1. Briefing 9 March

(Redacted)
Health Protection Division
9 March 2021

MINISTER FOR PUBLIC HEALTH, SPORT AND WELLBEING

Update on serious cervical screening incident

Purpose

1. To update you on a serious and complex incident that has come to light in the cervical screening programme.

Priority

2. Routine. Officials became aware of this incident earlier today, and will be in a position to provide a more comprehensive update when the full note of the incident management meeting is received.

Background

3. In 2020, a national invasive cancer audit found (redacted) women in NHS (redacted) who developed cervical cancer and were found to have been excluded (redacted) from the cervical screening programme because they had been coded as 'no cervix, no follow up'. The audit investigation found that in the case of these (redacted) women, the cervix had not been removed and the 'no cervix no follow up' exclusion (which should be applied to the records of screening participants who have had a total hysterectomy and have no residual cervical tissue remaining) was incorrectly applied. Unfortunately, (redacted) subsequently died.

4. Having found this, (redacted) selected 60 women who had a no-cervix exclusion applied but were likely to have had subtotal hysterectomies (according to operation notes created following their surgeries), and had their case notes reviewed by a consultant gynaecologist. This process has revealed that at least 14 had been excluded inappropriately from the programme.

5. For the records checked to date, there is not one source of explanation for the error, and there are a number of points on the pathway where it could occur. In some cases, the procedure listed on the pathology report or discharge letter was found to be incorrect, when cross-referenced with the operation

note. In other cases, the labs which analyse the pathology reports may have made coding errors when adding the information to the IT system (SCCRS). Some other users (including in primary care where women have moved into Scotland) can also add a no cervix exclusion to the records (although this is checked by the call / recall team).

6. Further action is needed to understand how widespread this issue is, though early advice from clinicians and screening coordinators is that it is likely that the (redacted) experience will be replicated across all Health boards.

7. It is important to note that the clinical view is that the risk to the excluded cohort as a whole is low. However, there could be very significant consequences for the individuals affected, and work to identify those who have been wrongly excluded is complex. The long latency period of cervical cancer may also mean that cases are only now starting to show up in invasive cancer audits.

8. Based on the (redacted) analysis, two potential significant areas of concern have been identified:
- subtotal hysterectomies that have wrongly had the exclusion applied; and
- subtotal hysterectomies that have been wrongly categorised as total, and thus had the exclusion code applied.

9. Identifying the women who have been wrongly categorised or excluded is further complicated by the differences in hysterectomy procedures.

10. (Redacted) identified around 13,500 women who had had a hysterectomy and were coded in the screening programme. (redacted)

Next steps

11. An adverse incident meeting was held on 9 March, attended by clinicians, screening programme managers and Scottish Government officials. A number of actions were developed.

12. As an immediate priority, labs will now verify the codes they provide by cross-referencing pathology reports with operation notes or direct contact with the operating surgeon, and from Monday, exclusion codes will only be applied to screening participants where they have come from a laboratory. In all other cases, exclusions will not be applied.

- It is acknowledged that more careful consideration must be given for how to address the issue of exclusions that have already been applied. The incident management team therefore agreed the following actions:

- All other Health Boards will carry out an audit on all women who were coded as 'no cervix, no recall' but who had had a sub-total hysterectomy recorded on the operation note, to understand if the concerns in (redacted) are replicated.
- Detailed work will be carried out to develop an options appraisal on how the classification of women can be evaluated when they have had a transabdominal hysterectomy.
- Modelling will be carried out to evaluate the actual risk (Redacted)

13. The complexities of the work mean it is difficult to present exact time scales for conclusions to be reached, though the need to move as quickly as possible is well understood. It is hoped that a fortnight will be sufficient for Boards to conduct the initial audit. The options appraisal will be instigated in parallel, though some of its findings may be informed by the information provided by the audits. Officials will provide regular updates as work progresses.

Comms and timescales

14. Comms representatives from NSD will join the next incident meeting, and ahead of that, will begin liaising with SG comms on reactive and proactive lines. It is expected that the families of the women identified by the audit will be informed of the error shortly, and messages will be developed for clinicians and screening coordinators. Officials will provide media lines for clearance as soon as they are developed.

