The Academy of Clinical Science and Laboratory Medicine

Review of Cervical Cytology Screening Service Developments 2000 – 2019

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Background

Uterine cervical cancer is generally caused by infection with sexually transmitted human papilloma viruses. There are at least 15 high-risk oncogenic HPV viruses. Screening of women between the ages of 25 and 60 years is considered the most effective protocol for early detection of HPV-induced cervical abnormalities. Although many EU countries established cervical screening programmes in the 1970s and 1980s, Ireland has only had a national cervical screening programme since 2008.

The Irish Cervical Screening Programme (ICSP) was set up in 2000, and a pilot screening service was in operation from 2001-2008. The Laboratory services were reviewed in 2002, and there were at that time fourteen laboratories providing the cervical screening service. In 2004 Dr Euphemia McGoogan reviewed the operations and recommended that four large regional laboratories should provide the cervical cytology service, one in the West, South and two in the East. According to McGoogan "In 2002, a total of 230,000 conventional smears were processed in the Irish laboratories, of that 70% were performed in five larger laboratories. Moving to Liquid Based Cytology (LBC) and streamlining internal quality control (IQC) practices should allow an additional throughput of at least 50% i.e. up to 345,000 capacity across all laboratories". In the report, a high-grade abnormality rate of 1.9% on average was determined in the five larger laboratories.

To increase capacity to undertake the additional cytology workload for the national cytology service, the Dublin Institute of Technology was approached by the ICSP. From 2005 an honours degree programme was offered in Medical and Molecular Cytology, to train an extra ten scientists a year for the service. The ICSP provided funding of €150,000 to the DIT to provide the training facility with appropriate equipment for Cytology training.

Cytology Screening Practice in Ireland prior to 2008

The Cytology services were upgraded in the public laboratories, moving to LBC and applying IQC and an EQA system operated through the Irish Association for Clinical Cytology. All smears were reviewed twice by trained medical scientists, firstly a rigorous manual screen of the full smear taking 6-10 minutes, followed by a second rapid review for 1-2 minutes by an experienced cytologist. All abnormal or equivocal smears were reviewed by a third cytologist or cytopathologist. The average workload of smears reviewed by each cytologist per day was 30-50. The Irish cytologists followed the British Society for Clinical Cytology (BSCC) guidelines on workload, auditing, training and quality assurance.

First Outsourcing of Cervical Smears

In 2007 all cancer screening services were placed under the National Cancer Screening Service, now the National Cancer Control Programme. The ICSP was rebranded as Cervicalcheck. In 2007, due to staff deficits and workload increases, there were delays in smear reporting and approximately 20,000 smears were outsourced to Quest Diagnostics in the US. Dr David Gibbons reviewed the data and discovered that the high-grade rate in the smears reported by Quest was 1.2%, compared to the expected 1.9%. In Cork University hospital a number of potential misses of high-grade abnormalities were also reported [Irish Medical Times September 2007].

A major concern regarding outsourcing to the US at that time was the higher smear throughput per cytotechnologist in the US, up to 100 per day for manual screening, according to Clinical Laboratory Improvement Amendments (CLIA) guidelines. The American Society for Cytopathology has since made new workload recommendations, stating that the FDA workload limits for automated screening were extremely high (200 per day) and "may be associated with significant reduction in sensitivity" (Elsheikh et al, Diagnostic Cytopathology, 2013). A further concern was ensuring that all smears were reviewed twice in the US, as this was not the routine practice for their smear analyses.

Tendering Process for the Cervical Cytology Screening Service

The tendering process required the laboratories to be fully accredited in order to be eligible to apply for the tendering of cytology work. Turn-around time and cost were important factors in the assessment of the international tender evaluation. Cervicalcheck awarded the contract for the entire service to Quest, to begin September 2008.

The Irish Association for Clinical Cytology, representing medical scientists and Cytopathologists wrote to Cervicalcheck and the Minister for Health, outlining their concerns regarding detection rates in the pilot samples sent to Quest. The IACC stated that the data showed there was "a risk of at least 30% lower detection of cases with pre-cancerous cells, excluding urgent smears". In a Dáil debate on 29th May 2008 the Minister for Health, Mary Harney, was implored by TDs Dr James Reilly, Jan O'Sullivan, Aengus O'Snodaigh and Emmet Stagg not to proceed with the outsourcing. However, the outsourcing proceeded and Quest was awarded all of the smear tests for two years.

It is unclear how this serious risk of lower detection was evaluated prior to making the final decision on outsourcing.

Impact of Outsourcing Cervical Cytology Samples

From September 2008 all of the screening programme smears were sent to the US, resulting in the closure of 13 cytology laboratories, and the Coombe Women and Infants University Hospital was the only laboratory retaining its cytology service. The MLSA successfully negotiated redeployment of all of the medical scientists within the public sector however this was an extremely stressful time for all staff involved in the service. The loss of their cervical cytology expertise through changing to another discipline had a long-term effect that impacted on the ability of the laboratories to tender for future contracts or increase screening capacity. The DIT programme also had to be discontinued, as there would be no employment prospects for future intakes of students.

