[redacted]

Subject: RE: New Topics - Micase

From: [Redacted]
Sent: 10 March 2021 10:12
To: [Redacted]
Cc: [Redacted]
Subject: RE: New Topics - Micase

Hi,

Some lines on the breast screening issue to use, line on the cervical incident will hopefully be agreed shortly.

We are aware that one of the less common potential side effects of the Covid vaccination is swollen glands in the armpit on the same side as the arm where you received your vaccine. This can last for around 10 days but if it lasts for longer we would urge you to contact your doctor.

This swelling could be detected during a breast screening appointment and may cause unnecessary concern. If you are due to attend a breast screening appointment you should mention this when you attend but there is no need to delay either your breast screening appointment or your Covid vaccination when invited.

Thanks,

[Redacted] I National Programmes I Health Protection Division I Scottish Government I Area 3E I St Andrews House I Regent Road I EH1 3DG I [Redacted] I [Redacted]

From: [Redacted]
Sent: 09 March 2021 10:19
To: [Redacted] ; [Redacted]
Cc: [Redacted]
Subject: New Topics - Micase

Morning,

For awareness, there could be some Micases in the coming days/weeks due to a couple of issues that have just arisen. We are drafting some lines just now but if you see anything mentioning these then please let us know.

Breast Screening – a potential side effect of the Covid vaccine is swelling in the armpit on the same side as the vaccine shot. This can be detected in the breast screening appointment but is not a cause for concern.

Cervical screening – There has been an issue to do with how peoples details were recorded after subtotal (partial) hysterectomy's. There is a meeting today to discuss so we should know more later on about what the approach to dealing with this is.

I'd personally expect more enquiries on the second one when if/when it hits the news so let's continue to keep an eye out in the media monitoring as well.

Thanks,

[Redacted] I Screening Policy I National Programmes I Health Protection Division I Scottish Government I Area 3E I St Andrews House I Regent Road I EH1 3DG [Redacted]

From:
Sent: 29 June 2021 15:20
To:
Subject: FW: AEMT - No Cervix / Hysterectomy
Attachments: 2021-03-09 AEMT ag.docx; No Cervix Problem Assessment Group Workbook.docx

Expires: 23 April 2021 00:00

Categories: AEMT - No Cervix / Hysterectomy

FYI

Freedom of Information
Cervical Cancer Screening Programme
08th March 2021 – 28th March 2021

[Redacted]

Business Manager | Health Protection Division | Directorate for Population Health
Scottish Government | St. Andrew's House, Regent Road, Edinburgh, EH1 3DG

Telephone: [Redacted]

E-mail: [Redacted]

gov.scot SG EU NATIONALS NETWORK

From: [Redacted]
Sent: 09 March 2021 12:30
To: [Redacted]
Subject: FW: AEMT - No Cervix / Hysterectomy

[Redacted]
[Redacted]
Ext: [Redacted]
Mob: [Redacted]

From: [Redacted]
Sent: 09 March 2021 10:06
To: [Redacted]
Subject: FW: AEMT - No Cervix / Hysterectomy

Hi

Papers for today.

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]

From: [Redacted]
Sent: 08 March 2021 19:13
To: [Redacted]
Subject: AEMT - No Cervix / Hysterectomy

Dear Colleagues

In advance of the AEMT meeting tomorrow at 12.15pm please find attached an agenda and PAG workbook which will be discussed.

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]

Specialist Healthcare Commissioning

National Services Division (NSD)
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB
Telephone 0131 275 6000
www.nsd.scot.nhs.uk

NHS National Services Scotland

Agenda

Adverse Event Management Team

Tuesday 9th March 2021, 12.15pm to 1.45pm

Click here to join the meeting

No.	Agenda Item	Lead
1.	Welcome, Introductions & Apologies	[Redacted]
2.	Remit of the Group	[Redacted]
3.	Background 3.1 Nature of Incident / SBAR 3.2 Current Exclusion Processes	[Redacted] [Redacted]/ [Redacted]
4.	Immediate Control Measures	[Redacted]
5.	Further Investigation 5.1 Confirmation of Local Processes 5.2 Potential Methods to Audit Participants with "No Cervix No Follow-up" Exclusion	[Redacted]
6.	Agreed Actions / Next Steps	[Redacted]
7.	Communications	[Redacted]
8.	Any Other Business	[Redacted]
9.	Date and Time of Next Meeting	

From:
Sent: 29 June 2021 14:15
To:
Subject: FW: Cervical Screening Incident
Attachments: 2021-03-11 No Cervix SBAR V2.docx

Categories: Cervical Screening Incident

From: [Redacted]
Sent: 18 March 2021 16:40
To: [Redacted]
Cc: [Redacted]
Subject: Cervical Screening Incident

Hi [Redacted],

I know [Redacted] is on leave this week, and he was supporting the screening team on drafting lines for the latest cervical screening incident. I have attached the latest SBAR for your information.

It was agreed holding lines would be drafted with NSS Media Relations, the contact is [Redacted].

Happy to answer any questions or chat if needed.

