australia, and which includes:
 - Clinical Pathology Laboratories (CPL) of Austin, Texas, USA;
 - MedLab Pathology Ltd of Sandyford, Dublin, Ireland;
 - The Doctors Laboratory of London, UK.

As outlined in the Final Report of the Scoping Inquiry published in September 2018, The Doctors Laboratory in London (TDL) is operating as a satellite of MedLab for the purposes of undertaking work on behalf of CervicalCheck. Based on the information available to the Scoping Inquiry, CervicalCheck is fully aware of the use of this laboratory. The laboratory was visited by members of the Scoping Inquiry team in the summer of 2018.

Additionally, some cytology services are provided by the Coombe Women & Infants University Hospital, Dublin (CWIUH). This service is provided based on a Memorandum of Understanding between the HSE/NCSS and CWIUH.

6.2 Information Received

Requests for tender occurred in 2008, 2010, and 2012. Each one was in a slightly different format, with the 2010 and 2012 requests being more detailed in nature. The 2008 and 2012 requests included Pre-Qualification Questionnaires that included a number of Pass/Fail criteria, while the 2010 did not.

The table (Table 6.2a) below shows some of the main criteria included in each request for tender with the approximate weighting. The 2010 request for tender did not include any Pass/Fail criteria, so criteria were given a weighting based on the section it was included in and the number of questions in the relevant section. For example, in the 2010 request for tender, third party accreditation was one of 16 questions in a section worth 18 marks overall, out of a total of 100 marks.

Criteria	Weighting		
	2008	2010	2012
Third Party Accreditation	Pass/Fail	1%	Pass/Fail
25,000 smear samples per annum	Pass/Fail	6%	Pass/Fail
Turnaround time of 10 working days	20%	10%	Pass/Fail
Quality assurance	25%	18%	15%
Capacity	20%	1%	2%
Fee Proposal	20%	35%	40%

Table 6.2a: Weightings used in tender process in 2008, 2010, and 2012

Although Third Party Accreditation is noted as having 1% weighting in 2010, it may have been considered as a Pass/Fail criterion. It is not clear from the documentation whether or not this was the case. The minimum of 25,000 smear samples per annum could be viewed in the same way.

It should be noted that capacity was specifically identified as part of the award criteria in the 2008 tender. 'Available Capacity, Resources & Readiness to Commence Provision of Services' comprised 20% of the overall marks during Stage 2 of the tender process. In subsequent requests for tender, capacity was not emphasised to the same degree. In both the 2010 and 2012 requests for tender, capacity was addressed as a question within a section of the request for tender. For example, in 2010, it was addressed as one of 13 questions under the Business Processes section, which was worth 10 out of 100 marks overall.

This limited focus on capacity is notable, as issues arose regarding laboratory capacity to handle surges that occurred in spring 2009. The 2010 request for tender was developed and published in 2009, only a few months after the impact of this unexpected surge on turnaround times was known to be a problem. The tender documents did, however, ask tenderers for their contingency arrangements to cover increases in workload. This was only one question in the entire tender and, based on the documentation provided to the Scoping Inquiry, there is no indication that contingency arrangements were a major consideration during the evaluation process.

The three elements that the requests for tender appeared to focus on, based on the information provided, are:

- the ability to screen a minimum of 25,000 smear samples per annum,
- a turnaround time of 10 working days, and
- the fee proposal.

The turnaround time and the fee proposal were separate criteria in the requests for tender in each of the years.

As part of the supplementary work, the Scoping Inquiry contacted all unsuccessful tenderers for any documentation from any of the three public competitions that they

still held. We appreciate the effort taken to locate and supply documents that the previous tenderers undertook and are very grateful for their assistance.

6.3 Determination of Accreditation

The tender documents for each of the public procurement processes required that the successful bidder or bidders have ISO 15189 accreditation. For example, the 2008 request for tender required bidders to:

'Please confirm that the Applicant (or the Lead Member/Sub Member carrying out the Services, in the case of a grouping) holds third party accreditation from a recognized accreditation body to International Standard ISO 15189 (Medical Laboratories – Particular Requirements for Quality and Competence) or International Standard ISO 17025 (General Requirements for the Competence of Testing and Calibration Laboratories) (or such other standards as the Authority at its sole discretion considers are equivalent thereto). The accreditation body shall be formally recognised as operating to the International Standard ISO 17011 (General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies). Formal recognition is achieved through that body being signatory to the Multilateral Recognition Agreements of the European Cooperation for Accreditation (FA) of the International Laboratory Accreditation Co-operation (ILAC).'²³

Having reviewed all of the documents received as part of the Scoping Inquiry, there is nothing included which provides any clarity as to how the tender evaluation panel, or those signing off on the contract award, assessed the equivalence of accreditation.

All of the subsequent competitions had the same requirement regarding ISO 15189 accreditation. This point was subsequently carried through to the contracts awarded and there were no discernible revisions made to tender documents at any stage to allow for any other acceptable accreditation.

Laboratory accreditation has been discussed in greater detail in Section Five.

6.4 Analysis

Procurement is a key part of the contracting process. As recommended in the Final Report of the Scoping Inquiry, successful proposals should be appended to the relevant contract. This would provide an easily accessible reference as to what contracted suppliers had committed to in their tender response documents.

In the case of the procurement processes described above, there is no evidence that prior operational issues were addressed when designing the subsequent tender

²³ National Cancer Screening Service Request for Pre-Qualification Submissions and Invitation to Tender to National Cancer Screening Service Board for the Provision of Cervical Cytology Laboratory (Liquid Based Cytology – ThinPrep) Screening Services 2008.

process. For example, in 2009, issues arose over the capacity and turnaround time of one of the laboratories. As outlined elsewhere in this supplementary report, the provider did make some suggestions about how this might be handled using additional laboratory locations. The NCSS specifically stated that they would '*not be supportive of this aspect of the plan*'²⁴, but when issuing a new request for tender later in the same year, the NCSS reduced the focus on capacity by almost eliminating it from the scoring despite these issues having occurred.

The weightings for the different procurement criteria changed significantly between 2008 and 2012. Quality assurance declined from a 25% weighting in 2008 to a 15% weighting by 2012. Capacity, as noted above, underwent a similar reduction in weighting. The documentation provided to the Scoping Inquiry does not indicate why these criteria were subject to such substantial reductions in their weighting in the tender evaluation process. Neither does the documentation indicate why the weighting of the fee proposal increased significantly, reaching 40% of the overall weighting in 2012. In summary; **as the weighting for quality assurance was reduced in the tender evaluation process, the price proposed by the bidder increased in importance.** This increased focus on price rather than quality assurance or capacity is notable following the capacity issues that occurred in 2009.

These issues reinforce the need to fully implement recommendation 22 of the Final Report of the Scoping Inquiry (recommendations from the Final Report can be found in Appendix 1) to ensure that price does not become the dominant determining factor during the decision-making process.

²⁴ Email to Quest Diagnostics from NCSS, dated 3rd June 2009

7 Contracting for Laboratory Services

7.1 Overview

After the completion of the tendering process, laboratories were required to sign contracts with the NSS/HSE for specified durations. There are four contracts, some of which were extended, for each of the companies.

