Royal College of Obstetricians & Gynaecologists

Meeting of the Joint Committee on Health

(Wednesday 18th December 2019)

Opening Statement by Professor Henry Kitchener, Lead Assessor RCOG Review

We would like to begin by thanking the Joint Committee on Health for the invitation to appear before it today and to state that we welcome the opportunity to engage with you in relation to the findings of our Review.

We would like to take this opportunity to thank all of the women or their next-of-kin who consented to participate in this Review. We would also like to acknowledge the contribution of the cytology laboratory at Monklands hospital in Scotland, other consultant cytopathologists, the members of the expert panel – including our two lay representatives – and our project manager at the RCOG, for their assistance throughout this process.

In May 2018, following serious public concern over failure to disclose the findings of a cervical cancer audit, the Irish Government commissioned the RCOG to conduct a review of the screening histories of all consenting women who had developed cervical cancer, having had any involvement in the CervicalCheck cervical screening programme between 2008 and 2018.

After a complex and demanding exercise, the RCOG had met its objectives with the completion of 1,038 individual reports for women or their next-of-kin by October 2019, and the publication on December 3 2019, of its aggregate report *'Cervical Screening in cases of cervical cancer in Ireland between 2008-2018*'. The timing of final report was dictated by the requirement to ensure every woman or their next-of-kin had received their individual report prior to the aggregate report being published.

At this point, we wish to state how acutely aware we are of the impact that screening failures have on the lives of affected women and their families. We also would like to recognise the 103 women in our Review who have died, and will neither be able to read their individual report, nor the final RCOG report. We hope that their individual reports will provide some service to their next-of-kin.

The primary purpose of the individual reports was to provide consenting women, or their next-of-kin, with a transparent independent analysis of their CervicalCheck cytology slides prior to their diagnosis of cancer, an explanation of the findings, and an independently drawn conclusion regarding the clinical implications of any discordant result.

Throughout this process we felt it was of the utmost importance to obtain input from participating women, with regard to the content, tone and style of letter which would convey their individual reports. In May 2019, we met with a group of women (and one next-of-kin) to discuss our proposed style of letter. We received broad approval and suggestions which we adopted. The group also

conveyed a strong message that any woman who so wished, should have access to an appointment with a health professional to receive her report. We were in full agreement and immediately conveyed this to the HSE.

The primary purpose of the final report was to aggregate the findings of the cytology slide review which directly compared the RCOG readings of 1,659 slides with those of CervicalCheck.

By way of background, the slide review panel was comprised of screeners in the Monklands Cytology Centre in Scotland, as well as consultant staff actively working in the English NHS Cervical Screening Programme. The role of the screeners was to identify those slides considered to be negative i.e. showing no abnormality. All slides considered at screening to show any abnormal cells were reviewed by a consultant, and if there was disagreement with the CervicalCheck result, a second consultant read the slides. If there was disagreement between the first and second consultant, the slides were reviewed by a consensus panel over a multi-header microscope to arrive at a final result.

Those reading the slides were always blind to the CervicalCheck result, but for reasons laid out in the report, to have tried to 'seed' the slides blindly, amongst routine day-to-day laboratory work would have been impracticable. We believe our methods were thorough and produced reliable results. We have acknowledged both in the report and in explanatory notes to each participant, that in a slide review of this type, the detection of abnormalities will be enhanced. Our role was not to assess the performance of the CervicalCheck laboratories, but to inform women whether or not the Review had found that abnormal cells had been missed.

The RCOG sought to determine in those cases where there was discordance between CervicalCheck and the RCOG Review, with respect to negative, low grade and high grade readings and whether this had exerted an impact on the clinical outcome in terms of failure to prevent cancer or failure to diagnose cancer at an earlier stage. This was done by the Expert Panel determining the likely quantum of delay in the diagnosis of cancer engendered by missing abnormal cells or under-calling cells in terms of grade, and applying this quantum to a set protocol of time intervals and stage at diagnosis.

The RCOG Expert Panel felt that the individual letters should not only include the results of the slide review but also a conclusion in relation to the effect any discordant reading had in terms of a delay in diagnosis. In the majority of cases, the Expert Panel considered there was no such effect but in half of the discordant cases, the panel concluded there had been a missed opportunity to prevent or diagnose at an earlier stage.