(redacted)
Health Protection Division
9 March 2021

(redacted)

Briefing – 31 March

(redacted)
Health Protection Division
31 March 2021

MINISTER FOR PUBLIC HEALTH AND SPORT

Update on serious cervical screening incident

Purpose

1. To provide an update on work to understand the scale of the adverse event in the cervical screening programme.

Timing

2. Routine

Background

3. (redacted)'s submission of 9 March confirmed that, in the course of an invasive cancer audit (redacted) had discovered (redacted) women had been excluded from the cervical screening programme due to 'no cervix no follow up' exclusions being incorrectly applied to their records. (redacted) the participants' cervixes had not been removed during a subtotal hysterectomy. In (redacted) one of these (redacted) cases, the cancer (redacted) sadly proved fatal. (redacted)

4. (redacted) are planning how they will communicate with, and offer support to the affected participants and families. (redacted)

5. Further analysis of (redacted) records had uncovered a number of additional cases where the 'no cervix' exclusion had been wrongly applied, either because the procedure carried out was a subtotal hysterectomy and the exclusion was applied incorrectly, or, in some cases, because the procedure listed on the pathology report or discharge letter was incorrect (when cross-referenced with the operation note).

6. A Problem Assessment Group met on 5 March in (redacted) and agreed that while the Board would continue to manage the adverse event reviews of the (redacted) participants identified in the invasive cancer audit, National Services Division (NSD) would convene an Adverse Event Management Team (AEMT) to consider the wider implications for the screening programme and agree a management plan for participants with the exclusion code applied to their SCCRS records. This meeting took place on 9 March and we provided briefing later that day.

7. As an urgent control measure, NSD emailed all call-recall offices, cervical laboratories and NHS Board screening coordinators to inform them that this exclusion should no longer be applied until the pathology report has been cross-checked with the operating surgeon to confirm the extent of hysterectomy carried out.

8. Our earlier submission noted that the following actions were agreed by the AEMT:

- All other Health Boards will carry out an urgent audit on all women who were coded as 'no cervix, no recall' but who had had a sub-total hysterectomy recorded on the operation note, to understand if the concerns in (redacted) are replicated.

- Detailed work will be carried out to develop an options appraisal on how the classification of women can be evaluated (redacted).

- Modelling will be carried out to evaluate the actual risk. (redacted policy development)

- NSD has subsequently conformed that there are around 200,000 participants with a 'no cervix' exclusion from the screening programme, but there is no evidence to suggest that the vast majority of these are not accurate.

The Audit

9. A key step in driving forward the actions will be driven by the findings of the initial audit, which is now underway.

10. To support Boards with this task, the screening IT provider and Public Health Scotland (PHS) extracted records for individual boards where a 'no cervix' exclusion was added, but where the operation code indicated the cervix had not been fully removed.

11. Just under 1,000 exclusions were identified across Scotland using this criteria. Subsequently, NSD has tasked each NHS Board with setting up a multi-disciplinary team to review the individual records and determine whether the 'no cervix' exclusion is appropriate.

12. This is a comprehensive review of a series of sources, requiring Boards to review SCCRS, the operation note, the discharge note, any additional Scottish Morbidity Records (SMR) and the pathology report. The SMR records reviewed are SMR01 (general) and SMR (02) maternity, the latter because some women had hysterectomies after complications in childbirth. Once the review is complete, Boards must make a clinical decision on whether the 'no cervix' exclusion is appropriate or should be removed and the participant reinstated to the screening programme.

13. Boards have been advised that no records should be amended whilst the audit is being carried out. The AEMT will instead review all the audit information collectively to ensure consistency across Scotland before agreeing further action.

14. NHS Boards were asked to conclude this initial audit by 2 pm yesterday (30th March). However, Boards have indicated that this date is extremely challenging, and the current agreement is that the Boards will share what they can by the deadline, to allow an update for the next AEMT to be prepared. (Redacted policy development)

15. The next AEMT will be held on 6 April, and we will provide a further update after this meeting.

Communications

16. Although a robust communications plan is needed to manage the whole incident, it is recognised that particular care must be taken when communicating the information about the incorrect exclusions to the families of the women who developed invasive cancer. (redacted) will share a communication when they have a final draft, along with a plan for any support to the families.

17. In terms of the wider messaging, the following suggested holding lines have now been drafted and agreed by NSD and the SG Communications team. These will be reviewed and cleared after the AEMT meeting on 6 April:

    The Scottish Cervical Screening Programme has been made aware of a small number of cases of cervical cancer in a single NHS Board involving women who had been excluded from the programme a number of years ago. It has now been established that the exclusion should not have been applied. Additional control measures have been put in place to prevent any new exclusions from being applied incorrectly. The Screening Programme is in the process of coordinating an urgent review across all NHS Boards to assess the potential risk of any further individuals being affected.