The Final Report published in September 2018 noted that the use of other laboratories not named in the contracts would need further consideration. The contracts with the two companies over the relevant years have been examined, specifically with regard to the use of laboratories not originally named in the contract. Expert opinion was obtained in relation to the contracts and the obligations regarding unnamed laboratories.

7.2 Contracts with Laboratories

7.2.1 *Quest Diagnostics*

The parties to the 2008 contract are Quest Diagnostics Incorporated (Quest) and the National Cancer Screening Service Board, later the National Screening Service/HSE. An overview of the Quest contracts, based on the documentation available to the Scoping Inquiry, can be seen in the table (Table 7.2.1a) below.

	2008 contract	2012 contract	2014 contract	2016 contract
Duration of contract	1 August 2008 to 31 July 2010	1 August 2012 to 31 July 2014	1 August 2014 to 31 July 2016	1 August 2016 to 31 July 2017
Option to extend?	For a further two years	For a further two years	For one year	For one year
Extended durations	1 August 2010 to 31 July 2012	None	None	<ul style="list-style-type: none"> • 1 August 2017 to April 2018 • 1 May 2018 to 14 October 2018
Laboratories named	<p><u>2008 contract:</u> Primary: Schaumburg IL Teterboro NJ Secondary: Horsham PA Tucker GA Irving TX Heston Middlesex UK</p> <p><u>2010 extension contract:</u> Teterboro NJ. Wood Dale IL for transition period of 90 days.²⁵</p>	Teterboro NJ Syosset NY	Teterboro NJ	Teterboro NJ

Table 7.2.1a: Summary of contracts with Quest Diagnostics

The 2008 Quest contract requires the provision of services at ‘*the Primary Laboratories (or its nominee) for the term*’. The 2008 contract provides that:

“Laboratory” means each primary laboratory, secondary laboratory or testing facility, as the case may be and as approved by the Board, whether owned or controlled by the Contractor, which is (a) involved in the provision of the Services; and (b) meets, to the satisfaction of the Board, the Accreditation Standards; and (c) is listed in Schedule 2, or as otherwise approved by the Board in writing and “Laboratories” shall be construed accordingly.’

The 2008 Quest contract includes the following provisions:

‘4.6 The Contractor recognises the importance for the Board to be forewarned of any developments that may have an adverse impact on the Contractor’s ability to meet its obligations under this Contract. The Contractor shall

²⁵

We understand that the laboratory is based in Schaumburg, Illinois, approximately 7 miles from the Quest corporate office in Wood Dale, Illinois, and that the location Wood Dale is mentioned in some documentation when in fact Schaumburg is the correct reference. In other Quest documentation, the laboratory is stated as being in Chicago. Schaumburg and Wood Dale are north-western suburbs of Chicago. The three names appear to be used interchangeably

promptly notify the Board of any changes to its business, including without limitation the replacement of any information systems, which the Contractor reasonably believes would impact materially on the provision of the Services.

'4.7 The Contractor shall immediately notify the Board, both verbally and in writing, of... (b) any Adverse Incidents which the Contractor is aware of ...'
The phrase 'Adverse Incidents', is defined at 1.1 as 'any incident, adverse event or near miss which has adverse consequences or potentially adverse consequences for the clinical management of any Eligible Client and includes without limitation any apparent suspected or confirmed incident of material non-compliance.'

'8. Storage and Disaster Recovery

8.1 The Contractor hereby agrees that it shall comply at all times with the storage and disaster recovery provisions set out in Schedule 13 and as amended from time to time by agreement between the parties including but not limited to the use of a Secondary Laboratory for the provision of the Services (only to the extent necessary during any period to which the provisions of Schedule 13 apply.)

20.1 The Contractor shall not assign, transfer, sub-contract or in any other manner make over to any third party the benefit and/or burden of this Contract except as provided for in Clause 20.2.

20.2 The Contractor shall not sub-contract the Services or any part of the Services to a sub-contractor unless the Board has, at its sole discretion, given its prior consent in writing and only if: (a) such sub-contract shall be granted on and subject to:

(i) the same terms (mutatis mutandis) as are herein contained save that such sub-contract shall provide for automatic termination upon termination or expiration of this Contract; or

(ii) such terms as are approved in advance and in writing by the Board.

21.1 This Contract embodies and sets forth the entire Contract and understanding of the parties and supersedes all prior oral or written Contracts understandings or arrangements relating to the subject matter of this Contract. Neither of the parties shall be entitled to rely on any contract, understanding or arrangement which is not expressly set forth in this Contract.

21.2 This Contract shall not be amended, modified, varied or supplemented except in writing signed by duly authorised representatives of the parties.'

The terms of the 2012 contract contain the same text as above in relation to the corresponding sections of the contract. Paragraph 4.7 is amended to the extent that it provides for the prompt, as opposed to immediate, notification in writing of any Adverse Incidents. The 'Board' is also appropriately substituted with the 'NCSS'.

Of the contracts supplied to the Scoping Inquiry, only the 2008 and 2012 contracts have a completed Schedule 13: 'Storage and Disaster Recovery Plan.' In the 2014 and 2016 contracts supplied to the Scoping Inquiry, this schedule is blank. The 2008 contract contains a detailed Disaster Recovery Plan from Quest. It refers to 'Operational Disruptions' and provides that '*Close communication will take place with all parties until disruption is corrected.*'

In the 2012 contract, Schedule 13, while still entitled 'Storage and Disaster Recovery Plan', has been changed substantially. It now includes a policy document with an effective date of 29 June 2012. It sets out '*specific guidelines for alternative workflow in the event of equipment downtime and uncharacteristic operation of instruments in any Quest Diagnostics, Ameripath and Dermopath Diagnostics laboratories.*' The enclosed guidelines are very detailed and relate to laboratory processes and procedures to be followed in such an event.

There is an additional document enclosed in Schedule 13 in the 2012 contract entitled 'Quest Diagnostics'. This document is headed: Anatomic Pathology Standard Policy and has an effective date of 15 July 2009. It appears to relate to the general handling of Irish samples rather than in a 'disaster' setting. It contains a term in the Definitions section that states '*Term IRE Company: QPS [Quest Pathology System] company that has been designated for TBR [Teterboro] Ireland specimens. Note: Offloaded / outsourced IRE work will be transferred to the appropriate QPS company*'. Certain clarifications as to the meaning of these terms have been supplied to the Scoping Inquiry, but there is no clarity as to what constitutes an 'appropriate' company and whether or not this term could possibly purport to provide for a general right on the contractor's part to outsource and/or transfer work, contrary to the core contractual terms outlined above.

Apart from the paragraphs cited above, the terms of the 2014 and 2016 Quest contracts remain almost unchanged in comparison with the 2012 Quest contract. The exceptions are the substitution of the 'Board' with the 'NCSS' as appropriate, and a blank under Schedule 13, other than the heading 'Storage and Disaster Recovery Plan'.

