
From:
Sent: 29 June 2021 17:13
To:
Subject: Review of Cervix AEMT Update
Attachments: No Cervix Exclusions on SCCRS - Audit of records required

Categories: No Cervix AEMT update

From: [Redacted]
Sent: 24 March 2021 17:03
To: [Redacted]
Cc: [Redacted]
Subject: No Cervix AEMT Update

Dear Colleagues

I hope this finds you all well.

Just to update that a request has went out to NHS Boards to carry out an audit as agreed at the AEMT meeting. Please find details attached. It has been advised by many NHS Boards that the deadline date of the 30th March is extremely challenging therefore I have requested that Boards send what they can by the 30th and keep me updated on progress thereafter.

We are due to meet on the 6th April where we can discuss further however any queries in the meantime please do not hesitate to get in touch.

Kind regards
[Redacted]

[Redacted]
[Redacted]

National Specialist and Screening Directorate (NSD) | Procurement, Commissioning and Facilities (PCF)
NHS National Services Scotland | Gyle Square | Area 062 | 1 South Gyle Crescent | Edinburgh EH12 9EB
tel: [Redacted] | mob: [Redacted]

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From: [Redacted]
Sent:
To:

Cc:
Subject: No Cervix Exclusions on SCCRS - Audit of records required
Attachments: 2021-03-11 No Cervix SBAR V2.pdf

Dear Colleagues

Following the email below I now attached an SBAR which outlines the adverse event in more detail.

Following investigation it has been highlighted that there are a number of records on SCCRS with the no cervix exclusion applied with an operating procedure code on the SMR database which indicates a sub total hysterectomy has been carried out (just under 1000 across Scotland). I am therefore requesting that a multi-disciplinary team is set up in each Health Board please, to review these records to ascertain whether the no cervix exclusion is appropriate on SCCRS.

In order to do this I am requesting that a series of sources are integrated. These being, SCCRS, the operation note, the discharge note, any additional SMR codes and the pathology report. Once this is done for each case I ask that a clinical decision is made on whether the no cervix exclusion is appropriate or should be removed and the participant reinstated to the programme. These details are included in the spreadsheet which you will receive for your Health Board with the details of the records that require to be reviewed.

I ask that no action to records is undertaken while carrying out the audit. Please do not reinstate any participants. The AEMT would like the result of all audits to allow next actions to be consistently applied across Scotland.

Can I ask that Cervical Screening Coordinators / CRO Leads request their NHS Board file from [Redacted] after 2pm today and return the results to [Redacted] by close of play 30th March.

Please do not hesitate to get in touch if you have any questions regarding this and thank you in advance for your time in carrying out this audit during which I appreciate is already a very busy time for all.

Kind regards

[Redacted]

[Redacted]

[Redacted]

National Specialist and Screening Directorate (NSD) | Procurement, Commissioning and Facilities (PCF)
NHS National Services Scotland | Gyle Square | Area 062 | 1 South Gyle Crescent | Edinburgh EH12 9EB
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From: [Redacted]

Sent: 05 March 2021 17:40

To: [Redacted]

Subject: Adding Hysterectomies to SCCRS / No Cervix Exclusions

Importance: High

Dear Colleagues

Due to an adverse event in a NHS Board there requires to be an urgent short term change to the process for adding hysterectomies to SCCRS from immediate effect.

Laboratory colleagues, before adding a hysterectomy please ensure you have received confirmation of a total hysterectomy from the reporting Pathologist and the operating Gynaecologist. Adding a total hysterectomy, as you know, automatically puts on the no cervix exclusion so confirmation from both these sources that this is appropriate is required moving forward.

Call Recall Colleagues, if the alert you receive details that the exclusion was entered by anyone other than a lab source please close down the exclusion and add a journal note stating "No Cervix exclusion closed by the programme". This will allow us to review these records at a later date and reinstate the exclusion status if appropriate. Please then contact the source to advise that the programme has temporarily suspended the use of the no cervix exclusion due to an ongoing incident within the programme.

Colposcopy Colleagues and Cervical Coordinators copied in for information.

An adverse event management team are meeting next week where there will be further discussion on the incident and further action to be taken.

Please do not hesitate to get in touch if you have any questions.

Kind regards
[Redacted]

[Redacted]
[Redacted]

National Specialist and Screening Directorate (NSD) | Procurement, Commissioning and Facilities (PCF)
NHS National Services Scotland | Gyle Square | Area 062 | 1 South Gyle Crescent | Edinburgh EH12 9EB
tel: [Redacted] | mob: [Redacted]

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SBAR – Scottish Cervical Screening Programme

No Cervix Exclusion

SBAR : Cervical Screening Incident

* SITUATION

The 2020 invasive cancer audit carried out in one NHS Board identified [redacted] women who developed cervical cancer and were found to have been excluded from cervical screening call/recall due to “no cervix no follow up” exclusion. The audit investigation found that the cervix had not been removed and the “no cervix no follow up” exclusion was incorrectly applied.