In 2010, the service was re-tendered and the contract for cytology was split, with 50% going to Quest and CPL laboratories, respectively. In 2012, Medlab Pathology was awarded half the service, with Quest, and MedLab Pathology subsequently established a Cytology laboratory in Sandyford, Dublin. The Coombe Women and Infants University Hospital initially analysed smears from outside the screening programme, including colposcopy referrals, but subsequently was contracted by Cervicalcheck to screen approximately 10% of the programme smears.

Cervicalcheck issued annual reports with Cytology data reported as an average of all laboratories results from 2008. No annual reports have been published since 2016.

Vicky Phelan

In April 2018 Vicky Phelan was awarded €2.5 million against CPL laboratories for mis-reading of her smear. She and another 206 women had been diagnosed with invasive cervical cancer following smears which had been misinterpreted and reported as negative. Vicky bravely insisted on open disclosure of the court case and has spoken out repeatedly on how those affected are being treated. Most of the women affected had not been told immediately about the incorrect smear results, which is why there has been a huge outcry in the media. Many are currently suing the relevant laboratories and/or the HSE. There is a patient support group called 221plus for those affected by the cervical screening errors.

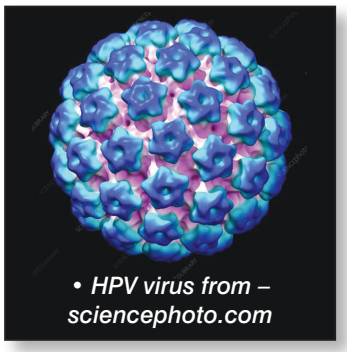
Dr Gabriel Scally was asked to review the Cervical Cytology screening service and has published two reports to date. The Scally report from the scoping inquiry made 50 recommendations, which are still being implemented at this time, and for a profession committed to quality assurance, some of the information in the reports is truly shocking. The reports are available online for detailed reading but some statements from the reports are included below. This is an evolving situation, with a report from a slide review by the Royal College of Obstetricians and Gynaecologists (UK) due later this year. There are still significant gaps in the information regarding the cytology practices in the US laboratories, the number of cases of cervical cancer, and the cytology screening data from 2008-2019.

As suggested by Marie Culliton, Academy Council, on RTE in early June, the laboratories in which the errors occurred should be identified for all cases, so that any clusters are identified, investigated and addressed. Extensive data analysis of the cytology detection results and cervical cancer incidence should be performed to establish what the performance is of each laboratory. One of the most shocking findings of the Scally reports was that instead of three laboratories, the cytology smears had been analysed in sixteen different sites. Recently it has also been discovered that multiple of the original slides of those affected cannot be found (Sunday Times June 16th).

Extracts from the two Scally Scoping Inquiry Reports [SR1 Sept 2018, SR2 - June 2019]

- There were only five Cytology Quality Assurance visits in total to the laboratories providing the cytology services. There were no visits from 2014 on. [SR1 – 6.9.2]
- In 2008 the weighting of cost for tender evaluation was 20% and QA 25%, in 2012 the cost weighting was 40% and QA 15%. [SR2 – 7.3.5]
- An educational audit in Quest found 17.6% of 222 smears previously reported as negative should have been reclassified. [SR1 – 6.9]
- Data collection and analysis is insufficient to monitor and take action on performance differences which might require action. [SR1 - 6.10]
- 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. [SR2 – 4.5]
- '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.' [SR2 Introduction]

Human Papillomavirus Testing



• *HPV virus from – sciencephoto.com*

HPV testing has been used for many years to triage patients, but in recent years it has been introduced as the primary screening test for the cervical screening services in other countries. This would mean that all cervical smear samples would be tested first for HPV and the positives would then be referred for Cytology. The advantage of this method in terms of operations is the ease of rapidly analysing large numbers of samples, and reduced requirements for cytology smear review. In 2017 HIQA produced a report entitled "HTA assessment of HPV testing for primary screening", in which they recommended the introduction of HPV testing as the primary screening test. Work is ongoing to introduce HPV testing as the primary screening test in the near future which will lead to laboratory expansion and associated employment opportunities in Ireland.

HPV Vaccination

Vaccination against high-risk HPV types is a proven method of preventing development of many cervical and other epithelial cancers, as HPV 16 and 18 alone cause up to 70% of cervical cancers. In 2016 vaccination of girls in 1st year of secondary school was introduced. There are three different vaccines available, which protect against two, four and nine HPV types respectively. Recently, HIQA recommended the use of the Gardasil®9 vaccine that protects against nine HPV types. Boys will also receive the vaccine from autumn 2019. Vaccination will significantly reduce the incidence of cervical cancer in future generations, but screening will still be required as not all HPV types will be covered by vaccination.