7.2.2 Sonic Healthcare (Ireland) Limited and MedLab Pathology

As regards Sonic Healthcare (Ireland) Ltd, the first contract provides for services from 1 August 2010 to 31 July 2012. The parties to the contract are the National Cancer Screening Service Board, described as The Board, and Sonic Healthcare (Ireland) Ltd described as the Contractor (Schedule 1). An overview of the Sonic and MedLab contracts, based on the documentation available to the Scoping Inquiry, can be seen in the table (Table 7.2.2a) below:

	2010 contract	2012 contract	2014 contract	2016 contract
Duration of contract	1 August 2010 to 31 July 2012	1 August 2012 to 31 July 2014	1 August 2014 to 31 July 2016	1 August 2016 to 31 July 2017
Option to extend?	For a further two years	For a further two years	For one year	For one year
Extended durations	None	None	None	<ul style="list-style-type: none"> • 1 August 2017 to April 2018 • 1 May 2018 to 14 October 2018
Laboratories named	Austin TX	Austin TX Dublin IRE	Austin TX Dublin IRE	Austin TX Dublin IRE

Table 7.2.2a: Summary of contracts with Sonic Healthcare and MedLab Pathology

The definition of 'Laboratory' differs slightly from that in the Quest contracts in that it uses the term '*relevant laboratories*' as opposed to *Primary* or *Secondary laboratories*, but it retains a term requiring notification and an alternative approval requirement under the definition section.

According to the Sonic Healthcare (Ireland) Ltd contract:

“Laboratory” means each relevant Laboratory, as the case may be and as approved by the NCSS, whether owned or controlled by the Contractor, which is (a) involved in the provision of the Services; and (b) meets, to the satisfaction of the NCSS, the Accreditation Standards; and (c) is listed in Schedule 2, or as otherwise approved by the NCSS in writing and “Laboratories” shall be construed accordingly.’

Under Schedule 2, the only Laboratory identified was Clinical Pathology Laboratories (CPL) Incorporated, 9200 Wall Street, Austin, Texas.

The relevant sections of the contract regarding notification, disaster recovery, assignment, and sub-contracting are all identical to the terms of the Quest contract as set out above, and written approval from CervicalCheck is required in each such instance.

In the 2010 contract supplied to the Scoping Inquiry, Schedule 13 is still titled 'Storage and Disaster Recovery Plan', but is shorter than in the Quest contract and, instead of a policy document, there are three relatively short paragraphs. The Schedule provides that '*Sonic Healthcare Ireland Ltd is committed to developing a laboratory in Ireland that will have increasing capacity to undertake the cytology tests, although initially all tests will be undertaken in Austin Texas. In the event that CPL in Austin unexpectedly is unable to provide cytology services, workload can reliably be handled at other Sonic Group laboratories in the United States.*' It refers to a '*temporary transfer*' of staff being anticipated in the event that workload is shifted to other Sonic Group laboratories. It also states that, '*All Sonic laboratories in the US*

have compatible procedures, policies and IT systems with CPL. The necessary communication links are also already in place to facilitate the almost instant transfer of the tests.’ The Schedule states that ‘should there be any communication or transport disruption to the United States then TDL in London has the capacity, at least in the short term, to undertake all the tests required in Ireland or if necessary the test could be readily accommodated in Sonic’s Australian laboratories.’

The first MedLab Pathology Limited (MedLab) contract provides for services from 1 August 2012 to 31 July 2014. The parties to the 2012 contract are the HSE, the NCSS and MLP (The Contractor), with a place of business at Sandyford Business Park, Dublin 18. The definition of laboratory is identical to the contract definition in the 2010 Sonic Healthcare contract, as set out above. Two laboratories are now named in Schedule 2: Clinical Pathology Laboratories Incorporated Wall Street, Austin, Texas, and MedLab Pathology in Sandyford Business Park, Dublin.

Paragraphs 4.6 and 4.7 (notification) and paragraph 8 (Disaster Recovery) are identical to the terms of the Quest 2008 contract as set out above. Paragraph 20 (re assignment) and Paragraph 21 (variation) are identical to the terms of the Quest contract as set out above and require written approval by the NCSS.

Schedule 13 is different to the 2010 Sonic Healthcare contract and the Quest contracts. While entitled ‘Storage and Disaster Recovery Plan’, it provides for a broader interpretation that leaves scope for argument in that it appears to contemplate movement of tests to other locations, notwithstanding the overall contractual context. Again, however, there is no reference to this schedule overriding notification requirements.

‘Schedule 13. Storage and Disaster Recovery Plan

MedLab Pathology (MLP) is committed to maintaining a laboratory in Ireland that will have the capabilities to handle this programme. Support from our Sonic Group laboratory CPL, in Austin, Texas, allows MLP to continue to develop its capabilities to have increasing capacity to undertake all the cytology tests. In the event that MLP unexpectedly is unable to provide cytology services, workload can reliably be handled at CPL. Equally in the event that CPL in Austin unexpectedly is unable to provide cytology services, workload can consistently be handled at other Sonic Group laboratories in the United States.

It is anticipated that personnel from MLP/CPL could be transferred temporarily to these Sonic Group laboratories to provide the personnel needed for the shifted workload. All Sonic Group laboratories in the US have compatible policies, procedures and IT systems with CPL. The necessary communication links are also already in place to facilitate the almost instant transfer of the tests.’

The only reference to a crisis or disaster scenario is at the end of Schedule 13, which states: ‘should there be any communication or transport disruption to the United

States then TDL in London has the capacity, at least in the short term, to undertake all the tests required in Ireland or if necessary the tests could easily be accommodated in Sonic's other European and/or Australian Group laboratories.'

A MedLab contract provides for services from 1 August 2014 to 31 July 2016, or until such time as it is terminated by either party, with a one-year extension option.

A further MedLab contract provides for services from 1 August 2016 to 31 July 2017 with extension options until such time as it is terminated by either party.

The parties, the Contractor and the laboratories specified in the 2012, 2014 and 2016 contracts, remain unchanged.

7.3 Use of Other Laboratories

7.3.1 Quest Diagnostics

The related issue is the extent to which use of other laboratories is permitted in circumstances other than temporary disasters or 'adverse incidents'.

Paragraph 1.2 (b) of the 2008 Quest contract states that '*...a table of contents and headings are inserted for convenience only and shall be ignored in construing this Contract...*' Leaving aside, therefore, the specific heading at Schedule 13 which is 'Storage and Disaster Recovery Plan', one can nonetheless identify other aspects of the contract which suggest that Schedule 13 was indeed intended to be used for emergencies rather than as a general fall-back.

The use of a Secondary Laboratory is permitted '*only to the extent necessary*' as specified in Schedule 13. In the 2008 contract supplied to the Scoping Inquiry, Schedule 13 refers to scope for '*Any sustained operational disruption (greater than 48 hours) of either natural or man-made origin.*' The terms appear to contemplate a temporary finite disruption where '*close communication*' takes place '*until disruption is corrected*' and refers also to '*a resolution plan with backup instituted.*'

The use of another laboratory due to capacity issues is clearly an 'adverse incident' within the meaning of the contract, described as a reaction to overwhelming demand for screening which leads to capacity problems. This must have had '*potentially adverse consequences for the clinical management of any Eligible Client.*' As such, it appears that the incident (the laboratory being over capacity and having to outsource its screening of slides) contractually had to be notified to the Board (the NSS) by the Contractor (Quest). Seen in the light of the overall purpose of the contract, which was to promote public health and reliable screening, notification was important and should be interpreted as a condition of the contract.

