Statement by the Academy of Clinical Science and Laboratory Medicine on Cervical Screening.

Second Statement by the Academy (29/04/2018).

The Academy of Clinical Science and Laboratory Medicine extends its sympathy to Ms Vicky Phelan, and her family, on the failures which led to her delayed diagnosis. We admire her courage and tenacity in bringing this failure to the public domain. The Academy welcomes the review called for by the Minister and is willing to work with his Department, HSE and CervicalCheck to achieve the best outcomes for patients and the future of cervical screening in Ireland. The Academy is the professional body and competent authority representing medical scientists in Ireland and is available immediately to work with the Minister and his nominees. We are requesting that we are part of any review group or other group to consider the future of this service.

For any screening programme to be successful it must have the trust and confidence of the public. To ensure that this confidence is maintained the results of the audit of 2014 must be published. The Academy is deeply concerned that many of the 206 errors identified by audit in 2014 still may not have been reported to the patients involved.

The Academy advises and recommends that the entire service now be repatriated as soon as possible and will work with the Minister to achieve this. This will ensure that the analysis of cervical screens will conform to the current rigorous quality laboratory management systems, be performed by medical scientists specialising in cervical cytology and HPV investigations, and be accredited standard to the ISO: 15189 (2012). This service should be led by consultant medical scientists.

Recommendations for the audit and review process

The Academy welcomes the reviews called for by Minister Harris and is willing to work with his Department. The Academy urges that these reviews consider the following:

- The quality and consistency of the screening protocols in use. Where cervical screening is performed in Irish Laboratories the protocol is that all smears are separately screened by two independent medical scientists trained as cytologists which is comparable with the high standards of UK.
- The quality assurance and accreditation of the screening laboratories to ISO:15189; this is standard for Irish Laboratories.
- Evaluation of the qualifications and ongoing competence assurance of all the staff undertaking the screening.
- The annual quality assurance results of the Cervical Screening Programme in terms of case classification and comparison to the expected international norms.

In the interest of patient safety the Academy of Clinical Science and Laboratory Medicine seeks clarification on a number of issues raised;

Clarification is required on the error rate; are the 206 false negatives in the cohort that have since developed cancer in a three year audit period?

Were all these identified false negatives screens performed in the same laboratory?

Clarification is required on what is meant by "cases needed no further review".

Did the multi-disciplinary teams report false negatives to CervicalCheck and was this followed up?

Was the audit commissioned by CervicalCheck, or was it part of the laboratory quality assurance process (which it would be in our clinical diagnostic laboratories under our quality management system and INAB accreditation). Is there a robust quality assurance programme in place? In the 10 years of the programme what has been the audit programme?

As the contracts for outsourcing this laboratory work come up for renewal, what criteria are used apart from cost and turnaround times. What QA programme is required?

There is an excellent surveillance programme examining trends in infection and antibiotic resistance. All national screening and chronic disease management programmes would benefit from specialised surveillance scientists proactively reviewing laboratory data and correlating with clinical outcomes.

Background Information

Cervical screening was performed in screening centres and also in diagnostic laboratories in Ireland for 40 years until the commencement of the CervicalCheck programme. Although the screening was, in general, opportunistic, initiated by GPs, self referral by women or based on clinical suspicion, the analysis of these smears was to the highest quality standards. The smears were analysed by medical scientists dedicated to the provision of this service and who were subject to rigorous quality assurance and competence programmes. All smears were screened independently by two medical scientists specialising in cytology and any abnormal screens or where there was discordance in the finding were subject to a third review with a consultant pathologist.

The service was difficult to maintain, reporting times were weeks to months for screens dependent on workload, influence of public awareness campaigns and staffing. Staffing recruitment was exacerbated by the recruitment ban in 2007.

In preparation for the launch of the CervicalCheck Programme the Academy of Clinical Science and Laboratory Medicine, in conjunction with the National Cervical Screening Programme and Dublin Institute of Technology put in place a dedicated undergraduate programme in Medical and Molecular Cytology to produce an increased number of scientists to deliver this expanded cytology screening service.

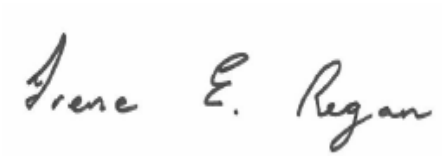
The National Cancer Screening Service (NCSS) decided to tender for the laboratory services to support their programme. A number of Irish laboratories submitted for the work but due

to their inability to compete on price, accreditation status and turn around times with a commercial tender the decision was made to offer the contract to Quest in the US. Concerns expressed at the time by medical scientists, pathologists and gynaecologists regarding the error rates, the difference in the re-screening programme timeframes in the US, expertise, report types and indeed smear referral overseas were ignored.

In 2007, outsourcing of a proportion of cervical smears commenced under the direction of the HSE. Concerns were expressed again about the underreporting of positive smears (false negative rate) but again ignored. In 2008 the contract was awarded and, as the new specifically trained graduates were emerging, the systematic dismantling of the cytology laboratories in the country began with redeployment of 60 specialist scientists. One public laboratory only, remained with reduced staffing to carry out a small proportion of this work for training and QA purposes. However, within two years the national competence had been decimated and many of the highly qualified and competent medical scientists with specialism in cervical cytology were now working outside the service.

In 2010 another company entered the market and developed its laboratory so that some smears are now screened there. Former Master of the Rotunda Hospital in the Irish Times 27th April 2018 said 'We too warned the Minister, HSE and NCSS of the folly of outsourcing based on cost and the perils of divorcing the testing from the rest of the clinical service'.

The Academy advises and recommends that the entire service now be repatriated as soon as possible and will help to achieve this. This will ensure that the analysis of cervical screens becomes part of the current rigorous quality laboratory management systems and be interpreted by medical scientists trained as cytologists or specialising in cervical cytology. This service should be led by consultant medical scientists which is now emerging as a standard practice in the UK.



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