18. We will continue to work with SG Communications colleagues on the incident and will prepare a more detailed Comms plan once the audit is complete.

(redacted)

(redacted)
Health Protection Division
8 April 2021

MINISTER FOR PUBLIC HEALTH AND SPORT

Adverse event in the cervical screening programme

Purpose

1. To provide you with the latest information relating to the adverse event in the cervical screening programme, which we first briefed you on in the submission sent by (redacted) on 9 March, and again in briefing sent by (redacted) on 31 March.

Timing

2. Routine

Key points

3. On 6 April, a second adverse event management meeting was held to discuss the issue of unsafe exclusions in the cervical screening programme. Attendees included clinicians and representatives from Scottish Government, National Screening Oversight function (NSOF), (redacted) and NSS National Services Division (NSD).

4. As noted in our last briefing, an initial audit of around 1,000 records is underway across all Health Boards, where women were coded as 'no cervix, no recall' despite having a subtotal hysterectomy recorded on the operation note. This is proving more complex than anticipated due to the cross-checks involved and findings are not expected until the end of April – this is a month later than the deadline of 30 March we advised you of previously.

5. Initial findings suggest there is a national issue, and that a significant number of the 1,000 participants have been wrongly excluded from the cervical screening programme.

6. Based on further work since the first meeting, it is thought that around 200,000 participants have been excluded from the cervical screening programme on the basis of no cervix/no recall codes applied to their records following a hysterectomy.

7. Unlike the 1,000 participants that make up the first audit, who were selected because there is evidence to suggest they have been excluded despite only having had a subtotal hysterectomy, the vast majority of excluded participants will have

had total hysterectomies (where the cervix is completely removed) and therefore exclusion will have been appropriate.

8. A plan will be developed to communicate with the participants identified as being wrongly excluded at the end of April following completion of the first audit. It is likely that the affected participants will be invited to attend screening, but specific communications will be developed so that they are not issued with the standard prompt to make an appointment.

9. Work continues to determine how best to find the small number of participants of the much larger cohort who may have been wrongly excluded. (redacted)

10. A third meeting of the adverse event management team will be held in the next few weeks, ahead of which options for identifying participants will be further developed. A member of SG Comms attended the 6 April meeting and will feed into discussion around potential options.

Communications

11. (Redacted) More generally, the provisional holding lines we previously provided remain the most up-to-date and are provided below again for reference.

> ***The Scottish Cervical Screening Programme has been made aware of a small number of cases of cervical cancer in a single NHS Board involving women who had been excluded from the programme a number of years ago. It has now been established that the exclusion should not have been applied. Additional control measures have been put in place to prevent any new exclusions from being applied incorrectly. The Screening Programme is in the process of coordinating an urgent review across all NHS Boards to assess the potential risk of any further individuals being affected.***

12. When options have been clarified, SG Comms will work with NSS and any other relevant boards to develop a more comprehensive comms approach.

(redacted)
Health Protection Division
Ext: (redacted)

(redacted)

(redacted)

4. Briefing – 7 June

(redacted)
Health Protection Division
7 June 2021

MINISTER FOR Public HEALTH, WOMEN'S HEALTH AND SPORT

Adverse event in the cervical screening programme

Purpose

1. To provide you with the latest information relating to the adverse event in the cervical screening programme, which we briefed Ms Gougeon on in a number of submissions: on 9 March, sent by (redacted); on 29 March, sent by (redacted); and on 8 April, sent by (redacted).

Timing

2. Routine; however, to allow officials to confirm and begin planning a Parliamentary statement, it would be very helpful to have a response as soon as possible.

Background

3. As noted in previous submissions, on 9 March 2021, we were made aware of a serious incident within the cervical screening programme. In 2020, during an annual invasive cancer screening audit, (redacted) identified (redacted) participants who had been excluded from cervical screening on the basis of having no cervix (redacted). Investigations subsequently revealed that the women had had subtotal hysterectomies (meaning part of the cervix remained) and therefore should not have been excluded. (redacted)

4. In cases where participants who are eligible for screening have a total hysterectomy and therefore no longer have a cervix, they are excluded from screening using either a 'no further recall (NFR)' or a 'no cervix' code. These exclusions are generally added by pathology lab staff, following pathological examination of the hysterectomy sample. GPs can also exclude participants, for example for those who have moved into Scotland and had a hysterectomy performed elsewhere.