Schedule 13 provides details on how to react to disruption and includes communications plans in that regard. It confirms the parties' intentions as to how

Contractors should react to unforeseen disruption and shows the central role communications are expected to play.

In the 2012 contract supplied to the Scoping Inquiry, Schedule 13 also contained a detailed policy document that appeared to cover the general handling of samples in circumstances other than a disaster situation. Reference was made to the outsourcing of Irish samples to 'appropriate' 'QPS' companies. There is no definition as to what constitutes an 'appropriate' company. One plain interpretation of this provision is that outsourcing can be arranged within Quest companies. If so, this is a matter that the NCSS should have regard to in relation to ongoing and/or future contracts. This affects the interpretation of whether NCSS should have been notified, but it does not appear to relate to the slides that were sent to additional laboratories in 2009 and 2010, as the contract is dated 2012.

There is an argument that if Quest sought this new term, and NCSS agreed to it in 2012, and if it does allow more flexibility in outsourcing, this is strong evidence that there was no comparable term in the earlier contracts. This reinforces the view that communication, notification and approval were of paramount concern, whether in temporary situations or not, at all times when screening services were redistributed, and that this was to ensure that NCSS maintained control over and ability to monitor the quality of the screening services provided.

The fact that Schedule 13 is blank in later contracts is arguably irrelevant, as the 2008 Quest contract was the one in being when the disputed slides were read in laboratories not named therein. In any event, seen in context, the parties may be taken to have agreed that the schedule remained as before. It appears unreasonable to suggest that they agreed to abandon the disaster recovery plan in its entirety, unless there was some replacement document.

7.3.2 Sonic Healthcare (Ireland) Limited and MedLab Pathology

Schedule 13 of the Sonic and MedLab contracts is entitled 'Storage and Disaster Recovery Plan'. All of the Sonic and MedLab contracts contain an identical term to that in the Quest contracts regarding headings being inserted for convenience only and not to be relied upon for construing the contract. However, as set out in Schedule 13 of the Quest contracts, other aspects of the Sonic contracts can be identified which suggest that Schedule 13 was intended to be used for emergencies rather than as a general fall-back and there is nothing to suggest that it was intended to override the notification requirement. Schedule 13 specifically refers, for example, to emergency scenarios such as '*communication or transport disruption in the United States*'.

Schedule 13 of the 2010 contract refers to 'unexpected' and 'temporary' transfers but has no detailed disaster plan as set out in the Quest contract.

In the 2012 and 2014 contracts supplied to the Scoping Inquiry, Schedule 13 provides that the '*workload can be consistently handled*' at other Sonic laboratories.

This may suggest that Schedule 13 permitted samples to be sent elsewhere within the group under the later contracts. However, the use of the word '*consistently*' seen in context suggests only that the Contractor considers the work to be consistent. It cannot be used to infer that work can be permanently re-located or affect the interpretation of other sections of the contracts regarding temporary measures.

The clear definition of laboratories remains largely unchanged throughout the relevant contracts, and requires that any laboratory used is either listed in the Schedule or is otherwise approved in writing by the other party and meets the required accreditation standard.

There is no evidence in the documentation supplied to the Scoping Inquiry that either NSS or CervicalCheck was notified in advance and in writing of the use of any additional laboratory facilities.

7.4 Notification and Correspondence with NSS

7.4.1 Quest

Based on the documentation available to the Scoping Inquiry, it appears that there was no advance written notification to NSS/CervicalCheck in relation to the use of the Grand Rapids, MI; Lansing, IL; Houston, TX; or of the actual use of the Irving (Dallas), TX laboratories.

Furthermore, Quest continued to use the Grand Rapids Laboratory from April to November 2009, the laboratory in Lansing from November to December 2009, and again in February, April, and May to July 2010; despite the NCSS giving specific and unequivocal written guidance in June 2009 that NCSS would not support the use of additional labs.

In the case of the Grand Rapids, Lansing, and Houston laboratories, these laboratories were not named in any contract and their use has only come to light in January 2019. Quest maintains that Grand Rapids and Lansing are satellite laboratories to the Schaumburg/Wood Dale laboratory, which is named in the 2008 Quest contract. Quest maintains that both the '*Lansing and Schaumburg laboratories has (sic) the same medical and Cytology Manager*²⁶. Quest also maintains that '*Cervical Check was informed of the involvement of the Grand Rapids / Wyoming, Dallas and Houston laboratories*²⁷.

Email correspondence indicates that Quest emailed NCSS in May 2009 notifying it of the intention to use four additional laboratories, described therein as being Quest Diagnostic sites. The four additional laboratories named were Auburn Hills, MI; Dallas, TX; Syosset, NY; and Horsham, PA. This was done due to the spike in testing as a result of the death of Jade Goody in March of 2009 and a NCSS advertising

²⁶ Quest letter dated February 5th 2019

²⁷ Ibid.

campaign. Two of the laboratories identified for planned future use, one in Horsham, PA, and one in Dallas, TX were named as Secondary Laboratories in the 2008 contract.

The only reference to Grand Rapids is made in the body of a separate document enclosed with the email from Quest, entitled NCSS Testing Status 05/20/2009. This revealed that the Grand Rapids laboratory had already been in use since April 2009 and that the current capacity at that stage was 200 patients per day. It further stated that *'Grand Rapids are withdrawing testing capacity and we are pursuing Dallas to replace capacity to remain at 800 patients per day.'*

The replying email in June 2009, as noted earlier in this report, states that the NCSS had reviewed the plan to use additional labs. It stated: *'We would not be supportive of this aspect of the planit would introduce a risk that we are not willing to accept. We recommend that you have a plan in place that uses the two existing labs to handle any future surges.'*²⁸

Notwithstanding the NCSS email, recent correspondence with Quest indicates that it continued to use the Grand Rapids laboratory from April to November in 2009, and the laboratory in Lansing from November to December in 2009, in February and April 2010, and from May to July 2010, despite the unequivocal and specific guidance from NCSS not to do so.

No reference can be found in the documentation provided to the Scoping Inquiry regarding the use of a laboratory in Houston, TX.

It is noted from the above correspondence and from our inquiries with the NCSS that the intention of the NCSS appears to have been that any testing should be confined to the two existing laboratories, i.e. the Primary Laboratories in Schaumburg, IL and Teterboro, NJ, as identified specifically in the 2008 contract.

	2009							2010								
	Apr	May	Jun	Jul	Aug	Sep	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	
Grand Rapids	17,660 slides															
Lansing							1,772 slides					1,927 slides				
Houston		2,289 slides														
Dallas		917 slides														

Table 7.4.1a: Additional Quest laboratories, workload, and time periods

The service was effectively redistributed to additional laboratories that were owned and managed by Quest in Grand Rapids, Lansing, and Houston, none of which were named in the 2008 contract, nor in subsequent Quest contracts. Not only was there no prior agreement by the NCSS to their use, but, when it was suggested to NCSS

²⁸ Email to Quest Diagnostics from NCSS, dated 3rd June 2009

that additional laboratories might be used to clear a backlog, the NCSS expressly refused to approve their use. These three laboratories do not fall within the specified definition of 'Laboratory', which definition clearly requires written approval by the Board, whether owned or controlled by the Contractor, and requires that they meet accreditation requirements to the Board's satisfaction. Even if permitted under paragraph 8, and that is not necessarily the case, it is permitted only when agreed and notified in writing to the Board, i.e. the NSS.