We applied scrutiny to those cases where prolonged colposcopy management was identified, and found that in a quarter of such cases, colposcopy management was suboptimal, sometimes further complicated by discordant cytology and sometimes not.

This slide review formed the basis of providing women with individual reports. The thoroughness and quality of the slide review combined with full disclosure of the findings, means that women can have confidence in their individual reports. The Expert Panel have made it absolutely clear that these

reports are not a judgement with respect to medical negligence, and that such a matter would require others to determine. An explanatory note to this effect was included with the individual reports.

This compilation of individual reports disclosing both the findings and the implications, together with an aggregate report based on a 'point in time' slide review of over l,000 women diagnosed with cervical cancer is, as far as the authors can determine, unique both in scale and scope. It represents a transparent approach which others can reference and with which future comparisons can be made.

We chose to compare our slide review findings with the only other published large scale slide review, which was conducted as part of a national Cervical Screening Programme protocol in England. Both involved slides of liquid based cytology, and both involved the slides being reviewed in the knowledge that cancer was the outcome. The intention was to determine whether or not the findings of the RCOG Review represented an outlier, or was in line with what might be expected. In the event it was the latter.

The findings of the RCOG Review were striking in the sense that a high proportion of discordant readings were found, many with significant implications. This however was not unexpected, not only because similar discordance rates were found in the English NHS Cervical Cancer Audit, but also because the natural history of cervical cancer indicates that it is highly probable that the cervix would have shed abnormal cells for a number of years prior to the diagnosis of cancer, whether it was screen detected or not.

Our Review therefore illustrates the limitations of cervical cytology, rather than pointing to a screening service that falls below what might be expected. Indeed, data published by the National Cancer Registry of Ireland, shows both falling incidence and deaths from cervical cancer since CervicalCheck was established in 2008. These endpoints are the cardinal signs of effective cervical screening. The findings of our Review back this up with the high proportion of early stage cancer identified in the Review cohort, which indicates that screening undoubtedly saved the lives of many women in the Review.

In order to address concerns expressed regarding the verification process of finalising the individual reports, we have submitted a detailed statement to the committee. When these concerns were initially raised with us in October, we offered to meet with participants and patient representatives and came over to Dublin to outline the process in detail, and answer any questions they had.

In a complex study of this size involving more than 1,000 women and 20,000 individual data items, including 3,300 smear results, we acknowledge there is capacity for error. As we note in the statement, in a very small number of cases (fewer than five) it has been necessary to issue supplementary reports because new information came to light, and in two of these cases the conclusion was updated. While these isolated incidents are regrettable, they in no way impact the overall conclusions or recommendations laid out in our aggregate report.

We would be concerned if unfounded criticism of our evidence based report undermined trust in our findings and confidence in the CervicalCheck Programme. This could have the effect of diminishing coverage, which could only place more lives at risk. It is very important that the benefits of cervical screening in the existing programme are accurately portrayed in terms of public health.

Vaccination against high risk human papillomavirus (HPV) was introduced in Ireland for early adolescent girls in 2010, and in this year for adolescent boys. As already demonstrated in Australia and Scotland where screening begins at age 20 years, with high coverage this can reduce considerably, the incidence of abnormal smears and therefore precancer in young women, and will result in a further reduction in deaths from cervical cancer. The introduction of primary HPV testing has been shown to increase detection of precancer in the English Pilot, and its introduction in Ireland can be expected to be cost-effective by not only saving lives, but also permitting increased screening intervals.

We believe that the RCOG Review has provided all eligible women with open disclosure of their slide review and has provided an aggregate picture of the overall results. Our conclusion that the CervicalCheck Programme is working effectively, both in terms of the effectiveness of cytology and colposcopy, is supported by incidence and mortality data published by the National Cancer Registry of Ireland, which demonstrates year on year falls since 2010, and follows the establishment of the CervicalCheck Programme.

This shows that the primary objectives of cervical screening are being met, and should restore trust in cervical screening in Ireland. With high coverage, the CervicalCheck Programme, which will soon incorporate primary HPV testing, combined with the impact of high coverage vaccination, should ensure that cervical cancer prevention in Ireland will become as good as it can be, and that cervical cancer deaths should eventually decline to the point where they become a rarity.

I would like to conclude by saying that we were privileged to have been tasked with undertaking this important piece of work, which we hope will have benefitted the women who participated in the Review.

Professor Henry Kitchener, Lead Assessor RCOG Review
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18 December 2019