5. A small audit of records performed by (redacted) following the discovery of the (redacted) wrongful exclusions suggested a potentially systemic problem, and an adverse event management team (AEMT) was established. It comprises stakeholders from across Scotland including clinical and public health experts, screening programme managers and primary care representation. It has met several times, most recently on 3 June.

6. Work done to date has confirmed that exclusions have been wrongly applied across Scotland. Checks also indicate that there is not one source of explanation for the error, and there are a number of points on the pathway where it could occur. In some cases, the procedure listed on the pathology report or discharge letter was found to be incorrect, when cross-referenced with the operation note. In other cases, the labs and GPs may have made errors when adding the exclusion to the IT system (SCCRS). In a further complication, clinicians have advised that hysterectomies on a patient's SMR record (the national hospital episode reporting system) are signified by a wide range of codes. Some of these codes will very clearly indicate whether a total hysterectomy has been performed, but this will not be the case for all codes; in some procedures, for example following a caesarean section, it may not be clear whether the full cervix has been removed, or whether a small amount remains.

7. Until a fuller assessment of the safety of exclusions can be carried out, steps have been taken to ensure no others are added in error. They can no longer be added by GPs, and labs can only add them where they can be verified as correct from two sources, including the operating gynaecologist/obstetrician.

Current assessment

8. To date, priority work has focused on auditing a cohort of around 1,000 participants who were excluded after 1997 but whose records clearly indicated a subtotal hysterectomy had been carried out. It has subsequently been discovered that around a further 500 participants have also been excluded prior to 1997, despite also having SMR records which indicate a subtotal hysterectomy.

9. Significant work has been done to review the records of and develop a treatment pathway for the 1,000 participants who were thought to have had a subtotal hysterectomy after 1997. This is set out below. Similar work is now being carried out to audit the records of participants thought to have had subtotal hysterectomies before 1997.

10. Beyond this small cohort, analysis indicates that there are around 199,000 participants who have been excluded using either the 'no cervix' or 'NFR' code. The majority of these are from the last 30 years, but dates go back as far as 1959. It should be noted that:
    - Historically, the NFR code was used for participants who had hysterectomies, and the 'no cervix' code was introduced later. It is therefore necessary to include the NFR code, though this can signify exclusions that have been applied for reasons other than having no cervix.
    - This total includes participants who were excluded while they were outwith the eligible age ranges for screening, meaning that the overall total could be lower.
    - Around 30,000 participants included in these records are now deceased. Immediate work will therefore likely focus on the records of participants who are still alive, though work is also ongoing to ensure that cervical cancer was not a main or contributory factor as a cause of death for those participants who have died.

14. Analysing the remaining 199,000 participant records is a challenging and time intensive process. (redacted) It is hoped that this analysis will provide a clearer understanding of the extent of the errors and the potential risks, and thereby enable a robust options appraisal to be carried out on the way forward. However, while work will progress as quickly as possible, the complexities of the procedures; the difficulty of locating and interpreting paper records; and the pressures already facing clinicians and Health Boards mean that it may take a number of weeks to complete.

15. Another AEMT meeting will be scheduled within the next two weeks, following which we hope to be able to update further on the progress (redacted).

Work on participants with subtotal hysterectomies

16. For the cases after 1997 where SMR records gave a clear indication that the exclusion could have been added in error (ie a sub-total hysterectomy had been carried out), Health Boards were notified of cases within their area and asked to audit these to determine if the exclusion had been correctly applied, using the patient's operation note, discharge letter, pathology report, SCCRS record and GP records. All but one Health board has now submitted a return, and while analysis is on-going, the findings have allowed the participants to be divided into a number of groups with appropriate care pathways:
    - Group 1: around 300 participants who were correctly excluded from the programme, and for whom no further action is needed.
    - Group 2: around 190 participants whose age makes them eligible for screening, and who have had a confirmed subtotal hysterectomy and therefore should not have been excluded. These participants will receive a formal letter of explanation and apology and be re-instated to the screening programme. In the first instance, they will be directed to primary care for screening, and will be fast-tracked for further assessment or treatment if necessary.
    - Group 3: around 110 participants whose age means they are no longer eligible for screening, but who have had a confirmed subtotal hysterectomy and therefore should not have been excluded from the screening programme while they were eligible. These participants will be directed to gynaecology to discuss next steps, with the potential for an examination and, if it is determined that a cervix is present, screening at the same appointment.
    - Group 4: around 160 participants, whether eligible or ineligible for screening, whose records are either unavailable or inconclusive about the type of hysterectomy performed. As above, these will be directed to gynaecology for discussion followed by examination and screening if required.
    - Group 5: around 110 participants who should not have been excluded but who are now deceased. Work is being undertaken to verify whether cervical cancer was either a main or contributory cause of death, although the view is that the risk of this is low.