7.4.2 **Sonic Healthcare**

There is no evidence based on the documentation provided to the Scoping Inquiry that Sonic Healthcare notified NSS or CervicalCheck in advance, in writing, in relation to the use of laboratories in San Antonio, TX; Las Vegas, NV; Victoria, TX; Honolulu, HI; or Orlando, FL. Sonic Healthcare asserts that NSS/CervicalCheck was made aware of the use of a laboratory in Greater Manchester, UK. This has been discussed earlier in this report.

In the case of Sonic Healthcare, samples were sent to six laboratories (one of which continues to review slides). None of the six was named as a Laboratory in any of the three applicable contracts from 2010 to date.

What relevant contract applies depends on exactly when samples were sent to the different laboratories and that is not clear from the documentation provided to the Scoping Inquiry. However, the terms of the various relevant contracts are set out in detail above and are similar in effect.

There is no evidence, based on the documentation provided to the Scoping Inquiry, that Sonic Healthcare notified the NSS in advance and/or obtained its written approval in relation to five of the laboratories used.

It is known that Sonic Healthcare sent samples to two additional laboratories in 2010, which were not named in the 2010 Sonic contract. Sonic Healthcare invoked Schedule 13 of the 2010 contract, the schedule entitled 'Storage and Disaster Recovery Plan' to justify the sending of samples to the Honolulu and Orlando laboratories.

The Final Report of the Scoping Inquiry in September 2018 stated that: '*There is no record available to the Scoping Inquiry that would suggest that CPL advised CervicalCheck of either the use of these laboratory facilities or any conditions that might be judged under Schedule 13 to require the use of these facilities.*'²⁹ As set out above at Section 7.3.1, even if the heading to this schedule is ignored, the other provisions suggest that this was indeed a schedule to be used in emergencies and for temporary capacity. Again, nothing appears to override the notification requirements set out elsewhere in the contract.

²⁹ Final Report of the Scoping Inquiry into the CervicalCheck Screening Programme, September 2018, pg 55

7.5 Penalties Contained in the Contract

The contracts between the NSS and the laboratories contained a financial penalty for failure to meet the stipulated turnaround time for slides. There was therefore a financial incentive for the laboratories to take action to ensure that targets for turnaround were met.

This further reinforces the concerns of the Scoping Inquiry that turnaround time was the key measurement within the contract. Where the turnaround time was missed, there was a sliding scale of penalties based on the percentage of slides that did not meet the requirement.

According to the information available to the Scoping Inquiry, the sum of approximately €120k has been withheld from the laboratories for this reason since the inception of the programme: a relatively small amount in relation to the overall cost of the cytology services. We have been informed that the damages were not collected from the laboratories but were used to offset costs incurred by the laboratories in the delivery of additional screening services that were not explicitly covered in the terms and conditions of the contracts.

7.6 Analysis

Based on the documentation and expert opinion available to the Scoping Inquiry, we conclude that laboratories not explicitly named in the contracts were not to be used in fulfilling the contracts. The contracts required that a laboratory be '*approved by the Board [or NCSS or NSS] in writing*' if it was not explicitly named in Schedule 2 of the contract.

There is no evidence, based on the documentation provided to the Scoping Inquiry, that this advance written notification from either provider took place before the additional laboratories were used.

We noted that Schedule 13 was blank in the later Quest 2014 and 2016 contracts supplied to the Scoping Inquiry. While it is likely that the parties agreed that the schedule remained as before (discussed in Section 7.3.1), the fact that there is such a lack of clarity about these issues should prompt a review of contracts and highlights the need for increased clarity as to the circumstances in which outsourcing or sub-contracting can take place. Clarification is needed on whether this is to be confined to disaster scenarios, or can be done in any other circumstances; and whether there are any circumstances in which services can be carried out elsewhere without prior notification and approval.

As per the first recommendation in Section 4.5.6, the Scoping Inquiry remains of the view that CervicalCheck should ensure that no laboratory provider should utilise locations other than those specified in the contract, without its prior written permission.

8 Recommendations

Many of the issues of concern that have been explored in detail in this supplementary report were the subject of recommendations in the Final Report of the Scoping Inquiry published in September 2018. There are however two further recommendations that I believe to be important in light of this further work on laboratories.

1. Future CervicalCheck contracts for the provision of cytology and other laboratory services should contain even more explicit provisions to ensure that no contracted cytology or other laboratory activity should be carried out anywhere other than in the precise locations, and by the precise company, identified in the written contract, without prior written permission from CervicalCheck.
2. The quality assurance (QA) process developed and operated by CervicalCheck must be based on a consistent and thorough approach to the quality of the laboratory services being provided to the cervical screening programme. This QA system must be designed and operated irrespective of the physical location of laboratories and the possession of external accreditation by the laboratory should not be viewed as in any way replacing or diminishing the need for QA processes.

Appendix 1 – Recommendations from September 2018 Report

Method of Approach

- 1) The Department of Health and the HSE should revise their policies in respect of document management. This should ensure that good quality records are created and maintained which are authentic, reliable, and complete in searchable format. They should be protected and preserved to support future actions and ensure current and future accountability.

Listening to the Voices of the Women and Families Affected

- 2) The Minister for Health should give consideration to how women's health issues can be given more consistent, expert and committed attention within the health system and the Department of Health.
- 3) The Department of Health should examine the current arrangements for patients to have access to their hospital medical records so that such access can be achieved in a timely and respectful way.

CervicalCheck – Organisation and Governance

- 4) The Minister for Health should consider seriously the appointment of two patient advocates to the proposed new Board for the HSE.
- 5) A National Screening Committee should be constituted to advise the Department of Health and the Minister on all new proposals for screening and revisions to current programmes.
- 6) The NSS, whatever its location within the HSE, should be able to access senior levels of the organisation and be located close to strategically and logically linked services.
- 7) A far greater component of professional and public health expertise should be deployed across the screening services, not as external advisors but with significant roles within the screening programmes.
- 8) The implementation of new governance arrangements for the HSE should include a substantial revision to the organisational approach to risk management and its reporting.

CervicalCheck – Laboratory Services

- 9) CervicalCheck should revise its programme standards to clarify what is mandatory, and to clarify the level of reliance on external accreditation processes. This is particularly important in respect of laboratory service providers in other jurisdictions.
- 10) As a priority all providers should fully implement a single agreed terminology for the reporting of results and ensure that criteria for defining the different grades of abnormality are consistently applied.
- 11) Based on revised programme standards, a specification for a new and more robust quality assurance procedure should be documented and form part of the contract for services with cytology providers.