* BACKGROUND

Within the Scottish Cervical Screening Programme IT System SCCRS, an exclusion code of “no cervix no follow up” should be applied to the records of participants who have had a total hysterectomy and have no residual cervical tissue remaining in situ. It should be noted that when the hysterectomy has been carried out due to cervical cancer, follow-up is required for a limited period afterwards.

Pathology results from hysterectomy cases are collated by pathology labs and sent to the cervical screening labs, where exclusions are added to participants' SCCRS records, based on the pathology report stating that a total hysterectomy has been performed. The exclusion can also be applied by GP practices. National guidelines state that in these cases, an alert is created for the Board's call-recall team, who should contact the practice to confirm that the code has been applied correctly. This should be recorded as a journal entry on SCCRS.

During 2006, in preparation for the migration to the new IT system, SCCRS, a data cleaning exercise was carried out where GP practices were provided with a list of women who were notified to the programme as having “no cervix with no follow-up” but had since had a subsequent test i.e. a smear test date/s more recent than the date that the “no cervix with no follow-up” status was applied. To ensure the quality of data was accurate for seeding SCCRS and to ensure that patient care was not compromised GPs were asked to check the records of the women listed and confirm if the “no Cervix with no follow-up” status had been applied correctly. It should be noted that the list did not include the details of women where “no cervix with no follow-up” had been applied and no further smear tests had been recorded.

The exclusions for the [redacted] women identified in this Board's audit were applied in 1995 and 2000 however there was no subsequent screening history therefore these records would not have been picked up in the 2006 audit.

During 2016 and 17 there were further audit and clean up exercises carried out by NHS Boards due to an issue initially identified within SCCRS in relation to anomalies in mapping of sub-total hysterectomy and the application of recommended management resulting in automatic inappropriate exclusion status – ‘No Cervix’.

During the exercise a number of issues were highlighted by NHS Boards. A number of errors were made in adding the initial sub-total hysterectomy information; these errors were in part down to human error and inadequate quality assurance checks at the lab but also indicated problems with the lack of clarity regarding the hysterectomy type information provided from secondary care. There were a number of records where the lab and secondary care advice were at odds. Further, misuse of ‘no cervix’ exclusion by

sample takers had compounded the situation, for example where GP practices had added 'total hysterectomy' in error to a record already updated as 'sub-total hysterectomy', this despite the date of procedure in many cases being identical. Journal entries were not always present, however, Call Recall Office Nationally Agreed Procedures for alerts 'No Further Recall Exclusion created for and No Cervix has been created for this patient state that these alerts should be checked and a journal note added.

Several recommendations were made as a result of these exercises as outlined below –

- NHS Board Screening Coordinators should liaise with secondary care seeking clarity of information provided in communications to reporting laboratories, in particular to be clear about the type of hysterectomy procedure undertaken and the screening recall management required, where appropriate.
- NHS Boards should remind laboratory staff of the consequence of adding incorrect information to SCCRS and also ensure that laboratories have a robust quality assurance process in place.
- NHS Boards should remind sample taker locations of the limited circumstances in which exclusions, in particular 'no cervix', should be applied by them to records on SCCRS.
- NHS Boards should ensure that the Call Recall Office Nationally Agreed Procedures for alerts 'No Further Recall Exclusion created for and No Cervix has been created for this patient' are being adhered to.
- NSD are happy to continue to work collaboratively with Boards and to offer advice where appropriate.

* **ASSESSMENT**

On discovering these cases in the invasive cervical cancer audit, as described in the Situation above, the Board interrogated SMR data to ascertain what operation had been recorded as being carried out using the operation codes. There were 129 records where the operation code indicated that the cervix had not been fully removed. Case notes were then reviewed for 60 of these records via Clinical Portal by a consultant gynaecologist. This showed that a significant number (at least 14) had been excluded inappropriately, either because the procedure carried out was a sub-total 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).

The potential for confusion about the extent of a hysterectomy and the need for follow up smears poses a significant risk to the integrity of the screening programme.

* **RECOMMENDATIONS**

NSD attended a Problem Assessment Group in the affected Board on 5/3/21 and it was agreed that whilst the Board would continue to manage the adverse event reviews of the [redacted] participants identified in the invasive cancer audit, NSD would convene an Adverse Event Management Team 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.

As an urgent control measure, NSD emailed all call-recall offices, cervical laboratories and board 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.