[Redacted]

[Redacted] | [Redacted] | National Programmes | Health Protection Division | The Scottish Government | St Andrews House I Regent Road I EH1 3DG I [Redacted] I

NHS National Services Scotland

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 11:25
To:
Subject: FW: Cervical Screening incident

Categories: Cervical Screening Incident

From: [Redacted]
Sent: 23 March 2021 17:20
To: [Redacted]
Cc: [Redacted]
Subject: RE: Cervical Screening incident

Hi [Redacted]
[Redacted] will be able to confirm tomorrow but I think she was informed by ATOS that there are currently around 200,000 women on the system with a "no cervix" exclusion. I'm happy with the holding lines.
Thanks
[Redacted]

From: [Redacted]
Sent: 23 March 2021 16:37
To: [Redacted]
Cc: [Redacted]
Subject: Cervical Screening incident

Good afternoon,

I am just checking in on numbers for the cervical screening incident. [Redacted] you helpfully shared the line below for FMQ briefing last week, can I check that 200,000 is the best estimate of the numbers involved? I know in the initial meeting we discussed that potentially 140,000 participants were involved, it would helpful to understand what number I should use in the briefing to our director.

"It is difficult to quantify participants who may be affected; however, there are around 200,000 with a no cervix exclusion but there is no evidence to suggest that the vast majority of these are not accurate"

The following holding lines were agreed by our comms team and [Redacted], last week, I will liaise with our comms team internally once the audit is complete to discuss a more details comms plan.

"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."***

Thanks

[Redacted] | [Redacted] | National Programmes | Health Protection Division | The Scottish Government | St Andrews House I Regent Road I EH1 3DG I [Redacted] I

From:
Sent: 29 June 2021 11:25
To:
Subject: FW: Cervical Screening Incident

Categories: Cervical Screening Incident

From: [Redacted]
Sent: 19 March 2021 17:33
To: [Redacted]
Cc: [Redacted]
Subject: RE: Cervical Screening Incident

Yes that's a good point actually, should have spotted that. A small number is better.

Thanks
[Redacted]

[Redacted]
[Redacted]
Scottish Government
[Redacted]

From: [Redacted]
Sent: 19 March 2021 17:32
To: [Redacted]
Cc: [Redacted]
Subject: RE: Cervical Screening Incident

Hi [Redacted],

Just jumping in here to say that we agreed with [Redacted] last week to use the words 'a small number' rather than [redacted], to protect patient confidentiality.

We are currently preparing briefing for an oral Q next week on cervical screening. We think this is unlikely to come up as a supplementary question but propose to use these lines, as lines to take, if needs be.

[Redacted]
[Redacted]
Population Health Directorate, Scottish Government
☎ [Redacted]

From: [Redacted]
Sent: 19 March 2021 17:27
To: [Redacted]
Cc: [Redacted]
Subject: RE: Cervical Screening Incident

Hi [Redacted]

I had a chat with [Redacted] today and the following holding lines are proposed:

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.

Thanks

[Redacted]
[Redacted]
Scottish Government
[Redacted]

From: [Redacted]
Sent: 19 March 2021 09:22
To: [Redacted]
Cc: [Redacted]
Subject: RE: Cervical Screening Incident

Hi [Redacted],

Yes I have attached the ministerial submission, the Cab Sec was copied into the sub along with FM Briefing Unit and SpAds.

Thanks

[Redacted]

From: [Redacted]
Sent: 19 March 2021 09:19
To: [Redacted]
Cc: [Redacted]
Subject: RE: Cervical Screening Incident

Thanks [Redacted], we can pick this up with [Redacted] today.

Can I check that ministers and spads are aware of this issue?

Thanks
[Redacted]

[Redacted]
[Redacted]
Scottish Government
[Redacted]

From: [Redacted]
Sent: 18 March 2021 16:40
To: [Redacted]
Cc: [Redacted]
Subject: Cervical Screening Incident

Hi [Redacted],

I know [Redacted] is on leave this week, and he was supporting the screening team on drafting lines for the latest cervical screening incident. I have attached the latest SBAR for your information.

It was agreed holding lines would be drafted with NSS Media Relations, the contact is [Redacted].

Happy to answer any questions or chat if needed.
[Redacted]

[Redacted] | [Redacted] Policy | National Programmes | Health Protection Division | The Scottish Government | St Andrews House I Regent Road I EH1 3DG I [Redacted] I

From:
Sent: 29 ' ıe 2021 15:20
To:
Subject: FW: Meeting on cervical screening issue

Categories: Meeting on cervical screening issue

From: [Redacted] **On Behalf Of** Minister for Public Health and Sport
Sent: 09 March 2021 12:02
To: [Redacted] Minister for Public Health and Sport <MinisterPHS@gov.scot>
Cc: [Redacted]
Subject: RE: Meeting on cervical screening issue

Hi [Redacted],

Can you confirm who [Redacted] is and do you have an email address? I can't find any [Redacted] on staff directory?

Regards

[Redacted]
[Redacted] to Mairi Gougeon MSP
Minister for Public Health and Sport
2N.15 | St Andrew's House | Regent Road | Edinburgh | EH1 3DG
Tel: [Redacted]

From: [Redacted]
Sent: 09 March 2021 11:42
To: Minister for Public Health and Sport <MinisterPHS@gov.scot>
Cc: [Redacted]
Subject: Meeting on cervical screening issue

[Redacted]

The Minister mentioned at our catch up that she would like to meet with us after the adverse event meeting this afternoon to discuss the screening issue. The adverse event meeting concludes at 2pm and it would be helpful if [Redacted] could be included in the meeting with the Minister.

Best wishes,

[Redacted]

[Redacted]
[Redacted]
Population Health Directorate, Scottish Government
☎ [Redacted]