- 12) CervicalCheck should adopt a formal risk management approach to parameters which do not reach acceptable standards despite full intervention and monitoring.
- 13) CervicalCheck should document which organisation (e.g. CervicalCheck, HSE, Providers) has responsibility for pursuing issues of continued non-compliance and the consequences thereof. An advisory group of cytopathologists and other laboratory based staff should be established to advise on this process, and this should include input from those who work for non-State providers.
- 14) CervicalCheck should collate and publish annual data on reporting rates for all categories broken down by provider.
- 15) In order to obtain comparable data CervicalCheck should amend data specifications to exclude samples taken from colposcopy, and analyse and publish all performance statistics on samples taken in primary care, or equivalent, only.
- 16) When this change to comparable data is made further epidemiological investigation is required to establish whether the differential rates of abnormality persist and, if so, to what extent they can be attributed to underlying population differences.
- 17) The different rates of sensitivity for ASCUS+ identified by second screen at each provider require further investigation by CervicalCheck.
- 18) The different inadequate rates are not a cause for immediate concern. The Scoping Inquiry recommends that the findings of the English health technology assessment (HTA) study referenced in Appendix 1 are implemented across all providers to try to obtain more consistency.

Procurement of Laboratory Services

- 19) Winning proposals should be appended to the relevant contract and not destroyed until at least one year following the termination of the contract (and any extension thereof).
- 20) A system should be put in place for proactive contract governance in order to safeguard the future of the service and the relationship of the service with the market place.
- 21) Procurement processes for external laboratory services should be designed to test the market at reasonable intervals (e.g. every four years), to ensure that CervicalCheck does not become overly reliant on a small number of incumbent suppliers, and to ensure that innovative approaches and added value can be formally captured within the procurement process.
- 22) CervicalCheck should ensure that its procurement approach maintains a balanced focus on qualitative factors, supplier experience, and innovation, alongside cost considerations.
- 23) CervicalCheck should ensure that future procurements incorporate measures to test performance in the current contract.

- 24) External professional assistance should be sought in the construction of any future RFP, and the evaluation of proposals in order to ensure that best practices developed across the public sector since 2012 are incorporated into key areas such as development of RFP documents, supplier briefings, construction of award criteria, construction of evaluation panels, establishment of governance and continuous improvement programmes, etc.
- 25) Assurances should be sought with respect to the capability to deliver the service as specified and without material change. Where change is possible, robust change management procedures, which include approval by the procuring authority, should be defined.

Auditing Cervical Screening

- 26) Audits should continue to be an important component of cervical screening as this complies with all good clinical practice. Common, robust and externally validated approaches to the design, conduct, evaluation and oversight of audits should be developed across the screening services.
- 27) There should be a minimum of two patient advocates involved in the oversight of clinical audits for the screening services.

Open Disclosure and the HSE

- 28) The HSE's open disclosure policy and HSE/SCA guidelines should be revised as a matter of urgency. The revised policies must reflect the primacy of the right of patients to have full knowledge about their healthcare as and when they so wish and, in particular, their right to be informed about any failings in that care process, however and whenever they may arise. The revision process should be overseen by a working party or committee with a minimum of two patient advocates amongst its members.
- 29) The option of a decision not to disclose an error or mishap to a patient must only be available in a very limited number of well-defined and explicit circumstances, such as incapacity. Each and every proposed decision not to disclose must be subject to external scrutiny and this scrutiny process must involve a minimum of two independent patient advocates.
- 30) A detailed implementation programme must be developed that ensures the principles and practice of open disclosure are well understood across the health service. In particular, medical staff must be required, as a condition of employment, to complete training in open disclosure.
- 31) A governance framework for open disclosure must be put in place that includes evaluation and audit.
- 32) An annual report on the operation of open disclosure must be presented in public session to the full Board that is to be appointed to govern the HSE.

Open Disclosure and the Medical Council

- 33) The Department of Health should enter into discussions with the Medical Council with the aim of strengthening the guide for registered medical practitioners so that it is placed beyond doubt that doctors must promote and practice open disclosure.

Open Disclosure and CervicalCheck

- 34) A statutory duty of candour must be placed both on individual healthcare professionals and on the organisations for which they work.
- 35) This duty of candour should extend to the individual professional-patient relationship.

Cancer Registration

- 36) NCRI should urgently negotiate and implement data sharing agreements with all major providers and users of registration data. This is necessary in order to meet the requirements of the new EU General Data Protection Regulation but also, and more importantly, represents good governance. Where such an agreement is with an overarching statutory body, such as the HSE, there should also be individual MoUs in place with distinct organisational users of data, such as the cancer screening programmes.
- 37) Timely data is important to assure the effectiveness of both cancer screening and treatment services. This is a patient safety issue. To fulfil its role properly as a cancer registry:
 - (a) NCRI must be given additional support to recruit cancer registration officers and strengthen its public health medicine capacity.
 - (b) The Department of Health and the HSE should commit to make progress on electronic data capture by NCRI from hospitals, and set clear targets for its achievement.
- 38) NCRI should review data definitions related to cervical cancer and CIN (cervical intra-epithelial neoplasia) cases to ensure that the screening flags are meaningful for analysis of the effectiveness of the CervicalCheck programme
- 39) The need to duplicate the collection of patient level details of cervical cancers by both NCRI and CervicalCheck should be reviewed. It is notable that both CervicalCheck and NCRI have identified patients that the other has not. If it is determined that both systems should continue then properly functioning data sharing agreements must be put in place.
- 40) The Department of Health must review the composition of the Board of NCRI in order to ensure more robust governance, in particular in QA, data sharing and patient safety.
- 41) Any future consideration of the governance of the NSS needs to acknowledge, and contribute to the effective oversight of, the specific role played by NCRI in working in conjunction with the cancer screening programmes.

- 42) The Department of Health should work with the Board of NCRI to commission an annual peer review, for at least the next three years, by external cancer registration and cancer control experts. The report of each review and the response to it by NCRI should be forwarded to the Minister for Health.
- 43) NCRI should establish stronger and more regular contacts with external clinical and public health experts to ensure scrutiny of, and advice on, outputs from NCRI so as to enhance the level of its clinical and public health interpretation, importance and impact.
- 44) One of the requirements for the establishment and good management of a screening programme is that health services should be of a good standard to manage those people detected with disease by the screening programme. NCRI, through links with the clinical community, should seek to engage actively in the assessment of the quality of cancer services, comparing these for screen and non-screen detected cases.

Other Screening Programmes

- 45) Considering the clinical and technical differences that characterise the different screening programmes, NSS needs to advance its thinking on cross programme learning, external QA, and governance oversight of the QA programmes.
- 46) The composition and duration of appointments for all QA Committees should be reviewed, in conjunction with emerging clinical advisory committee structures.
- 47) The QA Committees should review and confirm the adequacy of the arrangements within their respective screening programmes for introductory training and continuing staff development, as well as the arrangements at all levels in the quality system for identifying and appropriately responding to inadequate technical or clinical performance.
- 48) NSS should consider, with external assistance, the relevance of the HSE policy on 'Open Disclosure' as it develops in light of this Scoping Inquiry, for all of its screening programmes.

Resolution

- 49) The Department of Health should consult with interested parties as to how women and families who wish to, can be facilitated in meeting with the clinician who was involved with their care and/or disclosure.
- 50) The Department of Health should encourage and facilitate (but not necessarily participate in) a meeting involving the presidents of the Medical Council, the Royal Colleges and their faculties, leaders of other leading medical organisations and representatives of the women and families involved with the cervical screening problems.