Summary of recommendations

1. Convene AEMT (arranged for 09/03/21) Update – Meeting took place
2. Inform all relevant stakeholders of additional checks to be fulfilled before exclusion can be applied Update - communication sent 5/3/21
3. Brief NSD senior management, NSOF and Scottish Government Update – All have been briefed

Recommendations / Actions following the AEMT Meeting on the 09/03/21

1. Holding lines to be drafted with NSS Media Relations.
2. Atos and PHS Colleagues to extract data for NHS Boards which details records with the No Cervix exclusion added however where the SMR operation code indicates that the cervix has not been fully removed.
3. NHS Boards to carry out an audit of records identified by Atos and PHS colleagues to ascertain whether the No Cervix exclusion has been applied correctly or not.
4. Following the audit, review the results to ascertain whether there is a national issue.
5. If national issue is identified, options appraisal to be carried out to determine next steps based on risk stratification.
6. Programme National Agreed Procedures to be reviewed to ensure both are as robust as possible.
7. Continue to brief NSD senior management, NSOF and Scottish Government

From:
Sent: 29 June 2021 15:37
To:
Subject: FW: SG comms/SCSP
Categories: SG comms/SCSP

From: [Redacted]
Sent: 10 March 2021 18:52
To: [Redacted]
Cc: [Redacted]
Subject: RE: SG comms/SCSP

I agree with [redacted] and [Redacted] about delaying until we know more.

The national AEMT was set up to investigate the accuracy of exclusions (“no cervix no follow up”) from cervical screening of women who had hysterectomies in the past as an audit found that a number of women have been incorrectly excluded.

I would also kindly remind everybody about our duty of confidentiality - any numbers below 5 should not be published.

Kindest regards,

[Redacted]

[redacted]
[Redacted]
[Redacted]

From: [Redacted]
Sent: 10 March 2021 18:23
To: [Redacted]
Cc: [Redacted]
Subject: RE: SG comms/SCSP

Thanks [Redacted] – yes, we definitely need to gather more info before we agree the final lines. It will take a few weeks to even extract the data for the Board audits so we have some time. In the meantime I’ll work with the clinicians on some more detailed wording around hysterectomies. The other important thing to stress in the lines will be that the overall risk of cervical cancer is low.

From: [Redacted]
Sent: 10 March 2021 18:09
To: [Redacted]
Cc: [Redacted]
Subject: RE: SG comms/SCSP

Thanks [Redacted], that's helpful.

I was pretty sure I'd be oversimplifying it, and I recognise the reluctance to be too specific while we don't know all the detail ourselves.

But I think we need to find a wording that's a bit more informative than the lines suggested, because once this is public knowledge the media will ask for detail in relation to an issue like this. If the information is too vague they will keep asking, or will lodge Fol requests, so we are better to acknowledge the complexity, at least to some extent.

It could be that we need to wait until we know more before finalising lines. We'll need a decision from the Cab Sec at some point about the timing of any announcement,

Regards,
[Redacted]

From: [Redacted]
Sent: 10 March 2021 17:41
To: [Redacted]
Cc: [Redacted]
Subject: RE: SG comms/SCSP

Thanks [Redacted] – we usually refer to sub-total or total hysterectomy, but clinicians have advised that the actual situation is not as clearcut as that, and some “total hysterectomies” do actually involve part of the cervix remaining in situ. There are about 14 different codes OPCS codes for different types of hysterectomy – ie it's very complex, which led us to come up with the very high level wording. We don't yet have the full medical histories of the women affected yet as the procedures were carried out so long ago so I would be wary of being too specific.

Unfortunately we are not yet in a position to be able to say how we will manage the wider screening population. We are planning an initial audit in Boards to look at just the sub-total hysterectomies to start with, to indicate whether similar issues have occurred elsewhere. However, the task of reviewing the records of all women excluded from the programme due to all types of hysterectomy is enormous and we need to do a detailed options appraisal to find the best approach to manage the situation safely, whilst not compromising the care of women who currently require cervical screening and colposcopy. We will go back to clinical colleagues to look for an alternative form of wording if the lines below are insufficient.

From: [Redacted]
Sent: 10 March 2021 17:26
To: [Redacted]
Cc: [Redacted]
Subject: RE: SG comms/SCSP

Hello [Redacted],

Thanks for sight of these suggested lines. From an SG comms perspective, I'd want to amend them to explain the situation more clearly in plain English.

I don't think it would be clear to the average reader of a newspaper what the problem was here and that risks giving the impression of a lack of openness. I'd propose some changes, as below.

I've used the term 'partial hysterectomy' as opposed to 'incomplete' as I think the latter suggests the procedure was unfinished or incomplete by accident. If we need to use the term 'incomplete' I think it needs a background note explaining that this is normal, and when/why it would be used or explaining the significance of trans-abdominal surgery.

