Royal College of Obstetricians & Gynaecologists

RCOG CervicalCheck Screening Review Protocol

The purpose of the Review is to determine which cases of cervical cancer that occurred since the establishment of CervicalCheck in 2008, could reasonably be attributable to errors in screening and reporting of cytology. A determination will also be made as to whether such errors affected the treatment and outcome. In order to achieve this:

1. The HSE's National Screening Service (NSS) in conjunction with the National Cancer Registry of Ireland (NCRI) has identified the cases of cervical cancer that have occurred in Ireland since the national screening programme began in September 2008. A total of 1856 cases will be reviewed which have been reported through the CervicalCheck programme and the NCRI.

2. These will be identified by the CSP-ID, a unique number used to identify individuals in the CervicalCheck Screening Programme.

3. Women who had no record of being screened within the CervicalCheck programme will be identified and no further investigation performed.

4. In cases of cervical cancer registered since the inception of CervicalCheck in 2008, all preceding slides taken within the CervicalCheck programme will be reviewed. Slides taken prior to CervicalCheck, and those taken outside the programme, for example within the private sector are considered outside the scope of this CervicalCheck review. Thus any case of cancer where all antecedent cytology was either pre-2008 or outside the programme will be treated as if there had been no recorded screening samples.

5. The slides will be given a review number enabling anonymised linkage between the CSP-ID and the outcomes of the reviewed slides.

6. A database will be created within the lead centre for the review. This will encompass the minimum dataset included in the Coding Guide for the NHS Audit of Invasive Cervical Cancer (March 2013).

7. The dataset will comprise; personal and cancer details, cytology history, colposcopy history and review, cancer histology (dates and details), cytology review. It is not planned to review any histology as part of the current review.

8. The slides will be shipped to the lead review centre in the UK from the originating laboratories. Here slides will be identified, logged and given review numbering.

9. Slides will then be sent to the UK laboratories where the review readings will take place. The slides will be logged and provided to screeners for reading and reporting.

10. The slides will be read blind to the original report. The slides will initially be read by accredited cytoscreeners or biomedical scientists in the manner that is standard within the NHS programme. Slides that are reported as negative will be subject to rapid review. Slides where abnormalities are identified will be checked by individuals of Consultant Bio-Medical Scientist or Consultant Cytopathologist grade as would happen in the NHS programme.

11. Where review reports concur with the original CervicalCheck report, no further cytology review will be carried out. Where a discrepancy exists, these cases will be re-read by a Consultant cytopathologist, and if this does not confirm the review result, a third read would be undertaken. Where required, a panel of cytopathologists would be convened for discussion with a multi header microscope, which will be conducted at the lead review centre.

12. The final cytology report will include a statement on whether the abnormalities present were particularly difficult to identify, or where interpretation is felt to have been influenced by the review process.

13. The categories of discrepancy requiring further review will include negative/low grade or high grade and low grade/high grade.

14. In cases where the review result indicates that a colposcopy referral should have occurred but did not, the clinical records will be reviewed. This would also happen in cases where colposcopy referral did occur prior to the diagnosis of cancer. This includes cases with concordant abnormalities when colposcopy was performed more than 6 months prior to the diagnosis of cancer. Cases where abnormal antecedent cytology was correctly reported within six months of the cancer diagnosis, would be assumed to be screen detected.

15. The review of clinical records will be performed by a panel of specialised colposcopists and gynaecological oncologists, who will determine using standardised criteria, such as the referral threshold for colposcopy at that time, which cases of cancer could reasonably be determined to have been preventable had the cytological abnormalities not been missed and also how treatment and outcome were affected.

16. This will be determined as follows
    a) Should colposcopy referral have occurred, and if so what would have been the likely sequence of events?
    b) If colposcopy referral had been performed prior to cancer diagnosis, what was the sequence of events? Had colposcopic mismanagement contributed to the subsequent development of cancer?
    c) What was the time interval between the screening discrepancy and the cancer being detected?
    d) What was the stage and histology of the cancer, as well the treatment and clinical outcome?

e) How would the clinical outcome have differed had the colposcopic mismanagement not occurred?

17. A summary in standard format will be prepared for every woman who was in the review stating whether her cancer was considered preventable had cytological abnormalities not been missed.

18. These summaries will be offered to each of the women, should she wish to receive it, and such information provided where relevant, within the context of 'receiving bad news' and provided by the woman's practitioner in a sensitive and professional manner.

19. In cases where death has occurred, the summary will be offered to the family, the responsibility for which will rest with the Irish Health Service, in terms of locating and informing the appropriate family member.