Appendix 2 – Comparison of Laboratory Accreditation Schemes

	CAP	ISO 15189
Background to accreditation process	<p>The College of American Pathologists (CAP) Laboratory Accreditation Program accredits the entire spectrum of laboratory test disciplines with customized checklist requirements developed by the CAP.</p> <p>The CAP peer-based inspector model provides a balance of regulatory and educational coaching supported by a pathology organization.</p> <p>The Laboratory Accreditation Program inspects a variety of laboratory settings from complex university medical centres to physician office laboratories, and covers a wide array of disciplines and testing procedures.</p> <p>Offers accreditation mainly in the USA but also to international laboratories overseas.</p>	<p>ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee.</p> <p>The main task of technical committees is to prepare International standards. Draft international standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an international standard requires approval by at least 75 % of the member bodies casting a vote.</p> <p>The ISO standard is used by national accreditation bodies (e.g. UKAS in the UK)</p>
Assessors / inspectors	<p>Uses multidisciplinary teams of laboratory professionals as inspectors. Inspectors have discipline specific knowledge and experience</p>	<p>Uses discipline specific assessors in the UK who are either biomedical scientists, clinical scientists or medical qualified pathologists</p>
Accreditation Cycle	<p>On site laboratory inspection every two years</p>	<p>Four year cycle with full assessment every four years covering full repertoire of the service</p>
Self or external assessment	<p>Self-inspection using material provided by CAP in the years where there is no on-site inspection</p>	<p>Annual surveillance visits (on years 1-3) focussed on specific areas/tests to cover the full repertoire over the 4year cycle</p>
Basis of assessment / inspection	<p>Based on checklists which are subject to annual updates to reflect current practice</p>	<p>Based on assessment against the ISO standard using template reports and feedback spreadsheets supplied by national accreditation body. Current 2012 standard is under review.</p>

	CAP	ISO 15189
Scope of assessment	All testing performed at a single location under the leadership of one laboratory director must be inspected. CAP does not accredit portions of laboratories	Laboratory specifies scope of practice and can remove elements of the service from the assessment process.
Accreditation award	CAP laboratory accreditation certificate awarded upon successful completion of inspection	The national standards/accreditation body will offer accreditation against the ISO standard upon successful completion of the assessment and clearance of any findings.
Assessment process	Inspectors and laboratory staff use the same checklists	No checklists used. Scope of practice is defined by the laboratory. National accreditation bodies supply standard templates for assessment and reporting.
Application process	On line application process	Application forms completed electronically and sent to accreditation body by email.
Timescales for assessment	Initial Inspection within 6 months of submission of on line application	Will vary from country to country depending on workload of national accreditation body
Pre-planning	All subsequent inspections are unannounced and performed within the 90 day period preceding the anniversary date.	All assessment visits are pre-planned with agreed dates
Feedback to the laboratory	Summation report provided during a summation conference and copy of deficiencies left by the inspection team.	All findings, non-conformities and corrective action are agreed at closing meeting with laboratory management team.
Response time	Responses to summation report and deficiencies must be submitted within 30 calendar days after the inspection date	3 months to respond to the full assessment findings. 1 month to respond to the surveillance visit findings
Collaboration with assessors /inspectors	Collaboration with CAP technical specialists on follow up questions	Accreditation body will liaise between laboratory and assessment team.
Timescale for decision	Accreditation decision within 75 days of the inspection.	Will vary from country to country depending on workload of national accreditation body
Interim assessment /inspection	Self-inspection CAP material sent on anniversary of the initial inspection.	Surveillance visit is the equivalent in the UK

	CAP	ISO 15189
Laboratory director	Laboratory director must have an MD, DO, DPM PhD or commensurate education and experience	No specific qualifications for the lab director. The laboratory director must have the competence and delegated responsibility for the repertoire of tests. The laboratory director is responsible for professional, scientific, organisational, and educational matters relevant to the stated scope of practice
Staff qualifications	CAP requires that all high complexity testing personnel hold an associate degree in a laboratory science or medical technology from an accredited institution.	No specific statement on specific qualifications beyond the overall assessment of the qualifications and suitability of all staff for the repertoire of the laboratory
EQA	Laboratories subject to U.S. regulations must enrol and participate in a CAP-accepted PT program for all required tests	Strong focus on EQA and IQC and the use of inter-laboratory comparison schemes (ILCS) if no accredited EQA available.
Key documents and procedures	To meet CAP Laboratory Accreditation requirements, the laboratory must have the following key documents/processes: <ul style="list-style-type: none"> • Quality Management Program • Chemical Hygiene Plan • Document Control Process • Competency Assessment Program • Test Method Validation Documentation • Laboratory Director Oversight Documentation • Laboratory Information System (LIS) – if applicable 	To meet the ISO standard, the laboratory must have documents/processes including the following: <ul style="list-style-type: none"> • Quality policy and Quality manual • Quality manager • Document control process • Laboratory information management system (LIMS) • Quality objectives • Management review • Document control system • Competency assessment system
Additional resources	Additional resources can be purchased from CAP	A pre-assessment visit can be arranged for additional payment
Fees	Annual accreditation fees are based on the institution's laboratory sections, list of testing performed (activity menu), organization structure and complexity.	Fees are based on complexity of the laboratories workload and geographic location (s)

	CAP	ISO 15189
Quality Management	The laboratory must have a written quality management (QM) program that systematically ensures the monitoring and evaluation of the quality and appropriateness of its patient care services, resolution of identified problems, and implementation of the program throughout all laboratory sections by the laboratory director.	Laboratory management must establish measurable and consistent quality objectives which fit with the quality management system. Laboratory management must ensure that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.
Staff concerns	The laboratory must have a written policy that encourages employees to communicate any concerns or complaints about the quality of patient testing and safety to proper authorities. This policy must indicate that no retaliation will occur because of expressed concerns or complaints. The investigation and analysis of employee complaints and suggestions, with corrective and/or preventive action as appropriate, should be a part of the laboratory quality management program and specifically addressed in laboratory quality management records	The laboratory must have a documented procedure for the management of complaints or other feedback received from clinicians, patients, laboratory staff or other parties. Records must be maintained of all complaints and their investigation and the action taken. Laboratory management must encourage staff to make suggestions for the improvement of any aspect of the laboratory service. Suggestions must be evaluated, implemented as appropriate and feedback provided to the staff. Records of suggestions and action taken by the management must be maintained.
Personnel	Instructions for sampling and evaluating laboratory personnel records are included in the Team Leader section of the Inspector’s Inspection Packet. The inspector should use those guidelines to select and review personnel files. Technical personnel records for each employee must include all of the following: <ul style="list-style-type: none"> • Summary of training and experience • Copy of an academic diploma, transcript, or primary source verification report demonstrating that the employee meets required educational qualifications • Laboratory personnel license, if required by the state • Certification if required by the state or employer 	The laboratory must have a documented procedure for personnel management and maintain records for all personnel to indicate compliance with requirements. Laboratory management must document personnel qualifications for each position. The qualifications must reflect the appropriate education, training, experience and demonstrated skills needed, and be appropriate to the tasks performed. The personnel making judgments with reference to examinations must have the applicable theoretical and practical background and experience.