In addition to the text below I think we need to say what will be done if the Health Board reviews throw up additional cases and what people should do if they are worried, particularly those who have had partial hysterectomies, or think they may have done.

In terms of having lines ready to go out, my view is that we need at least to have reactive lines ready in case the media get wind of this when the request is made of boards for an audit of women in their area.

Hope this is helpful,

regards

[Redacted]

From:
Sent: 20 June 2021 15:39
To:
Subject: FW: SG comms/SCSP
Categories: SG comms/SCSP

From: [Redacted]
Sent: 11 March 2021 09:33
To: [Redacted]
Cc: [Redacted]
Subject: RE: SG comms/SCSP

Hi

I hope this finds you all well. Apologies for not responding before now. I took some leave yesterday afternoon.

I agree that we cannot finalise communication until we obtain further information.

In terms of the initial audit, Atos have already provided the SCCRS extract to PHS colleagues who are now working on the SMR development as priority. I will get an update on progress from PHS later today however I would hope, subject to there being no issues with developing the code required and accessing the SMR data, that we will have data to provide Health Boards mid / late next week.

Kind regards
[Redacted]

[Redacted]
[Redacted]

NHS National Services Scotland | Gyle Square | Area 062 | 1 South Gyle Crescent | Edinburgh EH12 9EB
tel: [Redacted] | mob: [Redacted]

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From: [Redacted]
Sent: 11 March 2021 09:06
To: [Redacted]
Cc: [Redacted]
Subject: Re: SG comms/SCSP

[Redacted] - is this consistent with your meeting with ATOS and PHs yesterday?

From: [redacted]
Sent: Thursday, March 11, 2021 9:04:18 AM
To: [Redacted]

Cc: [Redacted]
Subject: RE: SG comms/SCSP

Hi [Redacted]

Just for clarity, we're talking about a few weeks to extract the data for the Boards, and then around a fortnight (at best) for the boards to complete the audit. So around 5 weeks in total before we would have results?

Cheers.

[Redacted]

[Redacted]

Ext: [Redacted]

Mob: [Redacted]

From: [Redacted]
Sent: 10 March 2021 18:23
To: [Redacted]
Cc: [Redacted]
Subject: RE: SG comms/SCSP

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Regards,

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Subject: RE: SG comms/SCSP

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To: [Redacted]
Cc: [Redacted]
Subject: RE: SG comms/SCSP

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In addition to the text below I think we need to say what will be done if the Health Board reviews throw up additional cases and what people should do if they are worried, particularly those who have had partial hysterectomies, or think they may have done.

In terms of having lines ready to go out, my view is that we need at least to have reactive lines ready in case the media get wind of this when the request is made of boards for an audit of women in their area.

Hope this is helpful,

regards

[Redacted]

The Scottish Cervical Screening Programme has been made aware of [redacted] cases of cervical cancer in a single NHS Board involving individuals who had been excluded from the programme many years ago. It has now been established that these exclusions should not have been applied.

The patients affected had had hysterectomies and had been excluded on the basis that they no longer had cervixes. However in a small proportion of cases where partial hysterectomies are carried out the cervix, or part of it, may remain.

Additional control measures have been put in place to prevent any new further patients who have had partial hysterectomies from being incorrectly excluded from the Screening Programme.

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.

From: [Redacted]
Sent: 10 March 2021 14:46
To: [Redacted]
Cc: [Redacted]
Subject: RE: SG comms

Hi [Redacted]

[Redacted] met with ATOS and PHS today so will be able to advise how long it will take them to be able to pull out all the records on women with an exclusion status on SCCRS who have a record of sub-total hysterectomy on SMR01 or SMR02. I imagine this will be at the very least a week (if not more), so probably 3 weeks minimum before we can ask boards to audit the women.

I've drafted some media lines which I'm just about to share with the AEMT group for comments. Here they are:

The Scottish Cervical Screening Programme has been made aware of [redacted] cases of cervical cancer in a single NHS Board involving individuals who had been excluded from the programme many 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.

Thanks
[Redacted]

[Redacted]
[Redacted]

NHS National Services Scotland
Tel [Redacted]

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From: [Redacted]
Sent: 10 March 2021 14:32
To: [Redacted]
Cc: [Redacted]
Subject: SG comms

Hi all

Just to confirm that [Redacted] from SG (copied in) will lead on comms from our end, so it would be useful if he could be kept involved with any comms discussions.

Can I also check when the boards will be asked to begin their initial audits? I know potentially a fortnight to complete them was agreed, but I'm not sure if a date for the request was decided on, given that PHS were going to do some work first. Having lines ready to go for when the ask goes out is our current thinking.

Cheers.

[Redacted]

[Redacted]

Ext: [Redacted]

Mob: [Redacted]

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