17. A further six participants have transferred out of Scotland. Where their residence is known, arrangements will be made with the relevant health authorities for care as required. Where residence is unknown, the exclusion

code will be removed from their record, so that they will be recalled to the screening programme if they return to Scotland.

18. As only 190 women will be redirected to primary care, it is not expected that this will place an undue burden on practices. The AEMT has begun a process of engagement with GP representatives, and this will continue over the next two weeks. Practices will be asked to carry out the screens within a few weeks of the participant making contact to request an appointment.

19. It was noted that there is considerable pressure for gynaecology services, although this varies between Boards. (Redacted) Work is therefore underway with Health boards and clinicians to establish how best these participants can be accommodated and what, if any, additional support/resource might be required. It is hoped that letters inviting women to gynaecology can include an appointment time and that there will be only a few weeks between receipt of the letter and attending an appointment.

20. To support all affected health professionals, the AEMT will develop a Q&A on the situation; potential risks; and arrangements in place to respond. Work has also begun with Jo's Cervical Trust – a charity that works to raise awareness of cervical cancer and support individuals who have been diagnosed – to explore establishing a helpline for affected participants. NHS24 have also been consulted about the development of a helpline.

21. This work will progress separately, and will not be delayed by the uncertainties surrounding the larger cohort which were set out above. It is hoped that sufficient progress will have been made on the logistical arrangements to issue letters by the end of June or very early July.

Communications

22. (redacted)

23. To date, we have developed holding lines, which have been approved by SpAds. These are as follows:

The Scottish Cervical Screening Programme has been made aware of a small number of women in a single NHS Board area who had been excluded from the programme a number of years ago, but who subsequently developed cervical cancer.

It has now been established that the exclusion should not have been applied. The NHS Board has contacted those affected by the incident locally to offer an apology and discuss what has occurred. The Scottish Government and Scottish Cervical Screening Programme also acknowledge the distress this will have caused and offer their sincere apologies.

Additional control measures have been put in place to prevent any new exclusions from being applied incorrectly. The Screening Programme is currently in the process of coordinating an urgent review across all NHS

Boards to assess the potential risk of previous exclusions having been applied incorrectly. Preliminary results suggest this may be the case. This is a complex review and is taking some time, but once this wider audit is completed anyone affected will be contacted directly by the screening programme and will be given personalised advice.

It is important to stress that the overall risk of developing cervical cancer remains low and individuals should not be unduly alarmed. It does however remain important for everyone, whether affected by this issue or not, to be alert for symptoms of cervical cancer; If you have unusual discharge, or bleeding after sex, between periods or after the menopause, contact your GP practice. These are usually caused by something other than cancer but it's important to have them checked.

'Further information on symptoms can be found on the NHS Inform at https://www.nhsinform.scot/illnesses-and-conditions/cancer/cancer-types-in-adults/cervical-cancer

24. A proactive statement has not yet been made as we have been mindful of the need not to create undue anxiety while understanding of the issue was so limited and there was no clear pathway in place to respond to the participants who have definitely been excluded in error. However, we propose to release proactive statements ahead of the letters issuing to participants in the next few weeks. We will work with Comms to develop a media release, and if Ministers agree we will also seek a slot to make a statement to Parliament that will set out the issue in as much detail as we can.

25. This will require careful handling, particularly as we recommend seeking a Parliamentary statement before recess, which might predate the issuing of the letters. For transparency, we also advise reporting to Parliament that there is wider work on-going to ensure the safety of exclusions within the programme. This will also require extremely careful handling, particularly given the uncertainty surrounding the way forward; however, on balance, we believe confidence in the investigation and the wider programme will be best served by being as open and transparent as possible.

26. We have had preliminary discussions with the office of the Minister for Parliamentary Business, who have confirmed that there is already significant pressure on the remaining time before recess. They have therefore advised that we should seek a slot as soon as possible to allow our request to be considered.

Recommendation

27. We recommend that you:

- Note the information provided; and
- Confirm if you agree to a Parliamentary statement before recess, covering both the exclusions known to have been made in error, and the wider work being carried out.

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