	CAP	ISO 15189
	<ul style="list-style-type: none"> • Description of current duties (may be generic to a position) • Records of continuing education • Records of radiation exposure where applicable • Work-related incident and/or accident records • Dates of employment 	<p>Records of the relevant educational and professional qualifications, training and experience, and assessments of competence of all personnel must be maintained. These records must be readily available to relevant personnel and must include but not be limited to:</p> <ul style="list-style-type: none"> • educational and professional qualifications • copy of certification or license, when applicable • previous work experience • job descriptions • introduction of new staff to the laboratory environment; • training in current job tasks • competency assessments • records of continuing education and achievements; • reviews of staff performance
Supervisors	The qualifications and responsibilities of supervisory personnel, including technical supervisors, general supervisors, technical consultants, and clinical consultants, are defined in the Laboratory General Checklist.	No specific comments on supervisors
Personnel Competency Assessment	The laboratory must retain documentation that all testing personnel have satisfactorily completed initial training on all instruments/methods applicable to their designated job. The inspector will look for records indicating that the laboratory has assessed the competency of each person to perform his or her assigned duties annually. Assessment every 6 months is required during the first year of an individual's duties. The laboratory must have a corrective action plan to retrain and reassess employee competency when problems are identified with employee performance. The inspector will look for evidence that the laboratory	<p>Following appropriate training, the laboratory must assess the competence of each person to perform assigned managerial or technical tasks according to established criteria. Reassessment must take place at regular intervals. Retraining must occur when necessary. Competence of laboratory staff can be assessed by using any combination or all of the following approaches under the same conditions as the general working environment:</p> <ul style="list-style-type: none"> • direct observation of routine work processes and procedures, including all applicable safety practices;

	CAP	ISO 15189
	reassessed competency and found it acceptable after implementation of a corrective action plan.	<ul style="list-style-type: none"> • direct observation of equipment maintenance and function checks; • monitoring the recording and reporting of examination results; • review of work records; • Examination of specially provided samples, such as previously examined samples, inter-laboratory comparison materials or split samples. • Competency assessment for professional judgment should be designed as specific and fit for purpose.
Annual assessment /inspection	Laboratories must perform a self-inspection each year that an onsite inspection by the CAP does not take place. The laboratory is given 60 calendar days (from receipt of materials) to complete the self-inspection and return the signed forms indicating completion of the self-inspection to the CAP. If deficiencies are found, the laboratory must record corrective action for each deficiency.	Annual surveillance visits that focus on specific areas or tests. Reports with non-conformities are produced and agreed at the closing meeting. The laboratory has one month to supply evidence to clear the findings.
Assessors /inspectors - Cytopathology	The Cytopathology inspector must be a pathologist or supervisor-qualified cytotechnologist actively involved or experienced in the current practice of cytopathology, and conversant with contemporary quality management practices and the CLIA regulations pertinent to cytopathology	The national accreditation body assess the competence and experience of assessors to assess specific laboratory disciplines.
On site case review	The on-site inspection will require review of slides and reports, direct observation of technical procedures, and careful review of quality management practices. On-site case review of at least 10-15 randomly selected cases from a range of diagnostic categories is performed by the inspector	No on-site slide or case review specified by the standard.

	CAP	ISO 15189
	Laboratories that do not file slides on-site (e.g. “read-only” laboratories) must retain a sample of slides on-site on all days when the laboratory is subject to its regular on-site inspection. The sample must, at a minimum, include all slides accessioned over a continuous two-week period within the previous two years. The laboratory must also be able to produce any slide upon the request of an inspector during the required five-year retention period for gynaecologic slides.	
Cytology qualifications and experience	The inspector must review the qualifications of the pathologist director (technical supervisor), general supervisor, and cytotechnologist(s), and assess records that affirm performance of their respective responsibilities as outlined in the checklist. The cytopathologist may serve as the general supervisor. Alternatively, a qualified cytotechnologist with at least three years of full-time experience within the preceding 10 years may also serve as the general supervisor.	No specific focus beyond the overall assessment of the qualifications and suitability of all staff for the repertoire of the laboratory.
Workload limits	Very specific calculations of individual workload to ensure staff do not exceed CLIA established workload limits. This includes staff who work in more than one laboratory and the impact of semi-automated screening devices.	No specific guidance in this area. National professional guidance and standards on workload are used in the UK.
Information for users	The laboratory must have a written policy to educate providers of cervical specimens that the Pap test is a screening test for cervical cancer with an inherent false-negative rate. The preferred mechanism is an educational note on all Pap test reports that are negative (within normal limits) or display benign cellular changes. Other	The laboratory must establish arrangements for communicating with users on the following: <ul style="list-style-type: none"> • clinical indications and limitations of examination procedures • professional judgments on the interpretation of the results of examinations

	CAP	ISO 15189
	mechanisms include sending periodic educational information to providers.	<ul style="list-style-type: none"> Consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria.
Equipment	<p>The laboratory must record the appropriate technical and interpretive training for each instrument used. Instrument performance must be routinely verified and monitored, with corrective actions recorded and procedures for handling cases during instrument failure.</p> <p>Ongoing monitoring of instrument function and maintenance on all devices must be recorded.</p> <p>Monitoring of device operation must be in accordance with manufacturers' instructions. If the manufacturer does not provide monitoring recommendations, the laboratory must record the specific monitoring procedures used. Limits of acceptable variation must be defined in laboratory procedures.</p>	<p>The laboratory must verify upon installation and before use that the equipment is capable of achieving the necessary performance and that it complies with requirements relevant to any examinations concerned.</p> <p>Equipment must be operated at all times by trained and authorized personnel.</p> <p>Current instructions on the use, safety and maintenance of equipment, including any relevant manuals and directions for use provided by the manufacturer of the equipment, must be readily available.</p> <p>The laboratory must have a documented procedure for the calibration of equipment that directly or indirectly affects examination results.</p>
IQC – Technical Assessment	A sample of slides from slide preparation instruments, including those using liquid-based technology and cytocentrifuge or filtration methods, must be routinely reviewed microscopically for technical acceptability.	No specific guidance. The section on IQC is generic and states that appropriate steps must be taken to ensure the quality of the test result.
Quality Management (QM) - Cytopathology	<p>The facility's Quality Management program must address the validation of both normal and abnormal diagnoses and the assessment of laboratory and personnel performance.</p> <p>Quality measures for abnormal findings must include such activities as peer and hierarchical review, correlation of cytology findings with histologic and clinical findings, recorded evaluation of significant discrepancies, and appropriate use of intradepartmental and extra-departmental consultation.</p>	<p>The laboratory must establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.</p> <p>The quality management system must provide for the integration of all processes required to fulfil its quality policy and objectives and meet the needs and requirements of the users.</p> <p>No specific guidance on quality measures in cytopathology.</p>

	CAP	ISO 15189
Internal audit	No focus on internal audit	The laboratory must conduct internal audits at planned intervals to determine whether all activities in the quality management system, including pre-examination, examination, and post-examination conform to the requirements of the standard and to requirements established by the laboratory.