



The Academy of Clinical Science and Laboratory Medicine

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MacCraith Rapid Review Report Welcomed; Many Questions Answered, However the Saga of Ineptitude Continues

The Academy of Clinical Science and Laboratory Medicine welcomes the report of Professor Brian MacCraith and its exposition of the issues relating to the ongoing failure of outsourcing of cervical screening in terms of commissioning, governance, quality assurance and oversight.

Serious questions remain regarding the quality management systems in place in these laboratories. While an unexpected increase in workload may explain why a cohort of HPV tests may have expired in late 2018, it does not explain the processes whereby 11,577 samples from 2015-18 were tested outside the guidelines. This is a systematic failure of quality management.

It is not unexpected that the IT system in one laboratory which had not been heretofore configured to report electronically to the NSS may need a software update to do so. The requirement for seamless reporting was stipulated but obviously not tested prior to service commencement - another failure of quality management. The report makes it clear that this IT incompatibility was known by January 2019. The introduction of a manual workaround permitted reports to be issued to GP's but not to the women waiting for their results. The 797 'rescued samples' were reported in April but it was June before it became clear that the reports had not been received. It is still not clear that automated reporting is verified as functioning satisfactorily. As the days, weeks and months went by with no reports being issued directly to women it is extraordinary that, given the private and public interest in this service and the need to maintain confidence, no public announcement was made via media or website that the standard reporting system was suspended and that women should contact their GP. It is still unclear why this critical failure was not appropriately escalated, and remedial action taken.

For a cervical screening programme to be successful in reducing the mortality and morbidity associated with cervical cancer the correct triage to colposcopy is vital. This can only happen if the screening and triage process is quality assured with robust processes and oversight.

Prof MacCraith finds *'The addition of the QD Chantilly Laboratory as a CervicalCheck Test facility took place without proper operational due diligence, risk assessment of the downstream implementation and, therefore, risk mitigation.'* He also notes *'The almost total reliance on a single, outsourced, international supplier of laboratory services for CC is a source of significant fragility for the programme'*

The HSE has at its disposal a cohort of Laboratory Managers, Chief, Specialist and Senior Medical Scientists with the knowledge, skills and competences to provide quality assured laboratory diagnostics, reporting logistics and sample tracking. It is extraordinary that this debacle continues to rumble on without recourse to this expertise.

The importance of quality assurance at every step of the diagnostic testing process cannot be overemphasised. The best and most sophisticated tests are but nought without a robust quality management system (from patient sample to report issue) and competent medical scientists. The continuing failures exposed by this and other reviews are likely serving to undermine the public confidence in existing Laboratory Service provision at all levels in Ireland.

This Academy has over 1400 medical scientist members, all of whom are committed to providing a quality diagnostic laboratory service for this country.

The Academy calls on The Minister, The HSE, its new CEO, Mr Reid, and the NSS to engage with us to put an end to this never ending saga of poor performance in the provision of cervical screening. We will work with you to manage and mitigate issues as they continue to arise.

The Academy advises and recommends that the entire service now be repatriated soonest and will work with the department and HSE 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 trained as cytologists or specialising in cervical cytology and be accredited to the ISO 15189 standard. This service should be led by consultant medical scientists.

Women and their families deserve more.

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